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AI Therapy Chatbots in Youth With Attention-Deficit/Hyperactivity Disorder: A Nurse-Led, Risk-Tiered Policy Framework

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Abstract

AI-powered therapy chatbots and virtual companions are beginning to enter routine mental health care, yet safeguards for children and adolescents remain underdeveloped. For youth with attention-deficit/hyperactivity disorder (ADHD), these tools may offer brief coaching, psychoeducation, and structured between-visit check-ins across clinic, school, and home settings, but they also raise concerns about inappropriate content, overreliance, quiet model drift, privacy across health and education systems, and missed crisis escalation. In this Viewpoint, we propose a nurse-led, risk-tiered policy and implementation framework for integrating AI therapy chatbots into youth ADHD care safely, effectively, and equitably. The framework has 3 linked layers: policy levers, implementation enablers, and measurable outcomes. We emphasize child-specific safeguards, predetermined change control for adaptive models, equity-oriented procurement and reimbursement, interoperability and safety reporting, and nurse-led human-in-the-loop oversight. We further clarify that nursing-generated data—such as structured assessments, triage actions, escalation records, and supervision workload—can function both as governance inputs and as outcome-relevant signals within monitoring and service evaluation. We also outline a phased implementation road map and a concise indicator set that schools and clinics can monitor without major new infrastructure. A nurse-led, risk-tiered approach, combined with age-appropriate safeguards, equity-by-design implementation, and privacy-preserving real-world learning, can help health systems and schools move from ad hoc adoption toward safer and more equitable use of AI therapy chatbots for youth with ADHD while the evidence base continues to mature.

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KEYWORDS

attention-deficit/hyperactivity disorder; ADHD; therapy chatbot; virtual companion; nursing informatics; risk-tiered regulation; child safety; real-world evidence; artificial intelligence; AI

Introduction

Background

Attention-deficit/hyperactivity disorder (ADHD) is common and costly, with functional impact across home, school, and community contexts throughout development [1-4]. Clinical guidelines recommend multimodal treatment—behavioral interventions, supports in school, and medication when appropriate [1,2]. Capacity constraints and unequal access, however, remain stubborn problems for families. In parallel, AI-powered therapy chatbots and virtual companions have advanced quickly. Early studies suggest that conversational agents can be feasible and may offer short-term symptom benefits in adjacent populations and indications (eg, student and young adult samples and non-ADHD conditions) [5]. However, direct evidence for child- and ADHD-specific applications is still limited and uneven, and real-world workflows and safety reporting remain underdeveloped—one reason why we argue that governance and safety guardrails matter now, not later. These gaps motivate our implementation-focused framework.

Conversational agents are already reaching families. The more urgent question is how to use them safely and equitably and how to fit them into real clinic and school workflows without creating new risks—especially for minors with ADHD, who may be more sensitive to design choices that affect attention, impulse control, and time on task. Regulatory and standard bodies have issued broad guidance on AI ethics and risk management [6-9], and there is growing clarity on good machine learning practice and predetermined change control plans (PCCPs) for adaptive software [7,8]. However, concrete, child-specific guardrails and the day-to-day implementation

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infrastructure across clinics and schools remain incomplete. Nurses—particularly school nurses and care managers—are well positioned to provide human-in-the-loop oversight; integrate digital tools into measurement-based, stepped care pathways; and monitor both outcomes and safety [10-12]. Therefore, this Viewpoint offers a pragmatic governance and implementation framework tailored to therapy chatbots in ADHD care.

Aim of This Viewpoint

This Viewpoint aimed to propose a nurse-led, risk-tiered policy and implementation framework for integrating AI-powered therapy chatbots into youth ADHD care across clinic, school, and home settings. Our goal is not to endorse a specific product but to define near-term steps that health systems, schools, payers, and developers can take together.

Ethical Considerations

This Viewpoint did not involve human participants or identifiable data.

Why Therapy Chatbots for ADHD? What Could Go Wrong?

The promise is easy to understand. A conversational tool can help youth practice organization and time management skills, support caregivers with brief coaching ideas, and collect structured check-ins that can feed measurement-based care between visits. For families facing long waits, transportation barriers, or stigma, a low-friction tool can feel like a practical bridge rather than a replacement for care.

The risks are just as real, especially for minors. Without child-appropriate design and clear boundaries, chatbots can produce inaccurate or inappropriate content; blur the line between support and dependence; or encourage patterns of use that displace sleep, schoolwork, or offline coping. In ADHD in particular, engagement features that resemble rewards can unintentionally reinforce “more time on the app” even when that is not clinically helpful. The most serious risk is failure to recognize and escalate crisis signals such as self-harm language, threats of harm to others, abuse disclosures, or severe distress. Another risk is quiet model drift: adaptive updates can change performance over time, creating safety or equity problems that remain invisible unless they are monitored. Finally, youth ADHD care often crosses health and education settings, where privacy and consent rules differ; unless governance is explicit, well-intentioned integration can become legally and ethically fragile. These realities are why we argue for a nurse-led, risk-tiered approach that matches oversight and evaluation to intended use and potential impact.

A Nurse-Led, Risk-Tiered Governance Framework

Figure 1 summarizes a 3-layer framework that aligns policy levers, implementation enablers, and outcomes to guide responsible adoption of therapy chatbots and virtual companions in youth ADHD services. We start with what needs to be set at the system level, move to what must be in place for safe day-to-day use, and end with a small set of outcomes that keep performance visible rather than assumed. Nursing leadership is positioned as the practical anchor for human-in-the-loop oversight across clinic, school, community, and home settings, with clear coordination rather than replacement of interdisciplinary clinical and educational expertise. In this framework, nursing-generated data are not treated as passive documentation alone. Structured nursing observations, triage actions, escalation records, follow-up contacts, and supervision workload can serve as governance inputs and as outcome-relevant signals for safety oversight, resource planning, and service evaluation.

At the policy level, risk-tiered regulation and change control matter because many AI-enabled tools evolve through updates; PCCPs help make changes transparent, testable, and reversible when needed. Financing and procurement then determine whether safe implementation is feasible in routine care. When nurse time for triage, coaching, monitoring, and escalation is treated as “extra,” integration becomes fragile and inequitable; when it is recognized and supported, supervision becomes consistent and sustainable. Standards and ethics also need to be practical. For youth-facing tools, this means child-appropriate transparency, content safety and age gating, clear limits that prevent harmful engagement patterns, and escalation pathways that reliably connect a young person with human support when risk emerges.

On the implementation side, governance should follow a minimization mindset, use privacy-preserving approaches when possible, and make role-based access and auditability routine. Human factors are particularly important in ADHD because design choices can affect attention, impulse control, and time on task. Tools should be co-designed with neurodiverse youth and caregivers, match language and reading level, and include clear limits on session length and frequency so that engagement does not become a proxy for benefit. Workflow integration is equally critical: chatbots should feed measurement-based and stepped care pathways with defined handoffs rather than creating parallel “shadow care.” Equity by design should be operational from the start, including expectations for low-bandwidth or offline-capable use where needed and realistic pathways for device or connectivity support through schools, community partners, or payers. Independent evaluation completes the picture. A combination of sandbox pilots, safety testing before scale-up, and postdeployment monitoring for drift and adverse events helps prevent silent failures that only become visible after harm accumulates.

Finally, outcomes should extend beyond symptom scores alone. Programs should monitor access and equity, safety signals (including inappropriate content and escalation performance), clinical and functional outcomes (including school functioning where feasible), experience for youth and caregivers as well as staff supervision burden, and economic value. A feasible indicator set—reported regularly and interpreted with subgroup lenses—creates a feedback loop that can inform procurement, reimbursement, and change control as real-world evidence (RWE) accumulates [13-16].

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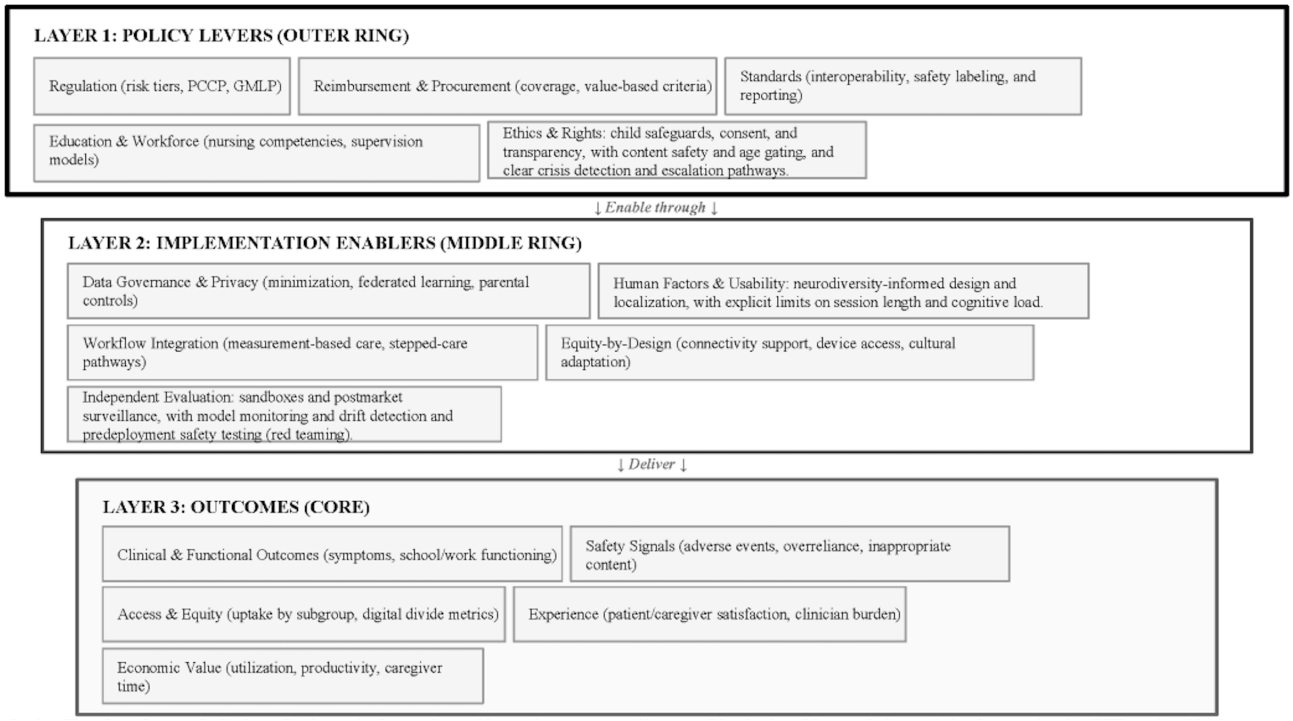
Figure 1. Nurse-led, risk-based governance framework for integrating AI into attention-deficit/hyperactivity disorder care across the lifespan. This framework aligns policy levers (regulation with risk tiers, predetermined change control plans [PCCPs], and good machine learning practice [GMLP]; reimbursement and procurement; standards for interoperability, safety labeling, and reporting; ethics and rights; and workforce development) with implementation enablers (data governance and privacy; human factors and usability—including limits on session length and cognitive load; workflow integration; equity by design; and independent evaluation with model monitoring, drift detection, and predeployment red teaming) and outcomes (access and equity, safety signals, clinical and functional outcomes, experience, and economic value). Nursing leadership provides human-in-the-loop oversight across clinic, school, community, and home settings, and nursing-generated data (eg, assessments, triage actions, escalation logs, and supervision workload) function as both governance inputs and outcome-relevant signals for ongoing learning.



Comparative Policy Options

Table 1 summarizes 5 policy options that are often discussed as separate levers—regulation, procurement, reimbursement, and evaluation infrastructure—but that tend to work best as a package. The goal here is not to argue for a single "best" approach; rather, the table makes trade-offs explicit so readers can match governance choices to local capacity, risk tier, and equity priorities.

In practice, settings with limited regulatory or technical capacity can still start by raising the procurement floor and clarifying the human-in-the-loop workflow while building toward stronger change control and cross-site learning over time.

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Table . Policy options for integrating AI therapy chatbots into youth attention-deficit/hyperactivity disorder (ADHD) care.

Option	Primary lever	Description	Benefits	Risks and limits	Feasibility	Equity impact
Status quo+industry self-regulation	Market self-regulation	Voluntary standards and vendor-led safeguards, with existing device and consumer protection rules applied when applicable	Fast deployment with minimal administrative burden	Inconsistent evidence and safety reporting, uneven child safeguards, and limited accountability for drift and subgroup harms	High	Often negative to neutral unless paired with access supports and monitoring
Risk-tiered regulation with PCCPs[a] for adaptive AI	Regulations and standards	Classify tools by intended use and risk tier and require transparency artifacts and PCCPs for adaptive updates	Improves transparency and change governance, supports drift management, and strengthens minor-specific safeguards	Requires regulatory capacity and may increase compliance costs and slow down iteration	Medium	Neutral to positive if fairness audits and subgroup performance reporting are required
Voluntary certification+public procurement criteria	Certification and procurement	Independent certification and buyer criteria for schools and clinics covering age-appropriate design, content moderation, transparency, and safety reporting	Scales minimum quality expectations and helps purchasers compare products	Variable uptake and risk of checkbox compliance or certification capture	Medium-high	Positive if criteria include accessibility, language support, and digital divide mitigation
Reimbursement for nurse-delivered digital ADHD care	Payment	Reimburse nurse-led triage, coaching, monitoring, and escalation work when using approved chatbot-supported workflows	Aligns incentives for safe integration and supports workforce readiness and supervision time	Requires payer alignment, guardrails, and documentation to prevent overuse and substitution for needed in-person care	Medium	Positive if paired with coverage for connectivity and device support and culturally responsive services
Federated RWE[b] registry and safety surveillance	Data governance and evaluation	Privacy-preserving cross-site evaluation using a shared harm taxonomy, common standardized data elements (including nursing and escalation data), and federated protocols where data remain local and only aggregated insights are shared	Enables continuous learning, consistent safety signal detection, and cross-site analysis of nursing-sensitive oversight indicators without centralizing sensitive data	Setup complexity and requires governance agreements, technical tooling, and sustained funding	Medium	Positive if inclusive by design and if low-resource sites are supported to participate

[a]PCCP: predetermined change control plan.

[b]RWE: real-world evidence.

Implementation Road Map

In low-resource school districts and community clinics, the road map should be treated as modular rather than all-or-nothing. A workable starting point is to define intended use and risk tier, assign a named human-in-the-loop lead with a clear escalation pathway, and track a small set of safety and outcome indicators; more complex elements such as federated evaluation infrastructure can be added later as staffing, governance capacity, and partnerships grow.

Preparation (0-3 Months)

A steering group spanning nursing, child psychiatry, pediatrics, school health, caregivers, students, regulators, payers, and developers should be convened. Risk tiers and intended use statements for therapy chatbots in ADHD should be agreed upon. A minimal outcome set and a safety signal set that includes inappropriate content, missed escalations, and adverse events should be specified. Procurement criteria modeled on existing frameworks that cover safety, security, interoperability, clinical safety, and usability should be selected [17-20].

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Pilot and Sandbox (3 - 9 Months)

School and clinic pilots with informed consent or assent, role-based human oversight (nurses as primary supervisors), and prespecified escalation pathways should be launched. Privacy-preserving analytics, ideally using federated evaluation, should be configured [21,22]. Billing workflows that map nurse-delivered digital activities to covered services should be established, with documentation standards to prevent overuse.

Illustrative Nursing Workflow

Scale With Guardrails (9 - 18 Months)

Risk-tiered labeling and PCCPs for adaptive updates should be adopted. Only tools that meet certification criteria for appropriate design, content moderation, and transparency with fairness audits should be procured. Integration into measurement-based, stepped care pathways with clear tapering and exit criteria should be expanded. The federated RWE network should be activated, and quarterly dashboards with subgroup performance and safety signals should be published.

Continuous Learning (≥18 Months)

Procurement and reimbursement criteria based on RWE should be recalibrated. Red teaming and child safety audits should be refreshed annually. PCCPs should be updated using drift monitoring and postmarket findings.

Minimum Viable Implementation Considerations

Overview

We emphasize that not all elements of the road map need to be implemented simultaneously. In resource-constrained school districts or community clinics, a minimum viable implementation may consist of clearly defined intended use and risk tiering, nurse-led human oversight with basic escalation pathways, and a small core set of safety and outcome indicators. More advanced components—such as federated evaluation networks or formal certification—can be layered in over time as institutional capacity grows.

Evaluation Framework

For day-to-day operations, we recommend a short indicator set that most schools and clinics can track without major new infrastructure. In addition to chatbot-derived use and symptom data, this minimum dataset should include structured nursing data elements already generated in routine care—for example, triage category; follow-up completion; escalation timing; unsuccessful contact attempts; supervision time; and documented concerns related to sleep, functioning, or caregiver strain. At a minimum, programs should monitor access and equity, including uptake and retention and stratified outcomes by key demographic and socioeconomic proxies [17,18,23,24]. They should also monitor safety, including inappropriate content, time to escalation for crisis flags, adverse events graded by severity, and model rollback events. Clinical and functional outcomes should include validated ADHD symptom measures and, where feasible, school functioning, such as attendance and work completion alongside adherence to behavioral plans [1,2,11]. Because implementation succeeds or fails on acceptability and workload, programs should track youth and caregiver experience and nurse supervision burden. Finally, economic value should be assessed in practical terms, such as avoided no-shows or urgent visits, staff time reallocation, caregiver time saved, and net program costs relative to benefits.

Standardized nursing data may also serve as a practical bridge between governance and predictive intelligence: if captured consistently and audited appropriately, they can support subgroup monitoring; more tailored follow-up intensity; and earlier human review of clinically concerning patterns across clinic, school, and home settings.

Financing and Procurement

In the near term, many systems can finance nurse-led digital care using existing codes—behavioral health integration or collaborative care for coordination and supervision and remote therapeutic or patient monitoring for structured data review—when services meet eligibility and documentation requirements. Procurement can leverage established assessment criteria to mandate safety, interoperability, evidence thresholds, and transparency artifacts such as model cards and data sheets [17,23,24]. For child-facing tools, age-appropriate design, content moderation, parental controls, and reliable crisis escalation should be required in the request for proposals [18-20]. Vendors that support federated evaluation and publish postmarket performance should be preferred.

Ethical, Legal, and Social Considerations

Minors' rights require developmentally appropriate consent, transparency, and parental controls. Content safety and age gating should be active prior to deployment, and crisis detection must escalate rapidly to human support. Data should be minimized and processed on the device when feasible, with auditable logs and role-based access. Because care traverses clinics and schools, compliance must distinguish HIPAA (Health Insurance Portability and Accountability Act)-governed health data from Family Educational Rights and Privacy Act–governed education records and set appropriate data sharing agreements [25,26]. Fairness should be treated as a practical obligation: subgroup performance should be documented, and disparities should be remediated with targeted outreach, assistive technologies, and human review for edge cases [17,18,23,24].

Regulatory examples drawn from the United States and Europe are presented as illustrative rather than prescriptive. The framework is meant to be adapted to local laws, workforce models, and cultural contexts—including Asia-Pacific settings—where the day-to-day reality may look different (eg, school nursing roles and staffing vary widely, and many systems rely more heavily on family- and community-based support than on school-based health infrastructure). In these contexts, the core requirements remain the same—clear intended use and risk tiering, practical child safeguards, and reliable human escalation—but the responsible human-in-the-loop lead may be a community nurse, primary care team, or another locally appropriate role rather than a US-style school nurse.

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Positioning the Nurse-Led, Risk-Tiered Framework Relative to Existing Governance Models

Existing digital health and AI governance frameworks—such as National Institute for Health and Care Excellence guidance, the Food and Drug Administration's digital health policies, and the World Health Organization's AI governance recommendations—provide essential high-level principles for safety, evidence generation, and risk management. However, these frameworks do not explicitly address how day-to-day oversight should be operationalized for minors with ADHD across clinical, school, and home settings. Our framework does not propose a new regulatory standard; rather, it translates these established principles into a practice-facing, nurse-led governance and implementation model. Its distinctive contribution lies in foregrounding (1) nurse-led human-in-the-loop supervision; (2) risk-tiered safeguards tailored to pediatric ADHD, including overreliance and crisis escalation risks; and (3) a concrete implementation road map that links regulation, reimbursement, and procurement with frontline workflows and outcome monitoring. In this way, the framework complements existing governance instruments by addressing gaps at the point of care where conversational agents are actually deployed.

For safety governance, the chatbot incorporates predefined crisis flag categories and escalation thresholds aligned with pediatric mental health practice. Over time, such rule-based safeguards may be complemented by cautiously implemented predictive review tools derived from standardized nursing data while nurse-led judgment remains primary. Crisis flags include but are not limited to explicit self-harm or suicidal language, acute emotional dysregulation persisting across multiple sessions, or repeated expressions of hopelessness unresponsive to in-chat de-escalation prompts. When a high-risk flag is triggered, the system initiates an alert to the designated nurse within a predefined time window (eg, immediate escalation for imminent risk and within 24 hours for high-risk but nonimminent flags), prompting nurse-led assessment and triage. Depending on severity, the nurse escalates care through established handoff pathways to physicians, child psychiatrists, school health professionals, or emergency services. This protocolized workflow ensures that the chatbot functions as an adjunctive early warning system rather than a stand-alone crisis intervention.

Limitations

This Viewpoint has several limitations. First, the evidence base for AI-powered therapy chatbots specifically targeting ADHD in minors remains small, heterogeneous, and short in duration. Most studies evaluate feasibility or short-term symptom change in convenience samples, with limited replication; inconsistent outcome measures; and scarce reporting on school functioning, caregiver burden, or long-term adherence. Safety outcomes are also underreported; few studies use standardized harm taxonomies or prospectively capture inappropriate content, missed escalations, or overreliance.

Second, generalizability is uncertain. Usability, engagement, and effectiveness can vary by age, developmental stage, language and literacy, co-occurring conditions (eg, learning disabilities, anxiety, and autism), and social determinants (eg, connectivity and device access). Our equity recommendations are grounded in principle but require local tailoring and co-design with youth and caregivers to avoid unintended exclusion.

Third, policy and regulatory contexts are evolving and jurisdiction specific. Risk classification, the applicability of device regulations, and the operationalization of PCCPs differ across regions and may change rapidly. Similarly, reimbursement pathways for nurse-delivered digital care vary by payer and country, and our examples (behavioral health integration, remote therapeutic monitoring, and remote patient monitoring) may not apply universally. Procurement frameworks (eg, Digital Technology Assessment Criteria) also differ and may be updated over time.

Fourth, several elements of the framework are normative and have not yet been tested together as a complete package. We infer feasibility from adjacent digital health implementations and governance guidance, but the combined impact of risk-tiered regulation, certification and procurement criteria, financing mechanisms, and a federated RWE network remains to be demonstrated in prospective, multisite evaluations.

Fifth, important technical uncertainties persist. Adaptive models may drift; fairness audits and subgroup performance reporting are not standardized; and methods such as red teaming, age gating, and on-device processing need consistent benchmarks and transparent reporting. Interoperability and data minimization can be tense, and federated evaluation requires agreements and tooling that many organizations do not yet possess.

Finally, this paper does not address all legal and ethical issues exhaustively. We do not cover cross-border data transfers, vendor lock-in, or intellectual property constraints in depth, and we do not provide jurisdiction-specific legal advice. Readers should interpret the framework as a pragmatic starting point to be adapted with local legal counsel, clinical governance, and community input.

Despite these limitations, we argue that converging principles—risk-tiered regulation with PCCPs, age-appropriate design and transparency, financing for nurse-led integration, procurement aligned with safety and equity, and federated RWE—offer a credible pathway from cautious pilots to safe, equitable scale. Prospective, transparent evaluations that report benefits and harms by subgroup will be essential to refine and validate this approach.

Conclusions

AI-powered therapy chatbots and virtual companions are likely to become a routine adjunct to ADHD care across clinics, schools, and homes. Their promising psychoeducation, coaching between visits, and structured inputs for measurement-based care will only be realized if deployment is paired with safeguards that are proportionate to risk and responsive to the needs of children and families. Nursing leadership is central to

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this task. As supervisors of day-to-day use, nurses can anchor human-in-the-loop oversight, ensure that escalation pathways work in practice, and help translate technical standards into workable routines.

A pragmatic agenda emerges from our analysis. First, risk-tiered governance for conversational agents, including PCCPs for adaptive models, should be adopted so that updates are transparent and reversible. Second, the real work of nurse-delivered digital care—triage, education, coaching, monitoring, and escalation—should be financed so that integration is sustainable rather than discretionary. Third, procurement decisions should be made based on clear, child-appropriate criteria that require age-appropriate design, content safety, transparency artifacts (eg, model cards and data sheets), interoperability, and fairness audits. Fourth, a federated RWE and safety surveillance network should be established using a shared harm taxonomy and standardized indicators so that benefits and harms can be tracked across settings without compromising privacy.

These steps are actionable now even as science matures. They can expand access for underserved youth; reduce unwarranted variation; and surface problems early, enabling course correction before harms accumulate. Equally importantly, they will generate the cumulative, subgroup-specific evidence that has been missing from the literature. With nursing leadership at the helm and with governance that matches risk to oversight, health systems and schools can move from cautious pilots to safe, equitable scale—bringing the advantages of well-designed conversational tools to the young people who stand to benefit the most. More broadly, recent nursing research suggests that structured nursing activity and diagnosis data can contribute to outcome prediction and early warning workflows in other care settings, supporting the future feasibility of hybrid oversight models in which standardized nursing data complement rather than replace nurse-led judgment [15,27].

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Data Availability

No datasets were generated or analyzed in this study. Materials such as figure and table templates are available from the corresponding author on reasonable request.

Authors' Contributions

SI conceived the project. KK led the policy analysis. KK and SI drafted the manuscript. Both authors critically revised the manuscript and approved the final version.

Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
HIPAA: Health Insurance Portability and Accountability Act
PCCP: predetermined change control plan
RWE: real-world evidence

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The Impact of Digital Transformation on Nursing Professional Experience: Critical Interpretive Synthesis Review Developing the Fragmented Professional Transition in Nursing (FPT-N) Model

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Abstract

Background: Digital transformation through electronic health records (EHRs), telehealth, mobile health, and emerging AI has reshaped nursing work. Beyond questions of adoption and usability, nurses report disruptions to workflow continuity, professional identity, moral agency, and the meaning of care.

Objective: This study aimed to synthesize interdisciplinary evidence on how digital transformation reshapes nursing professional experience and to develop the fragmented professional transition in nursing (FPT-N) model as a critical sociotechnical explanatory framework.

Methods: A critical interpretive synthesis was conducted across nursing, health informatics, and organizational literature. A structured search of PubMed or MEDLINE, CINAHL, PsycInfo, and Scopus was followed by purposive theoretical sampling for conceptual richness. We included primary qualitative and mixed methods studies, 1 quantitative observational workflow study, and secondary syntheses used for triangulation. Qualitative evidence was appraised with the Critical Appraisal Skills Programme qualitative checklist to inform interpretive weighting. We used line-by-line coding, constant comparison, memoing, and synthesizing arguments.

Results: The search identified 2847 records. After removing 865 duplicates, 1982 records were screened, 124 full-text reports were assessed, and 13 evidence sources were included. The synthesis generated 3 interacting mechanisms: workflow fragmentation, epistemic injustice in data-centric care, and expansion of invisible digital articulation work. Quantitative triangulation showed that 2871 interruption events were recorded across 145 observed shifts in 1 EHR workflow study, supporting the interpretation that digital work can intensify cognitive load. Contextual moderators, including governance, staffing, interoperability, and digital capital, shaped whether nurses experienced adaptive reintegration or alienation.

Conclusions: Digital transformation may reconfigure important parts of nursing work around data production, potentially reducing the visibility of narrative clinical judgment and amplifying hidden coordination labor in some contexts. The FPT-N model offers a critical explanatory framework for examining when digital health implementation supports adaptive reintegration vs fragmented professional transition. The model identifies actionable targets for design and governance: aligning EHR workflows with nursing cognition, reducing interruptive documentation burden, recognizing invisible digital articulation work, preserving narrative clinical judgment, and involving nurses in sociotechnical decision-making.

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KEYWORDS

digital transformation; nursing informatics; electronic health records; professional identity; critical interpretive synthesis; epistemic injustice; invisible work; workflow fragmentation; artificial intelligence; AI

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Introduction

Background and Rationale

Digital transformation has become a defining feature of contemporary nursing practice. Electronic health records (EHRs), telehealth, mobile health applications, and emerging AI systems are now embedded in documentation, communication, coordination, and clinical decision-making [1]. Evidence syntheses show that information and communication technologies influence multiple domains of nursing care, including information access, documentation quality, time allocation, nurse autonomy, and nurse-patient interaction [2,3]. Recent evidence on documentation burden and EHR-related workload further suggests that digital tools can intensify rather than simply relieve nursing work [4,5].

The dominant implementation language around digital health often emphasizes adoption, efficiency, and standardization. These terms are important, but they do not fully capture nurses' lived experience of work redesign. Digital systems may standardize data fields while weakening narrative continuity; they may accelerate information retrieval while increasing documentation time; and they may improve traceability while creating new forms of invisible coordination. This tension is especially relevant to nursing because care depends not only on task completion but also on relational judgment, embodied knowledge, and continuous sense-making across changing clinical situations.

Why a Critical Interpretive Synthesis Was Needed

This review used critical interpretive synthesis (CIS) because the question was not only whether digital technologies are accepted or effective but how digital transformation reorganizes nursing knowledge, identity, and moral agency. CIS is appropriate when heterogeneous evidence must be interpreted to generate a conceptual explanation rather than aggregated into a single effect estimate [6]. We used PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 to transparently report structured search and screening procedures and ENTREQ (Enhancing Transparency in Reporting the Synthesis of Qualitative Research) to support reporting of qualitative and interpretive synthesis decisions [7,8].

Existing technology acceptance approaches help explain perceived usefulness and ease of use, but they often undertheorize the professional and epistemic consequences of digital work. This study therefore moves beyond the question of whether nurses use technology and asks how digital systems may reshape what counts as nursing work and nursing knowledge. The aim of this study was to synthesize interdisciplinary evidence on how digital transformation reshapes nursing professional experience and to develop the fragmented professional transition in nursing (FPT-N) model as a critical sociotechnical explanatory framework.

Methods

Design

We conducted a CIS following the methodology described by Dixon-Woods et al [6]. CIS combines systematic searching with iterative theoretical sampling. The goal is to develop a synthesizing argument that explains a phenomenon across heterogeneous bodies of evidence. In this review, the phenomenon was the effect of digital transformation on nursing professional experience. We used thematic synthesis techniques, including line-by-line coding and analytic theme development, as practical analytic tools within the broader CIS approach [9]. We report the structured search and selection stages using the PRISMA 2020 flow diagram for transparency. As CIS uses purposive theoretical sampling rather than exhaustive aggregation, certain PRISMA items that assume a fixed protocol (such as detailed reasons for excluding every full-text record at the conceptual sampling stage) are reported as not applicable; the rationale for the conceptual sampling decisions is documented in the audit trail (Multimedia Appendix 1).

Information Sources and Search Strategy

We searched PubMed or MEDLINE, CINAHL, PsycInfo, and Scopus for English-language literature published from January 2015 to December 2024. The search combined nursing terms with digital technology terms and professional experience constructs. Example search concepts included nurs*, electronic health record, telehealth, digital health, mobile health, artificial intelligence, workflow, professional identity, experience, workload, qualitative, interview, focus group, observational, and review. The full database-specific search strings are provided in Multimedia Appendix 2.

Eligibility Criteria

Sources were eligible if they examined nurses' professional experience in relation to digital technologies in clinical practice. We included primary qualitative studies, mixed methods studies with substantial qualitative findings, 1 quantitative observational study that directly quantified EHR-related workflow interruption, and secondary syntheses used for conceptual triangulation. We excluded studies focused solely on students, nonnursing populations, non–health care technologies, or technologies not central to nursing work. For the purposive CIS stage, conceptual richness was operationalized using four criteria: (1) thick description of nurses' digital work in real clinical settings; (2) explicit analysis of workflow disruption, workarounds, role strain, autonomy, communication, or identity tensions; (3) contribution of a transferable concept relevant to workflow fragmentation, epistemic authority, or invisible digital articulation work; and (4) sufficient proximity to practicing nurses' experience. Sources did not need to meet all 4 criteria, but inclusion in the interpretive sample required at least one strong empirical or conceptual contribution to the developing synthesizing argument.

Study Selection and Sampling

The database search identified 2847 records. After removing 865 duplicates, 1982 records were screened by title and abstract. We assessed 124 full-text reports and included 13 evidence

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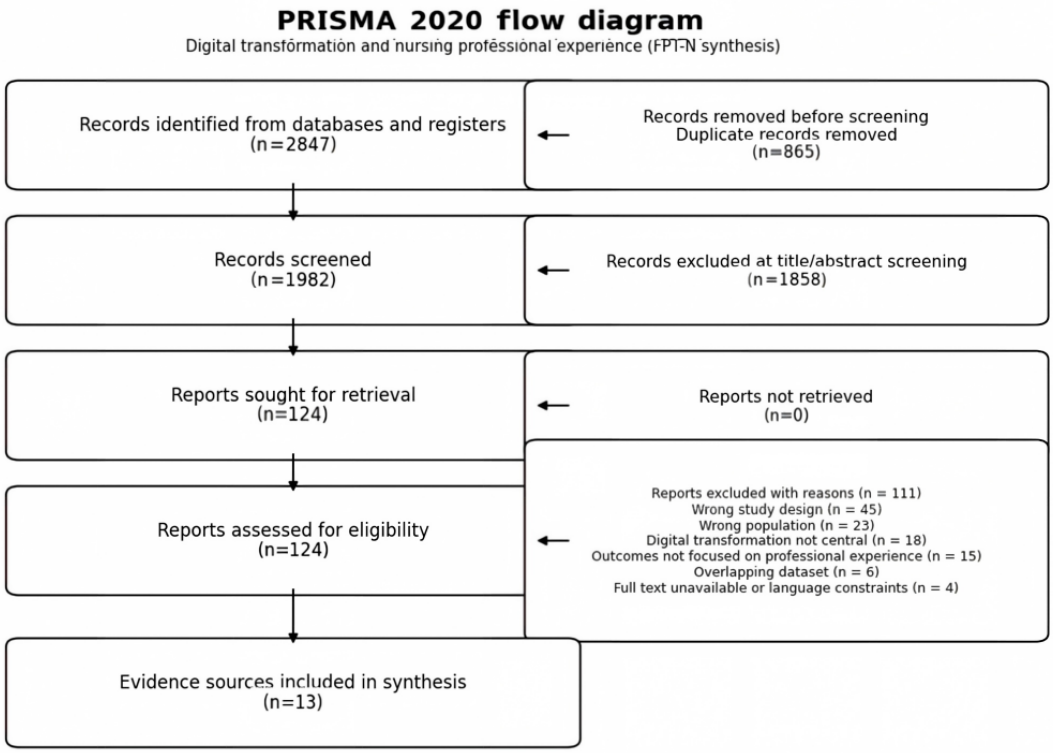
sources in the final synthesis (Figure 1). Two reviewers independently screened titles and abstracts, screened full texts, and resolved disagreements through discussion. During the CIS sampling stage, 1 reviewer led extraction and line-by-line coding, while a second reviewer checked inclusion rationales, construct allocation, and instances where an interpretive claim could exceed the immediate evidence base. Disagreements were resolved through discussion until consensus was reached. The structured search provided the initial sampling frame, and CIS purposive sampling was then used to identify sources with high conceptual relevance. Inclusion decisions were documented in a screening log and audit trail.

Figure 1. PRISMA 2020 flow diagram of evidence source identification, screening, eligibility assessment, and inclusion. FPT-N: fragmented professional transition in nursing.



Quality Appraisal and Interpretive Weighting

Primary qualitative studies were appraised using the Critical Appraisal Skills Programme (CASP) qualitative checklist [10]. In CIS, quality appraisal informs interpretive weighting rather than automatic exclusion. Studies with stronger methodological reporting were given greater weight when grounding empirical claims. Studies with narrower methods but high conceptual density were retained when they contributed to theory development, but their role was framed cautiously as conceptual rather than confirmatory evidence. For quantitative and secondary evidence, we assessed relevance, plausibility, and proximity to nurses' original experience rather than applying the CASP qualitative checklist as a universal tool.

Data Extraction, Synthesis, and Audit Trail

We extracted bibliographic information, evidence type, setting, sample or source composition, technology context, key findings, author interpretations, and relevance to FPT-N dimensions. Analysis proceeded through line-by-line coding, descriptive grouping, constant comparison, and memo-based development of analytic constructs [10]. To strengthen auditability, the audit matrix recorded (1) the empirical observation or review finding; (2) whether the source functioned as a primary empirical anchor or contextual or theoretical support; (3) the provisional FPT-N construct to which it contributed; (4) the memo rationale for retaining, merging, or revising the construct; and (5) whether the final statement was reported as an empirical finding or as a higher-order interpretation. The final synthesizing argument linked 3 constructs—workflow fragmentation, epistemic injustice, and invisible digital articulation work—into the FPT-N model. Analytic decisions, coding memos, inclusion rationales, and model development notes are summarized in Multimedia Appendix 1.

Managing Secondary Evidence and Double Counting

As the evidence base included secondary syntheses, we explicitly managed the risk of interpretive layering and double counting. Secondary sources were used to map the broader field and triangulate concepts, not to duplicate primary-study quotations or inflate evidence volume. Where a primary study was also represented in a secondary review, the primary source was treated as the closer empirical anchor. This approach preserved the conceptual breadth of CIS while acknowledging the reduced proximity of secondary evidence to original nursing experience.

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Results

Study Selection and Evidence Composition

The final synthesis included 13 evidence sources: primary qualitative or mixed methods studies, 1 quantitative observational study, and secondary syntheses that provided conceptual and contextual support. The included evidence covered EHR use, virtual care, telehealth, video consulting, digital competence, documentation burden, and workaround behavior. Table 1 summarizes the evidence type, setting or sample, main contribution, and FPT-N dimension supported by each source. These sources included a recent qualitative meta-synthesis of primary care digital health experiences [11]; a systematic review of digital competence [12]; an observational study of EHR interruptions [13]; and evidence on communication, workarounds, virtual care, and remote work [14-22].

Table . Characteristics of the included evidence sources and their contribution to the fragmented professional transition in nursing (FPT-N) model.

Evidence source	Evidence type	Setting or sample	Digital context	Key contribution	FPT-N dimension
Robles-Aguilar et al [11], 2025	Secondary	Primary care and qualitative meta-synthesis	Digital health	Adaptation and nurse-patient interaction	Professional transition and moderators
Krick et al [3], 2019	Secondary	Multiple care settings and 715 studies	Care technologies	Acceptance, effectiveness, and efficiency gaps	Efficiency illusion and implementation gap
Rouleau et al [2], 2017	Secondary	Overview of 22 systematic reviews	ICT[a] in nursing care	Documentation, time, autonomy, and communication	Workflow fragmentation and nursing process
Wisner et al [5], 2019	Secondary	Integrative review of 18 studies	EHR[b] cognitive work	Contextualization and synthesis of nursing information	Workflow fragmentation and epistemic injustice
Konttila et al [12], 2019	Secondary	Systematic review	Digital competence	Ethical, communication, and knowledge management domains	Contextual moderators and digital capital
Shan et al [13], 2023	Primary quantitative	Observational study and 145 shifts	EHR workflow interruption	Interruptions and multitasking increased mental workload	Workflow fragmentation
Blijleven et al [17], 2017	Primary qualitative	Hospital observations or interviews	EHR workarounds	Workflow misfit and workaround consequences	Invisible work and workflow fragmentation
Fraczkowski et al [18], 2020	Secondary	Integrative review	Nurse EHR workarounds	Workaround types and drivers	Invisible digital articulation
Bianchi and Ghirotto [19], 2022	Primary qualitative	Phenomenological interviews	Clinical workarounds	Unmet professional needs and moral tensions	Invisible work and moral agency
Forde-Johnston et al [14], 2023	Secondary	Integrative review	EHR and nurse-patient communication	Task-driven and closed communication patterns	Epistemic injustice and narrative loss
James et al [20], 2021	Secondary	NASSS[c] systematic review	Video consulting scale-up	Hybrid care and coordination work	Moderators and digital articulation
Vaughan et al [21], 2024	Primary qualitative	Primary care nurses during COVID-19	Virtual care	Reshaped workflow, documentation, and autonomy	Professional transition and moderators
Anderson et al [22], 2024	Primary qualitative	General practice nursing and GenCo Study	Remote technology-mediated work	Transactional work and reduced decision involvement	Epistemic injustice and identity strain

[a]ICT: information and communications technology.

[b]EHR: electronic health record.

[c]NASSS: Nonadoption, Abandonment, Scale-up, Spread, and Sustainability.

To maintain alignment between evidence and interpretation, results were reported at 2 levels. First-order empirical findings refer to observations reported in included studies or reviews, such as documentation burden, interruptions, workarounds, and changes in virtual care communication. Higher-order interpretive claims refer to the CIS-derived explanation that these findings may interact to produce fragmented professional transition. We therefore use cautious wording, such as may, can, and suggests, when moving from evidence description to model-level interpretation.

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Theme 1: Workflow Fragmentation and the Efficiency Illusion

The first mechanism was workflow fragmentation. In the included evidence, digital systems could reorganize nurses' work around documentation queues, alerts, authentication steps, and screen-based coordination. Secondary evidence showed that information and communications technology affects documentation time, information access, and communication [2,3]. EHR-specific syntheses described how documentation demands can shift attention away from situated clinical sense-making [5]. The quantitative observational study by Shan et al [13] recorded 2871 interruptions across 145 shifts, providing numerical triangulation for the interpretation that EHR-related work can increase cognitive load.

We define the efficiency illusion as the gap between promised technical efficiency and nurses' experienced workload. The concept does not claim that digital tools are universally inefficient. Rather, it explains how apparent gains in retrieval, legibility, or standardization can be offset by hidden work, such as duplicated documentation, cross-system reconciliation, and repeated recovery from interruption. This definition responds directly to the need to clarify key concepts on first use.

Theme 2: Epistemic Injustice in Data-Centric Care

The second mechanism was interpreted as epistemic injustice in data-centric care. Across the included evidence, structured digital systems could privilege codified, machine-readable data over embodied, narrative, and relational nursing knowledge. Evidence on EHR-mediated communication suggests that structured documentation can reduce the space for narrative interaction and create more task-driven communication patterns [14]. Digital competence literature also shows that training often focuses on technical operation, while ethical judgment, communication, and knowledge management capacities are equally important [12].

According to Fricker [15], epistemic injustice refers to wronging people in their capacity as knowers. In the nursing digital context, this concept helps interpret situations in which nurses' experiential judgment is treated as secondary to data fields, templates, or algorithmic outputs. This is a higher-order interpretation built from empirical signals in the included evidence, rather than a direct empirical finding from any single study. We therefore frame erosion of epistemic authority as a possible mechanism in some digital implementation contexts, not as a universal consequence of digitalization.

Theme 3: Expansion of Invisible Digital Articulation Work

The third mechanism was invisible digital articulation work. In the study by Allen [16], the sociology of nursing work shows that nurses perform extensive coordination labor that keeps health care systems functioning. In digital settings, this work can expand into data repair, cross-platform reconciliation, informal troubleshooting, workaround labor, and patient support for technology-mediated care. Evidence on EHR workarounds shows that nurses bypass or repair digital processes when system logic does not fit clinical contingencies [17,18]. Phenomenological evidence further suggests that workarounds may represent unmet professional needs and moral tensions rather than mere noncompliance [19].

We define invisible digital articulation work as the often-unrecognized work nurses perform to connect fragmented digital systems, clinical realities, and patient needs. Examples include reconciling information across platforms, documenting after the fact to match system requirements, mediating between remote and face-to-face care, and compensating for interoperability gaps. Recognizing this work is crucial because it determines whether digital implementation truly improves care or shifts costs onto nurses.

Synthesizing Argument and the FPT-N Model

The FPT-N model integrates these 3 mechanisms into a critical sociotechnical explanation of how digital transformation may be experienced as fragmented professional transition. In this evidence base, digital transformation appeared to fragment nursing work when it interrupted workflow, narrowed the visible space for narrative judgment, and expanded hidden digital articulation labor. These mechanisms do not operate deterministically. Contextual moderators, including governance, staffing, interoperability, digital capital, and nurses' involvement in technology decisions, shape whether digital transformation leads to adaptive reintegration or alienation. Evidence from virtual care and remote general practice nursing shows that technology-mediated work may become more transactional and may weaken nurses' participation in decision-making if implementation is rapid and insufficiently participatory [20-22]. The model should therefore be read as a transferable explanatory heuristic that requires empirical testing in specific nursing contexts, rather than as a universally generalizable taxonomy.

Discussion

Principal Findings

This CIS found that digital transformation may reshape nursing professional experience through 3 interacting mechanisms: workflow fragmentation, epistemic injustice in data-centric care, and invisible digital articulation work. The main contribution of the FPT-N model is not the identification of any single burden, as prior studies have already described documentation burden, workarounds, and virtual care challenges. Its contribution is integrative and explanatory: it shows how these burdens may interact to produce a fragmented professional transition in which nurses renegotiate the meaning of care, their epistemic authority, and their role boundaries within digital systems. Recent work on digital technology and professional identity, documentation burden measurement, and health system documentation workload further supports the need to integrate professional identity and workload metrics in future implementation evaluations [23-25].

Recent nursing-focused evidence further confirms that technology may have mixed effects on workload, adoption, identity, implementation, and relational care, reinforcing the need for context-sensitive governance rather than efficiency-only evaluation [26-30].

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Novelty Relative to Existing Frameworks

Traditional technology acceptance models are useful for explaining perceived usefulness and ease of use, but they do not fully capture identity-level and epistemic consequences. General sociotechnical frameworks emphasize interactions among people, tools, tasks, and organizations, but they may not specifically theorize how nursing knowledge becomes less visible or how invisible digital articulation work expands. The FPT-N model adds value by framing digital transformation as a professional transition rather than only an implementation problem. This framing highlights that nurses are not simply users of technology; they are knowledge workers whose authority and moral agency can be strengthened or weakened by design and governance choices.

Implications for Nursing Identity, Autonomy, and Moral Agency

Framing digital transformation as fragmented professional transition shifts attention from technology adoption alone to the professional consequences of digitally mediated care. Nursing identity is sustained through relational presence, narrative judgment, coordination, and accountability for continuity of care. When digital systems make documentation completion more visible than clinical sense-making, nurses may experience a mismatch between what the system measures and what they understand as good nursing. This mismatch can create identity strain, especially when nurses are expected to maintain relational and ethical care while absorbing additional documentation, troubleshooting, and cross-system reconciliation work.

Professional autonomy is also affected by how digital systems allocate authority. Decision support, standardized templates, and algorithm-mediated prompts can be useful when they extend nurses' situational awareness and reduce preventable omissions. They become professionally problematic when they narrow the space for contextual judgment or require nurses to translate complex patient narratives into fields that do not capture uncertainty, relational cues, or moral priorities. The FPT-N model therefore emphasizes that moral agency should be treated as a matter of design and governance rather than solely as an individual competency.

Data-Centric Care and Professional Governance

The wider implication of data-centric care is that nursing value may be inferred from what is easiest to capture, rather than from what is most important for safe and humane care. Documentation completeness, response time, and protocol adherence are legitimate metrics, but they do not fully represent anticipatory care, narrative interpretation, emotional support, or coordination across fragmented systems. A critical sociotechnical approach therefore requires governance structures that protect nurses' epistemic contribution when data standards, EHR templates, and AI tools are introduced.

Practically, this means involving nurses in procurement, workflow redesign, implementation monitoring, and algorithm review; requiring usability assessments that include interruptions, narrative space, and hidden coordination work; and treating workaround patterns as diagnostic signals of sociotechnical misfit rather than as individual noncompliance. These governance mechanisms could help shift digital transformation from fragmentation toward adaptive reintegration.

Contextual Moderators and Practice Implications

The moderators identified in the model specify practical levers for change. Governance can shift outcomes by involving nurses in procurement, workflow redesign, and algorithm review. Staffing models can recognize documentation, reconciliation, and patient technology support as real work rather than discretionary add-ons. Interoperability can reduce cross-system data repair, and digital capital can reduce inequity by ensuring that both nurses and patients have access to training and support. These actions operationalize the recommendation to recognize invisible digital articulation work through metrics, workload assessment, and participatory governance.

For health systems, recognizing invisible digital articulation work could involve time-motion audits, documentation burden dashboards, and structured reporting of workaround frequency. For technology developers, design evaluation should include nursing cognitive workflow and narrative clinical judgment, not only task completion time. For educators, digital competence should include ethical reasoning, epistemic humility, and communication in hybrid care, not only software operation.

Boundary Conditions and Generalizability

The FPT-N model is intended as an explanatory framework for interpretation and further empirical testing. It should not be read as implying that all digital health implementations fragment nursing experience. The direction and magnitude of transition are likely to differ across clinical specialty, staffing model, digital maturity, interoperability, organizational culture, and the degree of nurse participation in design and governance. In settings where digital systems reduce duplication, preserve narrative communication, and make coordination labor visible, digital transformation may support professional reintegration rather than fragmentation.

Strengths and Limitations

This review's strengths include a transparent search process, explicit use of CIS, appraisal-informed interpretive weighting, and integration of primary, quantitative, and secondary evidence. The main limitation is that the final evidence base was relatively small and included several secondary sources. This composition increased conceptual reach but reduced proximity to original qualitative data in some areas. We addressed this by avoiding duplication of primary quotes from reviews, distinguishing empirical findings from higher-order interpretation, and treating secondary syntheses as contextual rather than confirmatory evidence. As CIS is designed for theory generation rather than prevalence estimation, the model should be considered provisional until tested in diverse nursing settings. Future empirical work should examine whether the proposed moderators predict adaptation, moral distress, turnover intention, perceived professional autonomy, or perceived epistemic authority.

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Conclusions

Digital transformation can improve information access and care coordination, but it may also fragment nursing professional experience when implementation privileges documentation logic over nursing cognition, marginalizes narrative clinical judgment, and expands unrecognized coordination work. The FPT-N model provides a critical explanatory framework for understanding these dynamics and for designing digital health implementation that protects nursing knowledge, reduces hidden labor, and supports adaptive professional reintegration. The broader significance of the synthesis is that digital nursing governance should evaluate not only whether systems are adopted but also whether they preserve professional identity, autonomy, moral agency, and nurses' contribution as clinical knowers. Future research should operationalize the FPT-N mechanisms in empirical studies and test whether participatory governance, interoperability, and workload-sensitive design reduce professional fragmentation across nursing contexts.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Critical interpretive synthesis audit trail summary, including screening decisions, coding memos, and model development notes.
[DOCX File, 38 KB - apinj_v10i1e94189_app1.docx]

Multimedia Appendix 2
Full database search strategies.
[DOCX File, 38 KB - apinj_v10i1e94189_app2.docx]

Checklist 1
PRISMA 2020 checklist.
[DOCX File, 43 KB - apinj_v10i1e94189_app3.docx]

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Abbreviations

CASP: Critical Appraisal Skills Programme
CIS: critical interpretive synthesis
EHR: electronic health record
ENTREQ: Enhancing Transparency in Reporting the Synthesis of Qualitative Research
FPT-N: fragmented professional transition in nursing

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PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Effect of BMI on Mortality in Patients With Tuberculosis and HIV Coinfection in Asia and Africa: Systematic Review and Meta-Analysis

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Abstract

Background: Tuberculosis (TB) continues to pose a major global health threat, particularly in low- and middle-income countries. An estimated 10.8 million people developed TB in 2023, corresponding to 134 cases per 100,000 population. The Southeast Asia region accounted for 45% of global TB incidence, while the African region contributed 24%. Nutritional status, particularly low BMI, is a key modifiable determinant of adverse clinical outcomes. However, its overall impact on mortality among TB-HIV coinfected populations in Asia and Africa remains poorly quantified.

Objective: This study aimed to systematically assess the association between BMI and mortality among patients with TB-HIV coinfection in Asia and Africa.

Methods: A systematic review and meta-analysis were conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 guidelines. Cohort studies published between 2000 and 2024 were identified through PubMed, Scopus, and ProQuest. Data extraction and risk of bias assessment were performed independently by 3 reviewers using the Risk of Bias in Non-Randomized Studies – of Exposure tool. A random effects model with the DerSimonian-Laird method was applied using RevMan 7.2 (Cochrane) to estimate pooled risk ratios with 95% CI. Heterogeneity was quantified using the I^2 statistic, and subgroup analyses were conducted by geographic region.

Results: Seven cohort studies met the inclusion criteria. The pooled estimate indicated that patients with BMI less than 18.5 kg/m² had approximately twofold higher mortality risk compared to those with normal or higher BMI (risk ratio=2.01; 95% CI 1.63 - 2.48; P<.001). Despite moderate heterogeneity (I^2=64%), the association remained consistent across subgroups. Although most studies were rated as having high or moderate risk of bias, sensitivity analyses confirmed the robustness of the results.

Conclusions: Low BMI significantly increases the risk of mortality among patients with TB and HIV coinfection in Asia and Africa, underscoring its prognostic and modifiable role in clinical outcomes. Routine nutritional screening, BMI monitoring, and targeted supplementation should be integrated into national TB-HIV management programs, particularly in resource-limited settings. Strengthening TB-HIV nutrition service integration is essential to improve survival and achieve global End TB and United Nations Programme on HIV/AIDS 95-95 - 95 targets.

Trial Registration: OSF Registries osf.io/74qwh; https://osf.io/74qwh/overview

(Asian Pac Isl Nurs J 2026;10:e81905) doi:10.2196/81905

KEYWORDS

Asia; Africa; BMI; HIV; meta-analysis; mortality; tuberculosis

Introduction

Tuberculosis (TB) and HIV represent 2 converging epidemics that amplify each other's clinical and epidemiological impact. This syndemic interaction remains one of the most formidable challenges to achieving global health targets. TB and HIV remain major global public health threats, particularly in low- and middle-income countries [1]. The interaction between TB and HIV is synergistically detrimental, as HIV significantly increases the risk of progression from latent TB infection to active disease, while TB accelerates the progression of HIV-related immunosuppression [2,3]. In 2023, an estimated

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10.8 million people developed TB globally, an increase from 10.7 million in 2022, reflecting a continued rebound following disruption caused by the COVID-19 pandemic. TB caused an estimated 1.25 million deaths, including 161,000 deaths among people living with HIV. Although mortality has declined by 23% since 2015, this progress remains far below the End TB Strategy milestone of a 75% reduction by 2025 [4]. These figures underscore the urgent need for integrated approaches to meet the World Health Organization End TB Strategy and United Nations Programme on HIV/AIDS 95-95 - 95 targets, which emphasize early detection, treatment adherence, and reduction of preventable deaths.

The burden of TB is disproportionately concentrated in low- and middle-income countries, particularly in Asia and Africa, which together account for nearly 87% of global incident cases. A total of 5 countries—India, Indonesia, China, the Philippines, and Pakistan—alone contribute more than half of the global TB burden. The African region continues to experience the highest mortality rate, estimated at 24 deaths per 100,000 population among HIV-negative individuals, compared with only 2.4 in the European region. Coinfection with HIV remains a major driver of mortality, with an estimated 662,000 people living with HIV developing TB in 2023, yet only 58% receiving both TB treatment and antiretroviral therapy (ART) [4].

Several factors exacerbate TB-HIV transmission and mortality. These include socioenvironmental determinants such as poverty, overcrowding, malnutrition, smoking, and exposure to environmental pollutants like biomass fuel and mining dust [5-7]. HIV infection independently contributes to poor nutritional status, which in turn influences TB disease progression and treatment outcomes [8-10]. Compounding this, the COVID-19 pandemic disrupted TB diagnostic and treatment services globally, particularly in Africa and Asia-Pacific, leading to delayed case detection and treatment initiation [11].

Among the modifiable determinants of survival, nutritional status, particularly BMI, plays a crucial role. From a biological standpoint, low BMI reflects impaired nutritional and immunological status, which weakens host defense mechanisms and predisposes patients to severe disease progression and poor treatment outcomes. Undernutrition remains the leading global risk factor for TB incidence, surpassing HIV, diabetes, and alcohol use in its attributable burden. Low BMI (<18.5 kg/m²) has consistently been linked to increased early and all-cause mortality during TB treatment [12]. A prospective cohort study in Ethiopia demonstrated that BMI improvement following initiation of ART was significantly associated with reduced mortality, regardless of initial BMI classification [13]. In contrast, BMI decline within the first month of TB treatment was linked to higher mortality among HIV-positive individuals in Myanmar and Zimbabwe [14]. Additional evidence from Taiwan suggests that underweight male patients have significantly higher TB-specific and non–TB-specific mortality risks during treatment [15].

HIV-associated wasting, often reflected by reduced midupper arm and muscle circumference, further highlights the intersection between nutrition and immune function in TB-HIV management [8,16]. While early ART initiation alongside TB therapy—especially for individuals with cluster of differentiation 4 positive (CD4+) counts less than 50 cells/µl—has been shown to improve survival [17], nutritional assessment and interventions remain underintegrated in TB-HIV care programs, particularly in resource-limited settings.

Despite a growing body of research examining the relationship between BMI and mortality in patients with TB and HIV coinfection, the evidence remains fragmented and inconsistent. Existing studies vary widely in design, sample size, and nutritional cut-off definitions, resulting in heterogeneous findings and limiting the reliability of pooled mortality estimates. Furthermore, no comprehensive systematic review or meta-analysis has been conducted to quantitatively synthesize the magnitude of this association, particularly within high-burden settings such as Asia and Africa, where the dual epidemics of TB and HIV intersect with widespread malnutrition. This lack of consolidated evidence has hindered the development of integrated clinical-nutritional strategies aimed at improving survival among patients with coinfection.

Therefore, this study aims to fill this critical gap by conducting a systematic review and meta-analysis of cohort studies evaluating the effect of BMI on mortality among patients with TB-HIV coinfection in Asia and Africa. This study provides the first quantitative synthesis focusing specifically on Asia and Africa—regions that jointly bear nearly 90% of the global TB burden—offering critical evidence to guide regionally tailored public health interventions. We hypothesize that a lower BMI (<18.5 kg/m²) significantly increases the risk of mortality compared to a normal or higher BMI (≥18.5 kg/m²). The results of this study are expected to provide robust, evidence-based insights to guide targeted clinical interventions and public health strategies for this highly vulnerable population.

Methods

Ethical Considerations

This study was conducted using secondary data. This systematic review and meta-analysis is being reported in accordance with the reporting guidance provided in the PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol) statement [18-20] (Checklist 1).

Eligibility Criteria

Eligibility criteria for this review included cohort studies (retrospective or prospective) published in the period 2000 - 2024 in PubMed, Scopus, and ProQuest databases, with a focus on adult patients (>15 y) with TB and HIV coinfection in Asia and Africa. Only academic journal articles with full-text access were included, while literature reviews, case reports, short reports, proceedings, and studies without mortality data were excluded. The primary outcome evaluated was mortality in populations with TB or HIV coinfection, so studies that did not report mortality rates or examine pediatric populations were excluded from the analysis.

Data Sources and Search Strategy

A comprehensive literature search was conducted in PubMed, Scopus, and ProQuest to identify relevant studies from

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2000 - 2024. The search strategy combined Medical Subject Heading (MeSH) terms and free-text keywords related to TB-HIV coinfection, BMI, and mortality. Only studies published in English and involving adult populations (>15 y) were included. Mendeley reference management software (Elsevier) was used to import and maintain the retrieved studies. On October 30 - 31, 2024, a search was done to find studies that would be suitable for meta-analysis and systematic review. The full boolean search string used was ("Coinfection"[Mesh] OR "Co-infection" OR "Multiple infection") AND ("Tuberculosis"[Mesh] OR "TB" OR "Tuberculosis") AND ("HIV Infections"[Mesh] OR "HIV" OR "Human Immunodeficiency Virus" OR "TB?HIV") AND ("Adult"[Mesh] OR "Mature" OR "Person over 18") AND ("Body Mass Index"[Mesh] OR "BMI") AND ("Mortality"[Mesh] OR "Fatal*" OR "Death" OR "Case fatality rate" OR "Mortality rate") AND ("Cohort Studies"[Mesh] OR "Cohort study" OR "Cohort").

Screening and Selection Process

A total of 3 independent reviewers participated in the methodical and comprehensive screening and research selection procedure. To make it easier to filter titles and abstracts based on preset inclusion and exclusion criteria, all database search results were uploaded to the Rayyan artificial intelligence app (Rayyan Systems, Inc). Before moving on to the full-text screening phase, which was also carried out individually by the 3 reviewers, articles that were found to be duplicates were eliminated. Discussion and agreement were used to settle any disagreements. Data such as author name, year of publication, area, sample size, and number of events in the experimental group (BMI <18.5 kg/m²) and the control group (BMI ≥18.5 kg/m²) were retrieved from publications that satisfied the selection criteria. The data were then recorded in Microsoft Excel spreadsheets to facilitate further management and analysis.

Risk of Bias Assessment

The risk of bias assessment in this study was performed using the Risk of Bias in Non-Randomized Studies – of Exposure (ROBINS-E) tool, which was specifically developed for evaluating nonrandomized observational studies that investigate the relationship between exposures and outcomes [21]. This tool is particularly appropriate for the present meta-analysis, as all included studies examined the effect of BMI as an exposure on mortality outcomes among patients with TB and HIV coinfection. ROBINS-E assesses 7 domains of potential bias: (D1) bias due to confounding, (D2) bias arising from measurement of the exposure, (D3) bias in selection of participants into the study, (D4) bias due to postexposure interventions, (D5) bias due to missing data, (D6) bias arising from measurement of the outcome, and (D7) bias in selection of the reported result.

Each domain was rated as "low risk," "some concerns," or "high risk," and the overall risk of bias for each study was determined based on the highest level of bias observed across all domains. The use of ROBINS-E was supported by its ability to provide a structured and transparent framework for assessing the internal validity of exposure-outcome relationships in epidemiologic research [22].

Data Extraction

A total of 3 independent reviewers performed data extraction using a standardized Microsoft Excel spreadsheet developed based on a predefined checklist. Extracted information from each primary study included the author's name, year of publication, study location, sample size, study design, and the number of deaths and survivors in both groups: the experimental group (BMI <18.5 kg/m²) and the control group (BMI ≥18.5 kg/m²). Any discrepancies between reviewers were resolved through discussion and consensus to ensure data accuracy and consistency prior to quantitative synthesis.

Outcome Variable and Measures

The primary outcome assessed in this review was mortality among patients with TB and HIV coinfection, measured as the proportion of deaths between the experimental group (BMI <18.5 kg/m²) and the control group (BMI ≥18.5 kg/m²). The measure of association used was the risk ratio (RR) with a 95% CI. For studies that reported odds ratios or hazard ratios, the estimates were converted into RR values using the method proposed by Zhang and Yu (1998) [23], which adjusts for baseline risk in the control group. This standardization ensured that all effect measures were expressed on a comparable scale, facilitating accurate pooling in the meta-analysis.

Data Synthesis and Analysis

The quantitative synthesis was conducted using Review Manager (RevMan) version 7.2 (Cochrane), applying a random effects model (DerSimonian-Laird method) to account for potential heterogeneity between studies [24]. The pooled effect estimates were expressed as RR with corresponding 95% CI. Heterogeneity was quantified using the I^2 statistic, categorized as low (<25%), moderate (25% - 50%), or high (>50%) [25]. Subgroup analyses were performed based on geographical region (Africa and Asia) to explore potential sources of heterogeneity and assess regional differences in the effect of BMI on mortality. The overall and subgroup pooled estimates were visualized using forest plots.

Protocol Registration and Deviations

This systematic review and meta-analysis was prospectively registered in the Open Science Framework (OSF.IO/74QWH). Minor deviations occurred between the registered protocol and the final analysis. Specifically, the risk of bias tool was changed from the Hoy tool to the ROBINS-E instrument to better align with cohort study designs. These modifications were made prior to data synthesis and did not affect the overall analytic framework or study objectives.

Results

Selection of Studies

A comprehensive literature search yielded 814 articles from 3 major databases, namely PubMed (n=220), Scopus (n=292), and ProQuest (n=302). After 43 duplicate articles were removed, a total of 771 articles were screened at the title and abstract screening stage, of which 748 were excluded as they did not meet the inclusion criteria. A total of 23 articles were then retrieved for full review, but 1 article could not be retrieved, so

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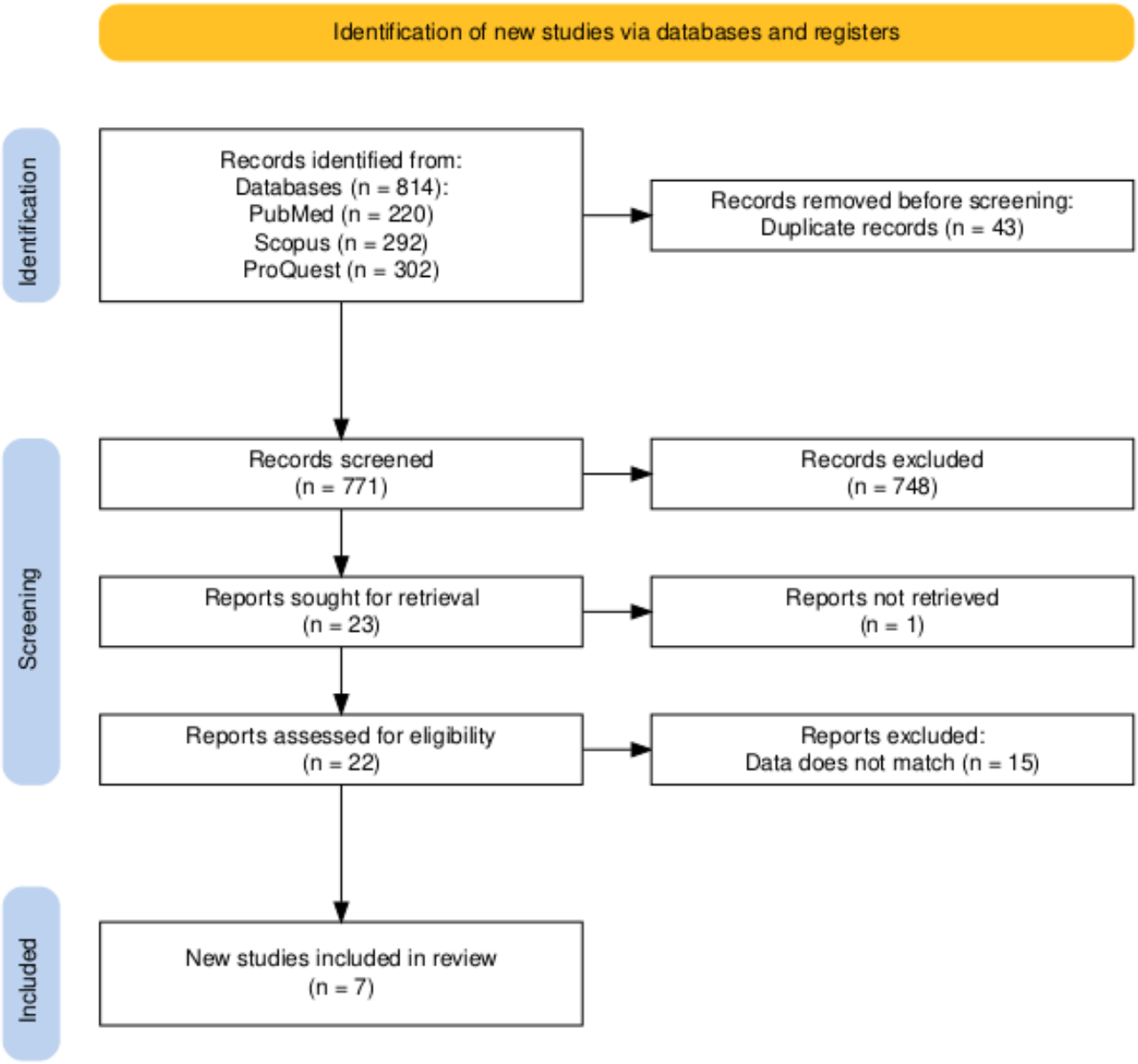
22 articles were assessed for eligibility. At this juncture, 15 studies that failed to meet the requisite data criteria were excluded, resulting in the inclusion of 7 articles in the systematic review and meta-analysis [14,26-32]. The study selection process is detailed in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram (Figure 1).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Findings

The characteristics of the included studies are summarized by key baseline demographic, clinical, and epidemiological features of TB-HIV coinfected populations across the seven cohort studies. These features include variations in age distribution, sex composition, nutritional status as measured by BMI, HIV clinical stage, CD4 cell count categories, and ART status at baseline. These variables provide essential context for understanding population heterogeneity and for interpreting the pooled mortality estimates derived from the meta-analysis, as detailed in Table 1.

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Table . Data extraction from the included studies.

Author(s) [reference]	Key baseline characteristics[h]	Method	Population/sample	Result
Kegne et al [26]	• Age distribution: <15 (3.7%), 15-24 (9.5%), 25-34 (36.7%), 35-44 (31.4%), ≥45 (18.7%) • Sex: Male (56.6%), Female (43.4%) • BMI categories: <18.5 (40.1%), 18.5-24.5 (47.6%), >24.5 (12.2%) • WHO[a] HIV clinical stage: Stage I (6.0%), II (4.7%), III (44.9%), IV (44.4%) • CD4[b] count (cells/µL): <200 (24.2%), ≥200 (75.8%) • ART[c] status/adherence: good (88.3%), fair (7.0%), and poor (4.7%) • Variables NR[d]: symptomatic TB status, household TB contact, and viral load	A retrospective cohort study was conducted among patients coinfected with TB[e]-HIV who were treated for TB at public health facilities in Bahir Dar city	The study included 401 patients coinfected with TB-HIV treated between July 2018 and June 2022	Among the 401 patients monitored, 59 (14.7%) passed away during the follow-up period. The research identified several significant predictors of mortality related to BMI. Specifically, patients with a BMI of less than 18.5 kg/m² experienced a mortality risk that was 3 times higher than those with a normal BMI. This finding was substantiated by an aHR[f] of 3.00, with a 95% CI ranging from 1.44 to 6.28, indicating a statistically significant relationship between lower BMI and increased mortality risk (P<.05) [26]
Bayowa et al [27]	• Age distribution: mean 34.6 (SD 10.5); categories <35 (51.54%), ≥35 (48.46%) • ART status at baseline: on ART (95.5%); ART-naïve (4.5%) • ART regimen: 1st line (62.1%); 2nd line (4.4%); and 3rd line (33.4%) • Viral load categories: detectable (9.7%); undetectable (14.4%); and unknown (75.9%) • BMI categories: <18.5 (36.67%); ≥18.5 (63.33%) • Variables NR: symptomatic TB status, household TB contact, newly initiated ART, CD4 count, WHO HIV stage	The study used a retrospective cohort design that involved reviewing medical records of patients coinfected with DR-TB[g] and HIV who were registered at the Mulago Tuberculosis Unit from January 1, 2014, to December 31, 2019	The study included 390 participants who met the eligibility criteria of having confirmed DR-TB and documented HIV positive status, resulting from an initial review of 412 records. Participants were aged from 1 to 80 y, with a mean age of 34.6 y (SD 10.5), and the majority were male participants (53.9%).	The results indicated a mortality rate of 33.2% (95% CI 28.7-38.1) among the study population. Specifically, regarding the relationship between BMI and mortality, a BMI of less than 18.5 kg/m² was associated with an increased likelihood of death. The adjusted incidence rate ratio for those with BMI less than 18.5 kg/m² was 0.91 (95% CI 0.85-0.97), with a P value of .007, which suggests a statistically significant protective effect against mortality for individuals with a higher BMI. This highlights the critical importance of maintaining an adequate nutritional status as a determinant of mortality outcomes in this vulnerable population [27]
Gevorgyan et al [28]				

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Author(s) [reference]	Key baseline characteristics[h]	Method	Population/sample	Result
	• Age distribution: ≤37 (8.3%); 31-40 (32.8%); 41-50 (32.8%); >50 (26.2%) • ART status at baseline: favorable (74.4% on ART); unfavorable (51.1% on ART) • CD4 count (cells/mm3): ≤50 (27.6%); 51-200 (18.5%); >201 (17.7%); unknown (55.3%) • BMI: underweight (27.4%); normal (45.6%); overweight or obese (8%) • Variables NR: Symptomatic TB status, household TB contact, viral load, WHO HIV stage.	The study was conducted in Armenia and used a cohort study design using routine programmatic data of HIV-associated patients with TB receiving treatment from 2015 to 2019.	The population for this research included both pulmonary and extrapulmonary patients with HIV-associated TB, and the study comprised a total of 351 treatment episodes involving 320 individual patients. The authors detailed the sociodemographic and clinical characteristics of these patients through data collected from the National TB database, National HIV database, and patients' medical records.	The results indicated a significant association between BMI and mortality rates among the patients with HIV-associated TB. Specifically, underweight patients had an increased risk of death, reflected in an aHR of 2.5 (95% CI 1.3-4.5), with a *P* value of less than .01. This finding underscores the critical role of nutritional status in influencing health outcomes within this vulnerable population, highlighting the necessity for addressing malnutrition as a part of TB management and care protocols in clinical settings [28]
Kosgei et al [29]				
	• Age distribution: 15-24 (11.7%); 25-29 (20.7%); 30-34 (23.8%); 35-39 (20.2%); 40-44 (15%); 45-49 (8.6%). Mean age in years (SD) was 33.3 (7.5) • BMI: <15 (12.1%); 15-18.5 (40.8%); 18.5–24.9 (34.1%); >25 (3.1%); missing (9.9%) • Time of ART start after TB treatment: <14 days (23.1%); 15-30 days (13.3%); 31–60 days (10.1%); >60 days (7.4%); before TB treatment (29%); not started (17.1%) • Variables not reported (NR): Symptomatic TB status, household TB contact, CD4 count, viral load, WHO HIV stage	This study used a retrospective cohort design, analyzing healthcare records from individuals treated for TB between 2012 and 2015. The primary outcome of interest was all-cause mortality during TB treatment.	The study analyzed a total sample of 9026 patients with smear-positive pulmonary TB, aged 15-49 y, who were coinfected with HIV.	The findings revealed that men exhibited a higher mortality rate (11%) compared to women (9%), with a statistically significant difference (*P*=.004). The risk ratio indicated that women had a 17% reduced risk of mortality compared to their male counterparts (aHR 0.83; 95% CI 0.72-0.96; *P*= .013). A higher BMI was associated with a reduced risk of death during treatment; specifically, those with a BMI higher than 18.5 had a lower mortality risk compared to those with a BMI less than 15, underscoring the importance of maintaining a healthy body weight in this population for better treatment outcomes. These results suggest that both gender and BMI significantly influence survival among patients coinfected with pulmonary TB-HIV, highlighting areas for targeted interventions in health care delivery [29]
Naidoo et al [30]				

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Author(s) [reference]	Key baseline characteristics[h]	Method	Population/sample	Result
	• Age distribution: median age by BMI groups: 33-36 y (IQR 29-43) • ART baseline status: uniform (all initiated ART); detailed categories not reported • CD4 count groups: only continuous medians available • Viral load categories: only mean viral load reported • WHO HIV stage: stage 1-3 and 4 reported by BMI • Variables not reported: symptomatic TB status, household TB contact	This study used a retrospective cohort design. Clinical data from HIV-infected patients was evaluated, using statistical methods to assess the correlation between BMI and mortality outcomes. Key analysis tools included multivariate proportional hazards regression to adjust for confounding variables and the log-rank test for comparing survival distributions across BMI categories.	The study comprised a total of 1000 HIV-infected patients. However, due to missing height or weight measurements for 52 patients, the final analysis included 948 patients, split into different BMI categories for assessment. Among these, 389 patients were also coinfected with TB.	The findings indicated that underweight patients (BMI < 18.5 kg/m²) faced a significantly increased risk of mortality compared to those with a normal BMI (18.5-24.9 kg/m²). Specifically, the aHR for mortality in underweight patients was 2.9 (95% CI 1.5-5.7; *P*=.002). This result underscores a notable correlation between low BMI and elevated mortality rates among HIV-infected individuals, highlighting that underweight patients possessed a nearly threefold elevated risk of death relative to their normally weighted counterparts. The study confirms the essential role of baseline BMI as a prognostic indicator, irrespective of TB coinfection status. Notably, mortality rates for those categorized as overweight (BMI 25.0-29.9) and obese (BMI ≥ 30.0) were not significantly different from those with normal BMI, further establishing the critical impact of being underweight on survival outcomes in this population [30]
Wejse et al [31]				
	• Age distribution: 15-30 (46%); 30-40 (24%); 40-50 (16%); >50 (14%) • All symptomatic; duration reported; asymptomatic NR. • HIV status categories: HIV-negative (71.1%); HIV-1 (18.4%); HIV-2 (7.1%); dual (3.4%) • CD4 count (cells/mm3): >500 (9.7%); 200-500 (4.9%); <200 (13.3%) • Variables NR: Household TB contact, ART baseline status, viral load, WHO HIV stage	The study used a longitudinal, prospective cohort design. Patients were identified through daily visits by field assistants to local health centers and a national referral TB hospital. The diagnosis of TB was made according to WHO criteria, and both smear-positive and smear-negative cases were included based on defined medical and clinical parameters.	The study included a total of 1312 patients with TB who had completed their anti-TB treatment by September 1, 2013. Among these patients, 379 were HIV-infected, comprised of those with HIV-1, HIV-2, and dual infections.	The findings of the study indicated a significant relationship between BMI and mortality among patients with TB. Specifically, the results demonstrated that patients with a BMI less than 17 kg/m² had a crude hazard ratio of 1.42 (95% CI 0.81-2.49), and this association reached statistical significance with a *P* value of .021. This emphasizes that lower BMI is correlated with increased mortality rates in the context of TB management. The study underscores the necessity of monitoring and addressing nutritional status as a critical component of TB treatment protocols [31]
Benova et al [14]				

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Author(s) [reference]	Key baseline characteristics[h]	Method	Population/sample	Result
	• Age distribution: median (34-y-old); IQR (29.5-40.2) • BMI: <16 (23.6%); 16-18.49 (36.8%); 18.5-24.99 (36.8%); ≥25 (2.8%) • ART status at TB treatment start: prior to TB treatment (21.3%); within 2 wk (8.7%); within 2-4 wk (18%); after 4 wk (31.9%); after end of TB treatment (20.1%) • CD4 count (cells/mm3): ≤100 (57.8%); 101-200 (21.5%); 201-350 (14.2%); >350 (6.5%) • Variables NR: symptomatic TB status, household TB contact, viral load, WHO HIV stage	This retrospective cohort study involved analyzing data collected over 7 y from patients with TB in clinical programs. The study employed Cox proportional hazards regression to evaluate the association between changes in BMI category during the first month of TB treatment and subsequent mortality. Adjustments were made for potential confounders, including sex, age group, project site, and ART status as a time-dependent covariate.	The study included a total of 1090 new adult patients with TB who were HIV-positive, specifically focusing on those diagnosed with smear-negative and extrapulmonary TB. Data were drawn from 3 clinical programs across the mentioned countries.	The analysis revealed a robust association between changes in BMI category during the initial months of TB treatment and mortality outcomes. Patients who remained severely underweight or moved to a lower BMI category had aHR of 4.05 (95% CI 2.77-5.91, *P*<.001) for mortality compared to those who either maintained or moved to a higher BMI category. This indicates a significantly elevated risk of death associated with BMI category deterioration. Similarly, those who remained severely underweight or lost a BMI category showed over twice the rate of unfavorable TB treatment outcomes, with an aHR of 2.53 (95% CI 1.87-3.42). These findings underscore the importance of monitoring BMI changes in identifying individuals at heightened risk of mortality during TB treatment in HIV-positive populations [14]

[a]WHO: World Health Organization.

[b]CD4: cluster of differentiation 4.

[c]ART: antiretroviral therapy.

[d]NR: not reported.

[e]TB: tuberculosis.

[f]aHR: adjusted hazard ratio.

[g]DR-TB: drug-resistant tuberculosis.

[h]Note: Absolute frequencies (n) are reported alongside percentages where available. Variations in n values across categories reflect differences in reporting formats and sample denominators in the original studies included in this review.

Meta-Analysis

In this study, the meta-analysis was conducted using Review Manager (RevMan) version 7.2, using the inverse-variance method under a random effects model to account for possible heterogeneity among the included studies [32]. This analytical approach assumes that the true effect size varies across studies due to differences in study design, populations, and settings, making it suitable for combining data from both Asian and African regions. The DerSimonian-Laird method was used to estimate the between-study variance (τ^2), providing a more conservative and generalized pooled estimate [24].

Effect sizes were expressed as RR with corresponding 95% CI. Statistical heterogeneity was assessed using the I^2 statistic and Cochran Q (χ^2) test, which quantify the proportion of total variation across studies that is due to heterogeneity rather than chance [33]. Additionally, a 95% prediction interval was calculated to indicate the expected range of true effects in future studies conducted under similar conditions. The overall results of the meta-analysis are illustrated in the forest plot (Figure 2).

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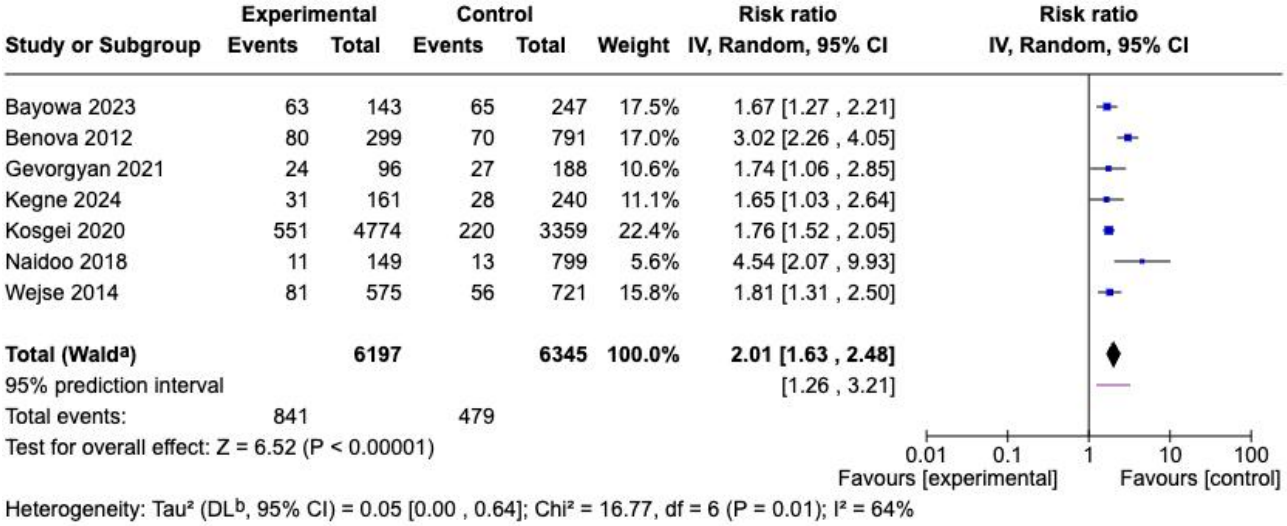
Figure 2. Forest plot of pooled meta-analysis showing the association between low BMI and mortality among patients with tuberculosis and HIV coinfection. The diamond represents the pooled risk ratio estimated using a random-effects model (DerSimonian and Laird method). The 95% CIs were calculated using the Wald-type method [14,26-31].



A total of 7 studies involving 12,734 participants (6197 in the low BMI group and 6345 in the normal BMI group) were included in the pooled analysis. The random effects meta-analysis revealed a significant association between low BMI (BMI <18.5 kg/m²) and increased mortality among patients coinfected with TB and HIV. The combined effect estimate indicated that individuals with low BMI had approximately twofold higher mortality risk compared to those with normal or higher BMI (RR=2.01; 95% CI 1.63 - 2.48; *P*<.001).

The overall heterogeneity among the included studies was moderate (I^2=64%; *P*=.01), suggesting that the observed variation in effect sizes was not entirely due to chance. Such heterogeneity was acceptable in meta-analyses of observational studies, particularly given the differences in population characteristics, study design, and regional contexts (Africa and Asia). The estimated between-study variance (τ^2=0.05) also indicates that the heterogeneity was not excessive.

Further, a subgroup analysis by geographic region was conducted to explore potential sources of heterogeneity (Figure 3). The African subgroup yielded a pooled RR of 1.81 (95% CI 1.53 - 2.14; *P*<.001; I^2=31%), indicating a stable and consistent association between low BMI and mortality with low heterogeneity. The Asian subgroup, meanwhile, showed a stronger pooled effect of RR=2.38 (95% CI 1.39 - 4.07; *P*=.002; I^2=72%), reflecting greater variability likely due to smaller sample sizes and study-level differences. However, the test for subgroup differences (*P*=.34) revealed no statistically significant difference between the 2 regional estimates, implying that the detrimental effect of low BMI on survival was consistent across both continents.

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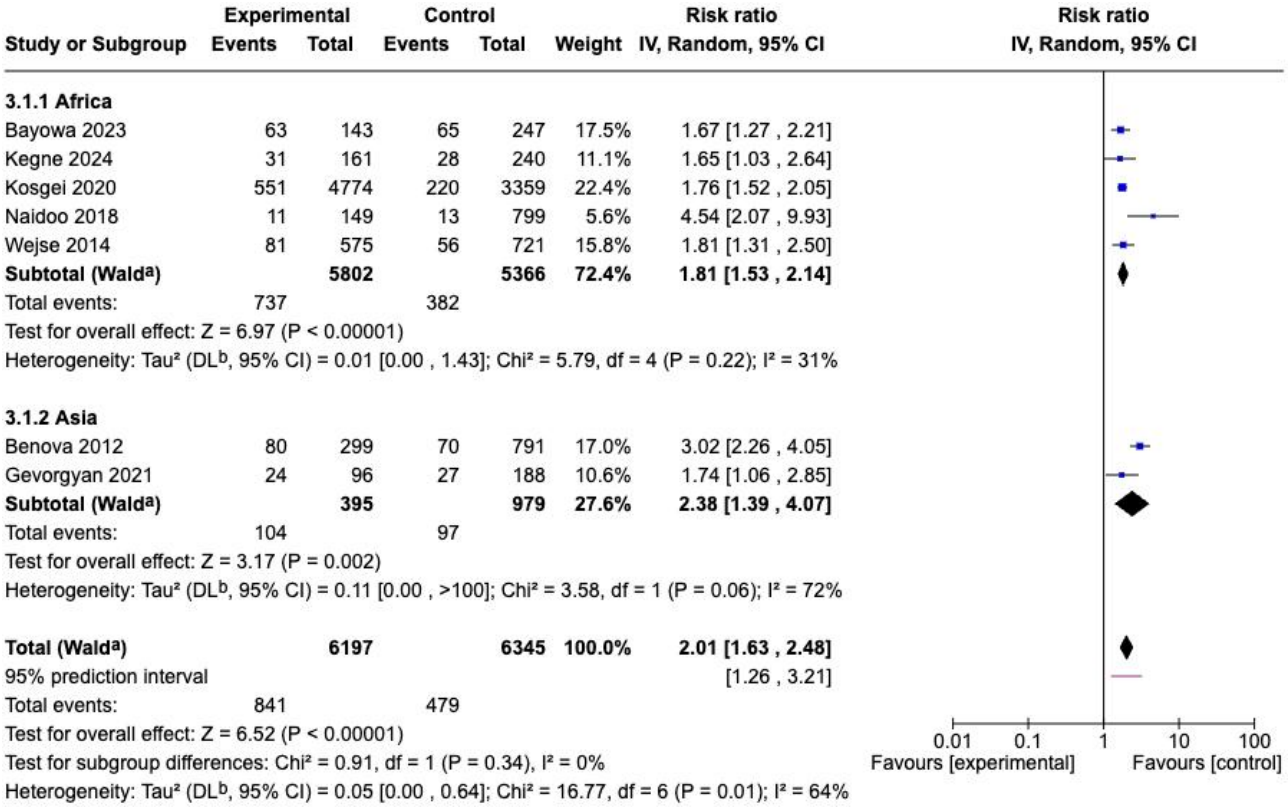
Figure 3. Subgroup analysis of the association between low BMI and mortality by geographic region (Africa and Asia) [14,26-31].



These findings provided robust evidence that low BMI was a significant and consistent predictor of mortality among patients with TB and HIV coinfection in both Asia and Africa. The 95% prediction interval (1.26 - 3.21) further indicated that future studies conducted under similar conditions were expected to observe a harmful effect of low BMI on survival, even after accounting for between-study variability.

To ensure the robustness and internal validity of the pooled estimates presented in both the overall and subgroup analyses (Figure 2), a risk of bias assessment was conducted for all included studies using the ROBINS-E tool. This step was crucial to evaluate potential methodological limitations that might have influenced the observed association between BMI and mortality among patients with TB and HIV coinfection. The detailed assessment across the 7 ROBINS-E domains is illustrated in Figure 4, while the overall summary of bias distribution is presented in Figure 5.

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Figure 4. Risk of bias assessment by domain using the risk of bias in nonrandomized studies of exposures tool [14,26-31].

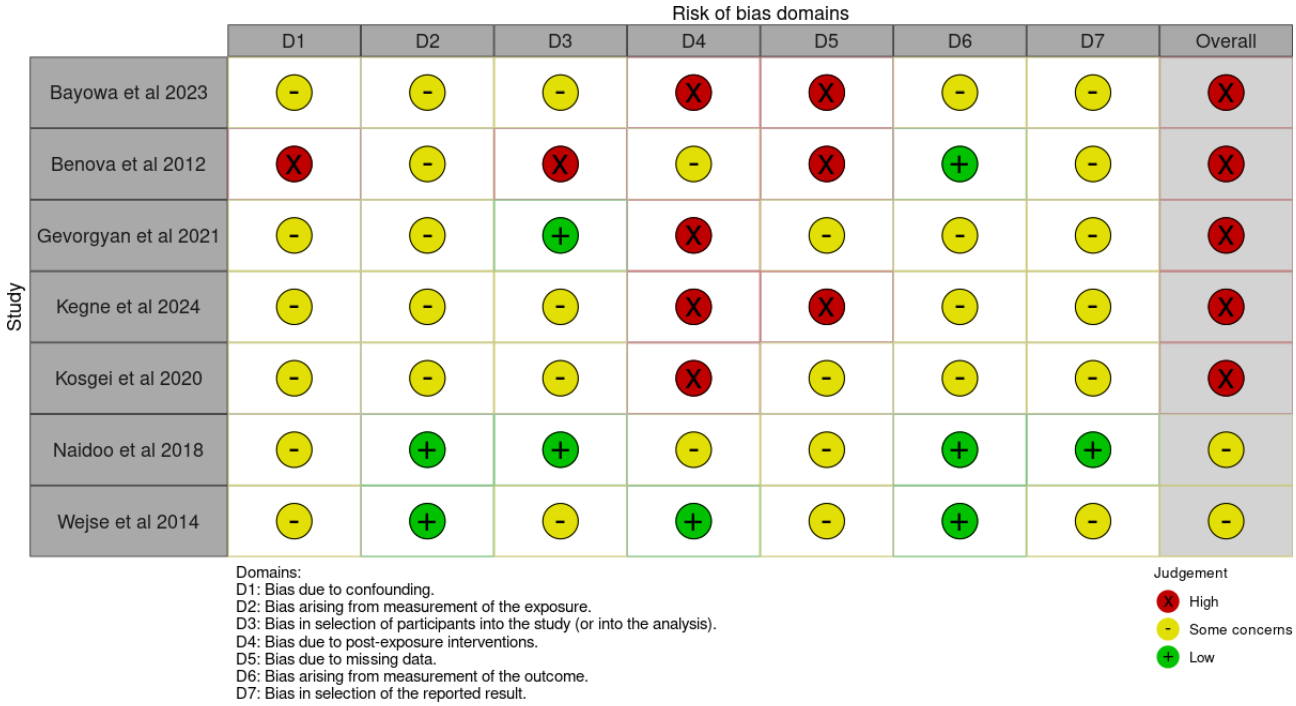

Figure 5. Summary of overall risk of bias distribution across included studies.

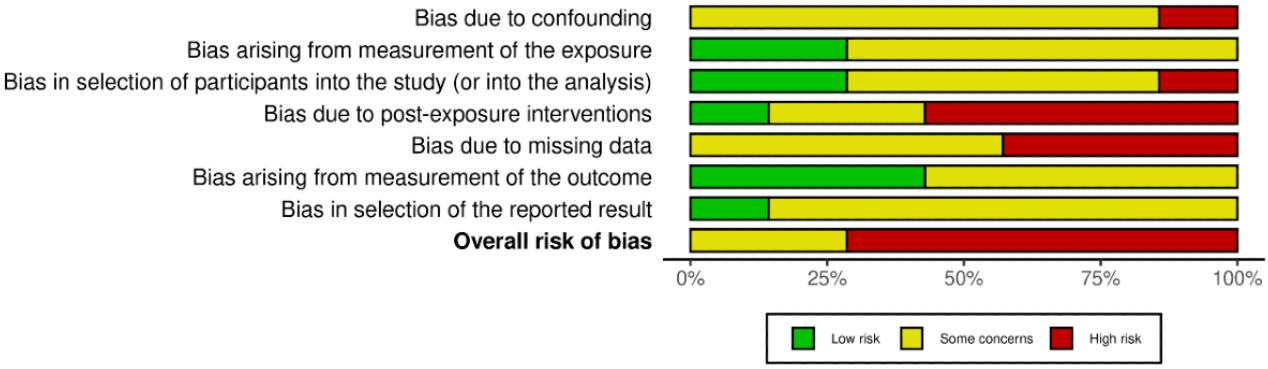

Figure 4 presents the domain-specific assessment of risk of bias for all included studies using the ROBINS-E tool. Most studies showed some concerns in several domains, particularly related to confounding (D1), postexposure interventions (D4), and missing data (D5). A few studies, Benova et al [14] and Kosgei et al [29], demonstrated high risk of bias in multiple domains, mainly due to incomplete adjustment for confounders and lack of clarity regarding data completeness. Conversely, Naidoo et al [30] and Wejse et al [31] exhibited relatively lower risk levels, particularly in domains concerning exposure and outcome measurement. Overall, these findings indicated that while some studies presented notable limitations, the collective evidence base remained methodologically sound for synthesis.

The aggregated distribution of bias levels presented in Figure 5 showed that approximately 60% - 70% of the included studies had some concerns, while a smaller proportion had high risk in at least 1 domain. Importantly, no study was classified as low risk overall, reflecting the inherent methodological limitations typical of observational designs. Despite the predominance of high-risk ratings, all studies were retained for quantitative synthesis because they contributed valuable information and were consistent with the inclusion criteria. Furthermore, sensitivity analysis indicated that exclusion of high-risk studies did not substantially alter the direction of the pooled effect.

In summary, the synthesis of all ROBINS-E domains indicated that the evidence in this review was at moderate to high risk of bias. No studies met the criteria for low risk overall, reflecting the inherent methodological limitations of observational cohort studies in TB-HIV populations, including confounding factors, incomplete baseline information, and heterogeneity in clinical measurements. Nevertheless, the direction and magnitude of the effect estimates remained consistent across studies, and the pooled RR value showed stability in sensitivity analyses. These findings suggested that the association between low BMI and mortality remains strong and credible despite moderate to high risk of bias.

Discussion

Principal Findings

The present meta-analysis demonstrated a significant association between BMI and mortality among patients with TB and HIV

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coinfection in Asia and Africa. The pooled estimate revealed that individuals with BMI less than 18.5 kg/m² had approximately twice the risk of death compared with those with normal BMI. This finding provides strong quantitative evidence that low BMI is an independent predictor of mortality in TB-HIV coinfected populations. The direction and magnitude of this association remained consistent across subgroup analyses by region, further reinforcing the robustness of the effect.

These results corroborate previous observational and cohort studies that have consistently shown that better nutritional status improves survival outcomes in individuals with TB-HIV coinfection. Maintaining or improving BMI during treatment has been associated with faster clinical recovery, reduced incidence of opportunistic infections, and improved immune reconstitution. Conversely, undernutrition compromises immune function, increases susceptibility to severe disease progression, and reduces treatment tolerance, mechanisms that likely explain the higher mortality observed among patients with low BMI.

Subgroup analysis (Figure 3) demonstrated that the association between low BMI and increased mortality remained consistent across both regions, although the magnitude of risk was higher among African cohorts compared to those from Asia. This may reflect regional differences in baseline nutritional status, ART coverage, and health care infrastructure. In Africa, a higher prevalence of advanced immunosuppression at TB or ART initiation and limited access to nutritional support programs likely amplify the impact of malnutrition on mortality. Conversely, in Asian settings, although the overall BMI distribution tends to be higher, undernutrition still poses a significant mortality risk among individuals with HIV-associated wasting and late TB presentation. These findings reinforce the universality of BMI as a prognostic marker, regardless of regional or demographic variation.

For instance, a study in South Africa reported that HIV-infected individuals with a BMI less than or equal to 18.5 experienced significantly higher mortality rates compared to those with a BMI more than 30 kg/m², with corresponding rates of 10.4 and 1.6 per 100 person-years, respectively [34]. Similarly, Yen et al [15] found that patients with TB with a BMI less than 18.5 kg/m² exhibited significantly increased risks of all-cause mortality with adjusted odds ratio (aOR) 1.66, TB-specific mortality (aOR 2.14), and non-TB mortality (aOR 1.58) [15]. Further supporting evidence is provided by studies conducted in Myanmar and Zimbabwe, which demonstrated that remaining severely underweight or experiencing a decline in BMI during the first month of TB treatment significantly increased mortality among HIV-positive patients with smear-negative and extrapulmonary TB [14]. Conversely, in the same South African cohort, overweight and obese HIV-infected individuals had notably lower mortality risks, with adjusted hazard ratios of 0.59 and 0.48, respectively, compared to those with normal BMI [34]. These findings underscore the prognostic value of BMI as an indicator of clinical outcomes in this population.

Malnutrition appears to be a major risk factor contributing to elevated mortality in patients with TB-HIV coinfection. In Taiwan, Lai et al [12] reported that patients with TB with poor nutritional status had a 2.22-fold higher risk of early death within the first 8 weeks of treatment [12]. Likewise, in sub-Saharan Africa, Koethe et al [35] found that low baseline BMI at ART initiation was a robust predictor of early mortality among HIV-infected adults [35].

Several biological and clinical mechanisms may underlie the observed association between BMI and mortality. Low BMI often reflects underlying malnutrition, compromising immune function, including reduced CD4 lymphocyte counts. A CD4 count less than 200 cells/mm³ is widely recognized as a critical threshold of severe immunosuppression, associated with heightened vulnerability to opportunistic infections and increased mortality [36,37]. Additionally, a high HIV viral load (>100,000 copies/mL) reflects impaired immune control and has been linked to increased incidence of TB and mortality risk.

Beyond immunosuppression, malnutrition may exacerbate systemic inflammation. Individuals with low BMI often display a proinflammatory state, characterized by hypercoagulability, endothelial activation, and the development of disseminated intravascular coagulation, a complication associated with poor clinical outcomes [37]. Elevated levels of proinflammatory cytokines and related biomarkers have also been observed in patients with TB and HIV coinfection. They may contribute to tissue damage and multiorgan failure, further elevating the risk of death [38].

In contrast, a higher BMI may provide metabolic and energy reserves that help mitigate the physiological stress of chronic infection. Nutritional status has also been shown to influence treatment efficacy; malnutrition may delay therapeutic response, prolong hospitalization, and worsen overall prognosis [39]. Therefore, comprehensive and individualized nutritional assessments are essential for optimizing treatment outcomes [40]. Furthermore, interactions between food and medications may modulate treatment effectiveness or side effect profiles, reinforcing the bidirectional relationship between nutritional status and treatment success [41].

Clinical and Public Health Implications

The implications of these findings are substantial for public health strategies. Given the consistent association between low BMI and increased mortality, nutritional interventions should be considered a fundamental component of TB-HIV management protocols. Timely nutritional support—such as the provision of food supplements and access to nutrient-rich diets—alongside early diagnosis may significantly improve clinical outcomes [42,43]. Community-based strategies that incorporate routine nutritional monitoring and adherence support also have great potential to improve survival rates in this population. Evidence shows that food insecurity is a major barrier to adherence in both HIV and TB care, while food baskets and nutritional supplements have been shown to improve treatment adherence and completion [44]. Integrating systematic BMI checks and early assessment of malnutrition risk into routine TB-HIV service delivery will ensure that high-risk patients are identified quickly and that nutritional support is provided as part of standard care, rather than as an additional service.

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A coordinated approach linking nutritional rehabilitation with ART initiation and directly observed therapy, short course (DOTS), can further strengthen treatment outcomes. Patients living with TB-HIV who are malnourished often begin therapy with advanced immunosuppression and high vulnerability to early mortality, making nutritional management synchronized with pharmacological therapy crucial. This is particularly important because food insecurity has been shown to worsen ART side effects and reduce adherence when medications are taken without sufficient food [44]. Developing operational guidelines that clearly integrate nutritional support into ART and TB treatment service flows can encourage more consistent and effective implementation across health care facilities.

Finally, at the policy and health system level, integrating structured nutrition services into national TB and HIV guidelines—accompanied by program budget adjustments to maintain food supplementation packages—will be key to long-term sustainability. Strengthening the supply chain for nutrition commodities and including nutrition-related indicators in routine TB-HIV monitoring and evaluation systems can further improve service continuity. These measures offer a viable and sustainable integrated approach to improving TB-HIV coinfection management outcomes in high-burden regions of Asia and Africa, while emphasizing the importance of institutionalizing nutrition-based interventions in the context of resource-constrained health services.

Conclusion and Recommendations

This systematic review and meta-analysis confirm that low BMI (<18.5 kg/m²) is a strong and independent predictor of mortality among patients coinfected with TB and HIV in Asia and Africa. The pooled estimate (RR=2.01; 95% CI 1.63 - 2.48) indicates that individuals with BMI less than 18.5 kg/m² experience approximately twofold higher mortality risk compared to those with normal BMI. This finding reinforces the critical prognostic role of nutritional status in TB-HIV comanagement. Although moderate heterogeneity (I^2=64%) and variations in study quality were observed, the association between low BMI and increased mortality remained consistent and statistically robust across subgroup analyses.

These findings reaffirm that nutrition forms a cornerstone—not an adjunct—of TB-HIV clinical management. Given the two-fold increase in mortality risk observed among underweight patients, integrating nutritional assessment, intervention, and routine BMI monitoring into TB and HIV programs is essential to improve survival outcomes. National health systems in Asia and Africa should prioritize early nutritional screening and timely supplementation, particularly for underweight patients and those initiating ART. Furthermore, policy frameworks should promote the integration of TB, HIV, and nutrition services through intersectoral collaboration. Future studies and policy evaluations should assess the effectiveness of structured nutrition-ART interventions and explore context-specific BMI thresholds for predicting mortality and enhancing long-term treatment success among TB-HIV coinfected populations.

Limitations

Several limitations should be considered when interpreting these findings. First, only 7 cohort studies met the inclusion criteria, which may have limited the generalizability of findings to broader TB-HIV populations across diverse clinical settings and precluded stratified analyses (eg, by sex, ART status, or CD4 count). This reflects the scarcity of prospective studies assessing mortality outcomes among TB-HIV coinfected populations in Asia and Africa. Second, substantial heterogeneity (I^2=64%) was observed, likely arising from differences in study design, clinical settings, ART coverage, and the operational definition of BMI and mortality. Third, variation in BMI categorization and timing of measurement across studies may have introduced misclassification bias. Fourth, although cohort designs support temporal inference, residual confounding remains possible, as critical covariates, such as CD4 cell count, viral load, ART adherence, socioeconomic factors, and comorbidities, were inconsistently reported, potentially leading to residual confounding in the polled estimates. Additionally, none of the included studies reported symptomatic versus asymptomatic TB status, preventing further stratified analyses based on this clinically important variable. Finally, restricting inclusion to English-language publications may have led to language bias and underrepresentation of studies published in local Asian or African journals.

Despite these limitations, this meta-analysis provides robust and consistent evidence that BMI serves as a clinically relevant and modifiable predictor of mortality in patients with TB and HIV coinfection. Strengthening integrated nutritional and clinical care, along with context-specific program implementation, is therefore vital to reduce preventable deaths and to achieve the global End TB and United Nations Programme on HIV/AIDS 95-95 - 95 targets.

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Artificial intelligence tools (ChatGPT) were used during the writing process to improve the readability and language quality of this manuscript. The author affirms full responsibility for the content and interpretation presented.

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Data Availability

All data analyzed during this study are included in this published article.

Authors' Contributions

MASMI and TYMW were responsible for developing the protocol. They were involved in various aspects of the study, including designing the study, selecting the eligible studies, extracting data, performing statistical analyses, drafting the initial versions, and revising the manuscript. PNCI, WWL, and LAN edited the final draft of the manuscript, which was subsequently read and approved by the first and second authors.

Conflicts of Interest

None declared.

Checklist 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File, 32 KB - apinj_v10i1e81905_app1.docx]

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Abbreviations

aOR: adjusted odds ratio
ART: antiretroviral therapy
CD4: cluster of differentiation 4
MeSH: Medical Subject Heading
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol
ROBINS-E: Risk of Bias in Non-Randomized Studies – of Exposure
RR: risk ratio
TB: tuberculosis
WHO: World Health Organization

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Complementary Therapies for Diabetic Foot Ulcer Healing Among Patients in Asia: Scoping Review

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Abstract

Background: Diabetic foot ulcers (DFUs) are a severe complication of diabetes mellitus that can lead to amputation and mortality. Conventional treatments may be insufficient, leading to an interest in complementary therapies such as herbal medicine, acupuncture, maggot debridement therapy, and biological therapies. These approaches are widely used in Asia, yet their effectiveness and integration into clinical practice remain underexplored.

Objective: The scoping review aimed to map the types of complementary therapies used for DFU healing in Asia and evaluate their reported effectiveness, implementation challenges, and opportunities for integration into conventional care.

Methods: A scoping review was conducted using the PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses for Scoping Reviews) framework and the methodology of Arksey and O'Malley. Articles were sourced from the PubMed, Scopus, and ProQuest databases, covering studies published from 2014 to 2024. The population, concept, and context model guided the selection of studies, focusing on patients with DFUs, complementary therapies, and the Asian region.

Results: Eight studies met the inclusion criteria. The most commonly used therapies included herbal treatments (eg, traditional Chinese medicinal foot soaks and *Teucrium polium*), biological therapies, including maggot debridement therapy and platelet-rich fibrin with hyaluronic acid), physical therapy (acupuncture), and psychological therapies (music therapy). Topical *T polium* significantly reduced wound size, and platelet-rich fibrin combined with hyaluronic acid increased vascular endothelial growth factor levels while reducing inflammation. Music therapy lowered the diabetes-related distress score. Despite these promising results, challenges remain, including a limited number of large-scale randomized controlled trials, regulatory barriers, and cultural perceptions affecting therapy acceptance.

Conclusions: Complementary therapies are promising adjuncts for DFU management in Asia, where traditional medical practices are prevalent. Multidisciplinary collaboration between health care providers, policymakers, and traditional practitioners is essential for safe and effective integration. Further well-designed randomized controlled trials are required to confirm the efficacy of these therapies and inform evidence-based policies.

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KEYWORDS

diabetic foot ulcer; complementary therapies; wound healing; Asia; PRISMA; Preferred Reporting Items for Systematic reviews and Meta-Analyses

Introduction

Diabetic foot ulcers (DFUs) are a severe complication of diabetes mellitus that can have significant health consequences, including amputation and increased mortality. Their highly complex pathophysiology involves a combination of ischemic neuropathy and infection, which hinders wound healing. Furthermore, prolonged hyperglycemia, hypertension, and hyperlipidemia contribute to oxidative stress and impaired blood flow, making DFUs particularly challenging to heal [1]. The lifetime incidence of foot ulceration among people with diabetes is estimated at 19% to 34%, and this burden is projected to increase due to longer survival and more complex comorbid conditions [2]. A systematic review estimated the global prevalence of DFUs to be approximately 6.3%, while a local study in Pakistan reported a prevalence of 16% among patients with diabetes [3]. Moreover, DFUs are associated with an increased risk of lower-extremity amputation and higher mortality, particularly among older adults and individuals with comorbid conditions [4]. Given the high prevalence and serious complications of DFUs, a comprehensive treatment approach is essential. In addition to conventional medical therapy, various adjunctive interventions have been developed to support wound healing, including complementary therapies, which have garnered increasing attention in the management of DFUs.

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The integration of complementary therapy in the management of DFUs in Asia faces various challenges that may affect its effectiveness and acceptance, one of which is a lack of understanding and knowledge about complementary therapies among patients and health care professionals. In recent years, the incorporation of complementary therapy into DFU management has gained increasing attention, as these approaches can be used alongside conventional medical treatments and improve patient outcomes [5]. Traditional medicine plays a significant role in DFU management in Asia, with traditional Chinese medicine (TCM) and Ayurveda being widely practiced. These approaches have been shown to offer benefits in wound healing and infection control through herbal medicine, acupuncture, and dietary modifications to accelerate the healing process and restore balance to the body [6]. Recent studies have indicated that specific TCM formulations, such as *shengji* ointment, can significantly enhance the healing rate of DFUs, highlighting the potential for integrating these therapies into conventional treatment protocols [7]. Similarly, Ayurvedic practices have been reported to reduce infection rates and improve the overall quality of life of patients with DFUs [8]. Despite the promise of complementary therapies to support DFU healing, challenges remain in their integration into clinical practice. Therefore, further research and evidence-based approaches are necessary to ensure the safety, efficacy, and acceptance of these therapies for the holistic management of DFUs.

Complementary therapy is essential for health care management, including in the context of patients with DFUs in Asia. Research indicates that although many patients are interested in complementary therapy, they often lack adequate information regarding its effectiveness and safety [9]. Complementary therapies such as acupressure and massage effectively reduce pain and improve patient quality of life; however, many individuals remain uncertain about integrating these therapies with conventional medical treatments [10]. A study revealed that among 653 patients with DFUs, 21.7% used topical alternative treatments, while 31.2% combined conventional and alternative therapies [11]. This trend underscores the importance of health care providers being aware of various treatment modalities that patients may use to complement standard medical care. The efficacy of some complementary therapies has been documented in recent literature, such as ozone therapy, which has shown promising results in DFU healing, as evidenced by case reports highlighting its success in high-risk patients [12]. As the number of patients using complementary therapy in DFU management continues to increase, a more inclusive and evidence-based approach is necessary to integrate these therapies into clinical practice. Collaboration between health care professionals and complementary therapy practitioners is crucial to ensure that patients receive maximum benefits safely and effectively.

Complementary therapy in Asia for DFU healing has increased patient interest in alternative treatments rooted in local medical traditions. However, challenges regarding regulation, education, and integration with conventional medical care remain. Past findings highlight the importance of nutritional factors in DFU healing, which may encourage patients to seek nutrition-based complementary therapies aligned with their traditional medical practices [13]. In addition, the frequency of DFUs among patients with diabetes underscores the need for a multidisciplinary approach that incorporates complementary therapy despite existing integration barriers [14]. A study examining DFU prevalence in Ethiopia highlighted the importance of health education in improving patients' understanding of foot care, which may incorporate complementary therapies rooted in local practices [15]. Although this study focuses on therapies delivered by nurses in person, it is also important to note that digitalized approaches to complementary therapies are now emerging. The use of apps based on TCM and mind-body practices has become a popular alternative, expanding the reach of these therapies to patients accessing health services via mobile devices [16]. However, to date, no studies have specifically examined the effectiveness of complementary therapy for DFU healing in Asia. The question remains as to how effective complementary therapies are for promoting healing of DFUs in this region. Therefore, the primary aim of this scoping review was to map the types of complementary therapies applied to DFU healing in Asia. The secondary aim was to evaluate their reported effectiveness and identify the challenges and opportunities for integration into clinical practice.

Methods

We conducted a scoping review based on the PRISMA-Scr (Preferred Reporting Items for Systematic reviews and Meta-Analyses for Scoping Reviews) guidelines [17] to collect and summarize the literature on complementary therapies for DFU healing in Asia.

The methodology used in this review followed the 5-stage framework developed by Arksey and O'Malley [18]. This approach maps the available literature, identifies research gaps, and provides a comprehensive overview of the existing evidence. The methodological stages applied in this review include stage 1, formulating the research question; stage 2, identifying relevant studies; stage 3, selecting studies for inclusion in the review; stage 4, charting data from the selected studies; and stage 5, analyzing, synthesizing, and reporting the findings.

Stage 1: Research Question

The research question in this review is as follows: How effective are complementary therapies in promoting the healing of DFUs in Asia?

Stage 2: Relevant Studies and Search Strategy

This review focuses on complementary therapies for DFU. A comprehensive literature search was conducted across PubMed, Scopus, and ProQuest databases between May and September 2023. To ensure the inclusion of the most recent evidence, the search was updated on January 18, 2025. The search was restricted to full-text articles published in English between January 2014 and December 2024, in accordance with the predefined 10-year review period. The search strategy used Medical Subject Headings terms and relevant Boolean operators, adapted for each database. Detailed search strings for all databases are provided in Multimedia Appendix 1.

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Stage 3: Study Selection

Studies were screened based on predefined inclusion and exclusion criteria (Multimedia Appendix 2) in accordance with PRISMA-ScR guidelines [17]. All records were managed in Rayyan AI (Rayyan Systems, Inc) [19]. Duplicates were removed before title, abstract, and full-text screening.

Stage 4: Data Extraction

Data were extracted to obtain key information from journal articles relevant to the research topic, including authors' names and publication years, titles, research objectives, study methods, findings, and conclusions. This step aimed to facilitate the extraction of essential data required for the synthesis of the study.

Stage 5: Thematic Summary and Key Findings

The literature findings were used to identify the results based on emerging keywords. This review analyzed all articles based on their titles, abstracts, and full texts, followed by a thorough examination. All analyzed articles contained information regarding complementary therapies for DFU healing in Asia.

Ethical Considerations

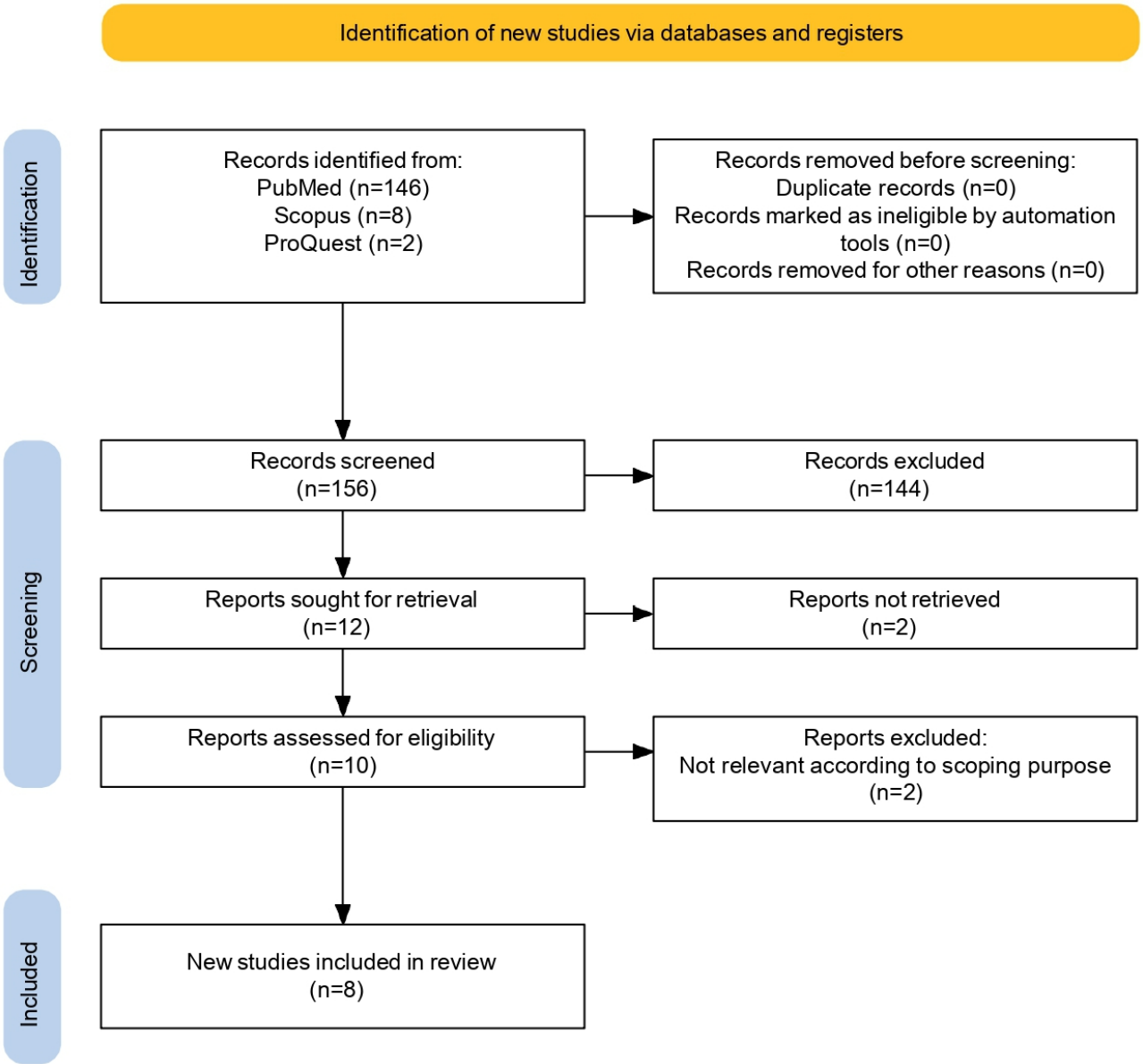
This study was declared exempt by the institutional review board of Universitas Hasanuddin, as the analyzed articles only contained anonymized information or did not include any personally identifiable information.

Results

Effectiveness of Complementary Therapies

The review included a final total of 8 studies [6,20-26] (Figure 1). Several interventions demonstrated potential benefits for DFU management.

Figure 1. PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses for Scoping Reviews) flow diagram of the study selection process.



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Herbal Therapies

A randomized controlled trial (RCT) on *Teucrium polium* ointment showed significantly greater wound size reduction and higher complete healing rates compared with placebo, with no notable adverse effects [22]. Another RCT protocol investigating a herbal foot bath decoction aims to evaluate its effects on inflammatory cytokines, including interleukin-6, as well as clinical outcomes in patients with diabetic peripheral neuropathy. [6].

Biological Therapies

Maggot debridement therapy (MDT) significantly increased microRNA-126 expression, enhancing angiogenesis and wound healing [21]. Similarly, the combination of advanced platelet-rich fibrin and hyaluronic acid resulted in higher vascular endothelial growth factor expression and lower interleukin-6 levels, indicating improved angiogenesis and reduced inflammation [26].

Psychological Therapies

A quasi-experimental study of music therapy found significant reductions in distress levels among patients with DFUs, highlighting the potential role of psychological interventions in improving patient well-being [25], which may ultimately facilitate the healing process for DFUs.

Sociocultural Factors and Complementary and Alternative Medicine

Patterns of complementary and alternative medicine use were reported in both Indonesia and Thailand. In Indonesia, 54.3% of patients with type 2 diabetes used complementary and alternative medicine, with herbal medicine (100%), spiritual healing (68.3%), and massage (42.3%) being the most common, often recommended by family members. Key determinants included affordability, perceived safety, and cultural beliefs [20]. In Thailand, complementary and alternative medicine use was more prevalent among women and farmers, reflecting sociodemographic influences [23]. A qualitative study in rural China further revealed that traditional beliefs, limited access to health care services, and high treatment costs were significant barriers to timely medical care-seeking for DFUs [24]. These findings highlight the role of socioeconomic and cultural factors in shaping health behaviors and care choices among Asian populations with diabetes. In addition, DFUs impose a substantial economic burden in the region: in Iran, the economic impact was estimated at US $8.7 to $35 billion, representing 0.6% to 2.4% of the national GDP, whereas in Indonesia, in-hospital treatment costs for DFUs were Rp 65 million per episode (approximately US $3800), posing a considerable financial strain on patients and families [27,28].

Study Characteristics, Implementation Challenges, and Emerging Models

The included studies were conducted across several Asian countries: 2 in Indonesia [20,26], 3 in China [6,21,24], and 1 each in India [25], Thailand [23], and Iran [22], as illustrated in Figure 2. Settings varied, with most studies conducted in hospitals (n=3) [21,22,26], followed by primary health care centers (n=1) [23] and traditional hospitals (n=1) [6], as well as at a tertiary hospital (n=1) [25] and in rural communities (n=2) [20,24]. Study designs included 3 RCTs [6,22,26], 2 cross-sectional surveys [20,23], 1 quasi-experimental studies [25], 1 experimental (pre–post clinical study) [21] and 1 qualitative study [24]. Sample sizes ranged from 15 participants (in a qualitative study) to 628 participants (in a cross-sectional survey).

The key characteristics of the included studies are summarized in a synthesis grid (Table 1). Despite promising findings, the studies highlighted challenges in integrating complementary therapies into DFU management. These included small sample sizes, limited standardization of interventions, and variability across health care settings. At the same time, emerging models such as nurse-led telehealth and mobile health interventions showed potential for enhancing patient education and self-care practices. However, their clinical effectiveness in DFU outcomes requires further validation.

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Figure 2. Geographic distribution of included studies on complementary and alternative therapies for diabetes and diabetic foot ulcers across Asia. Map generated using MapChart (Minas Giannekas) [29].

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Table . Synthesis grid of included studies.

Authors (year)	Country	Study design	Sample size, n	Intervention/therapy	Main outcomes
Fan et al [6] (2018)	China	Randomized controlled trial	640	Foot bath decoction and placebo foot bath (traditional Chinese medicine)	Primary outcome: change in Toronto Clinical Scoring System score. Secondary outcomes: nerve conduction velocity, blood glucose (fasting blood glucose, postprandial blood glucose, hemoglobin a_{1C}), blood lipids (total cholesterol, triglycerides, high-density lipoprotein, low-density lipoprotein), inflammatory cytokines (tumor necrosis factor-α, interleukin-6, C-reactive protein), quality of life (EQ-5D), and traditional Chinese medicine symptom scores.
Sari et al [20] (2021)	Indonesia	Cross-sectional	628	Assessment of self-reported CAM[a] use (herbal medicine, spiritual practices, massage, honey	CAM use: 54.3% (herbal 100%, spiritual 68.3%, massage 42.3%); predictors: affordability (OR[b] 4.59, 95% CI 3.01 - 7.01), safety (OR 2.04), perceived effectiveness (OR 1.75).
Zhang et al [21] (2017)	China	Experimental (pre–post clinical study)	60	MDT[c]	Patients with diabetic foot ulcers had significantly lower microRNA-126 levels compared with patients without them (*P*=.001). Following MDT, microRNA-126 levels significantly increased (*P*=.04).
Fallah Huseini et al [22] (2024)	Iran	Randomized controlled trial	70	*Teucrium polium* ointment	Wound size decreased significantly from 3.52 (SD 1.47) cm^2 to 0.717 (SD 0.19) cm^2 in the intervention group, compared with a reduction from 3.21 (SD 1.67) cm^2 to 1.63 (SD 0.72) cm^2 in the placebo group (*P*=.0001). Complete wound healing was achieved in 51.7% of patients in the intervention group versus 15.4% in the placebo group (*P*=.001)
Wanchai and Phrompayak [23] (2016)	Thailand	Cross-sectional	508	Self-reported use of CAM	CAM use was higher in women (*P*=.02) and farmers (*P*=.007).

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Authors (year)	Country	Study design	Sample size, n	Intervention/therapy	Main outcomes
Zhu et al [24] (2024)	China	Qualitative (interviews)	15	Exploration of sociocultural factors influencing wound care–seeking behavior	Barriers included traditional beliefs, limited access, and high treatment costs.
Ullas et al [25] (2023)	India	Quasi-experimental	30	Music therapy intervention	The distress score significantly decreased, from 3.7 (SD 0.6) at baseline to 2.4 (SD 0.2) after the intervention (*P*=.04).
Kartika et al [26] (2021)	Indonesia	Randomized controlled trial	30	Advanced platelet-rich fibrin combined with hyaluronic acid	Vascular endothelial growth factor levels increased significantly on day 3 (*P*=.003) and day 7 (*P*<.001), while interleukin-6 levels decreased significantly on day 7 (*P*=.02).

[a]CAM: complementary and alternative medicine.

[b]OR: odds ratio.

[c]MDT: maggot debridement therapy.

Discussion

Effectiveness of Complementary Therapies

Our scoping review highlights the potential role of complementary therapies in DFU management, including herbal interventions such as TCM foot bath decoction [6] and *Teucrium polium* [22], demonstrated anti-inflammatory and pro-angiogenic properties, consistent with their use in Asian traditional medicine practices [6,21,26]. Despite encouraging results, most studies were limited by small sample sizes, inadequate randomization, and a lack of standardized dosages, reducing the generalizability of findings. Biological therapies, including MDT and platelet-rich fibrin combined with hyaluronic acid, also showed promising effects in enhancing angiogenesis and reducing inflammation. However, evidence remains inconsistent across studies, with some RCTs questioning the superiority of MDT over standard care [21]. These findings underscore the need for rigorously designed clinical trials to establish safety, efficacy, and standardized protocols for complementary therapies in DFU care.

Sociocultural and Economic Context in Asia

Sociocultural and economic contexts strongly influence treatment-seeking behaviors and the adoption of complementary and alternative medicine in Asia. In Indonesia and Thailand, complementary and alternative medicine use is widespread among patients with diabetes, primarily driven by affordability, cultural beliefs, and family influence [20,23,30]. In rural China, traditional beliefs, limited access to health care services, and high treatment costs were reported as significant barriers to timely DFU care [24]. These patterns reflect broader socioeconomic challenges in many Asian countries, where limited insurance coverage and high out-of-pocket costs make conventional DFU treatments less accessible. Consequently, patients often turn to complementary and alternative medicine as a perceived affordable and culturally acceptable alternative. Addressing these structural factors is essential to improving equity in DFU management and to ensuring that evidence-based complementary therapies are safely integrated into clinical practice.

Holistic and Emerging Models of Care

Psychological and digital health interventions offer additional opportunities to complement medical and surgical approaches to DFU care. Music therapy, for example, was associated with significant reductions in diabetes-related distress, which may improve adherence to wound care and overall patient well-being [25]. Evidence from external studies also suggests that mindfulness and other behavioral interventions may enhance glycemic control and reduce distress, although their direct impact on DFU healing remains unclear [31]. Emerging models, including mobile health apps and nurse-led telehealth programs, have demonstrated feasibility in improving patient education, self-care practices, and remote consultation [30,32]. While clinical outcomes have not been consistently reported, these approaches highlight the potential for integrating psychological support and digital health innovations into holistic DFU management, particularly in resource-limited settings.

Opportunities and Implications for DFU Management

Long-term clinical trials are necessary to assess the sustained effects of complementary therapies on wound healing and patient quality of life. Future studies should also explore the underlying biological mechanisms of herbal interventions to understand their therapeutic potential [22]. Investigating combined approaches, such as platelet-rich fibrin, hyaluronic acid, and antibiotics, may offer integrative treatment pathways for DFUs [26]. Collaboration between conventional clinicians and complementary therapy practitioners is vital to ensure evidence-based, safe, and practical implementation [20]. Additionally, enhancing patient education and public awareness about the realistic benefits and limitations of these therapies can promote more informed decision-making.

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Evaluation of Cost-Effectiveness

Economic evaluations of complementary therapies are required to compare their cost-effectiveness with that of conventional treatments. For instance, assessing the cost-benefit ratio of acupuncture for improving glycemic control or comparing MDT with antibiotic therapy in preventing amputations may help justify their integration into standard care [33,34]. Such analyses would provide valuable insights into the feasibility and scalability of incorporating complementary therapies into national health care systems.

Recommendations

Future research is recommended to further investigate the effectiveness, biological mechanisms,and integration of complementary therapies in managing diabetes mellitus and DFUs. One critical direction for future studies involves conducting long-term clinical trials to evaluate the sustained effects of complementary therapies with a minimum follow-up period of 6 months or longer. This would provide a comprehensive understanding of their impact on wound healing, blood glucose control, and patient quality of life.

Qualitative studies of patients' perceptions of complementary therapies are also important from social and cultural perspectives. Many patients with diabetes, particularly those in rural communities, tend to prefer traditional therapies to conventional medical treatments. Therefore, exploratory research should investigate the social, economic, and cultural factors that influence patients' decisions to use complementary therapies. This can provide valuable insights into the factors driving therapeutic choices and contribute to the development of culturally sensitive health care interventions.

Lastly, cost-effectiveness studies of complementary therapies are necessary to compare their financial and therapeutic benefits with those of conventional treatments. Future research is expected to provide more robust scientific evidence regarding the efficacy, safety, and integration of complementary therapies for the management of diabetes and DFUs. This evidence-based approach will support the incorporation of complementary therapies into holistic and patient-centered care strategies, ultimately benefiting patients and the health care system.

Critical Appraisal of Included Studies

Although we did not perform a critical appraisal because it is not mandatory in a scoping review, we observed that several included studies had limitations in study design. These included small sample sizes, a lack of randomization or blinding, and an absence of standardized outcome measures. The heterogeneity of study designs, ranging from case reports to quasi-experimental studies and RCTs, complicates the interpretation and generalization of our results. These limitations suggest that while the findings are promising, they should be interpreted cautiously and validated through further high-quality research.

Opportunities and Implications

The integration of complementary therapies into clinical DFU care in Asia faces multiple barriers, as reflected by the studies included in this review. Regulatory frameworks for traditional and complementary therapies vary widely across countries, and are often incomplete or inconsistent, resulting in limited institutional support and ambiguous clinical guidelines. Furthermore, a lack of formal education and training for health care providers in evidence-based complementary practices contributes to uncertainty and resistance to implementation. Cultural perceptions also play a role, with some clinicians and patients viewing such therapies as informal or unscientific despite their profound historical and cultural relevance.

Study Limitations

Although this scoping review indicates the potential of complementary therapies to support the healing of DFUs, there are several limitations in the current body of research. These limitations include a lack of long-term evidence and standardized therapeutic protocols, as well as challenges in integrating complementary therapies with conventional treatments. Therefore, further research using more rigorous clinical trial designs with larger sample sizes and comprehensive cost-effectiveness evaluations is warranted to ensure the safety and efficacy of complementary therapies in DFU management.

Conclusion

Complementary therapies have significant potential for supporting the healing of DFUs in Asia; however, further research is necessary to confirm their efficacy and safety. Integrating complementary therapies into DFU management requires an evidence-based approach, more transparent regulatory frameworks, and comprehensive education for both health care providers and patients. With a thorough and evidence-based approach, complementary therapies can become part of a more holistic DFU treatment strategy, contributing to improved clinical outcomes and reducing the economic burden associated with diabetes complications.

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Authors' Contributions

ADMYP contributed to the study conceptualization, methodology, data analysis, and drafting of the manuscript. SY contributed to data screening, data extraction, and critical revision of the manuscript. HB and MJT contributed to manuscript review. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of literature search strategy—databases, keywords, and selection results.
[DOCX File, 17 KB - apinj_v10i1e76301_app1.docx]

Multimedia Appendix 2
Problem, concept, and context framework.
[DOCX File, 14 KB - apinj_v10i1e76301_app2.docx]

Checklist 1
PRISMA-ScR Checklist.
[PDF File, 190 KB - apinj_v10i1e76301_app3.pdf]

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Abbreviations

DFU: diabetic foot ulcer
MDT: maggot debridement therapy
PRISMA-ScR: Preferred Reporting Items for Systematic reviews and Meta-Analyses for Scoping Reviews
RCT: randomized controlled trial

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Effectiveness of Interventions to Improve Glycemic Control in US Asian and Pacific Islander Populations With Type 2 Diabetes: Systematic Review and Meta-Analysis

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Abstract

Background: Asian American and Pacific Islander populations are disproportionately affected by diabetes.

Objective: The purpose of this study was to assess the efficacy of nonpharmacologic interventions in reducing hemoglobin A_{1c} (HbA_{1c}) levels among Asian American or Pacific Islander individuals with type 2 diabetes.

Methods: A systematic review was conducted using the PubMed, Scopus, PsycInfo, and CINAHL databases, covering studies published from 1985 to 2019. Eligible studies were randomized controlled trials that evaluated nonpharmacologic interventions in outpatient settings for adults with type 2 diabetes in the United States, with at least 50% Asian American or Pacific Islander participants. Data extraction and risk of bias assessment were independently performed by 2 reviewers for each trial. The Cochrane Collaboration risk of bias tool and the Grading of Recommendations, Assessment, Development, and Evaluation approach were used to evaluate quality. Random-effects meta-analyses were conducted to estimate pooled effect sizes.

Results: A total of 1835 articles were screened, with 9 randomized controlled trials meeting the inclusion criteria, comprising 1492 participants, with a median follow-up duration of 6 (IQR 3-12) months. Interventions included diabetes self-management education, bilingual counseling, glucose or weight monitoring, motivational interviewing, and financial support, often tailored to the cultural context of the participants. Pooled analysis of the 9 trials demonstrated a significant average HbA_{1c} reduction of −0.39% (95% CI −0.64% to −0.14%; I^2=65%). Seven studies were judged to have a low risk of bias, 1 study had some concerns, and 1 study was assessed as high risk. The overall strength of evidence was high.

Conclusions: Nonpharmacologic interventions substantively reduced HbA_{1c} levels in Asian American or Pacific Islander individuals with type 2 diabetes, particularly when culturally and linguistically tailored.

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KEYWORDS

type 2 diabetes; systematic review; meta-analysis; Asian American; Pacific Islander; nonpharmacologic intervention; hemoglobin A1c; HbA1c; glycemic control

Introduction

Asian American and Pacific Islander (AAPI) persons are disproportionately affected by diabetes, with a higher prevalence of type 2 diabetes compared to White persons, even when individuals have similar BMI or waist circumference [1]. The high burden of disease becomes even more apparent when examining disaggregated diabetes prevalence across AAPI ethnic groups [1]. For example, in the United States, Filipino men have one of the highest type 2 diabetes rates among all ethnic groups (15.8%), and Korean women are 5 times more likely to be affected by type 2 diabetes compared to non-Hispanic White women [2].

As recommended by the American Diabetes Association, lifestyle and educational interventions are key components of diabetes care and empower patients to make informed health

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decisions in coping with their disease [3]. Such interventions have been shown to be highly effective in promoting diabetes knowledge and self-care behaviors. Diabetes self-management education, for example, has been shown to reduce hemoglobin A_{1c} (HbA_{1c}) in racial or ethnic minority populations [4]. However, only 3 reviews of diabetes interventions have focused on AAPI populations, and they have been limited in terms of geography, heterogeneity, and AAPI subpopulations included [5-7]. This systematic review and meta-analysis focused on AAPI persons with type 2 diabetes in the United States and aimed to broadly investigate the effect of nonpharmacological interventions on HbA_{1c} outcomes.

Methods

This review was registered with the International PROSPERO (CRD42019122625) database and has been reported in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Table S1 in Multimedia Appendix 1).

Search Strategy

A systematic search of the PubMed, Scopus, PsycInfo, and CINAHL databases was conducted from 1985 to 2019 without language restrictions, using search terms related to type 2 diabetes, study design, English as a second language, race or ethnicity, and disparities (Table S2 in Multimedia Appendix 1). After duplicate search results were removed, article titles and abstracts were reviewed, and studies that did not meet the criteria were excluded. A full-text review was conducted for the remaining articles. At each stage, articles were reviewed by at least 2 team members. Gray literature was not included in the search.

Inclusion and Exclusion Criteria

We included randomized controlled trials of nonpharmacological interventions intended for adults with type 2 diabetes in the United States and its territories. We excluded inpatient, nursing home, and emergency department–based interventions; drugs, devices, surgeries, procedures, and diets; and interventions focused on diabetes prevention, screening, or diagnosis. At least 50% of trial participants had to be Asian, Asian American, Native Hawaiian, or Pacific Islander. Trials had to be at least 3 months in duration and report HbA_{1c} as an outcome (Table S3 in Multimedia Appendix 1).

Data Extraction

Data were extracted by 2 independent reviewers using a standardized template, with discrepancies settled by a third reviewer or discussion with the research team. We extracted study characteristics, participant demographics, and HbA_{1c} outcomes. We categorized each intervention by its level (eg, individual, interpersonal, or community) and domain (eg, behavioral, sociocultural, or health care system) of influence based on the National Institute on Minority Health and Health Disparities Research Framework [8].

Among the randomized controlled trials (RCTs), HbA_{1c} results were reported in any of these 3 ways: (1) a difference in difference between intervention and control groups, (2) a difference between treatment and control groups at a specific follow-up time point, and (3) an HbA_{1c} value in a group at a follow-up time point (without group comparison). In the meta-analysis, we used 1 HbA_{1c} result per study, prioritizing the type of HbA_{1c} using this order.

Quality Review

The Cochrane Collaboration risk of bias tool for RCTs was used to assess the risk of bias for each study [9]. Quality of evidence across trials was assessed using the Grading of Recommendations, Assessment, Development, and Evaluation approach. Quality of evidence (ie, degree of confidence that estimated effect approximates true effect) was rated high, moderate, low, or very low based on risk of bias, inconsistency, imprecision, indirectness, and publication bias. A funnel plot and Egger test were used to assess publication bias.

Statistical Analysis

We conducted a random-effects meta-analyses and calculated a weighted average of the estimated effects within individual studies (a pooled effect estimate). We determined weights by the inverse of the within-study variance and between-studies variance for each study. We then constructed a z test and its associated 95% CI of pooled intervention effects. Heterogeneity was assessed with the I^2 statistic. To assess consistency of findings, we used the same methods to perform subgroup analyses based on study populations (ie, Asian, Pacific Islander, and non-English language preferred).

Results

Database searches returned 111,289 results. After removing duplicate results and screening titles and abstracts, 1835 articles remained for full-text review. Ultimately, 9 RCTs met all inclusion criteria (Figure 1) [10-18]. These enrolled a total of 1492 patients who were primarily aged between 40 and 60 years (Table 1); 5 RCTs included all AAPI patients. Specific races or ethnicities included Filipino, Samoan, Hawaiian, Micronesian, Bangladeshi, and Korean. Two RCTs only assessed whether patients identified as Asian or Pacific Islander.

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Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for the systematic review of randomized controlled trials of nonpharmacological interventions among Asian American and Pacific Islander populations with type 2 diabetes (1985 - 2019). HbA_{1c}: hemoglobin A_{1c}.

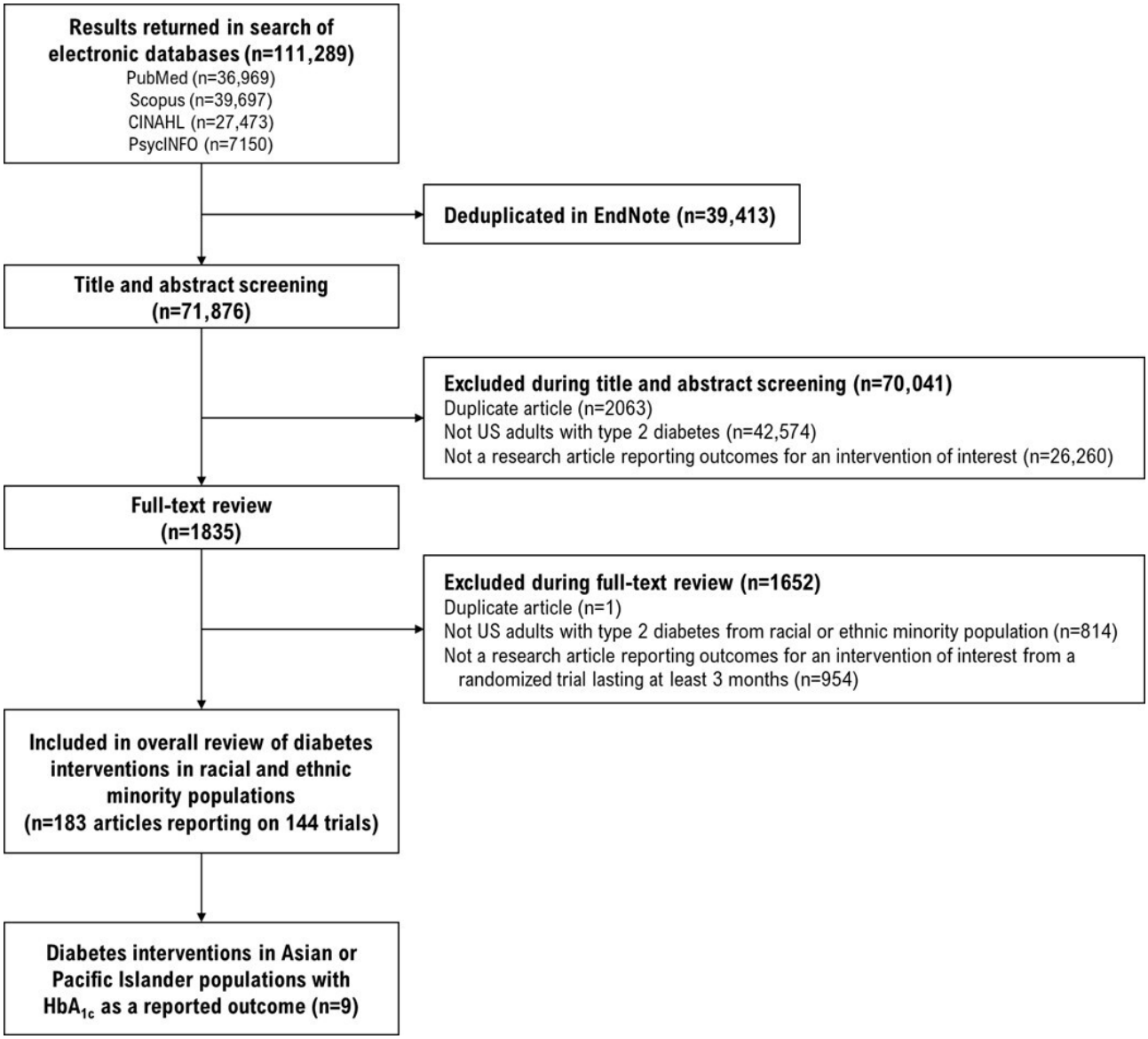

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Table . Randomized controlled trials of nonpharmacological interventions among Asian American and Pacific Islander populations with type 2 diabetes (1985 - 2019).

Study	Location	Enrolled/ screened, n/N (%)	Arms and participant characteristics	Length of follow-up

Bender et al [10], 2017	San Francisco, California	45/113, 39.8%	• Intervention: culturally adapted mHealth[a] weight loss lifestyle intervention with feedback, coaching, and support (level: individual and interpersonal; domain: behavioral and sociocultural)
			  • Mean age 58 (SD 10) years
			  • 60% female
			  • 100% Filipino
			• Control: waitlist
			  • Mean age 57 (SD 10) years
			  • 63% female
			  • 100% Filipino
				3 mo

DePue et al [11], 2013	American Samoa	268/406, 66%	• Intervention: culturally adapted education and care coordination delivered by nurse-community health worker team (level: individual and interpersonal; domain: behavioral, sociocultural, and health care system)
			  • Mean age 56 (SD 13) years
			  • 57% female
			  • 100% Samoan
			  • 66% preferred language Samoan
			• Control: waitlist
			  • Mean age 54 (SD 13) years
			  • 65% female
			  • 100% Samoan
			  • 80% preferred language Samoan
				12 mo

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Study	Location	Enrolled/ screened, n/N (%)	Arms and participant characteristics	Length of follow-up

Fernandes et al [12], 2018	Hawaii	320/793, 40.3%	• Intervention: financial incentives for diabetes management among Medicaid recipients (level: individual; domain: behavioral)
			  • Mean age 49 (SD 11) years
			  • 55% female
			  • 34% Native Hawaiian or Pacific Islander, 25% multiple races, 20% Asian, 17% White, and 6% Hispanic or Latino
			• Control: usual care
			  • Mean age 48 (SD 10) years
			  • 53% female
			  • 33% multiple races, 30% Native Hawaiian or Pacific Islander, 22% Asian, 14% White, and 9% Hispanic or Latino
				12 mo

Ing et al [13], 2016	Oahu, Hawaii	47/65, 72.3%	• Intervention: bimonthly community facilitator– and health professional–led support group meetings as follow-up after a culturally tailored, community-based educational intervention (level: individual and interpersonal; domain: behavioral and sociocultural)
			  • Mean age 55 (SD 11) years
			  • 40% female
			  • 56% Native Hawaiian, 32% Micronesian, and 8% Filipino
			• Control: bimonthly postcards reminders about diabetes self-management as follow-up
			  • Mean age 54 (SD 9) years
			  • 62% female
			  • 59% Native Hawaiian and 36% Micronesian
				3 mo

Islam et al [14], 2018	New York, New York	336/880, 38.1%		6 mo

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Study	Location	Enrolled/ screened, n/N (%)	Arms and participant characteristics	Length of follow-up

			• Intervention: culturally adapted, community health worker–led educational intervention including 5 group sessions and 2 one-on-one sessions (level: individual; domain: behavioral and sociocultural)
			  • Mean age 54 (SD 11) years
			  • 40% female
			  • 100% Bangladeshi
			  • 55% limited English proficiency
			• Control: one culturally adapted community health worker–led educational session
			  • Mean age 56 (SD 10) years
			  • 40% female
			  • 100% Bangladeshi
			  • 59% limited English proficiency	

Kim et al [15], 2009	Baltimore and Washington DC area	83/224, 37%	• Intervention: culturally tailored education, home glucose monitoring with tele-transmission, and nurse telephone counseling (level: individual; domain: behavioral and sociocultural)
			  • Mean age 57 (SD 8) years
			  • 51% female
			  • 100% Korean
			  • Predominantly Korean speaking
			• Control: waitlist
			  • Mean age 56 (SD 8) years
			  • 38% female
			  • 100% Korean
			  • Predominantly Korean speaking
				6 mo

Kim et al [16], 2015	Baltimore and Washington DC area	250/597, 41.8%		12 mo

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Study	Location	Enrolled/ screened, n/N (%)	Arms and participant characteristics	Length of follow-up

			• Intervention: community-based, culturally tailored, multimodal behavioral intervention including group education sessions and coaching by nurses and community health workers (level: individual; domain: behavioral and sociocultural)
			  • Mean age 59 (SD 8) years
			  • 41% female
			  • 100% Korean
			  • 61% see a Korean-speaking doctor
			• Control: waitlist
			  • Mean age 58 (SD 9) years
			  • 45% female
			  • 100% Korean
			  • 59% see a Korean-speaking doctor	

Ratanawongsa et al [17], 2014	San Francisco, California	362/910, 39.7%	• Intervention: culturally tailored, automated telephone self-management support and health coaching intervention (level: individual and interpersonal; domain: behavioral, sociocultural, and health care system)
			  • Mean age 57 (SD 8) years
			  • 77% female
			  • 61% Asian or Pacific Islander, 25% Latino, 6% Black, and 6% White
			  • 54% Cantonese speaking and 20% Spanish speaking
			• Control: waitlist
			  • Mean age 55 (SD 9) years
			  • 71% female
			  • 62% Asian or Pacific Islander, 20% Latino, 10% Black, and 7% White
			  • 55% Cantonese speaking and 18% Spanish speaking
				6 mo

Sinclair et al [18], 2013	Hawaii	82/91, 90.1%		3 mo

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Study	Location	Enrolled/ screened, n/N (%)	Arms and participant characteristics	Length of follow-up

			• Intervention: culturally adapted, community-based educational intervention (level: individual and interpersonal; domain: behavioral and sociocultural)
			  • Mean age 53 (SD 12) years
			  • 63% female
			  • 100% Native Hawaiian, Pacific Islander, or Filipino
			• Control: waitlist
			  • Mean age 55 (SD 10) years
			  • 62% female
			  • 100% Native Hawaiian, Pacific Islander, or Filipino	

[a]mHealth: mobile health.

Most RCTs (n=7) included a component of diabetes self-management education (DSME) in the intervention arm. Other strategies consisted of bilingual counseling (n=4), glucose or weight self-monitoring (n=3), motivational interviewing (n=1), and financial support (n=1). Approximately all (n=8) studies modified some element of their intervention toward the specific cultures of their study populations. Per the National Institute on Minority Health and Health Disparities Research Framework, studies were conducted at the individual (n=9) and interpersonal levels of influence (n=5), targeting primarily behavioral (n=9) and sociocultural domains (n=8). For controls, 6 RCTs used waitlist patients, 2 used a minimal intensity intervention, and 1 used usual care.

Overall, individuals were followed for a median of 6 (range 3 - 12) months. The interventions on average resulted in a −0.39% (95% CI −0.64 to −0.14%; I^2=65%; Figure 2; Table 2) decrease in HbA_{1c}. A similar pattern was observed with subgroup analyses for Asian individuals (n=5), with an average reduction in HbA_{1c} by −0.43% (95% CI −0.66 to −0.20%; I^2=43%) and for Pacific Islander individuals (n=3), with a decrease of −0.62 % (95% CI −0.94 to −0.29%; I^2=0%). For individuals who preferred non-English language (n=5), these interventions on average decreased HbA_{1c} levels by −0.47% (95% CI −0.70% to −0.23%; I^2=45%). The most effective interventions specifically described using culturally tailored and/or language-tailored modalities of DSME.

Table . Meta-analysis of effects of nonpharmacological interventions on hemoglobin A_{1c} (HbA_{1c}) outcomes among Asian American and Pacific Islander populations with type 2 diabetes (1985 - 2019).

	Trials, n (%)	HbA_{1c}[a], weighted mean difference (95% Cl)	I^2 statistic (%)
Overall			
Asian or Pacific Islander	9 (100)	−0.39 (−0.64 to −0.14)	65
Subgroup			
Asian	5 (56)	−0.43 (−0.66 to −0.20)	43
Pacific Islander	3 (34)	−0.62 (−0.94 to −0.29)	0
Non-English language preferred	5 (56)	−0.47 (−0.70 to −0.23)	45

[a]HbA_{1c}: hemoglobin A_{1c}.

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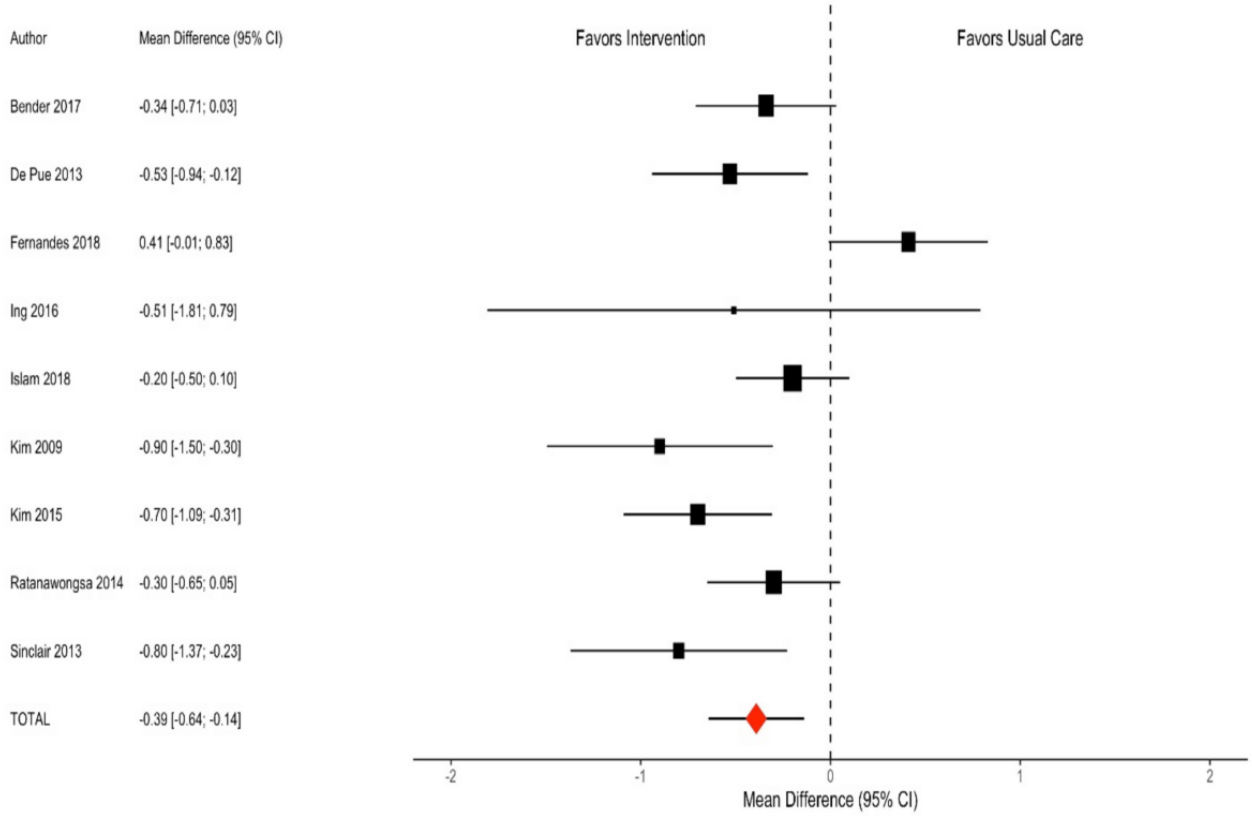
Figure 2. Forest plot of hemoglobin A_{1c} outcomes in nonpharmacological intervention trials among Asian American and Pacific Islander populations with type 2 diabetes (1985 - 2019) [10-18].



Using the Cochrane Collaboration risk of bias for randomized trials tool, 7 of the 9 studies were determined to be at low risk of bias (Table S4 in Multimedia Appendix 1). One study [12] had some concerns in the domain of deviations from the intended intervention, and another study [17] was at high risk for bias in the domain of missing outcome data. Publication bias was evaluated visually by plotting changes in HbA_{1c} by study on a funnel plot, where the y-axis represents study size and the x-axis the size of effect found (Figure S1 in Multimedia Appendix 1). Of the 9 RCTs, 8 fell within the expected 95%, and approximate symmetry was achieved with the exception of the single study, whose intervention relied solely on financially incentivizing diabetes self-management. Additionally, 1 study with a small sample size (n=47) and relatively large HbA_{1c} SD at baseline affected the vertical distribution. The Egger test indicated no evidence of publication bias (P=.22). Quality of evidence was high by the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach (Table S5 in Multimedia Appendix 1).

Discussion

We investigated the efficacy of nonpharmacologic interventions for type 2 diabetes in lowering HbA_{1c} in Asian American and Pacific Islander individuals. Our systematic review and meta-analysis identified a substantive reduction of HbA_{1c}, with an average change of −0.39% over 6 months. Most interventions incorporated components of DSME and social engagement such as counseling or other interpersonal interactions. Furthermore, nearly all of the interventions tailored their approach based on the languages and cultures of their target population, often collaborating with community health workers or community-based organizations.

Identifying evidence-based ways to enhance diabetes management is essential for populations at greater risk for type 2 diabetes development and progression, including AAPI persons. AAPI populations have experienced alarming rises in diabetes; for instance, one study found a 68% increase in incidence between 1993 and 2001, the highest among all racial or ethnic groups [19]. Consequently, the American Diabetes Association has incorporated race or ethnicity into adult screening guidelines, and people with AAPI race or ethnicity are considered a “high-risk” population [20]. Furthermore, while AAPI race or ethnicity is comprised of many heterogeneous populations, current practices typically aggregate them as “Asian” or “Other,” when in reality over 40 ethnic subgroups fall under this categorization [21]. Encouragingly, in this review, few studies reported AAPI as a single group, and a broad range of AAPI subpopulations were represented (Filipino, Samoan, Hawaiian, Micronesian, Bangladeshi, and Korean). Heterogeneity was moderately high for overall results but lower in subgroup analyses. Data aggregation across AAPI subpopulations can mask higher-risk subpopulations and negatively impact screening, diagnosis, and treatment. For example, the DISTANCE study, which delineated AAPI subgroups when estimating diabetes rates, found that Pacific Islander, South Asian, and Filipino individuals had the highest prevalence of diabetes (18.3%, 15.9%, and 16.1%, respectively)

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across all racial or ethnic categories [22]. They also detected substantial differences in the rates of diabetes-related complications across AAPI subgroups [22].

AAPI persons constitute 7.7% of the US population and are one of the fastest growing racial or ethnic groups. Nonetheless, research funding for studies focusing on AAPI populations has not progressed over the past several decades. From 1986 to 2000, AAPI was represented in 0.2% of health-related grants across 7 federal agencies [23]. Between 1992 and 2018, 0.2% of the National Institutes of Health budget was allocated to 529 AAPI-related clinical research projects [24]. In the same time frame, inclusion of Native Hawaiians and Pacific Islanders in extramural National Institutes of Health–defined phase 3 clinical trials decreased from 0.3% (n=1011) to 0.2% (n=271) [24]. Given the small and shrinking number of RCTs among people with AAPI race or ethnicity, additional RCTs are needed to further our understanding of optimal strategies to manage type 2 diabetes in people with AAPI race or ethnicity.

Nonpharmacological interventions can meaningfully improve prevention and management of diabetes and have been found to be cost-effective; however, underrepresentation of AAPI persons in trials reduces generalizability [25-28]. For instance, the landmark Look Action for Health in Diabetes trial showed that intensive lifestyle interventions improved glycemic control and cardiovascular outcomes [29]. Although the Look Action for Health in Diabetes trial aimed to recruit at least a third of participants from racial and ethnic minority groups, there were only 50 (<2%) AAPI participants [30]. A meta-analysis of 16 randomized lifestyle intervention trials in general populations with type 2 diabetes found an average change of −0.37% in HbA_{1c} [31]. While this meta-analysis did not report stratified results or primarily enroll AAPI populations, their reduction in HbA_{1c} is very similar to our findings (−0.39%), providing some reassurance in the generalizability of larger studies.

Given the tremendous diversity of genetics, culture, diet, and lifestyle within the AAPI category, the effectiveness of specific interventions may vary by population. With our limited sample size, we were unable to directly compare types of interventions. However, we identified DSME as the most common shared component in these studies, which is one form of intervention that is strongly supported in the literature. In a systematic review of 118 randomized trials for adults with type 2 diabetes, DSME resulted in a −0.74% reduction in HbA_{1c} [32]. Furthermore, the study found that combining individual and group engagement resulted in greater reduction in HbA_{1c}. However, studies that aggregate data at this level are unable to delineate racial or ethnic differences. Recently, different meta-analyses have demonstrated that nonpharmacologic interventions such as DSME may differ in effectiveness based on the population in focus. For example, in 2 meta-analyses, DSME interventions were shown to reduce HbA_{1c} (−0.24% and −0.25%) in Latino individuals with type 2 diabetes [33,34]. However, in another meta-analysis, DSME did not reduce HbA_{1c} in African American persons [35]. Mixed results have been reported in other meta-analyses, in which lifestyle interventions were effective in lowering HbA_{1c} for White individuals but not Black or African individuals or Hispanic populations [36]. Another systematic review found that lifestyle intervention reduced the incidence of type 2 diabetes more in the "(predominantly) White" group compared to the Asian group [37]. Moreover, beyond HbA_{1c}, significant differences may exist in the impact on 2-hour glucose, BMI, and waist circumference depending on the racial or ethnic subgroup [38]. Taken together, these studies suggest that a uniform approach for nonpharmacologic management of type 2 diabetes would not lead to optimal health outcomes or reduction in health disparities.

In a report by the National Heart, Blood, and Lung Institute on improving cardiometabolic risk factors in Asian American individuals, the committee recommended more research to understand the social and cultural contexts of lifestyle interventions, perceptions, and barriers to addressing such risk factors [39]. This notion has taken root in the United States—for example, several studies focusing on South Asian individuals, such as the South Asian Healthy Lifestyle Intervention, use culturally tailored strategies to reduce cardiovascular risk factors [40]. Reviewing lifestyle interventions in South Asian individuals found that tailoring interventions to linguistic and cultural norms such as modifying traditional Indian cooking and incorporating physical activities from South Asia were effective in lowering HbA_{1c} [41].

In our study, 8 [10,11,13-18] of the 9 studies culturally tailored their intervention prior to implementation—for instance, Ing et al [13] in Hawaii created their intervention by partnering with local organizations and based their educational content on prior focus groups created in the community, highlighting relevant images, foods, and physical activities in Hawaii. In other studies, community health workers, who often are trusted members of the community, were employed to effectively carry out interventions in the study population. Overall, these studies highlight the potential benefits of actively partnering within and beyond traditional public health institutions, including community organizations and services, to bring culturally and linguistically appropriate care. Given the financial and logistical barriers to providing these more customized interventions to patients, telemedicine may be a promising approach. In the studies we reviewed, telephone counseling and remote blood glucose monitoring were strategies that proved effective in reducing HbA_{1c}. Results of recent meta-analyses also support the effectiveness and potential cost-saving of telehealth and digital interventions for improving glycemic control [42-47]. Therefore, culturally adapting interventions, collaborating with community organizations, and using telemedicine and digital health tools are all possible strategies that health care systems can incorporate to improve healthy behaviors and outcomes for type 2 diabetes in AAPI communities.

This study has several limitations. First, a relatively small number of trials met all inclusion criteria for this meta-analysis. In part, this reflects a greater need for clinical trials to increase enrollment across underrepresented races or ethnicities, including those of AAPI backgrounds. While not feasible to conduct comparable studies by individual subgroup, stratifying AAPI populations by a limited number of diabetes and cardiovascular risk groups may prove useful to guide screening and management. Additionally, as with any meta-analysis, the

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dissimilarity of interventions makes differences in effect on HbA_{1c} difficult to compare. This is particularly true with nonpharmacologic interventions, given that each study developed a unique intervention for their populations. A larger sample size and further exploration of heterogeneity related to intervention approaches and study populations would be useful for understanding the generalizability of findings. Finally, it is possible that there are intervention studies published in the gray literature or indexed in other databases that were not included in this analysis.

In summary, this meta-analysis examined 9 nonpharmacologic interventions for type 2 diabetes for primarily AAPI populations. Random-effects meta-analysis found that such interventions substantively lowered HbA_{1c}, offering support to leverage these interventions in clinical practice and community efforts. Successful interventions were culturally tailored and often used diabetes self-management education. More RCTs are needed to add to the small body of literature of effective nonpharmacologic interventions for AAPI populations with type 2 diabetes. Additionally, future studies are required to evaluate how other markers of cardiovascular risk and systemic health can be improved in these populations. Developing evidence-based approaches to managing type 2 diabetes in AAPI populations will further reduce the burden of diabetes in the United States and enhance quality of care.

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Data Availability

Data collection forms and datasets generated and analyzed in this study are available from the corresponding author upon reasonable request.

Authors' Contributions

JX and JY acquired and interpreted the data and drafted the work. EMS and NL made substantial contributions to the design, acquired and interpreted the data, and reviewed the work for critical important intellectual content. AND acquired and interpreted the data and reviewed the work for critical intellectual content. AJK, MEP, and ESH made substantial contributions to the design and reviewed the work for critical important intellectual content. NCT and WW analyzed the data and reviewed it critically for important intellectual content. All authors provided final approval before publishing and agree to be accountable for the accuracy of the work. NL is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional tables and figures: search terms, inclusion criteria, risk of bias, funnel plot, strength of evidence.
[DOCX File, 210 KB - apinj_v10i1e75751_app1.docx]

Checklist 1
PRISMA checklist.
[PDF File, 59 KB - apinj_v10i1e75751_app2.pdf]

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Abbreviations

AAPI: Asian American and Pacific Islander
DSME: diabetes self-management education
GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
HbA_{1c}: hemoglobin A_{1c}
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial

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Online Media Platform and Continuous Positive Airway Pressure Machine Purchasing Prior to Bariatric Surgery: Qualitative Study

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Abstract

Background: Bariatric surgery offers quick weight reduction for patients with morbid obesity. Those who plan for bariatric surgery require perioperative preparation, including obstructive sleep apnea (OSA) evaluation, and treatment using a continuous positive airway pressure (CPAP) machine is recommended. There are limited data on how patients have prepared for bariatric surgery or for those who have decided to purchase a CPAP machine prior to surgery.

Objective: This study aimed to use a qualitative method to evaluate how obese patients with OSA who were scheduled for bariatric surgery received information regarding bariatric surgery, including their decision to purchase a CPAP machine prior to bariatric surgery.

Methods: This qualitative study enrolled adult patients who planned to undergo bariatric surgery, were diagnosed with OSA, and were treated with CPAP therapy at least 1 month prior to surgery. An in-depth interview was conducted with eligible patients, addressing their perspectives on obesity, strategies for weight loss, and reasons for purchasing or renting CPAP machines prior to bariatric surgery. The interview was conducted using content analysis and triangulation focused on a variety of data informants, theoretical sampling, and achieving data saturation. Themes were summarized and reported.

Results: There were 14 patients with obesity and OSA who planned for bariatric surgery. The average age of all patients was 27.21 (SD 4.98) years with male proportion of 28.57% (4/14) and single marital status of 78.57% (11/14). The average BMI was 45.28 (SD 7.58) kg/m^2 and the average apnea-hypopnea index was 40.42 (SD 29.61) events per hour. Seven themes were reported: the causes of obesity, effects of obesity, effects of weight loss, experiences of social media on weight loss, CPAP therapy prior to bariatric surgery, and experiences of social media on bariatric surgery. Morbidly obese patients with OSA who planned for bariatric surgery experienced physical and mental effects of obesity, including social stigmatization. These patients had failed in various weight loss programs and believed that bariatric surgery was the correct solution. Social media was used for data gathering in terms of bariatric surgery and CPAP therapy. CPAP rental or secondhand purchasing was preferred.

Conclusions: Social media platforms are a source of information prior to bariatric surgery. A CPAP machine is not a lifesaving machine; rather, it is a temporary treatment before surgery and may not be required after weight loss. CPAP rental or secondhand purchasing may be preferred. These are participant beliefs, not clinical conclusions.

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KEYWORDS

continuous positive airway pressure; bariatric surgery; social media; online information; weight reduction; support group; obstructive sleep apnea; CPAP; stigma

Introduction

Obstructive sleep apnea (OSA) and obesity are global public health issues and are closely related [1]. One study showed that approximately 936 million people worldwide were affected with OSA [2], while more than 1 billion people were overweight or obese in 2022 [3]. Both diseases are associated with cardiovascular diseases, such as hypertension or left ventricular hypertrophy [4,5]. A 10% weight gain increases the risk of apnea by 32%, while weight loss lowers the risk by 26% [6]. One study showed that after 10 years, a 7.1-kg weight loss resulted in an OSA remission rate of 34.4% [6].

Bariatric surgery is a quick method of weight reduction for patients with morbid obesity. This is indicated if the BMI is ≥35 kg/m^2, or BMI of 30 - 34.9 kg/m^2 with metabolic disease [7]. Weight loss by bariatric surgery may vary and depend on gender and procedures. Women had a total weight loss of 3.1% more than men, and the Roux-en-Y procedure resulted in 6.9%

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more weight loss than sleeve gastrectomy [8]. Additionally, bariatric surgery cured OSA in 54% (38/70) of patients, while 20% (14/70) still had moderate-to-severe OSA 5 years after surgery [9].

Preoperative preparation is crucial and includes a psychological and nutritional assessment, weight loss plan, and medical clearance [10,11]. Two previous studies found that although preoperative evaluation and preparation are essential, they were still lacking from both the patients' and health care providers' perspectives [12,13]. These issues included education materials, accessible sources, resource needs, and support groups. One Canadian study found that better resources for bariatric surgery are needed from the perspective of health care providers, while patients also reported that there is unmet information regarding bariatric surgery. As 1 patient mentioned, "I don't want to bother the doctor." Additionally, a continuous positive airway pressure (CPAP) machine is needed for several weeks prior to the surgery to prevent postoperative complications [11].

A systematic review found that patients with OSA are at risk for complications after bariatric surgery, with a relative risk of 1.23; *P*=.04 [14]. If treated with CPAP preoperatively, the major complications of bariatric surgery were comparable with those patients without OSA [15]. Despite the benefits of CPAP treatment preoperatively, the adherence was only 45% [16]. Some patients with OSA who planned to undergo bariatric surgery may not have purchased a CPAP machine for personal use, but such evidence is limited. Therefore, this study used a qualitative method to evaluate how obese patients with OSA who were scheduled for bariatric surgery received information regarding bariatric surgery, including their decision to purchase a CPAP machine prior to bariatric surgery.

Methods

Study Setting

This study was conducted at Khon Kaen University. OSA was diagnosed by the presence of an apnea-hypopnea index (AHI) of 5 or more events per hour using polysomnography. A CPAP machine was available at the hospital, online, or rented from CPAP representatives. The study was conducted between October 2023 and February 2024.

Study Design

This qualitative research, based on Husserlian descriptive phenomenology, studies the lived experiences of obese patients seeking weight loss through gastric surgery. The patients were required to prepare for bariatric surgery by using a CPAP machine for 1 month prior to the procedure. The research presentation follows the COREQ (Consolidated Criteria for Reporting Qualitative Research) 32-item checklist [17].

Researcher Positioning and Reflexivity

The research team consisted of 3 people, all holding doctoral degrees: 1 in marketing, 1 in nursing, and 1 in medicine. A research assistant, also with a doctorate in nursing, was responsible for collecting all qualitative data. Both the researchers and the research assistant were experienced and had undergone training and practical experience in qualitative interview research. No prior relationship was established with participants before the study. To minimize potential bias, the researcher maintained a reflexive journal to reflect on assumptions, positionality, and the influence of professional background during data collection and analysis. The research team emphasized bracketing to "switch off" biases and preconceived notions, in order to embrace the true experience of the informants, unadulterated by the researchers themselves.

Study Setting and Context

Thailand is a Southeast Asian country in which most of the population practices Buddhism. This study was conducted in Northeastern Thailand, locally known as Isan, a region with a population of approximately 21.7 million people, accounting for nearly one-third of Thailand's total population. Isan comprises 20 provinces across northern, central, and southern subregions and is predominantly rural and agricultural in nature.

Theravada Buddhism is the primary religion in Isan and strongly influences social values and everyday life. Its emphasis on the Buddhist middle path encourages emotional restraint and acceptance, alongside an optimistic worldview. These religious and cultural orientations shape interpersonal relationships and approaches for coping with life challenges.

Data collection took place in a public tertiary-level hospital, which provides advanced medical services and serves as a referral center for patients from both urban and rural areas. All study participants resided in the Isan region.

Isan society is characterized by strong familial and community ties, with cultural values emphasizing kinship, mutual assistance, and interdependence among family members. Extended family living arrangements are common, often involving 3 to 4 generations within the same household. There is limited cultural expectation for younger family members to live independently, and family interdependence typically continues across the life course, including after marriage.

Although urbanization and social change have influenced lifestyles—particularly among younger generations—core Isan cultural values remain prominent. A shared belief that individual suffering is collectively experienced by the family underpins caregiving practices and reciprocal support within households. These contextual and cultural characteristics form an important backdrop for understanding participants' experiences in this study [18,19].

Participants and Sampling

Participants were recruited using convenience sampling from patients scheduled for bariatric surgery who were using a CPAP machine and met the study inclusion criteria. Individuals who met the clinical criteria but declined participation were excluded. Information about the study was posted on an information board in the outpatient clinic area designated for the target group. A research assistant screened and identified eligible participants based on the predefined criteria, resulting in a total of 14 patients who participated in the study.

Eligibility criteria included having firsthand experience relevant to the phenomenon under investigation, the ability to communicate in either standard Thai or Northeastern Thai, and

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a willingness to participate. Interviews were arranged at times and locations convenient for participants. Data collection continued until phenomenological saturation was achieved, defined as the point at which no new meanings or insights emerged; saturation was reached after 14 interviews.

Data Collection

Data were gathered through in-depth phenomenological interviews using open-ended questions designed to elicit participants' experiences. Interview prompts included, "Please describe your experiences of being overweight, from the time you first perceived your body as larger than others to your decision to undergo gastric bypass surgery," "How did this situation make you feel?," and "What meaning does this experience have for you?"

All interviews were conducted by the same research assistant to ensure consistency. Prior to each interview, participants were informed of their rights, ethical considerations, and the voluntary nature of their participation. Participants then completed a brief demographic information form, and consent was obtained to audio-record the interviews. Each interview lasted approximately 60 - 90 minutes. Following each session, the research assistant documented field notes capturing contextual details, emotional expressions, pauses, and nonverbal cues. Audio recordings were transcribed verbatim within 18 hours of the interviews.

Data Analysis

Data analysis was conducted independently by researchers 1 and 2 at the initial stage. Their analytic outputs were subsequently subjected to peer debriefing and discussed collaboratively with the research team and research assistants to achieve consensus. The analysis adhered to Colaizzi's 7-step phenomenological approach [20]: (1) immersion in participants' narratives, (2) identification of significant statements, (3) formulation of meanings, (4) clustering of meanings into themes, (5) development of textural and structural descriptions, (6) synthesis of the fundamental structure of the phenomenon, and (7) validation of findings through member checking with participants. In case of coding disagreement, systematic consensus discussion with peer debriefing was performed to finalize the coding based on the raw data.

Trustworthiness and Rigor

Methodological rigor was established in accordance with the criteria proposed by Lincoln and Guba and was reported following COREQ items 28 - 32 [21-23]. Data saturation was achieved through iterative and concurrent data collection and analysis. Themes were inductively generated using the Colaizzi analytic framework. Credibility was strengthened through member checking, phenomenological validation, and peer debriefing. Dependability and confirmability were supported through the maintenance of an audit trail, the use of reflexive journals, systematic bracketing, and the inclusion of verbatim participant quotations. Transferability was enhanced by providing in-depth descriptions of the study context and participant characteristics. All themes were clearly delineated in the findings.

Ethical Considerations

Ethical approval for the study was obtained from the Human Research Ethics Committee of Khon Kaen University, Thailand (approval no. HE651187). Written and/or verbal informed consent was obtained from all participants prior to data collection. Confidentiality and voluntary participation were ensured throughout the study. To protect participants' identities, pseudonymous identification codes (eg, ID1 and ID2) were used in place of real names. Each participant received compensation of 300 Thai baht (approximately US $10).

Results

Participant Characteristics

Fourteen patients met the study criteria and agreed to participate in the study; no patients declined to participate in the study. Baseline characteristics of the patients are shown in Table 1. The average age of all patients was 27.21 (SD 4.98) years. The study included 28.57% (4/14) males; 78.57% (11/14) of all participants had a single marital status. Most patients had a monthly income of US $333 or more (13/14, 92.86%). Four patients had no comorbidities (4/14, 28.57%), and the other 4 patients had hypertension (4/14, 28.57%). Half of all patients (7/14, 50%) had basic universal insurance coverage. The average BMI was 45.28 (SD 7.58) kg/m^2 and an average AHI of 40.42 (SD 29.61) events per hour, indicating severe OSA was reported. All participants were employed, while 1 patient was working and in school. This study was conducted in northeastern Thailand, where the residential culture included large families comprised of 2 or 3 generations. The cultural beliefs for the family included taking care of the younger generations, as problems of the younger generations were considered family problems.

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Table . Baseline characteristics and polysomnography results in adult patients with obstructive sleep apnea who planned for bariatric surgery.

Factors	Results
Age (years), mean (SD)	27.21 (4.98)
Sex (male), n (%)	4 (28.57)
Education, n (%)	
Under Bachelor	3 (21.43)
Bachelor	11 (78.57)
Marital status, n (%)	
Single	11 (78.57)
Married or separated	3 (21.43)
Occupation, n (%)	
Government officers	6 (42.86)
Business	6 (42.86)
Freelance	1 (7.14)
Student	1 (7.14)
Income, US $/month, n (%)	
< US $333/month	1 (7.14)
≥US $333/month	13 (92.86)
Comorbid diseases, n (%)	
No	4 (28.57)
Hypertension	4 (28.57)
Diabetes	1 (7.14)
Fatty liver	1 (7.14)
Polycystic ovarian disease	3 (21.43)
Allergic rhinitis	1 (7.14)
Smoking	0
Alcohol consumption	9 (64.29)
Insurance, n (%)	
Government	5 (35.71)
Social Security Scheme	2 (14.29)
Basic universal coverage	7 (50.00)
Epworth Sleepiness Scale, mean (SD)	8.07 (2.75)
STOP-Bang score[a], mean (SD)	4.42 (1.22)
BMI (kg/m^2), mean (SD)	45.28 (7.58)
Neck circumference (cm), mean (SD)	41.14 (5.45)
Apnea-hypopnea index (events/h), mean (SD)	40.42 (29.61)

[a]STOP-Bang score: snoring, tiredness, observed apnea, hypertension, BMI, age, neck circumference, gender.

Perspectives of Adult Patients With OSA Who Planned for Bariatric Surgery

Qualitative research on the perspectives of young adults regarding gastric bypass surgery for weight loss due to severe obesity was conducted. The results explain the factors and conditions that influenced their approach to solving this problem and conclude with recommendations for best practices for similar situations in other contexts (Tables 2 and 3).

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Table . Examples of Colaizzi code-to-theme in adult patients with OSA[a] who planned for bariatric surgery.

Significant statements (raw data)	Formulated meanings (interpretation)	Cluster of meanings or subthemes	Emerging themes
"I don't care about weight; it does not matter to me, despite being bullied at school."	The digital era with its unlimited connections among people and devices may lead to a sedentary lifestyle of the younger generation.	Stuck in one's own private world	Love of eating leads to critical obesity
"I believed that my parents were uncomfortable too, but did not want to blame it on their children."	Protect your children from the ridicule of society.	Parents try to isolate their children from society, so they do not have to endure bullying.	Obese persons: strangers in society
"I was always bullied, and this made me ashamed, particularly in public transportation." "You are so big, you take more space; you take two seats in the public transportation. I cannot sit beside you. I was only just big sized."	Feeling ashamed, uncomfortable, and worried about their social appearance.	Never chosen to be a school representative by classmates or teachers	Obese persons: a stigma from society as incompetent
"Being obese, I have lost opportunities for jobs, as employers may think that I am not active or not flexible and not suitable for the work"	Being insecure about their future, jobs, economic security, and social acceptance.	Obesity leading to lost opportunities in life	Obesity and opportunity for job
"It was good to chat with the group. I chatted with others, as they had done that before me. For example, [they discussed] how to refer themselves to be treated with bariatric surgery at this hospital. It was a page called 'bariatric surgery' at University Hospital."	Online communities serve as platforms for sharing experiences and buying or selling inexpensive used CPAP[b] machines.	The benefits of joining groups on social media	Social media on weight loss

[a]OSA: obstructive sleep apnea.

[b]CPAP: continuous positive airway pressure.

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Table . Summary of themes of a qualitative study in adult patients with OSA[a] who planned for bariatric surgery.

Main themes and themes	Descriptions
Main theme 1: obesity-related themes (4 themes)	
Eating behaviors and an enduring attachment to food as pathways to obesity	• Obesity results from childhood development where parents and families use eating as a way to show affection, rather than encouraging physical activity. Furthermore, Thai society has a value system where overweight children are affectionately referred to as “chubby.”
Experiencing social othering and stigmatization as a person with obesity	• Overweight people feel alienated from society, uncomfortable in public, and have to endure hurtful questions about their weight. Their parents likely feel the same way, but do not say anything for fear of upsetting their children.
Perceived loss of life opportunities, particularly in employment, associated with obesity	• Being overweight often leads to social stigmatization, making students feel incompetent, overlooked, and insignificant. They are rarely nominated to represent their school in any activities.
The turning point: making a transformative decision to escape the condition of obesity	• Obesity can lead to a lack of confidence, making people hesitant to apply for competitive jobs and preferring less competitive work, while overweight individuals desire self-reliance and the ability to stand on their own 2 feet in society.
Main theme 2: weight loss experience (2 themes)	
The lived experience of CPAP[b] use as a transformative life passage	• When overweight individuals reach a point where they can no longer tolerate it, they decide to seek various weight-loss methods, but without success. They may lose weight temporarily, but then regain it.
Social media on weight loss	• In seeking ways to lose weight, they found diverse groups of friends online, which led them to decide to undergo gastric surgery.
Main theme 3: CPAP therapy prior to bariatric surgery (1 theme)	
CPAP purchasing and bariatric surgery from online platforms	• Preparation for gastric surgery requires checking for sleep apnea, which is common in obese individuals and often necessitates the use of CPAP for 1 month prior to surgery. • Information on social media regarding gastric surgery for weight loss contains both useful information and misconceptions that do not align with scientific data. Furthermore, many parties use this information as a source of recruitment and income for their health care businesses.

[a]OSA: obstructive sleep apnea.

[b]CPAP: continuous positive airway pressure.

There were 3 main themes, including obesity-related themes (4 themes), weight loss experience (2 themes), and CPAP therapy prior to bariatric surgery (1 theme). Details of each main theme and its themes are as follows:

Main Theme 1: Obesity-Related Themes (4 Themes)

Theme 1: Eating Behaviors and an Enduring Attachment to Food as Pathways to Obesity

The characteristics of informants included being a single child or 1 of 2 children in the family. The eating habits and love of eating began when they were children, leading to childhood obesity. Family members were proud to have a lovely, obese child. Patients developed the habit of overeating and never stopped eating particularly sweets, fried foods, and soft drinks. Parents allowed their children to overeat and never told them not to eat as they felt that their children were happy when they ate.

The digital era, with its unlimited connections among people and devices such as smartphones, tablets, and laptops, may result in a sedentary lifestyle for the young generation. Sitting, eating, and interacting with digital devices after school does not include regular exercise, which was part of the daily routine of the patients when they were children. The patients indicated that watching online content and consuming snacks and soft drinks after school were their happiest school-age moments. They did not like to exercise, claiming it was hot outside and they became tired, sweaty, and itchy.

Parents were aware of and unhappy about their children’s growth. They tried to find some solutions for weight reduction, which was unknown to their children. The patients claimed not to care about weight, despite being bullied by classmates.

> *I eat a lot, maybe two of three times that of my friends. I eat three big meals a day, and I have been obese*

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> *since I was a primary school child. I was bullied as an obese kid.* [ID06, male, 26 years, single, 113 kg]
>
> *I was a big kid since I was in primary school, but I did not feel anything was wrong with my body. But, my parents were afraid that I may have a health problem in the future, and they wanted me to lose weight. as they were really concerned about my life.* [ID10, male, 27 years, single, 150 kg]
>
> *When I was a child, I ate a lot. My parents took my food away, but I loved to eat.* [ID14, female, 30 years, single, 128 kg]

Theme 2: Experiencing Social Othering and Stigmatization as a Person With Obesity

Participants in this study did not use the word "obese" but used "big sized or overweight." They reported that they felt uncomfortable in society when someone asked their parents why their kid was obese. They also asked, "How much do you weigh?" They believed that their parents were uncomfortable too, but they did not want to blame their children.

> *I was a big sized kid and friends always bullied me by calling me 'obese kid' and 'disgusting.' They asked me, 'Why are you so obese?' I was very upset with these situations. I did not disturb anyone, but they bullied me about my body. Sometimes, I would cry and feel upset that I had a bad shape unlike others and why I had to be big sized.* [ID14, female, 30 years, single, 128 kg]

Theme 3: Perceived Loss of Life Opportunities, Particularly in Employment, Associated With Obesity

The worst scenarios for obese people occur in school. Obese kids in school were never chosen to be a school representative by classmates or teachers. This resulted in the social isolation of obese students. They did not attend school social events and felt disappointed for not being invited by others to attend these events.

Those who were obese also felt ashamed, uncomfortable, and worried about their social appearance as they were considered attractive as children. Children innocently asked their parents why this guy was so obese and pointed to them in public areas. Additionally, some people made obese individuals uncomfortable on public transportation as they were concerned that they took up more space for seating.

> *I was bullied about my body from children, adults, or even elderly people. I was very upset, as I did not want to be obese.*" [ID02, female, 36 years, married with two children, 127 kg]
>
> *I was always bullied, and this made me ashamed, particularly in public transportation. 'You are so big, you take more space; you take two seats in the public transportation. I cannot sit beside you.' I was only just big sized.* [ID04, female, 33 years, married with one child, 120 kg]
>
> *My neighbors bullied me, asking how I got a job or passed the exam. They thought that I did not do anything other than eat and sleep.* [ID05, female, 26 years, single, 115 kg]
>
> *I want to be healthy and active, but I could not lose weight despite several tries. I am not confident with my body shape when speaking in public. Additionally, I feel easily tired and get headaches.* [ID06, male, 26 years, single, 113 kg]
>
> *Being big sized made me insecure, and I felt unvaluable. Sometimes, I thought, 'Why am I so strange and unlike others?' I want to be good looking and get compliments from others.* [ID14, female, 30 years, single, 128 kg]

Theme 4: The Turning Point: Making a Transformative Decision to Escape the Condition of Obesity

Most patients had a job that was not competitive, such as working with family members or previous mentors. Participants felt a lack of confidence about their future, employment, economic security, and social acceptance. The main need of participants was social acceptance for obese people. Being obese is a repetitive social stigma with a significant impact, resulting in low self-esteem. How society interacts with and perceives obese people is a critical issue in the current era.

> *Being obese, I have lost opportunities for jobs, as employers may think that I am not active or not flexible and not suitable for the work.* [ID10, male, 27 years, single, 150 kg]
>
> *I may not work online forever. I hope that I can lose weight after bariatric surgery and that I may make myself healthier. I want to change my job and apply for a new one. If I am confident, I may get a good job.* [ID13, female, 24 years, single, 110 kg]
>
> *After college, I did not get a job for one year. I decided to work with my family at a bakery.* [ID06, male, 26 years, single, 113 kg]

Main Theme 2: Weight Loss Experience (2 Themes)

Theme 5: The Lived Experience of CPAP Use as a Transformative Life Passage

Participants reported several strategies for losing weight, which included diet control, exercise, and medication. They learned these strategies from various sources, such as family members, friends, the internet, and health care personnel. Participants were able to lose some weight with support from family members, but they gained the weight back and experienced yo-yo effects.

> *I tried low-carb diets and intermittent fasting, but it was difficult. I also used to attend the weight loss project at Herbalife for two months. Then, they tried to sell me some Herbalife products. As the products were so expensive, I quit the program.* [ID02, female, 36 years, married with two children, 127 kg]
>
> *I have tried several methods, but they did not work. I used to fast and did not eat dinner, but I was so hungry. I was able to do that for ten days. Then, I tried to exercise but it resulted in ankle pain which*

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occurred because of obesity. My doctor told me to walk instead. I also ate keto diets but I got a rash and syncope from keto diets. I tried keto diets for 15 days, but then I quit. [ID04, female, 33 years, married with one child, 120 kg]

I was bullied about my weight, so I tried to lose weight using over-the-counter medications and several other methods. I was able to lose some weight, but I gained weight back after I stopped taking the medication. I felt hungrier after quitting the medications. While I took them, I felt palpitations. I saw some news about the dangers of the medications; some people had died due to weight loss medications. My mom gave me some medication but I did not take them. [ID05, female, 26 years, single, 115 kg]

I tried to lose weight by diet control and intermittent exercise. But I felt fatigue and dyspnea from exercise. So, I quit exercise. [ID06, male, 26 years, single, 113 kg]

I tried to lose weight due to ankle pain. I could not stand when I woke up or after long sitting as it caused ankle pain. [ID07, female, 25 years, single, 175 kg]

I had to take medications for losing weight. If I took medication, my weight dropped to 150 kg. I weighed 170 kg or more if I did not take medications. I was afraid of weight loss medications. [ID08, male, 27 years, single, 150 kg]

I did not eat carbs or sugar. I lost 11 kg, but I gained weight after I stopped doing that. I could not sleep if I did not eat dinner, as I was hungry. [ID10, male, 27 years, single, 150 kg]

I was so lazy about losing weight. I was able to control my diet and do more exercise, but I did that for only a short period of time. [ID11, female, 19 years, single, 90 kg]

I have tried several medications since I was 20 years. If I stopped medications, I gained the weight back. There were several medications advertised on Facebook. [ID12, female, 29 years, single, 95 kg]

I tried several methods but they did not work as I worked on a shift. I was not healthy and felt dizzy while exercising. So, I decided to do surgery. [ID13, female, 24 years, single, 110 kg]

My highest weight was 130 kg. I lost 26 kg by eating a keto diet and exercising. My weight gained back to 130 kg after eating as usual. [ID14, female, 30 years, single, 128 kg]

Theme 6: Social Media on Weight Loss

The study participants were young adults with social stigma, which caused social isolation. Using digital media, these participants have access to content in such media, which includes several available methods for losing weight, including bariatric surgery. Searching on Facebook (Meta Platforms, Inc.) using the keywords “lose weight,” there were at least 50 groups with more than 24,000 members. Other platforms also have media on weight loss, including TikTok (ByteDance Ltd) and YouTube (Google LLC). These media were used for sharing experiences and receiving support from others. There were several hidden services in these platforms, such as multidisciplinary services for weight reduction.

I like these groups on Facebook, as I had someone to talk with regarding bariatric surgery, as it was so dangerous. My husband suggested I do bariatric surgery, as he was afraid that I may have a stroke like my aunt. I got a lot of useful information on bariatric surgery from these groups. It was a good platform for idea exchange as well as experience exchange on bariatric surgery such as post-operative pain. [ID04, female, 33 years, married with one child, 120 kg]

It was good to chat with the group. I chatted with others, as they had done that before me. For example, [they discussed] how to refer themselves to be treated with bariatric surgery at this hospital. It was a page called ‘bariatric surgery’ at University Hospital. [ID13, female, 24 years, single, 110 kg]

I was on TikTok but never thought about going to a page on bariatric surgery. I had a lot of followers on TikTok after I accessed that page. I told them every day about my symptoms after the bariatric surgery. Some patients who had had the bariatric surgery also shared their experiences on my page while those who planned to have the bariatric surgery would have ideas on it. [ID14, female, 30 years, single, 128 kg]

I found this weight loss clinic on TikTok, which popped up. The page reviewed bariatric surgery, how much weight reduction after surgery, and other contents. I never thought that I needed the bariatric surgery, but I was interested in doing the surgery after learning from that page on TikTok. I felt tired easily and unable to live normally, maybe from obesity. I decided to go for surgery, as it only took a few days to recover from bariatric surgery, which was mentioned on the page. [ID01, female, 34 years, single, 118 kg]

I found several pages on weight loss posted by several private hospitals. I found that many people underwent bariatric surgery. I did a study on bariatric surgery and found that it could result in a lot of weight reduction. I was unsure if I would go for the surgery. So, I did a study again and found that undergoing the bariatric surgery at the government hospital was a lot cheaper than the private hospital. I learned a lot from the weight loss pages on online media. [ID14, female, 30 years, single, 128 kg]

Main Theme 3: CPAP Purchasing Prior to Bariatric Surgery (1 Theme)

Theme 7: CPAP Purchasing and Bariatric Surgery From Online Platforms

Patients who planned to undergo bariatric surgery needed to be tested for OSA. Those with OSA required treatment with a CPAP machine for at least 1 month prior to the surgery. Patients

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in this study had an AHI between 12 and 100 events per hour. Even though some patients had a very high AHI, they were not concerned about OSA. They believed that OSA would be cured after the bariatric surgery, as their weight would be reduced. Therefore, CPAP treatment was temporary for these patients and not a lifesaving machine. Seven patients decided to buy the CPAP or a secondhand CPAP, while the other 7 patients decided to rent the CPAP for 1 month instead of purchasing it. For those who purchased the equipment, 3 patients (42.86%) had insurance coverage, and 2 patients (28.57%) who rented the CPAP also had coverage. In some circumstances, CPAP for rent was not available. Therefore, some patients looked for secondhand CPAP online using several platforms.

> *I had severe OSA with an AHI of 44 events/hour. I had to use a CPAP but it was so expensive. I did research online and found that my snoring and OSA would disappear if I lost weight after the bariatric surgery. I did not want to buy the CPAP, and chose to rent one instead for one month.* [ID14, female, 30 years, single, 128 kg]

> *Prior to bariatric surgery, my doctor told me to buy a CPAP and use it before the surgery. But, it was expensive and I chose to rent it. At that time, CPAP for rent was not available. I searched for CPAP online from Google and found a second-hand CPAP on Facebook. It was cheaper at US$ 266.* [ID02, female, 36 years, married with two children, 127 kg]

Online platforms have both advantages and disadvantages regarding bariatric surgery. The main advantages include sharing data before and after surgery, sharing information regarding used CPAP machines, working as a case finder for bariatric surgery, and psychosocial support. However, data on the online platforms may not be written by health professionals, and some information may be incorrect and misleading. Some people may have advantages from case finding or selling CPAP online for preoperative use.

Benefits

> *Individuals who underwent bariatric surgery may have different symptoms and responses to the surgery. I read from the online content and used that as a guide for our preparation. I did not feel lonely when searching or chatting on the online platforms. I felt like I had friends taking care of me. It is an experience sharing in the online platforms.* [ID13, female, 24 years, single, 110 kg]

> *Online information originates from anywhere in the country. Some people on the platforms acted like coordinators for bariatric surgery. They took care of patients who were willing to perform the surgery every step of the way, such as checking for the surgery queue, providing preoperative CPAP equipment, checking for insurance, or even taking care of the patients during the operative and postoperative periods. These were occupations for bariatric surgery. CPAP in these teams were sold to anyone as second-hand CPAP.* [ID04, female, 33 years, married with one child, 120 kg]

Disadvantages

> *Reading online content too much made me anxious and worried, such as severe vomiting after bariatric surgery, severe pain at the surgical site, or infected surgical wounds. Some information may not be correctly posted, as they are not doctors.* [ID12, female, 29 years, single, 95 kg]

Discussion

This qualitative study has shown causes of obesity, effects of obesity, experiences of weight loss and social media on weight loss, CPAP therapy prior to bariatric surgery, and social media regarding bariatric surgery. Social media was used mainly for weight loss and bariatric surgery preparation. Patients did not seek the benefits of CPAP therapy prior to the surgery.

This study found that morbidly obese patients who planned to undergo bariatric surgery showed that their condition caused several personal and social limitations. As shown in Themes 2 - 4, these patients were socially stigmatized and lost job opportunities. These findings were compatible with a previous qualitative study from the United Kingdom regarding shame and stigmatization [24]. This study added that obesity was mainly due to personal eating habits and/or parental responses. The results showed that a love of food was the main cause of obesity. Additionally, their parents did not prevent them from eating, which might be another cause of childhood obesity.

Even though patients tried several strategies to lose weight (Theme 5), they were unable to maintain a low body weight. These attempts resulted in seeking rapid weight loss or bariatric surgery. As previously reported, bariatric surgery is the most effective means for morbidly obese patients [25]. However, previous studies showed that data or resources were limited in terms of support groups or teen-friendly resources [12,13]. This study found that there were several support groups, resources, or information regarding both weight reduction and bariatric surgery on platforms, such as Facebook or YouTube. These social media sites are easily accessible and suitable for young adults to gain information. The two main limitations of these platforms were (1) data may not be valid as some pages or groups are not run by health care providers, and (2) some pages may benefit by recruiting patients to their health care systems. These may be employees who receive payments from the health care systems.

"CPAP machine is not a lifesaving machine and may not be required after bariatric surgery." (ID02) Even though several studies have shown the benefits of CPAP therapy on cardiovascular outcomes [26-28], morbidly obese patients who planned to undergo bariatric surgery did not believe that CPAP was a lifesaving machine; rather, it is a temporary treatment. Additionally, these patients did not plan to use a CPAP machine after the bariatric surgery. However, data have indicated that OSA still persisted after bariatric surgery. A meta-analysis found that the average AHI was decreased from 40.3 to 13.5 events per hour after bariatric surgery, which indicated that CPAP was still required [29]. The patients were not aware of this, even those who purchased the CPAP for use prior to the study. Like ID02, they may sell the CPAP machine as a secondhand machine

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for other patients to use for a month prior to bariatric surgery. Some patients believed that bariatric surgery offers hope to cure obesity as well as OSA [24,25].

These results may indicate that marketing strategies are required for morbidly obese patients who plan to undergo bariatric surgery. These include social media platforms for bariatric surgery information as well as customer packages for bariatric surgery. Such packages may include options of hospitals in various areas in Thailand, the cost of bariatric surgery at each hospital, and surgery options. This could be a new online occupation [25]. Another marketing strategy would be to use social media for bariatric surgery preparation, advertising such needs as secondhand CPAP or CPAP rentals. In addition, social media could provide support groups for patients who plan to undergo bariatric surgery. Such groups would consist of a multidisciplinary team including surgeons, nutritionists, sleep physicians, and psychiatrists or psychologists [13,24,25].

As previously reported, qualitative studies showed that online health information was the main source and had an increasing trend of using online or internet [30-32]. However, there were some barriers to online health information, including limited eHealth literacy or inconsistency of online information [32]. A systematic review also reported findings from qualitative studies showing that online health information was reliable in only 40% and 60% of health information consumers searched at least 3 different websites [33]. In this study, participants searched for data from social media and believed in the data. Therefore, the results of the study may not be correct based on clinical studies, but indicate the participants' beliefs. The previous qualitative study also suggested that the online platforms created by health care professionals may be more reliable and can be used for medical health decisions. However, individualized medical decision-making may be needed and crucial [34,35].

There are some limitations in this study. Most participants were young adults who were mainly single and female. These data aligned with previous studies indicating that female, young adult patients are concerned about their physical images [24,25]. However, data in this study were collected until data were saturated. Additionally, no intervention was applied in this study.

In conclusion, morbidly obese patients with OSA who were planning bariatric surgery experienced physical and mental challenges related to obesity. These patients had failed various other weight loss programs and believed that bariatric surgery was the correct solution. Social media platforms are sources of information prior to bariatric surgery. A CPAP machine is not a lifesaving machine but just a temporary treatment before surgery and may not be required after weight loss. CPAP rental or secondhand purchasing may be preferred. These are participant beliefs, not clinical conclusions.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

BS contributed to conceptualization, investigation, methodology, project administration, data curation, writing - original draft and review. DJ contributed to conceptualization, formal analysis, and writing – review & editing. KS contributed to conceptualization, and writing – review & editing.

Conflicts of Interest

None declared.

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Abbreviations

AHI: apnea-hypopnea index
COREQ: Consolidated Criteria for Reporting Qualitative Research
CPAP: continuous positive airway pressure
OSA: obstructive sleep apnea

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Breast Health Education as a Motivator for Breast Self-Examination Practice in High-Risk Women: Grounded Theory Analysis

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Abstract

Background: Women in low-resource regions face a higher risk of breast cancer. Implementing a breast health initiative that promotes breast self-examination practice could aid in the early detection and prevention of breast cancer complications.

Objective: This study aimed to explore and comprehend the experiences of high-risk women, focusing on their breast self-examination practice and the factors that influence their effectiveness in managing breast health.

Methods: This research used a qualitative approach to perform semistructured interviews with 11 high-risk women who had a family history of breast cancer recruited from the oncology department of a hospital using purposive and theoretical sampling during the period from August 2024 to April 2025. The analysis of the data was conducted using the grounded theory approach by Strauss and Corbin to formulate a theoretical model for breast self-examination practices.

Results: This study highlighted breast health education as a motivator of and the core category for breast self-examination practice. This study found perceptual, attitudinal, and familial support drivers of breast self-examination practice for early diagnosis of breast cancer and better living.

Conclusions: This study enhances the body of knowledge regarding the experiences of high-risk women. Health care providers play a significant role in using this framework to steer innovative educational interventions that promote breast health in culture-bound communities.

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KEYWORDS

breast self-examination practice; breast health education; breast cancer; high-risk women; breast self-examination

Introduction

Worldwide, 2.3 million women were diagnosed and 760,000 died of breast cancer (BC) in 2022 [1]. BC is the second most common type of cancer and among the major causes of pathological complications [2]. Approximately 15% to 20% of women diagnosed with BC have a family member who has also been diagnosed with the disease [3]. A family history of BC elevates the likelihood of developing the illness, particularly among close blood relatives who have had BC. Women with a first-degree relative (sister, daughter, or mother) diagnosed with BC face nearly double the risk. If a woman has 2 first-degree relatives diagnosed with BC, her risk increases by roughly 3 times [4].

In Asia, Pakistan records the highest rate of BC incidence at 23.1% [5]. Additionally, 23.8% of women in Pakistan have a family history of BC. The average age of family members diagnosed with BC has been found to be 49.2 years [6]. Moreover, 95.2% of these individuals have at least one family member who was affected. The most common relative diagnosed with BC is the mother, accounting for 47.6% [7]. The World Health Organization–recognized tools for BC screening are mammography, clinical breast examination, and breast self-examination (BSE) [1]. Although mammography has proven to be a reliable and valid BC screening method, awareness of this tool and its accessibility and affordability to women have been low in poor-resource countries [8]. BSE and clinical breast examination come in handy in such countries. BSE practice is a more acceptable method due to cultural issues, and evidence has proved that 40% of diagnosed BCs are detected through BSE [9], thus validating the usefulness of the procedure in BC screening [3].

Among high-risk Pakistani women with a family history of BC, merely 15% are knowledgeable about the disease, and only 4.18% use BSE as a screening measure for BC [10]. Just 1% regularly practices BSE, whereas 3.6% do so occasionally [11]. Furthermore, late-stage presentation of BC (stages III or IV) is

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prevalent throughout the country, with nearly 35.2% of delayed cases occurring among high-risk Pakistani women [12]. It has been demonstrated that 40% of diagnosed BCs are identified through BSE [13].

In Pakistani culture, the concept of the "breast" is more associated with sexuality than with health, making discussions about it taboo due to conservative societal norms [14]. Cultural influences significantly affect breast health awareness among Pakistani women, with many refraining from performing BSE due to the stigma surrounding self-examination and embarrassment over discussing private body parts or undergoing medical assessment [15,16]. Misunderstandings, societal expectations, and false beliefs hinder the BSE practice and lead to delays in seeking help among women. The influence of culture has resulted in women not being motivated to carry out BSE or being taught how to [17].

Despite the significance of cultural values, there is a lack of research on the implementation of BSE practice measures among women at high risk. To improve this situation, it is essential to investigate the BSE practice viewpoints of high-risk women. This study used a grounded theory approach to create a conceptual understanding based on participants' lived experiences, aiming to formulate a conceptual model or theory rooted in participants' perspectives.

The purpose of this study was to explore and comprehend the experiences of high-risk women, focusing on their BSE practice and the factors that influence their effectiveness in managing breast health.

Methods

Study Design

This study used the grounded theory approach by Strauss and Corbin [18] and adhered to the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist to ensure rigor [19]. Grounded theory is a qualitative research method aimed at developing a theory that is firmly based on data that are collected and analyzed systematically. This approach is especially effective for examining intricate social processes, such as BSE practice, as it seeks to understand how people develop and sustain behaviors about a specific health issue.

Participant Selection

The data were gathered between August 2024 and April 2025. The researchers applied both purposive and theoretical sampling to select data sources and participants. Oncology nurses asked 11 high-risk women to participate in the study, and no one declined to take part in the interviews. The timing and date were arranged based on the availability of the participants, and the researchers provided thorough explanations about the study. At first, purposive sampling was used to identify participants who met certain eligibility criteria: (1) female participants with mothers diagnosed with BC, (2) proficiency in the Urdu language, and (3) willingness to take part. When the investigation advanced, theoretical sampling was used to enhance evolving theory. Theoretical sampling is an iterative process in which data collection and analysis are conducted simultaneously, using the emerging analysis to guide the selection of subsequent data to collect. Collected data were coded and analyzed to form initial concepts, categories, and themes. The selection of new participants was based on their marital status (unmarried, married, or widowed) and level of education (primary school, middle school, tenth grade, or higher) to understand the concepts, fill the gaps, refine categories, and expand the theory. Theoretical sampling persisted until data saturation was reached, when no further relevant data or insights were produced. The aforementioned 11 high-risk participants from diverse communities took part in the study (Table 1).

Table . Participant characteristics.

Participant ID	Age (y)	Marital status	Educational level	Region
HRW1[a]	21	Married	Tenth grade	Urban
HRW2	24	Married	Tenth grade	Urban
HRW3	22	Married	Primary school	Urban
HRW4	21	Unmarried	Tenth grade	Rural
HRW5	26	Married	Graduation (16 years of education)	Urban
HRW6	24	Married	Primary school	Rural
HRW7	22	Married	Primary school	Rural
HRW8	27	Married	Tenth grade	Urban
HRW9	24	Widowed	Primary school	Semiurban
HRW10	25	Married	Middle school	Rural
HRW11	23	Unmarried	Twelfth grade	Semiurban

[a]HRW: high-risk women.

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Ethical Considerations

The Research Ethics Committee of the Institute of Allied Health Sciences associated with the hospital provided ethics approval for this study, with reference IAHS/WMC/786/008-02. All participants provided informed consent, and information was provided on their right to leave the study at any point without facing repercussions. Participant data were anonymized to ensure confidentiality, and all research materials were securely stored. Participants were not provided any compensation for their participation.

Data Collection

Data were gathered through semistructured interviews (Table 2). These interviews were conducted in person, with audio recordings made of participants, along with observations and verbatim transcriptions. Each interview lasted approximately 35 to 50 minutes. Field notes were kept providing contextual details. Several participants were interviewed more than once, with 81.8% (9/11) taking part in a second interview to enhance the data and facilitate clarification, deeper exploration, and a richer understanding of emerging themes. Data were gathered until data saturation was achieved, which is defined as the point at which no new themes or insights arise. Due to logistical constraints and participant preferences, transcripts were not returned to participants for member verification. Nonetheless, to maintain ethical standards and ensure the accuracy of the transcriptions, a method of double transcription and validation was used [20,21].

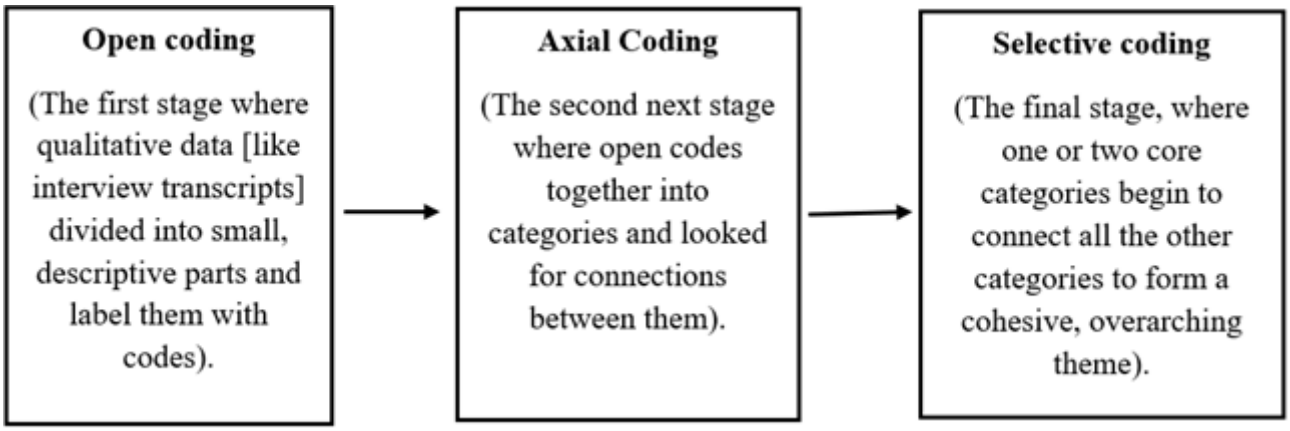
Table . Interview guideline.

Category	Questions
Opening questions	• "Do you think that you should take care of your breast health? Or do you think that breast health is important for women health?" • "What do you know about breast health as you are at risk of breast cancer or what do you know about breast cancer as your mother is suffering from the same condition?" • "Do you know how to do breast self-examinations practice or what are the methods of breast self-examination practice?" • "Do you examine your breast? Or do you think that you should do breast self-examination practice?"
Probing questions	• "Do you have the ability or confidence to do your breast self-examination practice?" • "What changes do you observe during breast examination?" • "Can you explain the change or discuss the changes with anyone, or do you think that change should be discussed?" • "What will you do to manage changes in your breasts to maintain your breast health?" • "Do you think that you need support or assistance, and how did you receive such support?"
Closing question	• "Is there anything you would like to share or add?"

Analysis

Analysis of the data was conducted following the grounded theory approach by Strauss and Corbin [18], which involved open, axial, and selective coding (Figure 1).

Figure 1. Coding process.



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Coding of interview transcripts was done using verbatim data. Conceptual sensitivity to achieve reflexivity and analytic consensus was maintained by using multiple coders in discussion, where codes were reached through ongoing discussions and adjustments to the coding framework. The coding tree (Table 3) shows that the initial codes were organized into 5 subcategories under a single main category and were subsequently combined to create the final thematic model. Constant comparative analysis was used for the development of themes, in which new data were continually assessed against existing codes and categories. This approach allowed for the refinement of the emerging theory and affirmed its applicability across diverse participant experiences [22,23], directed at identifying repeated patterns and connections within the data [20,24,25]. The process resulted in the documentation of the key themes: the desire for breast health awareness, family support, change in perceptions and attitude, and early diagnosis of BC (Figure 2).

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Table . Coding process for the category of breast health education as a motivator.

Level of coding	Code or category	Participant code
Open coding	• Realization of health issues related to BC[a]. • Awareness of BC symptoms. Motivation to seek information about BC. • Cultural issues related to delay in health-seeking behavior. • Family support from mother • Change of perceptions • Breast health awareness • Change in attitude	• "I know that I AM at risk of breast cancer because my mother is suffering from this and I saw my mother's condition." [Participant 1] • "My mother discusses her problems with me, and I feel her pain." [Participant 5] • "My mother is suffering from pain, stress, hair loss, and many other problems." [Participant 3] • "My mother told me that my condition was better if she know about breast cancer and she wish for me to have all information about breast cancer, and I also want to know about this." [Participants HRW 5] • "My mother hides her problem from all family and when she can't bear her problem than she disclosed to her mother-in-law and she agreed to visit the doctor." [Participants HRW 7] • "I saw my mother's condition, and I was worried. My mother guided me to touch the breast is not wrong it's our body part; we can discuss our problems with lady doctor because she is also women like us. She can understand us." [Participants HRW 4] • "I did breast examinations to feel any change in my breast like pain, swelling for early identification of cancer." [Participants HRW 11]
Axial coding	• Category: BSE[b] practice (subcategory 1: breast health maintenance; subcategory 2: symptoms awareness) • Category: influential factors (subcategory 1: change in perception of BC and BSE; subcategory 2: change in attitude; subcategory 3: family support)	• Open codes: "I can do breast examination by touch and observation." [Participant HRW 4] • Open code: "I know the symptoms like pain in breast, swelling in breast, discharge." [Participant HRW 6] • Open code: "My mother told me that breasts are like other body parts, breast problems are like other problems of body, breast touch is not wrong." [Participant HRW 9] • Open code: "Realizing the importance of early diagnosis, performing Breast examination." [Participant HRW 11] • Open code: "I can understand breast health issues and have support from mothers in early health seeking behavior such as to visit doctor for my problem." [Participant HRW 9]
Selective coding	• Category: breast health education as motivator	• Realization of breast health issues, and need for BSE practice for identification of any breast change, and that leads to early BC diagnosis for healthy living

[a]BC: breast cancer.

[b]BSE: breast self-examination.

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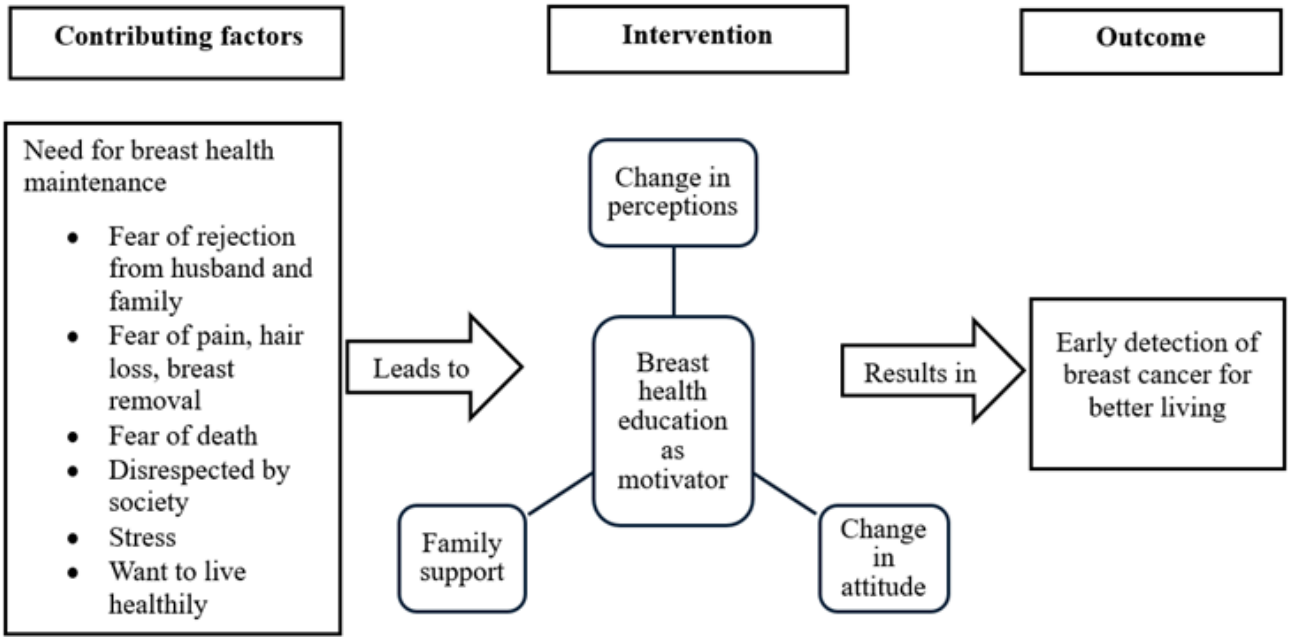
Figure 2. The theory of breast health education as a motivator among high-risk women for breast self-examination practice.



Credibility and Trustworthiness

The reliability and credibility of this study were maintained through implementation of several approaches as suggested by recognized qualitative research guidelines [26]. These included (1) member checking, in which initial interpretations and findings were shared with high-risk participants to check the accuracy and authenticity; (2) triangulation, which involved comparing various data sources—such as interview transcripts and field notes—to enhance the validity of the results; (3) investigator triangulation through ongoing team discussions during the data analysis phase to confirm consistency and individual bias reduction; and (4) an audit trail by keeping thorough documentation, such as coding decisions, to facilitate external review and transparency.

Results

The core category of the study was breast health education as a motivator, emphasizing the vital role that awareness and understanding of one's breast health plays in promoting BSE practice for BC screening (Figure 2).

Contributing Conditions: Need for Breast Health Maintenance

Understanding the mother's BC situation and being aware of BC symptoms such as pain or hair loss, fear of rejection from society, and stress creates the need for breast health maintenance and can inspire participants to take part in screening activities such as BSEs for early detection and instill hope for improved health. Family support, especially support from mothers who realized their own situation and understood their daughters' need for breast health, motivated participants to change their perceptions of health care choices and the way in which they sought health services and build a positive attitude to engage in health-seeking behaviors such as BSE practice.

Intervention Conditions: Key Factors Influencing BSE Practice

Change in Perceptions

Cultural factors significantly influence health care choices and the way in which individuals seek health services. The participants recognized that being aware of breast health is a key aspect of women's health. They adjusted their views regarding breast health and, through family support, appeared motivated to pursue health-seeking behaviors.

Change in Attitude

Cultural values shape women's attitudes, leading to feelings of anxiety surrounding BC diagnoses and embarrassment when discussing the topic. Participants acknowledged the significance of early detection for improving quality of life and demonstrated motivation for maintaining breast health.

Family Support

In Pakistani culture, family support, particularly from mothers, plays an essential role in influencing their daughters' perceptions regarding health care choices. The encouragement from mothers has a significant impact on promoting their daughters' health.

Outcome: Early Detection of BC for Better Living

The objective of BSE practice is to facilitate the early identification of BC through health education, thereby enhancing quality of life and promoting better living. Early diagnosis of BC significantly increases the likelihood of survival for patients.

This core category emerged in various driving themes, such as the realization of breast health issues, the change in participants' perceptions and attitude, and participants' need for BSE practice for identification of any breast change that would lead to early BC diagnosis (Table 4).

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Table . Major themes with participant quotes.

Theme	Participant quote
Need for breast health maintenance	• "I am aware that I have a higher risk of developing breast cancer because my mother is currently facing this illness, and I have witnessed her suffering from pain, stress, hair loss, and various other challenges." [Participant HRW 3]
Change in perceptions	• "I observed my mother's situation, and it concerned me. My mother taught me that examining our breasts is natural; it's a part of our bodies, and we can talk about our issues with a female doctor because she is also a woman like us. She can realize our experiences." [Participant HRW 4]
Change in attitude	• "I possess knowledge about breast self-examination and various methods, like using my fingers to feel any changes in the breast, such as discomfort or swelling, and I can also monitor any change between both breasts." [Participant HRW 11]
Family support	• "My mother shares her issues with me; I empathize with her struggles. She mentioned that her situation could have improved if she had been informed about breast cancer, and she hopes I have all the knowledge regarding it, which I also wish to acquire." [Participant HRW 5] • "My mother reminds my sister and me to conduct monthly breast checks, always assuring us that she is by our side." [Participant HRW 9]
Early detection of breast cancer for better living	• "I perform breast examinations every month because I am aware of my mother's situation; she was diagnosed very late. The doctors informed us that if she had been diagnosed sooner, her condition would be in a better state than it is now. Therefore, I have hope that I will not endure the same fate as my mother. I am determined to lead a healthier life." [Participant HRW 1] • "I perform breast self-examination regularly with a hope that I will live a healthy life." [Participant HRW 8]

Discussion

Principal Findings

The results of this research highlight the importance of health education in encouraging BSE practice among Pakistani high-risk women. This research adds to the grounded theory concerning BSE practice by demonstrating how health education influences various elements of preventive and promotional health care, such as perceptual change, attitudinal change, and familial support for BSE. The primary theme, breast health education as a motivator, emerged as a key factor influencing behaviors related to BSE practice. This observation is consistent with the health belief model, which suggests that people are likely to engage in health-promoting behavior when they recognize a significant degree of susceptibility to a health issue [27]. The findings of this study on BC symptoms served as a trigger for embracing BSE practice, underpinning the idea that awareness of potential health risks fosters change in behavior [28].

This research emphasizes that educating individuals about breast health plays a critical role in encouraging them to perform BSE. Those with greater knowledge about BC were found to be more motivated to engage in practices that promote breast health. This highlights the significance of educational programs aimed at improving people's understanding of BC, the misperceptions about it and its associated risks, and the advantages of different screening strategies [29].

Knowledge affects an individual's views and interpretations of sociocultural contexts, as well as their ability to foresee results and make choices. Greater awareness and a favorable change in perceptions of BC and the taboos of BSEs can greatly enhance BSE practice [30]. This aligns with the principles of social cognitive theory. According to social cognitive theory, knowledge affects perception by influencing how people decode social situations and anticipate outcomes [31].

Education about breast health can alleviate feelings of embarrassment and fear, resulting in a more favorable outlook on BSEs and the pursuit of medical consultations due to cultural impact [32]. These conclusions correspond with the change theory and the stages of change model by Lewin [33], which can be used to foster more constructive attitudes toward change. Individuals and groups adjust to new circumstances, handle resistance, and reinforce new behaviors [33].

Cultural context affects behavior change. The PEN-3 cultural model has also already demonstrated how cultural context matters in interventions, such as those for cancer awareness and screening [34]. Naturally occurring support from family members has been shown to increase healthy lifestyle behaviors such as BC screening measures (eg, BSE) through providing information and role-modeling. Family members have an impact

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on women's decisions and actions throughout their BC journey, such as (1) confirming breast changes, (2) managing personal emotions, (3) seeking the information, (4) seeking alternative forms of treatment, and (5) advocating for conventional treatment [35]. Family support, especially from mothers, acts as a significant environmental factor that plays an important role in influencing BSE practice. Respectable family support increases a woman's awareness of and interest in undergoing early cancer screening. If a woman receives good emotional support, then she is more likely to behave well for her health [36].

The influence of culture on perception, attitude, and family support, especially from mothers, regarding BSE practice is a core observation of this study. The participants' ability to adopt cultural practices such as family support and change in perception of and attitude toward women's breast health in response to health needs determines the importance of culturally sensitive interventions [37]. This study highlighted the need for BSE practices that are culturally and contextually relevant, such as breast health education targeting participant negative cultural beliefs related to BC and BSE (eg, the taboo of touching oneself) by fostering positive perceptions of this body part, such as the fact that it is a woman's body part, which means that it is also a part of health and not only a part of sexuality, and fostering a positive attitude about BC and its screening measures (eg, BSE) by encouraging women to talk about BC with their family members (eg, with their mothers). Family support motivates women regarding the fact that BSE is not a wrong concept. The breast is a part of their body, which they have a responsibility to be aware of. All these efforts will lead toward behavior change and the promotion of preventive behaviors.

Limitations

This study was carried out at a single hospital, representing a limited group of high-risk women in the area. Grounded theory seeks to create theories based on contexts and data, which might restrict the applicability of the results to different populations.

Conclusions

This study offers convincing evidence underscoring the vital role of breast health education in promoting BSE practices among high-risk women in Punjab, Pakistan. The findings provide essential insights into how improved breast health education can bring about positive changes in attitudes, perceptions, and the involvement of family support systems. This research marks the first effort to develop a grounded theory that presents a new conceptual model to understand the processes related to effective breast health management in similar culture-bound communities.

Funding

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Data Availability

The data from this study cannot be accessed publicly because of ethical reasons and the need to maintain the confidentiality of the participants.

Conflicts of Interest

None declared.

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Abbreviations

BC: breast cancer
BSE: breast self-examination
COREQ: Consolidated Criteria for Reporting Qualitative Research

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Maintenance of the Self-Reported Behavior Change Stage Among Male Bus Drivers Using Longitudinal Occupational Health Checkup Data: Retrospective Cohort Study

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Abstract

Background: Public bus drivers experience prolonged sitting, irregular shifts, limited breaks, and disrupted meals and sleep, making the maintenance of a healthy lifestyle difficult. Although occupational health checkups identify health risks, little is known about the duration of maintenance of self-reported stages of behavior change or their association with physiological markers.

Objective: This study examined the duration of maintenance of the self-reported stage of behavior change and its association with physiological markers and lifestyle behaviors among male bus drivers.

Methods: This retrospective cohort study analyzed occupational health checkup data collected from male bus drivers at a passenger bus company in Japan between 2006 and 2023. The primary exposure was the self-reported behavior change stage, based on a standard questionnaire item used in the Specific Health Checkups questionnaire. For the duration analysis, each participant's longest continuous action or maintenance episode was identified, and the Kaplan-Meier analysis was used to estimate the retention time. For the outcome analyses, participants who maintained the action or maintenance stage for at least 1.5 years after time 0 were classified as the sustained group. Those who returned to the preaction or preparatory stage at 6 months or 1 year comprised the comparison group. Physiological markers were compared using analysis of covariance adjusted for baseline values, age, and medication use. Lifestyle items were analyzed using multivariable logistic regression.

Results: The survival analysis dataset included 717 participants, of whom 566 (78.9%) returned to the preaction or preparatory stage, while 151 (21.1%) were right-censored. The mean age at the start of the maintenance episode was 47.2 (SD 7.0) years, and the median retention time was 362 (IQR 0-1087) days. Retention probabilities were 57.7% at 6 months, 44.1% at 1 year, 33.3% at 2 years, and 23.2% at 3 years. In the outcome analyses, the sustained and comparison groups included 249 and 468 participants, respectively. At baseline, waist circumference was lower in the sustained group (85.77 cm vs 87.54 cm; *P*=.02), whereas other markers and medication use did not differ significantly between groups. At 2 and 3 years, the sustained group had lower BMI, waist circumference, triglycerides, and higher high-density lipoprotein cholesterol levels. Glycated hemoglobin (HbA_{1c}) levels were lower in the sustained group at 3 years (*P*=.02). The sustained group had higher odds of an exercise habit (1 year: odds ratio [OR] 3.40, 95% CI 2.24-5.16; 2 years: OR 8.90, 95% CI 5.26-15.07) and daily physical activity (1 year: OR 2.51, 95% CI 1.61-3.91; 2 years: OR 5.17, 95% CI 2.93-9.13), and lower odds of current smoking (1 year: OR 0.36, 95% CI 0.14-0.95; 3 years: OR 0.26, 95% CI 0.09-0.75).

Conclusions: Maintenance of the self-reported behavior change stage often began in midlife but was difficult to sustain beyond 1 year. Long-term maintenance was associated with favorable physical activity–related lifestyle patterns, lower smoking prevalence, and more favorable metabolic profiles. Health guidance should evaluate not only numerical improvements but also sustained behaviors and the prevention of worsening under occupational constraints.

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KEYWORDS

bus drivers; occupational health; health checkups; behavior change; self-reported behavior change stage; lifestyle; physical activity; smoking; metabolic syndrome; retrospective cohort study

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Introduction

Background

Public bus transportation is an essential form of social infrastructure that supports mobility, participation in community activities, and access to health care, particularly in aging societies. However, the bus industry in Japan faces serious challenges, including an aging workforce and a shortage of drivers [1]. For bus operators, maintaining driver health is not merely an individual health issue but a prerequisite for sustaining safe and reliable public transportation services.

Bus drivers work under conditions characterized by prolonged sitting, continuous attention to road and passenger safety, irregular breaks, early-morning or late-night shifts, and limited flexibility in adjusting their eating, sleeping, and exercise habits. In response to these occupational conditions, regular health checkups are legally required at least once a year and once every 6 months for those engaged in late-night work. In addition, various screening examinations, such as brain checkups and screening for sleep apnea syndrome, are recommended to prevent serious accidents [2]. In daily operations, bus operators are required to conduct preduty and postduty roll calls to check drivers' health status and to establish systems that encourage drivers to promptly report warning signs or symptoms of serious diseases, such as stroke [3].

However, for bus drivers working under demanding schedules, initiating and maintaining healthy behaviors is difficult, even when health risks are identified during regular health checkups. Disrupted lifestyle habits [3], high smoking rates [4], and prolonged sitting have been reported among bus drivers and may increase their risk of diabetes and cardiovascular disease compared with the risk among general workers [5,6]. In Japan, health-related accidents and duty interruptions among commercial motor vehicle drivers, including bus and taxi drivers, have more than doubled over the past decade and remain at a high level; heart disease, cerebrovascular disease, and aortic aneurysm or dissection account for approximately 30% of these events [7]. Because these conditions are closely linked to modifiable risk factors such as hypertension, diabetes, dyslipidemia, obesity, smoking, insufficient sleep, and physical inactivity, regular health management and sustained lifestyle improvement are important for both driver health and public safety [7].

In Japan, Specific Health Guidance is provided to support individuals at risk of developing metabolic syndrome and to prevent lifestyle-related diseases. Although Specific Health Guidance has been associated with improvements in body weight and glycemic control, its effects on systolic blood pressure (SBP) and low-density lipoprotein cholesterol (LDL-C) levels have not been consistent, indicating challenges in lifestyle disease prevention [8]. For occupational groups with irregular work schedules, the provision of health information may be insufficient. Even when drivers understand the importance of healthy behaviors, they may face substantial barriers to initiating and maintaining new habits over time. Therefore, occupational health and nursing interventions need to address not only risk awareness but also motivation, self-efficacy, feasibility within work schedules, and the perceived personal benefits of behavior change.

Behavior change is a dynamic process rather than a single event. The transtheoretical model distinguishes stages such as contemplation, preparation, action, and maintenance, and emphasizes that long-term maintenance is required for stable health improvement [9]. However, in high-stress or highly constrained work environments, even initiated behavior change may be difficult to sustain, leading to discontinuation or relapse into previous habits [10,11]. Digital and mobile health (mHealth) studies suggest that support incorporating psychological benefits, such as empowerment, improved well-being, and personalized feedback, may facilitate behavior change beyond information provision alone [12,13]. Therefore, effective health support for bus drivers should help translate health checkup results into feasible, meaningful, and sustainable actions within their occupational constraints.

Occupational health checkups provide repeated longitudinal data that enable evaluation of self-reported behavior change stages and physiological markers over time. However, limited evidence is available on how long the self-reported behavior change stage is maintained among occupational drivers or whether long-term maintenance is associated with measurable differences in physiological markers. Therefore, this study examined the duration of maintenance of the self-reported behavior change stage and the association between long-term maintenance and changes in physiological markers, such as glycated hemoglobin (HbA_{1c}) and lipid profiles, using historical occupational health checkup data from male bus drivers. The findings may provide foundational evidence for developing occupational health and nursing support models that promote sustained behavior change among bus drivers.

Study Objectives

This study aimed to examine the duration of maintenance of the self-reported behavior change stage and the association between long-term maintenance of this stage and changes in physiological markers using longitudinal occupational health checkup data from male bus drivers.

Methods

Study Design and Participants

This retrospective cohort study analyzed occupational health checkup data collected from male bus drivers employed by a general passenger bus company in Japan (hereafter referred to as Company A) between 2006 and 2023. The eligible participants were male employees who had undergone at least 2 health checkups during the study period. All bus drivers are required to undergo regular health checkups. Health checkups were conducted annually until 2013 and twice annually from 2014 onward. The final observation year was 2023, for which data were available for all eligible participants.

Measures

We used anthropometric measurements obtained during mandatory health checkups, including waist circumference (WC), BMI, SBP, and diastolic blood pressure (DBP), and blood

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test results, including HbA_{1c}, measured according to the National Glycohemoglobin Standardization Program (NGSP), high-density lipoprotein cholesterol (HDL-C), LDL-C, and triglycerides (TG). Lifestyle habits, including exercise, dietary habits, alcohol consumption, smoking, and sleep, were assessed using a standard Self-Administered Questionnaire (SAQ) for Specific Health Checkups provided by the Ministry of Health, Labour, and Welfare [14]. The detailed definitions of the questionnaire items are provided in Table S1 in Multimedia Appendix 1.

Operational Definitions

Self-Reported Behavior Change Stage

The self-reported behavior change stage was operationally defined as the self-reported stage of behavior change based on the standard SAQ items used in the Specific Health Checkups questionnaire. The question was, "Do you intend to improve your lifestyle habits, such as eating and exercise habits?" The response options were as follows: (1) no intention to improve, (2) intend to improve within the next 6 months, (3) intend to improve within the next month and have already started taking action gradually, (4) already taking action for less than 6 months, and (5) already taking action for 6 months or more. In this study, responses (1) to (3) were classified as the preaction or preparatory stage and coded as a self-reported behavior change stage flag of 0, whereas responses (4) and (5) were classified as the action or maintenance stage and coded as a self-reported behavior change stage flag of 1 (Table S2 in Multimedia Appendix 1) [14]. This measure captures the self-reported stage of behavior change related to lifestyle improvement and does not objectively measure actual behavioral quantities, such as physical activity level or dietary intake.

At-Risk Status

At-risk status was defined as meeting at least 1 metabolic risk criterion in the Specific Health Checkups program: BMI≥25 kg/m² or WC≥85 cm; BP≥130/85 mm Hg; TG≥150 mg/dL or HDL-C<40 mg/dL; or HbA_{1c}≥5.6% [15].

Statistical Analysis

All analyses were performed using Python version 3.13.9. Statistical significance was assessed using 2-sided tests with α=.05.

Duration of the Self-Reported Behavior Change Stage Maintenance

Participants who never met the criteria for at-risk status during the observation period were excluded. Next, participants who had never entered the action or maintenance stage of the self-reported behavior change stage were excluded.

The date of self-reported behavior change stage initiation was defined as the health checkup date on which a transition to the action or maintenance stage (self-reported behavior change stage flag=1) was confirmed. This date was defined as time 0, the starting point for survival analysis.

In this study, we analyzed the longest continuous maintenance episode observed for each participant during the observation period, rather than the first episode of the self-reported behavior change stage transition. This approach was chosen because, in occupational health checkup data, temporary transitions into and out of the action or maintenance stage may be observed repeatedly from a young age, and the first episode may not necessarily reflect clinically meaningful, sustained behavioral changes. The aim of this study was not to estimate the natural course after the first initiation of behavior change but to describe the duration of the most stable behavior change maintenance episode achieved by male bus drivers during the observation period and to examine the physiological and lifestyle characteristics associated with long-term maintenance. Therefore, for each participant, we identified the longest episode during which the action or maintenance stage was continuously observed; the start date of that episode was defined as time 0. The start date of the longest episode was used as the individual baseline to calculate the subsequent survival time, that is, the maintenance duration.

Survival Analysis

To estimate the duration of the self-reported behavior change stage maintenance, the Kaplan-Meier method was used to estimate the median duration for which the action or maintenance stage was maintained from the start date defined above. Survival time was calculated from the start date to the health checkup at which discontinuation of the action or maintenance stage was first observed, or to the final health checkup for censored participants.

An event was defined as a transition from the action or maintenance stage (flag=1) to the preaction or preparatory stage (flag=0), indicating discontinuation of the action or maintenance stage. Participants who remained in the action or maintenance stage at their final observation in 2023 were right-censored. As self-reported behavioral transitions could be identified only at health checkup visits, the actual dates of initiation and discontinuation may have occurred within the interval between visits. As the health checkups were conducted annually until 2013 and semiannually thereafter, estimates of maintenance duration were subject to interval censoring.

Outcomes Associated With the Sustained Self-Reported Behavior Change Stage

Definition of the Sustained and Comparison Groups

To examine the association between the long-term maintenance of the self-reported behavior change stage and physiological markers and lifestyle items, we constructed a pseudo-prospective cohort dataset based on the longest episode identified for each participant in "duration of self-reported behavior change stage maintenance" and followed participants' health checkup data after time 0.

In the survival analysis for "duration of self-reported behavior change stage maintenance," the median duration of continuous self-reported behavior change stage maintenance was approximately 1 year. Because regular health checkups were conducted approximately every 6 months from 2014 onward, self-reported behavior change stage maintenance status was observed at discrete follow-up points, such as 6 months, 1, 1.5, and 2 years after time 0. Therefore, the first observation point at which maintenance beyond the median duration was

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confirmed was 1.5 years. Accordingly, participants who remained in the action or maintenance stage continuously for at least 1.5 years after time 0 were operationally classified as the sustained group. Participants who transitioned to the preaction or preparatory stage at 6 months or 1 year after time 0 were classified as the comparison group. As the groups were defined retrospectively based on the duration of self-reported behavior change stage maintenance, group differences were interpreted as associations with long-term maintenance rather than causal effects.

Baseline Characteristics

To assess the comparability of baseline characteristics between the sustained and comparison groups in the constructed cohort dataset and to support the validity of subsequent outcome comparisons, participant characteristics at time 0 were compared between the groups.

For continuous variables, including age, WC, BMI, SBP, DBP, HbA_{1c}, HDL-C, LDL-C, and TG levels, means and SDs were calculated, and between-group comparisons were performed using the 2-tailed Welch *t* test, which is robust to unequal variances and does not rely on the assumption of equal variances. For categorical variables, including the use of antihypertensive, antidiabetic, and lipid-lowering medications, frequencies and percentages were calculated, and between-group differences were assessed using the Pearson chi-square test.

Longitudinal Evaluation of Physiological Markers Using Analysis of Covariance

Between-group comparisons of physiological markers, including WC, BMI, SBP, DBP, HbA_{1c}, HDL-C, LDL-C, and TG, were conducted at each follow-up point (6 mo, 1, 1.5, 2, 2.5, and 3 y). Analysis of covariance (ANCOVA) was used to adjust for the baseline values of each marker. The model was designed to account for baseline physiological differences between the groups and regression to the mean. Each follow-up physiological marker was entered as the dependent variable, and the group status—that is, the sustained group vs the comparison group—was entered as the main explanatory variable. Covariates included the baseline value of the corresponding marker, baseline age, and the use of antihypertensive, antidiabetic, and lipid-lowering medications at baseline and at the corresponding follow-up time points. This approach allowed us to estimate differences in physiological markers between the sustained and comparison groups while accounting for the influence of medication use to the extent possible.

Association Between Lifestyle Items and Sustained Self-Reported Behavior Change Stage Using Logistic Regression

To explore lifestyle patterns that may be associated with differences in physiological markers observed in the sustained group, multivariable logistic regression analyses were conducted, using each of the 9 lifestyle items, including exercise habits, smoking status, and daily physical activity, as binary dependent variables coded as 1 for present or applicable and 0 for absent or not applicable.

Each logistic regression model included group status, baseline status of the corresponding lifestyle item, baseline age, and medication use at both baseline and each follow-up time point as covariates. Medications used included antihypertensive, antidiabetic, and lipid-lowering agents. We estimated odds ratios (ORs) and 95% CIs for the odds of each lifestyle item being present or applicable in the sustained group compared with the comparison group at each follow-up point. The 9 lifestyle items in this analysis were positioned for exploratory profiling to identify lifestyle patterns that may be associated with between-group differences in physiological markers accompanying long-term self-reported behavior change stage maintenance. Therefore, no uniform adjustment was applied for multiple comparisons.

Ethical Considerations

The study was approved by the Research Ethics Committee of the Research Institute of Nursing Care for People and Community, University of Hyogo (approval number 2022F08). Informed consent was obtained from participants through the company's internal bulletin board using an opt-out method. The employer irreversibly deidentified the dataset before transfer to ensure participant anonymity in accordance with Japanese privacy regulations.

Results

Duration of Self-Reported Behavior Change Stage Maintenance

The dataset constructed for survival analysis included 717 participants. Among them, 566 (78.9%) experienced an event that was defined as a transition back to the preaction or preparatory stage. The remaining 151 (21.1%) participants maintained the action or maintenance stage until the end of the follow-up and were treated as right-censored. At the start of the self-reported behavior change stage maintenance episode, that is, at baseline, the mean age of the participants was 47.2 (SD 7.0; range 25 - 67) years.

Kaplan-Meier survival analysis showed that the median retention time for self-reported behavior change stage maintenance was 362 (IQR 0-1087) days. After the start of the action or maintenance stage, the retention probability was 57.7% (95% CI 54.0% - 61.2%) at 6 months (183 d) and continued to decline over time. Specifically, the retention probability was 44.1% (95% CI 40.3% - 47.8%) at 1 year (365 d), 33.3% (95% CI 29.6% - 36.9%) at 2 years (730 d), and 23.2% (95% CI 19.9% - 26.7%) at 3 years (1096 d; Figure 1).

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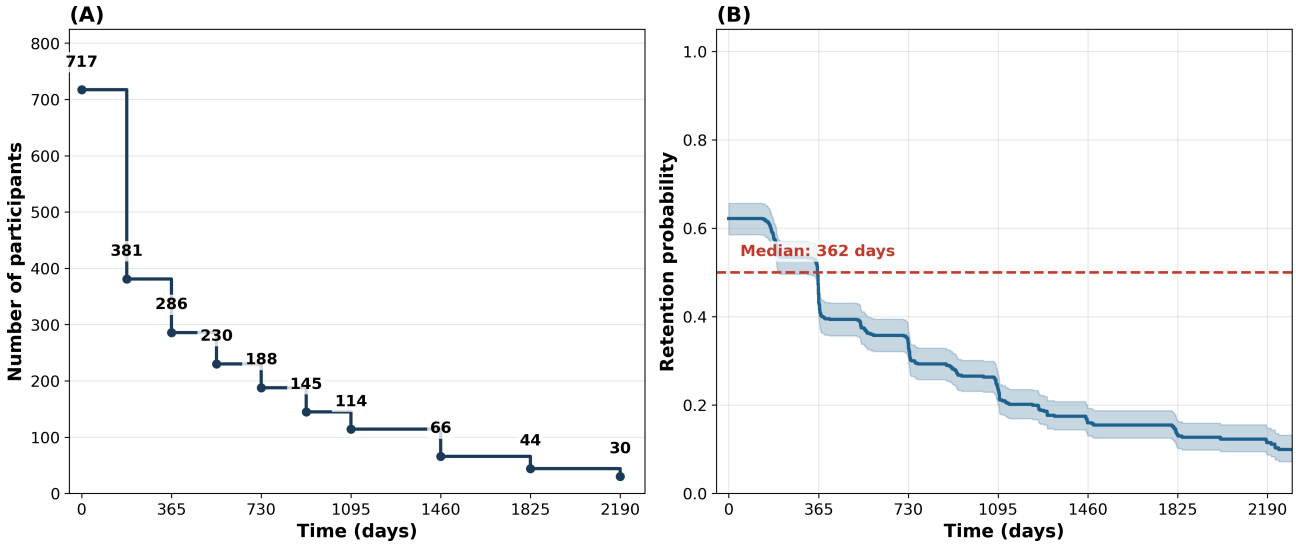
Figure 1. Duration of the self-reported maintenance of behavior change stage among male bus drivers. Panel A shows the number of participants continuing to maintain behavior change over time, and panel B shows the Kaplan-Meier retention curve.



Outcomes Associated With the Sustained Self-Reported Behavior Change Stage

Baseline Characteristics

The baseline characteristics of the sustained (n=249) and comparison (n=468) groups at time 0 are shown in Table 1.

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Table . Baseline characteristics of participants according to duration of self-reported behavior change stage maintenance[a].

Item	Comparison (n=468)	Sustained (n=249)	Statistic (*df*)	*P* value
Demographic characteristic, mean (SD)				
Age (y)	47.19 (7.14)	47.24 (6.78)	−0.09 (529.3)	.93
Anthropometric parameters, mean (SD)				
BMI (kg/m²)	24.98 (4.01)	24.46 (3.50)	1.82 (568.1)	.07
WC[b] (cm)	87.54 (10.74)	85.77 (9.16)	2.32 (578.6)	.02
Physiological parameters, mean (SD)				
SBP[c] (mm Hg)	128.57 (12.84)	127.68 (12.39)	0.91 (521.8)	.36
DBP[d] (mm Hg)	82.73 (9.88)	81.71 (9.44)	1.35 (526.0)	.18
HbA_{1c}[e] (%)	5.69 (0.60)	5.67 (0.54)	0.50 (549.6)	.62
TG[f] (mg/dL)	131.04 (96.98)	125.76 (91.99)	0.72 (529.7)	.47
HDL-C[g] (mg/dL)	58.95 (16.24)	59.44 (15.33)	−0.40 (531.8)	.69
LDL-C[h] (mg/dL)	126.48 (28.52)	127.05 (28.16)	−0.26 (511.6)	.80
Medication use[i], n (%)				
Antihypertensive	86 (18.4)	35 (14.1)	1.87 (1)	.17
Antidiabetic	32 (6.8)	13 (5.2)	0.47 (1)	.49
Lipid-lowering	69 (14.7)	29 (11.6)	1.07 (1)	.30

[a]Data were expressed as mean (SD) for continuous variables and n (%) for categorical variables. Test statistics were presented as *t* tests (*df*) for continuous variables and chi-square tests (*df*) for categorical variables. *P* values were calculated using the Welch *t* test for continuous variables and the Pearson chi-square test for categorical variables.

[b]WC: waist circumference.

[c]SBP: systolic blood pressure.

[d]DBP: diastolic blood pressure.

[e]HbA_{1c}: glycated hemoglobin.

[f]TG: triglycerides.

[g]HDL-C: high-density lipoprotein cholesterol.

[h]LDL-C: low-density lipoprotein cholesterol.

[i]Medication use referred to the use of antihypertensive, antidiabetic, or lipid-lowering medications at baseline.

At baseline, WC was lower in the sustained group than in the comparison group (mean 85.77, SD 9.16 cm vs mean 87.54, SD 10.74 cm; *P*=.02). However, no statistically significant differences were observed between the groups with respect to age; other physiological markers, including BMI, BP, lipid markers, and glycemic status; or the proportion of participants using the 3 types of medications. These findings indicate that the clinical characteristics of the 2 groups at the start of the self-reported behavior change maintenance stage were generally comparable, except for WC.

Longitudinal Evaluation of Physiological Markers Using ANCOVA

Between-group comparisons of physiological markers at each follow-up point (6 mo, 1, 1.5, 2, 2.5, and 3 y) were conducted using ANCOVA, adjusting for the baseline value of each respective marker. To concisely present the long-term trajectory during the follow-up period, Table 2 shows the adjusted mean differences, 95% CIs, and *P* values at the main annual follow-up points of 1, 2, and 3 years. The adjusted means for both groups and the full results for all follow-up points, including 6 months, 1.5 years, and 2.5 years, are provided in Table S3 in Multimedia Appendix 1.

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Table . Analysis of covariance-adjusted comparison of physiological markers over 3 years[a].

Item	Comparison/sustained group, n	Difference (95% CI)	*P* value
Anthropometry			
BMI, kg/m^2			
Year 1	390/247	−0.12 (−0.26 to 0.03)	.11
Year 2	299/233	−0.37 (−0.57 to −0.17)	<.001
Year 3	228/184	−0.36 (−0.61 to −0.10)	.006
WC[b], cm			
Year 1	390/247	−0.28 (−0.80 to 0.24)	.29
Year 2	299/233	−1.27 (−1.93 to −0.60)	<.001
Year 3	228/184	−1.24 (−2.10 to −0.38)	.005
Blood pressure			
SBP[c], mm Hg			
Year 1	390/247	−0.12 (−1.86 to 1.61)	.89
Year 2	299/233	1.21 (−0.81 to 3.22)	.24
Year 3	228/184	−0.56 (−2.79 to 1.67)	.62
DBP[d], mm Hg			
Year 1	390/247	0.15 (−1.06 to 1.37)	.80
Year 2	299/233	0.10 (−1.27 to 1.47)	.89
Year 3	228/184	−0.87 (−2.43 to 0.69)	.28
Glucose and lipids			
HbA_{1c}[e], %			
Year 1	390/247	−0.01 (−0.07 to 0.05)	.74
Year 2	299/233	−0.03 (−0.08 to 0.01)	.17
Year 3	228/184	−0.07 (−0.12 to -0.01)	.02
TG[f], mg/dL			
Year 1	390/247	6.44 (−6.63 to 19.51)	.33
Year 2	299/233	−17.03 (−30.51 to −3.56)	.01
Year 3	228/184	−21.22 (−37.28 to −5.15)	.01
HDL-C[g], mg/dL			
Year 1	390/247	1.31 (0.11 to 2.50)	.03
Year 2	299/233	3.17 (1.80 to 4.53)	<.001
Year 3	228/184	3.69 (2.09 to 5.29)	<.001
LDL-C[h], mg/dL			
Year 1	390/247	−0.58 (−3.71 to 2.56)	.72
Year 2	299/233	−0.40 (−4.22 to 3.42)	.84
Year 3	228/184	−0.55 (−4.61 to 3.51)	.79

[a]The difference indicates the adjusted mean difference, calculated as the difference between the sustained group and the comparison group. Negative values indicate lower adjusted means in the sustained group than in the comparison group. Differences, 95% CIs, and *P* values were calculated using analysis of covariance, adjusting for the baseline value of each marker, baseline age, and medication status for antihypertensive, antidiabetic, and lipid-lowering medications at both baseline and at each follow-up point.

[b]WC: waist circumference.

[c]SBP: systolic blood pressure.

[d]DBP: diastolic blood pressure.

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[e]HbA_{1c}: glycated hemoglobin.

[f]TG: triglycerides.

[g]HDL-C: high-density lipoprotein cholesterol.

[h]LDL-C: low-density lipoprotein cholesterol.

The sustained group had a lower BMI than the comparison group at 2 years (adjusted difference −0.37, 95% CI −0.57 to −0.17; *P*<.001) and 3 years (adjusted difference −0.36, 95% CI −0.61 to −0.10; *P*=.006). WC was also lower in the sustained group at 2 years (adjusted difference −1.27, 95% CI −1.93 to −0.60; *P*<.001) and 3 years (adjusted difference −1.24, 95% CI −2.10 to −0.38; *P*=.005). The sustained group maintained adjusted mean BMI values below the threshold for at-risk status. In contrast, the adjusted mean WC values in both groups remained above the predefined at-risk threshold of 85 cm throughout the follow-up period. At 3 years, the adjusted mean WC was 86.89 cm (SE 0.69 cm) in the sustained group and 88.13 cm (SE 0.67 cm) in the comparison group.

HDL-C values were higher in the sustained group at 1 year (adjusted difference 1.31, 95% CI 0.11-2.50; *P*=.03), 2 years (adjusted difference 3.17, 95% CI 1.80-4.53; *P*<.001), and 3 years (adjusted difference 3.69, 95% CI 2.09-5.29; *P*<.001). In addition, TG values were lower in the sustained group at 2 years (adjusted difference −17.03, 95% CI −30.51 to −3.56; *P*=.01) and 3 years (adjusted difference −21.22, 95% CI −37.28 to −5.15; *P*=.01). Regarding glycemic control, HbA_{1c} at 3 years was significantly lower in the sustained group than in the comparison group (*P*=.02). However, the adjusted mean HbA_{1c} values in both groups remained above the predefined at-risk status threshold of 5.6% throughout the follow-up period. At 3 years, the adjusted mean HbA_{1c} was 5.73% (SE 0.04) in the sustained group and 5.79% (SE 0.04) in the comparison group. No significant between-group differences were observed in SBP or DBP throughout the follow-up period.

Association Between Lifestyle Items and Sustained Self-Reported Behavior Change Stage Using Logistic Regression

We constructed a cohort dataset using each participant's maintenance episode of the self-reported behavior change stage, linked to health checkup data after time 0, to examine the association between long-term maintenance and physiological markers and lifestyle items.

As the groups were defined retrospectively based on the duration of self-reported behavior change stage maintenance, differences between the groups were interpreted as associations with long-term maintenance rather than causal effects. To explore lifestyle patterns that may be associated with between-group differences in physiological markers in the sustained group, multivariable logistic regression analyses were conducted using 9 lifestyle items as dependent variables. Table 3 shows the main lifestyle items that showed consistent between-group differences at 1, 2, and 3 years. The full results for all 9 lifestyle items and all follow-up points, including 6 months, 1.5 years, and 2.5 years, are provided in Table S4 in Multimedia Appendix 1.

In the exploratory analyses, the sustained group showed consistently higher odds of exercising and engaging in daily physical activity than the comparison group. The sustained group also showed significantly lower odds of current smoking at 1, 2, and 3 years.

Specifically, the prevalence of a regular exercise habit remained above 50% in the sustained group across the follow-up period (50.7% - 55.3%), whereas it was markedly lower in the comparison group (12.1% - 20.1%). Accordingly, the odds of having an exercise habit were significantly higher in the sustained group (OR range 3.40 - 8.90; *P*<.001). Similarly, the prevalence of daily physical activity remained at approximately 30% in the sustained group (29.2% - 32.7%) but was lower in the comparison group (7.5% - 12.8%). The sustained group showed significantly higher odds of daily physical activity at all annual follow-up points (OR range 2.51 - 5.17; *P*<.001). Regarding current smoking, the prevalence in the sustained group decreased from 25.5% at 1 year to 22.8% at 3 years, whereas it increased slightly from 31.5% to 32.5% in the comparison group.

In the adjusted logistic regression analyses, the sustained group had lower odds of current smoking at 1 year (OR 0.36, 95% CI 0.14-0.95; *P*=.04), 2 years (OR 0.32, 95% CI 0.12-0.87; *P*=.03), and 3 years (OR 0.26, 95% CI 0.09-0.75; *P*=.01). In addition, a higher proportion of participants in the comparison group (67.1% - 67.7%) than in the sustained group (46.2% - 53.3%) answered "No" to the question, "Is your walking speed faster than the speed of those of your age and sex?" The sustained group had lower odds of slow walking speed at 1 year (OR 0.60, 95% CI 0.38-0.95; *P*=.03), 2 years (OR 0.35, 95% CI 0.22-0.57; *P*<.001), and 3 years (OR 0.40, 95% CI 0.23-0.67; *P*=.001). Although not shown in the main table, the sustained group generally showed more favorable prevalence patterns for skipping breakfast, late-night dinner, and sufficient restful sleep than the comparison group; however, the differences were not consistent across follow-up years.

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Table . Association between sustained self-reported behavior change stage and lifestyle items at 1, 2, and 3 years[a].

Item year	Comparison, n/N (%)	Sustained, n/N (%)	Adjusted OR[b] (95% CI)	*P* value
Exercise habit				
Year 1	74/368 (20.1)	116/229 (50.7)	3.40 (2.24-5.16)	<.001
Year 2	34/281 (12.1)	120/217 (55.3)	8.90 (5.26-15.07)	<.001
Year 3	30/219 (13.7)	93/171 (54.4)	6.06 (3.52-10.41)	<.001
Daily physical activity				
Year 1	47/367 (12.8)	71/229 (31.0)	2.51 (1.61-3.91)	<.001
Year 2	21/281 (7.5)	71/217 (32.7)	5.17 (2.93-9.13)	<.001
Year 3	18/218 (8.3)	50/171 (29.2)	4.08 (2.13-7.83)	<.001
Slow walking speed				
Year 1	249/368 (67.7)	121/227 (53.3)	0.60 (0.38-0.95)	.03
Year 2	197/282 (69.9)	104/216 (48.1)	0.35 (0.22-0.57)	<.001
Year 3	147/219 (67.1)	79/171 (46.2)	0.40 (0.23-0.67)	.001
Current smoking habit				
Year 1	123/390 (31.5)	63/247 (25.5)	0.36 (0.14-0.95)	.04
Year 2	95/299 (31.8)	56/233 (24.0)	0.32 (0.12-0.87)	.03
Year 3	74/228 (32.5)	42/184 (22.8)	0.26 (0.09-0.75)	.01

[a]n/N indicates the number of participants endorsing each lifestyle item among those with available data. Year indicates the years after time 0. Adjusted ORs compare the sustained group with the comparison group for endorsing each lifestyle item and were calculated using logistic regression models adjusted for baseline habit status, baseline age, and medication status for antihypertensive, antidiabetic, and lipid-lowering medications at both baseline and at each follow-up point.

[b]OR: odds ratio.

Discussion

Principal Findings

This retrospective cohort study examined the duration of maintenance of the self-reported behavior change stage and its associations with physiological markers and lifestyle behaviors among male bus drivers. First, maintenance typically began in midlife (mean age 47.2, SD 7.0 y) but was difficult to sustain, with a median retention time of 362 (IQR 0-1087) days. Second, participants who sustained the action or maintenance stage for at least 1.5 years showed more favorable physical activity–related lifestyle patterns and lower smoking prevalence. Third, sustained maintenance was associated with more favorable metabolic profiles, including lower BMI and waist circumference at 2 and 3 years, and higher HDL-C, lower TG, and slightly lower HbA_{1c} at 3 years, although these differences did not indicate complete normalization of metabolic risk.

Self-Reported Behavior Change Stage Maintenance Emerged Around Midlife but Was Difficult to Sustain

An important finding of this study was that the maintenance episode of the self-reported behavior change stage among male bus drivers began in midlife. At time 0, the mean age was 47.24 (SD 6.78) years in the sustained group and 47.19 (SD 7.14) years in the comparison group. These nearly identical mean ages indicate little difference between the groups in the age at which the self-reported behavior change stage was initiated.

The initiation of the self-reported behavior change stage maintenance around the age of 47 years, as observed in this study, may be related to the occupational characteristics of bus drivers. Commercial motor vehicle drivers are an occupational group whose health status is routinely evaluated to ensure safe driving. In addition to regular health checkups, they undergo preduty and postduty roll calls, during which illness, fatigue, sleep deprivation, and other conditions are checked [7]. Moreover, because health status may affect driving eligibility and employment, emerging health risks may be perceived as practical concerns related to occupational life and income. Such institutional and organizational health management environments may therefore trigger health behavior change.

At the same time, such behavior changes may be initiated in response to health anxiety, workplace guidance, a sense of responsibility for continuing to drive, or a desire to avoid occupational disadvantages. In this case, motivation may be closer to external regulation or controlled motivation, as described in self-determination theory [16,17]. Although such motivation may contribute to the initiation of behavior change, it may be insufficient for long-term maintenance unless the behavior is internalized as part of an individual's values and daily life [18]. In this study, the retention probability decreased to 57.7% at 6 months and 44.1% at 1 year after initiation of the self-reported behavior change stage, highlighting the difficulty of sustaining behavior change as part of daily life and work routines.

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Therefore, health guidance for bus drivers should extend beyond communicating health checkup results or driving safety risks. It should help drivers view behavior change as a sustainable and worthwhile part of their efforts, rather than a temporary response to health concerns. Given the structural constraints specific to bus drivers, including early-morning and late-night shifts, irregular breaks, prolonged sitting, and restrictions on meal timing [19], support should include small, feasible behavioral goals that can be implemented during work and opportunities to accumulate experiences of successful continuation. Occupational health and nursing professionals play an important role in integrating health management that supports driving safety with support that promotes autonomous long-term behavior maintenance.

Long-Term Maintenance of the Self-Reported Behavior Change Stage Was Associated With Physical Activity and More Favorable Metabolic Profiles

The second important finding was that participants who maintained the self-reported behavior change stage over the long term consistently showed more favorable physical activity–related lifestyle patterns and trends in selected physiological markers (BMI, WC, HDL-C, TG, and HbA_{1c}). In the sustained group, approximately half of the participants reported having a regular exercise habit at 1, 2, and 3 years, whereas the proportion in the comparison group remained approximately 20%, even at its highest point. The proportion of participants who walked or engaged in an equivalent amount of physical activity for at least 1 hour per day in daily life was also consistently higher in the sustained group. In addition, the proportion of participants who answered that their walking speed was not faster than that of people of the same age and sex was significantly lower in the sustained group. These findings suggest that the self-reported behavior change stage in the sustained group may not have represented only intention or temporary efforts but may have been at least partly established as a habit of moving the body in daily life.

Regarding physiological markers, the sustained group had a significantly lower BMI and WC than the comparison group at 2 and 3 years. However, BMI in the sustained group remained within the 24 kg/m^2 range, suggesting that the findings should be interpreted not as a large reduction in body weight but rather as a suppression of the gradual increase in BMI observed in the comparison group. Similarly, although WC was lower in the sustained group than in the comparison group, the mean value did not fall below 85 cm throughout the follow-up period. Therefore, long-term maintenance of the self-reported behavior change stage may have been associated with the prevention of weight gain and increases in WC, rather than the complete resolution of obesity or visceral fat accumulation.

For lipid markers, HDL-C was consistently higher in the sustained group than in the comparison group from 1 to 3 years, and TG was significantly lower at 2 and 3 years. HbA_{1c} levels were also significantly lower in the sustained group at 3 years. However, these differences should be interpreted as the maintenance of a more favorable metabolic profile in the sustained group rather than the normalization of abnormal values or a large clinical improvement. In particular, the between-group difference in HbA_{1c} was small, and the adjusted mean values in both groups remained above the predefined at-risk threshold of 5.6%. Therefore, findings related to glycemic status require cautious interpretation.

Among lifestyle factors, current smoking also showed a more favorable pattern in the sustained group. The prevalence of current smoking in the sustained group decreased from 25.5% at 1 year to 22.8% at 3 years, whereas it increased slightly from 31.5% to 32.5% in the comparison group. According to a fiscal year 2023 survey of Specific Health Checkup questionnaire responses conducted by the National Federation of Health Insurance Societies [20], the proportion of men who reported habitual smoking was 31.4%, and the corresponding proportion among men aged 45 to 49 years—which is close to the mean age of the present study population—was 34.0%. The smoking prevalence in the comparison group in the present study was close to the national male average, whereas the sustained group showed a lower prevalence than both the national average and that among men of similar ages. However, because this study did not capture the timing of smoking initiation or cessation in detail, we cannot conclude that maintenance of the self-reported behavior change stage promotes smoking cessation. Rather, a health orientation toward nonsmoking or smoking cessation, self-management awareness, or sensitivity to health risks may be associated with long-term self-reported behavior change stage maintenance.

In contrast, challenges related to meal timing and sleep persisted even in the sustained group. In the same survey by the National Federation of Health Insurance Societies [20], 24.4% of men reported skipping breakfast at least 3 times per week, 37.9% reported eating dinner within 2 hours before bedtime at least 3 times per week, and 63.9% reported getting sufficient rest from sleep. Among men aged 45 to 49 years, the corresponding proportions were 29.6% for skipping breakfast, 42.9% for having late-night dinner, and 63.8% for having sufficient restful sleep. In contrast, in the present study, the prevalence of skipping breakfast was approximately 34% to 35% in the sustained group and 41% to 43% in the comparison group. The prevalence of late-night dinners was also high, at approximately 54% to 59% in the sustained group and 63% to 69% in the comparison group. In addition, the proportion of participants reporting sufficient restful sleep remained at approximately 46% to 54% in the sustained group and 38% to 44% in the comparison group. Although a direct comparison is limited by differences in age structure, occupation, and insurer composition, these findings suggest that male bus drivers may continue to face lifestyle challenges related to meal timing and restful sleep even when they maintain the self-reported behavior change stage over the long term.

Overall, long-term maintenance of the self-reported behavior change stage was mainly associated with established physical activity habits, lower smoking prevalence, the suppression of increases in BMI and WC, higher HDL-C levels, lower TG levels, and lower HbA_{1c} at 3 years. In contrast, lifestyle items related to daily rhythms, such as skipping breakfast, eating a late-night dinner, and having insufficient restful sleep, tended to be less favorable than those of men of similar age in the

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national survey, even among participants in the sustained group. These findings suggest that self-reported behavior change stage maintenance among bus drivers may be more readily reflected in individual behaviors, such as physical activity and smoking, whereas improvement in eating and sleeping habits may be limited by work schedules and driving timetables.

Reconsidering Health Guidance Strategies: Evaluating Maintenance That Prevents Worsening, Not Only Numerical Improvement

The findings of this study suggest the need to broaden the evaluation framework for health guidance among bus drivers from focusing on numerical improvement alone to the maintenance of behaviors and prevention of risk progression. In the sustained group, physical activity–related lifestyle patterns were more favorable, BMI and WC were lower, HDL-C was higher, and TG and HbA_{1c} showed more favorable trends than in the comparison group. However, these differences did not indicate complete normalization of physiological risk. For example, the mean WC in the sustained group did not fall below 85 cm, and the mean HbA_{1c} levels in both groups remained above the at-risk status threshold of 5.6%. Therefore, the significance of these findings lies not in complete normalization but in their association with more favorable maintenance of weight, WC, lipid metabolism, and glycemic markers under aging-related and occupational constraints.

Bus drivers work in environments that may worsen metabolic risk, including prolonged sitting, irregular shifts, restrictions on meal timing, and disrupted sleep rhythms [19]. Therefore, even when marked weight reduction or normalization of laboratory values is not observed, maintaining health-related behaviors and preventing deterioration should be regarded as important outcomes in this occupational group. Because body weight and metabolic risk tend to increase with age during adulthood [21], the absence of large numerical improvements should not necessarily be interpreted as a failure.

Health guidance in Japan often emphasizes numerical improvement, which is useful for motivating risk reduction. However, when behavior change does not lead to visible numerical improvement, participants may feel that their efforts are wasted, potentially leading to resignation or resistance [22,23]. Repeated guidance without clear improvement may also reduce the effectiveness of support among repeat participants [24,25]. To address this issue, health guidance should incorporate process evaluation in addition to outcome evaluation. Professionals should provide feedback that frames the maintenance of feasible habits as a meaningful success. Such feedback may strengthen self-efficacy through mastery experience [26], and motivational interviewing may help affirm self-determined behaviors even when numerical indicators remain unchanged [27]. This approach is also consistent with self-determination theory, which emphasizes competence, autonomy, and more autonomous motivation [16,17].

Lin et al [12] reported that psychological empowerment and hedonic well-being, rather than information provision or inspiration alone, supported sustained behavior change among users of a smoking cessation app [12]. This perspective is relevant to bus drivers, for whom health checkup results, preduty and postduty roll calls, workplace guidance, and concerns about driving eligibility may serve as external triggers for behavior change. However, motivation based mainly on external pressure or crisis awareness may be insufficient for long-term maintenance. Health guidance should therefore foster psychological empowerment and well-being by helping drivers recognize small, feasible achievements within their work routines.

Similarly, digital and mHealth tools should not merely provide alerts or reminders. They should offer personalized, work routine–compatible goals, progress tracking, visualization of small achievements, and positive feedback on continued efforts. Examples include walking during breaks, reducing smoking, adjusting meals after late-night shifts, and finding ways to secure sleep. Such support may help transform health checkup results into feasible and meaningful actions that can be maintained under occupational constraints.

Limitations and Future Directions

This study has several limitations. First, because this was a retrospective observational study, causal relationships between maintenance of the self-reported behavior change stage and changes in physiological markers could not be determined. The sustained and comparison groups were defined retrospectively according to the duration of maintenance after time 0; therefore, between-group differences should be interpreted as associations with long-term maintenance, not as effects of sustained behavior change.

Second, we analyzed each participant's longest self-reported behavior change stage maintenance episode rather than the first episode. This approach was used to capture the most stable maintenance state observed during the study period, but it may have overestimated maintenance duration. Accordingly, the Kaplan-Meier estimates should be interpreted as the distribution of the longest maintenance episode, not as the probability of continuation after the initial behavior change.

Third, behavior change stage and lifestyle habits were assessed using SAQs and may have been affected by recall and social desirability biases. In addition, the behavior change stage item captured self-reported intention and engagement in lifestyle improvement, not objective behavioral quantities such as physical activity, dietary intake, sleep duration, or amount of smoking.

Fourth, initiation and discontinuation of the self-reported behavior change stage could be identified only during health checkups. Therefore, the actual timing of these transitions may have occurred between visits, and interval censoring may have affected the estimates of maintenance duration. Differences in checkup frequency over time, with annual checkups before 2014 and semiannual checkups from 2014 onward, may also have influenced duration estimates.

Fifth, the study population was limited to male bus drivers from a single company in Japan, which may limit generalizability. Although medication use was adjusted for at baseline and at follow-up, detailed information on medication type, dose, adherence, and treatment changes was not available. In addition,

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psychological, social, and occupational factors that may influence behavior change maintenance, such as self-efficacy, health literacy, workplace support, work shifts, break availability, and anxiety about continuing to drive, were not fully measured.

Future studies should use prospective designs to follow the process of initiation, maintenance, discontinuation, and resumption of behavior change in greater detail. They should also incorporate objective measures of physical activity, sedentary time, sleep, and meal timing using wearable devices or smartphone applications, together with psychosocial and occupational factors. Qualitative studies may also help identify the strategies used by drivers who maintain behavior change and the barriers experienced by those who discontinue it. Such evidence may support the development of individualized occupational health guidance models that consider not only medical risk but also psychological readiness and the work environment.

Conclusions

Using longitudinal occupational health checkup data from male bus drivers, this study showed that the maintenance of the self-reported behavior change stage often began in midlife but was difficult to sustain beyond 1 year. Long-term maintenance was associated with more favorable physical activity–related lifestyle patterns, lower smoking prevalence, and more favorable metabolic profiles, although these findings did not indicate complete normalization of metabolic risk. These results suggest that occupational health guidance for bus drivers should evaluate not only numerical improvements but also sustained behaviors and the prevention of worsening under occupational constraints. Tailored long-term support that addresses work schedules, meal timing, breaks, physical activity, smoking, and sleep rhythms may be needed to help drivers maintain feasible health behaviors over time.

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Data Availability

The datasets generated and/or analyzed during the current study are not publicly available because of privacy restrictions regarding employee health data, but are available from the corresponding author upon reasonable request and with permission from the participating company.

Authors' Contributions

Conceptualization: EN, RS
Data curation: MN
Formal analysis: EN
Funding acquisition: RS
Investigation: MN
Methodology: EN, RS
Project administration: RS
Resources: RS
Software: EN
Supervision: RS
Validation: MM, MN
Visualization: EN
Writing – original draft: EN
Writing – review & editing: EN, RS, MM, MN

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Definitions of questionnaire items and self-reported behavior change stage, and supplementary results of physiological marker and lifestyle item analyses across all follow-up points.
[DOCX File, 47 KB - apinj_v10i1e93645_app1.docx]

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Abbreviations

ANCOVA: analysis of covariance
BP: blood pressure
DBP: diastolic blood pressure
HbA_{1c}: glycated hemoglobin
HDL-C: high-density lipoprotein cholesterol
LDL-C: low-density lipoprotein cholesterol
mHealth: mobile health
NGSP: National Glycohemoglobin Standardization Program
OR: odds ratio
SAQ: Standard Self-administered Questionnaire
SBP: systolic blood pressure
TG: triglycerides
WC: waist circumference

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The Effect of Culture-Based Breast Health Education Program on Breast Self-Examination Practice Among High-Risk Women: Randomized Controlled Trial

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Abstract

Background: Breast cancer (BC) symptom awareness through screening measures, such as breast self-examination practice (BSEP), is promoted in low-resource countries. The Muslim culture has a unique impact on family support for women's health care decisions, especially from the mother. Given the proven effect of educational intervention on breast health through interactive sessions and mobile health, implementation according to Muslim cultural values through family support, especially from the mother, was lacking, and this study was planned.

Objective: This study aimed to determine the effects of a culture-based breast health education program (CBBHEP) on BSEP in high-risk women.

Methods: A single-site randomized controlled trial was conducted in a hospital on 72 high-risk women, aged 20 - 50 years, from August 19 to November 29, 2024. The trial was registered prospectively (ID: ISRCTN-39194106). The participants were matched in pairs by age and educational level, and randomly assigned to experimental and control groups. The intervention program was based on social cognitive theory and the cultural identity concept of the PEN-3 model. The program consisted of face-to-face interactive sessions and a health app called a Women's Health app for promoting BSEP. The experimental group received CBBHEP, whereas the control group received the usual care. BSEP was measured at baseline and 12 weeks using a translated, valid, and reliable Toronto BSE frequency and proficiency of practice scale. Data analysis was performed using 1-way analysis of covariance and paired sample 1-tailed*t* test.

Results: The participants in the experimental group who received CBBHEP for 12 weeks increased their BSEP much better than those in the control group ($F_{1, 69}$=58.908, η^2=0.46; *P*<.001). The results also revealed a statistically significant effect of a higher BSEP in the experimental group (t_{35}=7.21, Cohen *d*=0.88; *P*<.001).

Conclusions: The findings suggest that health care practitioners can apply this program to increase BSEP among high-risk women through their family support, especially from mothers.

Trial Registration: ISRCTN ISRCTN39194106; https://www.isrctn.com/ISRCTN39194106

(Asian Pac Isl Nurs J 2026;10:e85340) doi:10.2196/85340

KEYWORDS

breast neoplasm; breast self-examination; cultural competency; health education; women; randomized controlled trial.

Introduction

Breast cancer (BC) is among the leading causes of death among women globally and the most frequent type of cancer among women [1,2]. Moreover, 15% of women with BC have a family history of BC [3]. Family history increases the risk of BC, especially if there are close relatives with the disease. If a woman has a mother, sister, or daughter with BC, her chances of developing the condition almost double [4,5].

The highest incidence of BC in Asia has been reported in Pakistani Muslim women (23.1%) [6,7]. There was a family history of BC in 23.8% of Pakistani women. The relative most affected by BC was the mother (47.6%) [8]. The breast self-examination practice (BSEP) notifies women to examine their breasts physically and visually shortly after their periods or at the same time every month to look for any abnormalities [9]. The first and most crucial step in empowering women through the BSEP was to encourage women to actively maintain their health [10]. The early detection of BC symptoms has been

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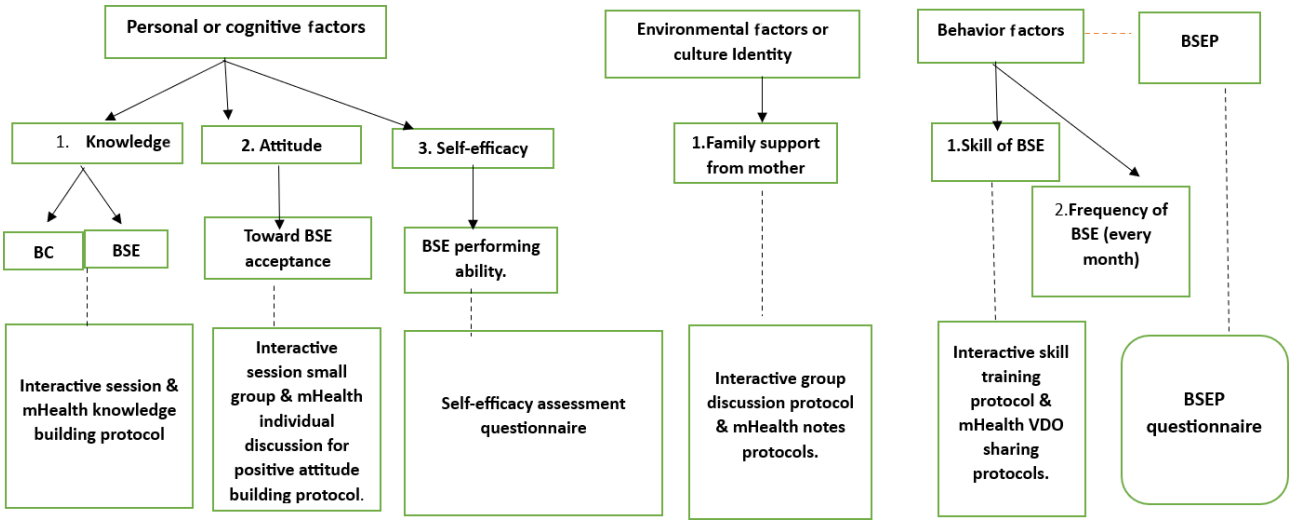
positively associated with BSEP [11], which enhances the outcome of treatment [12].

Behavior about BC screening among Pakistani Muslim high-risk women with a family history of the disease revealed that only 15% were aware of BC, and 4.18% were aware of BSE as a BC screening method [13]. BSEP was conducted occasionally by 3.6% of high-risk Pakistani women and frequently by just 1% [14]. All over the nation, patients with BC frequently present late at stage III or IV, with high-risk Pakistani women accounting for approximately 35.2% of these delayed cases [15]. Cultural values have a significant influence on Pakistani women's awareness of breast health issues, as the majority did not engage in BSEP for a variety of reasons, including the taboo against touching oneself, embarrassment about discussing private body parts, or fear of being examined by a doctor [16,17].

Among the best strategies for changing behavior in high-risk women is family support with BSE instructions or methods, demonstrations, information about health risks, and behavioral stimuli or prompts [18]. Culturally based interventions have proven to be the most successful in promoting health-seeking behaviors [19]. Family is a major unit in Pakistan's collectivistic Muslim society, which is bound by cultural values and family norms [20].

In this study, based on social cognitive theory (SCT) [21] and the cultural identity concept of the PEN-3 cultural model [22], an intervention was developed, called the Culture-Based Breast Health Education Program (CBBHEP). SCT components, such as personal, environmental, and behavioral factors, were already used for the promotion of BSE [23]. The PEN-3 culture model has also already demonstrated how cultural matters in interventions, such as in cancer awareness and screening [24]. The purpose of concept integration of cultural identity of the PEN-3 Culture model [22], into SCT [21], was to incorporate new ideas, such as the focus of the target group, which helps in the implementation of intervention in the cultural context, as the cultural identity domain of PEN-3 highlights the intervention points of entry. In this study, entry occurred at the level of the family, especially mothers, according to the culture. This CBBHEP included personal factors such as knowledge, attitude, self-efficacy, and environmental factors, as well as social support from the mother in a cultural context, such as a private place for women to promote behavior factors such as BSEP (Figure 1).

Figure 1. Social cognitive theory and PEN-3 model related to breast self-examination practice (BSEP). BSE: breast self-examination; mHealth: mobile health; VDO: ___.



Culture-based educational intervention was planned according to Pakistani culture, in which family support, especially from the mother, played an essential role in the health care decisions of their daughters. Cultural identity identifies the target group that should be addressed in health education according to the cultural context. The target group comprised high-risk women with a mother diagnosed with BC who received support from their mothers according to Pakistani culture [20]. BSEP was effectively promoted by educational interventions for BC and BSE, which were shared through interactive lectures, videos, group discussions, or mobile health (mHealth)–based apps [25,26]. Additionally, culturally relevant language and skill-focused mHealth intervention techniques are necessary for BSE [27].

This study was conducted on the proven effects of face-to-face interactive educational and mHealth-based app interventions on BSEP [25,26,28-30]. However, there was a lack of cultural values, such as mother support, which is important for behavioral change. This study fills this knowledge gap in the literature. If proven effective, this can be achieved by educating them about BC and its screening measures, fostering positive attitudes and confidence in their capacity to perform BSE, and with their family support, especially mothers' support, who are concerned about their daughters.

The objectives of the study were:

1. To compare BSEP between high-risk adult women in an experimental group who received a culture-based breast health program at 3 months with a control group who received usual care.
2. To compare BSEP among high-risk adult women before and after participating in a CBBHEP at 3 months.

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The goal of the nurse researcher's project was to enable high-risk women to recognize BC symptoms at an early stage, which would lower complications and increase the overall survival rate of those affected in low-resource Muslim nations.

Methods

Study Design

It is a single-blinded, prospective, and parallel randomized controlled trial using baseline and follow-up assessments with two arms, namely the intervention and control groups, to measure the aim of the study, that is, the effect of CBBHEP on BSEP. The experimental group received CBBHEP and usual care for 12 weeks, whereas the control group received usual care only.

Ethical Considerations

This study was approved by the Institute of Allied Health Sciences Research Ethics Committee at the National University of Medical Sciences with reference number IAHS/WMC/786/008/admin. The trial was registered at the World Health Organization registry site [31], with ID: ISRCTN-39194106.

Participants, Setting, and Sample Size

The eligible participants were women aged 20 - 37 years, able to speak verbally and write in the local Urdu language; their mother had a BC diagnosis and was receiving treatment at the oncology department of the hospital, had a smartphone with internet access, lived with family, were not pregnant, and were willing to take part in the study. Those who had previously participated in the breast awareness program and experienced known cognitive disorders were excluded. The study was conducted in the oncology department of the Hospital, Taxila, Pakistan, from August to November 2024. *F* test for analysis of covariance (ANCOVA) was used to determine the sample size using G. Power statistics, which were based on the effect size determined in a prior study (effect size=0.515) [28], an overall α=.01, power of .90, and attrition rate of 20% due to the sensitivity of the topic. An alpha value of .01 was selected to claim stronger evidence to conclude that an effect would be significant [32]. This resulted in a sample size of 72 participants. The intervention group required 36 subjects, and the control group required 36 participants.

Recruitment, Randomization, and Masking

The subjects were recruited from the oncology department with the help of a research assistant, who already planned follow-up visits for diagnosed patients. With the permission of the department head, during follow-up calls, the research assistant informed them about the BC awareness program for their daughters. Patient consent was already taken by the department for sharing important information so they can be contacted. In addition, a poster on breast health education was placed in the oncology department. All interested participants were screened for eligibility; 72 were eligible and provided signed consent to participate in the study. Participants were also matched on their age and educational levels. Matching was conducted sequentially as participants enrolled in the study. The minimum age was 20 years, and the maximum was 37 years, among the eligible participants. Age groups were matched within an acceptance range of 3 years. The minimum educational level was 10th grade. Levels were 10th grade, 12th grade, and 16th year of education upon graduation. Acceptance for educational matching was 10th grade, with 11th grade and 14th grade years of education considered for graduation.

After enrollment, 72 participants were randomized into 2 groups (1:1 ratio) by the principal investigator into intervention and control groups (36:36). The principal investigator randomly picked from the allocation concealment opaque envelope to assign the first subject to the assigned condition (experiment), and then, following subjects with similar matched pairs were placed in the second condition (control). Baseline assessment was done for each group after the random allocation into the intervention and control groups. The participants were blinded to the intervention and control groups until trial completion. The random assignment procedure adhered to the CONSORT (Consolidated Standards of Reporting Trials) flow diagram [33].

The CONSORT diagram showed the process of enrollment, random assignment into 2 groups, follow-up, and analysis phases of the study.

Intervention Material

Reciprocal determination and the self-efficacy construct of SCT [21] were used for the creation and implementation of CBBHEP. It offers a thorough examination of the factors that influence behavior change because human behavior is the result of a dynamic interaction between personal, environmental, and behavioral factors [21]. The personal factors were knowledge, attitude, and self-efficacy, while environmental factors, with integration of the cultural identity concept, the PEN-3 culture model [22], and mother support, which leads to behavior toward BSEP (Table 1). The program was developed by the principal investigator and validated by 3 nurse educators, one software developer, and one female oncologist as experts. Experts were selected based on their working experience in oncology or research. An internet app for women's health was created by a software developer. Before implementation, the principal investigator created learning materials for in-person classes, educational VDOs or multimedia, handouts, and infographics for mobile apps. The CBBHEP consisted of two parts: Part I, face-to-face sessions, and Part II, the mHealth app. In part-I, 3 face-to-face sessions (20 - 25 min) were focused on educational as well as training assemblies to increase knowledge about BC & BSE, building a positive attitude and self-efficacy toward BSE through lecture on PowerPoint presentation in a group of 15 - 20 women, structured small group discussion with 7 - 10 participants and their mothers for 15 - 20 minutes, and small group (7 - 10 participants) skill demonstration for 5 - 10 minutes, individual redemonstration training with mothers for 5 - 10 minutes in a private setting, which leads toward BSE practice. Through behavioral capabilities, people learn knowledge and skills, through positive reinforcement from mothers, can handle barriers, through modeling, learn and develop self-efficacy, which is related to actual behavior performance. Part II included an infographic about information on BC and BSE, the importance of BSE, facts of BC, benefits

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of BSE video for skill demonstration, a monthly reminder for maintaining continuing in BSE behavior, and writing notes on BSE findings every month with supportive words from family members for the duration of 12 weeks. The mHealth app also helped to improve knowledge, build a positive attitude, and self-efficacy in performing BSE, which ultimately promotes BSE practice in high-risk women. Five experts independently evaluated the quality of the program, its lesson plan and materials, and the mobile app and revised materials after pilot testing on 10% of the required sample. In the pilot testing, interactive lectures, skill training, and small-group discussions were conducted with participants. Additionally, the Women's Health app (WHA) was installed, and their opinions regarding its feasibility were gathered. The pilot testing was conducted before conducting the actual study, and these 10% of participants were not part of the actual study.

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Table . Culture-based breast health education program on components of social cognitive theory and culture identity concept.

SCT[a] and culture identity concept of the PEN-3 model and components of CBBHEP[b]	Intervention activities
Personal or cognitive factors, including knowledge, attitude, and self-efficacy of skill performance	
Part I: Face-to-face sessions • Knowledge • Positive attitude • Self-efficacy (mastery experience, vicarious experience, verbal persuasion, physiological, and affective responses).	• Information about BC[c] and BSE[d] through VDO[e] and lecture through PowerPoint presentation (20 - 25 min) in a group of 15 - 20 participants. • Positive attitude building toward BSE through a handout about facts of BC and BSE, structured discussion about misperceptions about BC, benefits of BSEP[f] in a small group of 7 - 10 participants (15 - 20 min). • Enhancement of self-efficacy to perform BSE in a small group (7 - 10 participants) training on BSE through VDO sharing and demonstration on breast model or simulator (5 - 10 min) for mastery experience and redemonstration by individual participants on breast model and simulator for vicarious experience and verbal persuasion (5 - 10 min).
Part-II mHealth[g] app • Awareness • Positive attitude • Self-efficacy	• Informative VDO on BC and BSE. • The infographic includes information for enhancing knowledge about BC & BSEP. • Infographic to develop a positive attitude through facts of BC and BSE, and the benefits of BSEP. • VDO demonstration for enhancing the self-efficacy of BSE performance. • Writing findings after doing BSE every month (physiological and emotional state)
Environmental factors or cultural identity, including physical environment and family member support. The culture identity concept also explains the context or setting according to cultural values, such as a private setting, and to identify the target to reach participants, such as mothers, to enhance family support, which improves attitude toward BSEP as well	
Part I: Face-to-face session • Positive attitude building with family member support. • Setting according to cultural context	• Provide a physical environment in the form of a private setting to maintain privacy and modesty for participants and their family members. • Mother involvement in a small group discussion with 7 - 10 participants, to develop a positive attitude toward BSEP about facts of BC, benefits of BSEP (15 - 20 min).
Part-II mHealth app • Positive attitude building with family member support.	• Writing supporting words from a family member every month.
Behavioral factors, including the frequency of BSEP every month at the same time and the skill of performing BSE. Mother support to promote behavior, such as BSEP, in participants	
Part I: Face-to-face session • Frequency of BSE • Skill of BSE	• BSEP every month, through knowledge enhancement about the timing of BSE (5 min). • Individual participant's skill in performing BSE on the breast model (5 min).
Part-II mHealth app • Frequency of BSE • Skill of BSE	• Monthly reminder for BSE at the same time each month. • Watching VDO on the app to improve the skill of BSE performance.

[a]SCT: social cognitive theory.

[b]CBBHEP: culture-based breast health education program.

[c]BC: breast cancer.

[d]BSE: breast self-examination.

[e]VDO: ___.

[f]BSEP: breast self-examination practice.

[g]mHealth: mobile health.

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Usual Care

The control group received usual care only, whereas the experimental group received CBBHEP with usual care. There are no distinct data for high-risk women in hospital settings. BC and its risk factors and treatment options have been discussed as part of usual care through a pamphlet in the local (Urdu) language.

Data Collection Procedure

The principal investigator gave the intervention to trained research assistants. Assistants were selected because of their experience in oncology, and training was given about the educational process. Intervention was started with the control group on different dates from the experimental group, and follow-ups were conducted to avoid contamination of the subjects. A trained research assistant collected data (for BSEP at baseline and at 12 wk, and for follow-up and self-efficacy as a mediating factor for program monitoring at baseline, 4th, 8th, and 12 wk). The principal investigator, with the help of a trained research assistant, conducted follow-up visits at the 4th, 8th, and 12th weeks of intervention with individual participants (10 - 15 min). An IT specialist collected participation feedback on WHA and mother support at the 4th, 8th, and 12th weeks. The IT specialist compiled the feedback from WHA into paper and shared it with the principal investigator for supporting discussion with participants (Table 2).

Table . Roles and responsibilities of the principal investigator and assistants during the study.

Component	Deliver	Activities
Recruitment	Assistant nurses	• Checking for eligibility for the study. • Getting consent to participate in the study. • Make matched pairs on the age and education level of participants willing to take part in the study. • Baseline assessment of participants.
Interactive session for lecture on BC[a] and BSE[b].	Principal investigator	• PowerPoint presentation (20-25 min) in a group of 15 - 20 participants on BC and BSE importance, mainly by the researcher only.
Small group discussion	Principal investigator and assistant nurses.	• Structured discussion about misperceptions about BC, benefits of BSEP[c] in a small group of 7 - 10 participants (15 - 20 min) by the researcher and assistant.
Skill training	Principal investigator and assistant nurses.	• Training of the steps of BSE on a breast model or female dummy (simulator) by the researcher and assistant in a small group of 7 - 10 participants (5 - 10 min). • Redemonstration of individual participants on breast model or simulator (5 - 10 min) by assistant.
Mobile app working	Principal investigator and assistant nurses. IT expert	• App installation, data entry, feedback submission, and alarm setting by both the researcher and assistant. • The IT expert complied with the participation feedback on the 4th, 8th, and 12th weeks.
Follow-up and app monitoring	Principal investigator, assistant nurses and IT expert	• At 4th, 8th, and 12th weeks. • IT expert check feedback from app and share with principal investigator. • Principal investigator discusses app experience with individual participant (10 - 15 min). • Individual participant self-efficacy monitoring by the nurse assistant (10 - 15 min).

[a]BC: breast cancer.

[b]BSE: breast self-examination.

[c]BSEP: breast self-examination practice.

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Measures

The Toronto BSE frequency and proficiency of practice scale [34] was adapted to measure the BSEP. The instrument was modified in terms of translation into the local Pakistani language and pretested on 30 high-risk women, the minimum sample size required. Cronbach α score was .90, indicating good reliability [35]. It is an 11-item scale that was used to assess BSEP in high-risk women using a five-point Likert scale (score 1 to 5, with 5 being a high score). The mean was obtained from the sum of the scores to determine the BSEP scale score. Higher scores and higher means were seen in this study as indicators of higher BSEP.

The instrument was translated into local language (Urdu) through backward translation techniques by Brislin [36] by followed steps; (1) Forward translation of original (English) version to Urdu version done by two experts (one official bilingual expert and one nurse educator with master's degree in nursing); (2) an assistant professor of nursing (PhD in nursing,) who is fluent in both languages then checked the translated Urdu version for ambiguous or hard-to-understand wordings; (3) after that, two translators (one official translator and one nurse educator with a master's degree in nursing) translated the Pakistani version backward to English while being "blinded" to the original English version; and (4) the initial version and modified version were reviewed for concept equivalence; an expert panel that involved all the experts in the translation process identified that the two versions of the instruments were equal and comprised no grammatical issues in meaning.

Program Monitoring

The self-efficacy scale for BSE [37] was used to monitor program effectiveness. Self-efficacy was selected because it acts as a mediating factor as well for promoting BSEP. The instrument was adapted with permission and translated into Pakistani (Urdu) and tested on high-risk Pakistani women [38]. The scale is scored on a range of 0 (cannot do at all) to 50 (moderately can do), to 100 (definitely can do). Self-efficacy monitoring was done by an experienced nurse educator as a nurse assistant. Additional training for measuring self-efficacy was given by the principal investigator. Nurse assistant did a self-efficacy assessment during follow-up at visits 4th, 8th, and 12th week by assessing individual participant BSE skill on the breast model and by filling a self-administered questionnaire. Participants' self-efficacy score of 50% and above was considered effective for the intervention during follow-up. A total score of 90% and above was considered satisfactory self-efficacy in the performance of BSE among high-risk women at the end of the intervention, taken from empirical evidence [37]. Participants' adherence to the program was demonstrated through feedback from the mHealth app.

Statistical Analysis

Eligible participants were randomized into treatment and control groups. In both groups, baseline characteristics were compared using inferential analyses of independent 1-tailed *t* tests and chi-square tests. This study compared gain scores between the experimental and control groups using one-way ANCOVA to investigate the impact of the CBBHEP on BSEP. The statistical significance level was set at $P<.01$, and the mean was used to determine the significant difference between the mean BSEP, between the intervention and control groups at baseline and 12 weeks, and covariance as the pre-test score [39]. Paired sample *t* statistics were used to measure differences in the mean BSEP level within each group's data at baseline and at the 12-week follow-up. Before the analysis, assumptions for the 1-way ANCOVA and paired 1-tailed *t* tests were computed. There was no missing data in the analysis.

Results

Sample Characteristics

After screening for eligibility, 72 subjects were eventually enrolled in the trial and randomized to one control group (n=36) and one intervention group (n=36; Figure 2). In the 12th week, the retention rate was 100%. At baseline, no discernible demographic differences were observed between groups. The average age was 28 (SD 5.72) years in both groups. The majority of the women in both groups had 10th grade (21/36, 58.3%) education and were mostly married (21/36, 58.3%; Table 3).

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Figure 2. The study CONSORT (Consolidated Standards of Reporting Trials) diagram.

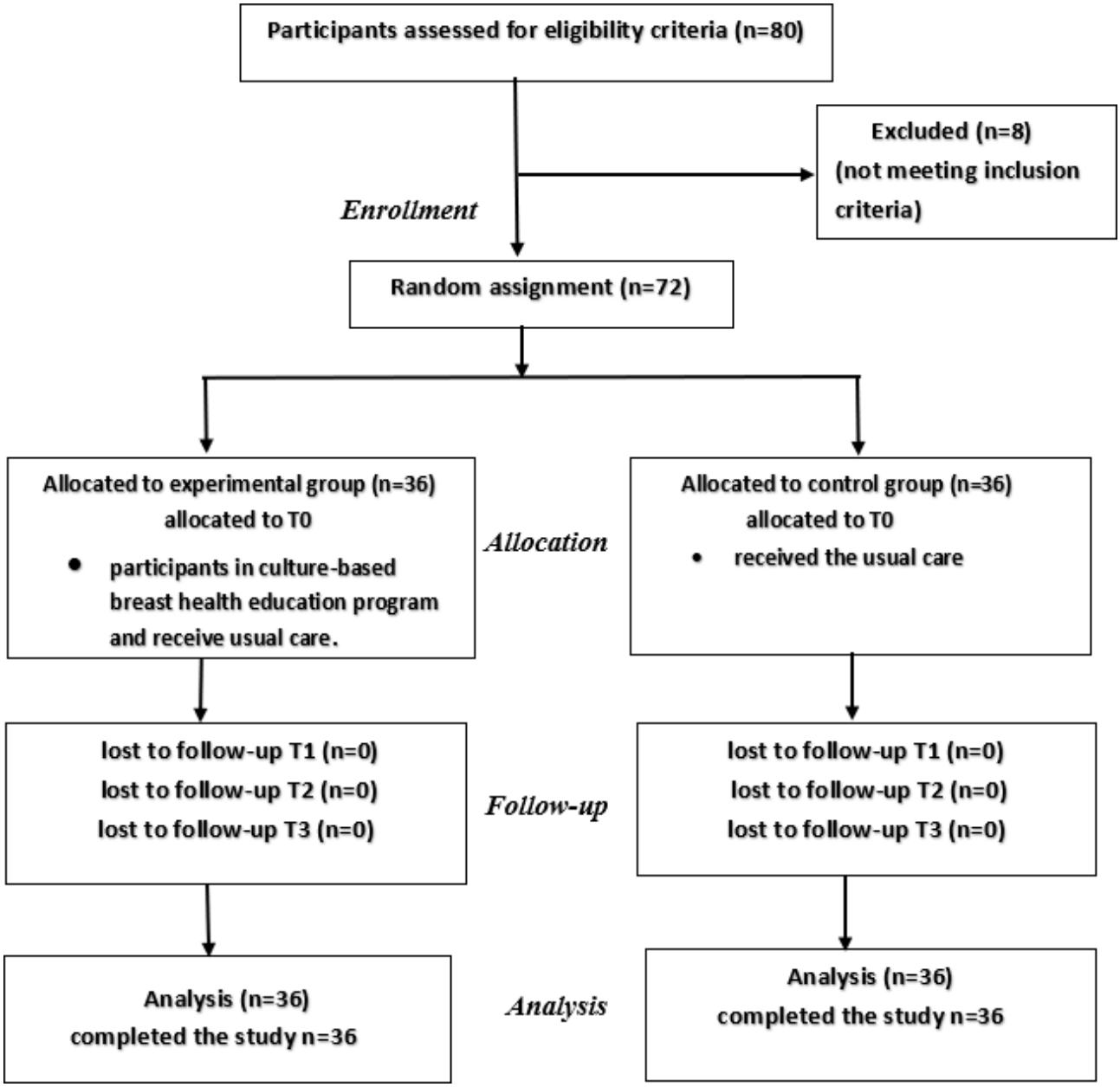

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Table . Characteristics of participants.

Characteristics	Intervention group, n (%)	Control group, n (%)	Chi-square (*df*)	*P* value
Age groups (years)			—[a]	—
20-26	16 (44.5)	13 (36.1)		
27-33	13 (36.1)	16 (44.5)		
>33	7 (19.4)	7 (19.4)		
Mean (SD)	28 (5.72)	28 (4.96)		
Educational level			—	—
10th grade	21 (58.3)	21 (58.3)		
12th grade	7 (19.4)	7 (19.4)		
Graduation	8 (22.3)	8 (22.3)		
Occupation history			0.676 (1)	.50
Working	11 (30.5)	10 (27.8)		
Nonworking	25 (69.5)	26 (72.2)		
Marital status			0.963 (1)	.23
Married	21 (58.3)	25 (69.5)		
Un-married	15 (41.7)	11 (30.5)		
Obstetric history (in marriage) having children			1.179 (1)	.55
Yes	14 (66.7)	15 (60)		
No	7 (33.3)	10 (40)		
Did breastfeeding			0.415 (1)	.81
Yes	9 (64.3)	8 (53.4)		
No	5 (35.7)	7 (46.7)		
Menstrual history			0.758 (1)	.28
Regular cycle	30 (83.3)	27 (75)		
Irregular cycle	6 (16.7)	9 (25)		

[a]Not applicable.

Intervention Effect on Outcome

The mean was obtained from the sum of the scores obtained to determine the BSEP scale score. The mean (SD) of BSEP at baseline and 12-week measurement in the intervention group and control group were calculated (Table 4).

Table . Comparison of mean and SD of breast self-examination practice.

BSEP[a]	Mean (SD)	MD[b]
Intervention group		7.93
Baseline	7.17 (4.62)	
12 weeks	15.1 (4.45)	
Control group		0.16
Baseline	7.31 (4.78)	
12 weeks	7.47 (4.92)	

[a]BSEP: breast self-examination practice.

[b]MD: mean difference.

The impact of CBBHEP on BSEP between the experimental and control groups was measured using an ANCOVA through gain scores by controlling for the pretest score. This was the difference between the posttest and pretest scores as covariates [39]. The analysis showed that participants who took part in the 12th week of CBBHEP had significantly higher BSEP than those in the control group ($F_{1,69}$=58.908; P<.001), suggesting

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that the program had a significant impact on the intervention group's improvement in BSEP (Table 5).

Table . One-way analysis of covariance comparison of the mean difference in breast self-examination practice in the intervention and control groups.

Source	SS[a]	*df*	MS[b]	*F* test	*P* value	Partial η^{2}[c]
Group	1066.797	1	1066.797	58.908	<.001	.46
Covariate	493.329	1	493.329	27.241	<.001	.28
Error	1249.560	69	18.110	__[d]	—	—

[a]SS: sum of square.

[b]MS: mean square.

[c]Partial ^{2}: effect size.

[d]Not available.

Paired sample *t* statistics were used to determine the mean difference in BSEP scores at baseline and 12 weeks within the groups (Table 6). The analysis also revealed that the BSEP of the experimental group at baseline and at 12 weeks differed significantly (t_{35}=7.214; *P*<.001), with BSEP being significantly greater at the 12th week than at baseline. Comparing the pretest and posttest BSEP pairwise for the control group revealed no discernible differences.

Table . Mean difference of breast self-examination practice score between baseline and 12 weeks within groups.

Variable	Group	*t* test (*df*)	99% CI (LB-UB)	*P* value	Cohen *d* value
BSEP[a]	Experiment	−7.21 (35)	(−10.94 to −4.94)	.<.001	0.88
	Control	−.403 (35)	(−1.29 to 0.95)	.69	0.03

[a]BSEP: breast self-examination practice.

Discussion

Principal Findings

CBBHEP based on components of SCT [21] with integration of culture identity concept of PEN-3 model [22] was found to be effective in promoting BSEP behavior among high-risk women through personal factors such as knowledge of BC and BSE, building positive attitudes toward BSE, and improving the ability to perform BSE with mother support according to their cultural values and local language, as environmental factors concluded over literature support [25-27].

CBBHEP was developed to create awareness about BC and its screening measures, especially BSEP behavior. Pakistani women have many cultural barriers that affect the BC screening behavior, including BSE [16,17,40]. The cultural issues were related to female shyness, modesty, and misbeliefs about breasts as the most sensitive parts of their body that should be concealed or hidden all the time, and it's only related to sexuality [16]. Embarrassment and an uncomfortable feeling to let practitioners do their breast examination and show it to female doctors for routine check-ups or tests, as it affects their confidentiality [17]. Misconceptions of BC about faith healers can cure the BC, and all lumps would be BC. A significant number also believed BC to be a result of God's curse or evil eye [41].

The program was conducted in the local (Urdu) language and in a separate room where no men were given access to minimize the cultural barrier related to the confidentiality of women, to reduce shyness, and to maintain female modesty. Mothers of high-risk women were also part of the study because in Pakistani culture, women's health-related issues are not openly discussed with male members of the family. Mothers were included because of their dominant role, especially for their daughters in families. During the interactive sessions, awareness about BC, screening measures such as BSE, and its importance was given through a PowerPoint presentation, and a VDO about the importance of breast health by religious women was shared to give them motivation and to make them aware that the breast is also like other parts of the body; it's not only an organ related to sexuality, so breast health is also important for women. During a small discussion group session with mothers and high-risk women, common beliefs and misperceptions about BC were discussed to make their attitude positive for BC screening, especially BSE, by educating them about the facts of BC and the benefits of BSE for breast health awareness. During the training session, a VDO for the BSE skill was shared, and a breast model and simulator were used for demonstration. Redemonstration by each participant was taken on the breast model separately in a private room to maintain privacy and modesty. In WHA, information about BC, BSE, benefits of BSE, and facts about BSE were given for their reading as well, and a VDO on BSE skill was also part of the mHealth app.

According to empirical data, SCT-based educational intervention for promoting BSE was found to be effective [42]. Smartphone apps have been proven to improve BSE performance. A reminder alarm for the intimation of proper time for BSE could have a positive effect on BSEP because people spend a lot of time on their smartphones, and the lessons they learn from these apps, which include educational films, stick in their memory [43]. A smartphone-based educational intervention that included BSE knowledge tasks and monthly reminder messages was found to be 4 times higher BSEP in the intervention group than in the control group [42]. CBBHEP was more effective in promoting BSEP behavior as it was in the local language,

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including WHA. The PEN-3 model [22] was integrated into SCT [21] as a mother support because it has a potential source to educate and promote BC awareness and prevention among daughters. A mother may affect her daughter's sense of self-efficacy in overcoming perceived barriers to BC prevention and early detection of BC symptoms in the form of informational support, such as advice or guidance, and by providing emotional support like empathy. Furthermore, exposure to a mother's attitude and health behavior practices toward BC prevention may influence a daughter's conception about the benefits and susceptibility of BC prevention. Thus, a mother's knowledge about family history, modeling norms of healthy lifestyle practices [44], and support of health prevention behaviors could be influential in their daughter's development of evolving behaviors that contribute to the awareness and prevention measures such as BC screening [45]. The program was acceptable for all participants, and they were motivated to continue the whole program after interactive sessions, as indicated by their feedback through WHA, which also indicates their acceptance of the program as an indication of a 100% retention rate. In the diary notes, participants shared their experiences with BSEP, including the fact that all results were normal, and that supportive remarks from my mother urged me to complete the BSE on time. "My mother reminded me of the BSE time and urged me to teach your sister the skill of doing BSE as well. This increased WHA's efficacy and fostered a favorable attitude toward BC and BSE behavior. Monthly participant feedback via online data made it easier to understand the role of mothers and the efficacy of the intervention. Participants shared that after participating in this program, mothers' attitudes were more positive: "She encouraged me to do BSE every month." "After meeting with you, my mother said, "You must do BSE." Social support-based educational interventions significantly improved women's screening behavior for BC [46]. Thus, smartphone apps have been proven to improve BSE performance, but social support will close the gap toward behavior, and eventually accelerate behavior change. Studies show that social support plays a key role in health screening and behaviors [43]. Family support, especially from the mother, played a significant role in promoting BSEP behavior in their daughters. Every month, participants' feedback through online data helped to understand the effectiveness of the intervention and the role of the mother more clearly.

Understanding BC and screening methods, such as BSE, for early awareness of BC symptoms was crucial. Research has shown that a lack of knowledge about BSEP is one of the reasons why people do not undertake it [47]. The results of the study were consistent with previous research showing that educational interventions that increase BSE knowledge through lectures, discussions, video sharing, or interactive demonstrations were effective in improving adult women's BSEP [48,49]. CBBHEP was more informative as misperceptions about BC were communicated with facts. Twenty-minute smartphone-based teaching sessions were similarly successful in encouraging BSEP behavior in adult women. Understanding BC (classification, common site, risk factors, and screening measures), BSE methods (procedures, time to do, and observation), and BSEP demonstration comprised the educational intervention. The BSEP score of women who received the educational intervention was higher than that of the control group [29]. WHA, a part of CBBHEP, has an additional feature of making diary notes and sharing feedback to show acceptability and engagement in the intervention for adapting the behavior of BSEP.

Positive behaviors regarding BC screening measures were produced through attitude-focused interventions. By providing information about facts, at-risk groups, and the significance of screening procedures, CBBHEP also incorporated actions to foster a positive attitude toward BSEP. Additional conversations on their concerns about BC and BSE were held with the participants and their mothers in small groups of five to seven people. Women's health apps received similar information. It was discovered that an educational intervention that encouraged a positive attitude toward BSEP worked well. Face-to-face group discussions during the educational interventions revealed a favorable attitude toward BSE, demonstrating a substantial increase in their views regarding BSEP following the group intervention [26,50]. CBBHEP was different as a positive attitude was enhanced through not only group discussion but also mother support.

Self-efficacy in conducting BSE was also assessed using a self-reported tool and at each follow-up session, including the fourth, eighth, and twelfth weeks of the intervention process. After the intervention, it consistently increased compared to the baseline. The program's activities are comparable to those found in the literature that support the enhancement of self-efficacy. A health education intervention has been implemented to enhance women's BSE performance. The intervention consisted of several techniques to boost women's self-efficacy, such as verbal encouragement, group support, studying the educator's conduct, and determining whether it is feasible. The self-efficacy and BSEP of the educational group were considerably greater than those of the control group [50]. Following the interactive in-person and online interventions, BSE self-efficacy levels increased significantly. The most significant predictor of behavioral change is self-efficacy [46]. CBBHEP was also effective in promoting self-efficacy with the addition of mother support, who continually encourages her daughters to perform BSE and teaches the steps to other daughters as well.

According to the study's findings, a CBBHEP in the clinical practice of nurses could benefit from incorporating SCT into the concept of cultural identity. The program improved women's knowledge, attitude, and self-efficacy for BSEP in their cultural context and values, which was crucial from a clinical standpoint for all aged women to be aware of BC and self-conscious of their breast health. Health education and family support, particularly from mothers, could raise BSEP to make it an alternative and successful approach to breast health awareness and early identification of BC symptoms. Mobile-based health education programs are the most popular and successful, and nurse-delivered interventions are required to apply these programs to high-risk women in culturally isolated communities by incorporating their culture. Future study could be conducted at multiple sites and in different communities for intervention effectiveness.

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Limitations

The study's shortcomings include that it was conducted at a single site to explore phenomena further, and the program needed to be conducted in more settings. Second, some participants delayed the timely submission of their input to the WHAs, which may have been caused by internet problems or a lack of funds to purchase internet packages. To further understand the barriers and pinpoint contextual elements linked to future long-term preventive behavior, qualitative research should be planned.

Contributions of the Study

The study made contributions to women's breast health awareness in the following ways,

1. The study created public awareness about negative cultural beliefs related to BC and BSE, such as taboo, to touch oneself, and making positive perceptions about body parts, such as a female body part, which is also a part of health, not only a part of sexuality.
2. This study created public awareness that BC can be treated if diagnosed at an early stage; early diagnosis increases the survival rate of patients. This study created public awareness about BSE as a cost-effective screening measure for self-awareness and early diagnosis of BC at a very early stage.
3. The study created confidence in women and made them responsible for their breast health, such as self-awareness, by reducing their shyness in performing BSE.
4. The study created empowerment among women and encouraged them to talk about BC with their family members, such as with their mothers; it is not related to any wrong concept; it is a part of their body for which they have a responsibility to be aware of.

Conclusions

The BSEP in high-risk women was significantly affected by the CBBHEP as an intervention. At the 12-week follow-up, the BSEP results were significant, indicating that the intervention had an impact. The promotion of BSEP behavior was significantly impacted by family support, particularly from mothers. Nurses in comparable faith-based communities can perform such interventions.

Funding

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Data Availability

The corresponding author has access to all data, which may be supplied upon request.

Conflicts of Interest

None declared.

Checklist 1
CONSORT checklist.
[DOCX File, 33 KB - apinj_v10i1e85340_app1.docx]

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Abbreviations

ANCOVA: analysis of covariance
BC: breast cancer
BSEP: breast self-examination practice
CBBHEP: culture-based breast health education program
CONSORT: Consolidated Standards of Reporting Trials
mHealth: mobile health
SCT: social cognitive theory
WHA: Women's Health app

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Effect of a Community-Based Enhancement Program on Emergency Assistance and Marine Patient Transfer Coordination Competency Among Community Health Volunteers on the Remote Islands of Southern Thailand: Quasi-Experimental Study

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Abstract

Background: Currently, remote areas face problems accessing health services. Although emergency medical systems have a policy of pushing more rapid response units into these communities, they still have not covered many areas due to the distance and the lack of a specific system that fits the community context. The resulting delays to medical treatment after accidents and emergency illnesses in these areas thus increase the risk of severe symptoms, disability, and subsequent death.

Objective: This study examines the effectiveness of a community-based enhancement program for emergency assistance and marine patient transfer coordination among community health volunteers (CHVs) on Phaluay Island, southern Thailand.

Methods: This quasi-experimental study followed a 1-group pretest or posttest design. The research sample consisted of 30 CHVs selected through nonrandom purposive sampling. The research instruments were demographic questionnaires, knowledge and skill measures of emergency assistance, and a competency assessment of marine patient transfer coordination. The data analysis employed descriptive statistics, repeated measures analysis of variance, and the Bonferroni test, with statistical significance set at P less than .05.

Results: The results revealed that the average scores on emergency assistance and marine patient transfer coordination knowledge were significantly higher (P<.001) after training compared to before, specifically at weeks 1 and 30. The average scores on emergency assistance and marine patient transfer coordination skills in weeks 1 and 30 in the CHVs were significantly higher (P<.001). The CHVs' mean scores for emergency assistance and marine patient transfer coordination competency before (at week 1) and after training (at week 30) were significantly higher (P<.001).

Conclusions: This research suggests that there is a need for policy advocacy by relevant agencies to further develop CHV competencies, which require continuous stimulation, monitoring, and reskilling to prepare these volunteers and other community members to respond effectively to emergencies in remote areas.

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KEYWORDS

knowledge; skill; training; technology; accident; health care; competency; marine transfer; remote Island; cardiopulmonary resuscitation; CPR

Introduction

The issue of health care system access remains a significant concern in various parts of the world [1]. As a middle-income country, Thailand needs to develop its structural and foundational systems to support its growing population, just as much as its aging citizens [2]. However, Thailand faces obstacles to structural development, such as inadequate transportation [3]. This factor alone prevents various population groups from accessing medical care promptly, especially in remote and island areas [4]. Limited medical facilities that support potential treatment, as well as a shortage of health personnel who serve the people in these remote areas, pose further issues [5]. As in other Southeast Asian countries, there is a persistent shortage of medical personnel. Many countries in the region maintain a doctor-to-population ratio below the recommended standard of

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10 per 10,000, especially in Cambodia, Indonesia, Laos, Myanmar, the Philippines, Thailand, Timor-Leste, and Vietnam. Cambodia reports the lowest ratio at 1.93 per 10,000, whereas Singapore achieves the highest ratio at 22.94 per 10,000 [6]. Although Thailand's emergency medical system has a policy of pushing more rapid response units into the community, it may not cover all areas [7]. The resulting delays in timely medical treatment after accidents and emergency illnesses increase the risk of severe symptoms, disability, and subsequent death [8].

Phaluay Island, an island located in Thailand's Surat Thani Province, has a population of approximately 500 people [9]. From the island, it takes more than 2 hours to reach the mainland by a small passenger boat. Emergencies such as motorcycle accidents and falls are common. As a result of its remoteness, Phaluay Island's population, including tourists who visit the site, has been deeply affected by these and other forms of accidents and emergency illnesses, though there are difficulties in mitigating this issue. According to local health officials, the island has 1 subdistrict hospital and only 2 public health personnel for health support. This limitation can affect life and health conditions during an emergency. Moreover, no referral system exists to facilitate effective care and assistance for patients on Phaluay Island.

To receive health care, the village residents have had to use expensive private boats or their own small longtail boats, the latter of which may be at risk during emergency transport due to wind and waves. Depending on wave conditions, transport to sufficient treatment facilities can endure for more than 2 hours. This may result in patients receiving insufficient care before arrival. Based on the data on illnesses and patient referrals from 2020 to 2022, 25 emergency cases from Phaluay Island required referral to a mainland hospital; of those, only a small percentage utilized emergency medical services. Most patients were transported via a small boat. These limitations put patients at risk of not receiving care from staff during transport.

This makes it essential to develop knowledge [10] and various competencies related to initial care during health emergencies on Phaluay Island [11]. In such situations, community health volunteers (CHVs) play a crucial role in supporting primary health care through adequate emergency response [12,13], as learned through sufficient knowledge and skill training [14]. Recent research has revealed the positive impact of scenario training on rural CHVs in emergency response situations [15]. There is also a less common training program that integrates digital technology specifically into the island context. In addition, guidelines for assistance and emergency referrals for people on remote islands in Thailand are being made available to the public [16]. One such development enables volunteer leaders to provide care and assistance in emergencies by integrating communication technology, including ambulance operation centers (AOCs), into the marine patient referral system.

This research, therefore, focuses on integrating Phaluay Island's AOC into its marine patient referral system to enhance patient care. This system has not yet been applied to small boat referrals, though utilizing technology can enhance this operational gap [17] and meet Thailand's transformational needs [18]. This integration can serve as a guideline for strengthening and supporting individuals in remote areas to take care of themselves. It also involves coordinating with network partners to establish health care systems that enhance access to and promote equality in health care [19]. It may lead to the ultimate goal of people being safe, continuing to reduce the risk of disability and death rates.

Specifically, this study examines the effectiveness of a community-based enhancement program on emergency assistance and marine patient transfer coordination competency among CHVs on Phaluay Island, southern Thailand. We hypothesized that CHVs' competency in providing emergency assistance and coordinating marine patient transfers after receiving this training will be statistically significantly higher than before the training (P<.05). This paper also highlights the process and impact of integrating the community context, technology-based approaches, and situated learning theory in the program's development.

Methods

This research followed a quasi-experimental, 1-group pre- or posttest design. It represents the third phase of the research and development project "Enhancement of Assistant and Referral Systems for Accidents and Emergency Illness on a Remote Island: Phaluay Island Safety Model."

Research Sample

Study Participants

To determine the effectiveness of the primary care knowledge and competency development program, people living on Phaluay Island were recruited as CHVs via nonrandom purposive sampling. A total of 30 people were recruited based on the following criteria: 18 years of age or older, no physical or visual limitations, no congenital diseases such as heart disease or asthma, willing to participate in the entire research process, and the ability to read and write in Thai. All participants were recruited and contacted by local health personnel to participate in this research.

Sample Size Calculations

This research compared the volunteers' mean scores on knowledge and skills assessments. The researchers calculated the sample size based on a previous study that examined the effect of simulation training on enhancing nursing students' perceptions to engage patients' families in treatment plans [20]. With a power ($Z\beta$) of 80% (0.84), a significance level ($Z\alpha$) of 0.05 (1.96), a mean difference of 1.1 (SD1 0.6 and SD2 0.3), k of 1 group, and statistical significance of 0.05, the sample size obtained for this study was 22 cases. To counter the chance of participants dropping out of the research, the researchers increased the sample size to 30 according to Cohen formula (n=22 cases) [21]:

$$\text{Effect size}=dpools=m1-m2SD1+SD2=f2=d22k=\delta2=0.744$$

$$n=(Z\alpha/2+Z\beta)2\times2\sigma2(1-\rho)\delta2$$

$$n=(1.96+0.84)2\times2(0.9)2(1-0.05)(0.744)2$$

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Research Instruments

Training and Data Collection

The research instruments consisted of 2 parts—the community-based enhancement program and the knowledge and skill measure of emergency assistance and marine patient transfer coordination competency. First, the community-based enhancement program utilized situated learning theory [22] as a framework for developing training activities. This theory focuses on learning as participation through social interaction and a community of practice in which the individual shares and learns together. The program activities are based on the elements of activities, artifacts, identities, and relationships.

These elements were intended to develop the sample group's knowledge and skills in providing basic health assistance to patients and referring marine patients. The details of the program are as follows: (1) organized activities, including lectures, demonstrations, reverse demonstrations, and practice simulations, developed CHVs' diverse knowledge and skills; (2) artifacts involved the integration of AOC technology into potential development of the patient marine transfer support; (3) the program utilized 4 emergency simulation situations consistent with the Phaluay Island community's identity and way of life to promote the application of available resources; and (4) emphasis on relationships promoted learning together in a group. The training program covered 5 operational stations: station 1, covering symptom assessment and first aid; station 2, on resuscitation and automated external defibrillator (AED) use; station 3, introducing maritime rescue and referral methods; station 4, concerning requests for assistance and communication; and station 5, for the implications of AOC system technology (Table 1). The development of these 5 station activities was underpinned by the elements of situated learning theory, which enhanced competency, knowledge, and skills in initial assistance for emergency patients, as well as the referral of marine patients from remote islands.

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Table . The 5-station training program based on situated learning principles.

Station	Learning objectives	Duration (min)	Learning methods	Expected competencies
1. Symptom assessment and first aid	1. Conduct rapid assessments of emergency symptoms using a structured methodology. 2. Identify clinical red flags and determine criteria for urgent referral. 3. Provide immediate first-aid interventions appropriate for common emergencies encountered in the island context.	50	Instructional strategies included realistic scenario briefings, guided practice with authentic cases, peer coaching, facilitator feedback, and integration of local contextual cues.	Expected outcomes are accurate primary assessments, effective prioritization, safe first-aid interventions, and timely escalation decisions.
2. Resuscitation and AED[a] use	1. Demonstrate high-quality cardiopulmonary resuscitation in accordance with American Heart Association guidelines. 2. Operate an AED correctly, including accurate pad placement, completion of safety checks, and appropriate shock delivery. 3. Coordinate team roles effectively during resuscitation, functioning as either a team member or leader.	60	Practice skills through simulation activities, team-based scenarios with defined roles, ongoing coaching, and structured debriefing sessions that focus on decision-making within time and distance limitations.	Competencies include proper execution of cardiopulmonary resuscitation steps, effective chest compressions, safe and accurate use of an AED, clear team communication, and rapid response.
3. Maritime rescue and referral procedures	1. Demonstrate safe maritime rescue principles and effective patient stabilization techniques for sea transfer. 2. Prepare patients for referral, including appropriate positioning, monitoring, and securing. 3. Utilize a standardized referral pathway for patient transfer from remote islands, specifying contact persons, timing, and required information.	60	Contextual demonstrations of boat and shore transfer workflows, task-based learning activities, and hands-on equipment handling.	Competencies include safe patient handling and movement, implementation of stabilization steps, risk mitigation for weather and sea conditions, accurate referral preparation, and completion of performance checklists with scenario-based decision points.
4. Requesting assistance and emergency communication	1. Demonstrate effective communication with dispatch and health services. 2. Deliver complete and accurate information to support decision-making processes.	50	Role-play exercises involving caller, dispatcher, and team roles; both scripted and unscripted communication drills; structured feedback on clarity and completeness; guided reflection on authentic community communication barriers.	Demonstrate clarity, completeness, and timeliness in communication; route requests appropriately; confirm and close communication loops; and achieve proficiency as measured by a communication rubric and call simulation.

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Station	Learning objectives	Duration (min)	Learning methods	Expected competencies
5. Implementation of technology and the AOC[b] system for marine transfer	1. Demonstrate understanding of AOC functions, including coordination, dispatch, tracking, and documentation. 2. Apply AOC-supported workflows, such as request initiation, status updates, and referral coordination.	50	System walk-through, hands-on practice with demonstration interfaces and workflows, case-based discussions on changes introduced by AOC, troubleshooting exercises, and reflective debrief sessions.	Competencies include accurate data entry and reporting, adherence to the correct workflow steps, timely updates and escalations, handling connectivity limitations, and successful completion of a task checklist.

[a]AED: automated external defibrillator.

[b]AOC: ambulance operation center.

The program was conducted in 2 phases (30 weeks apart) for a total activity period of 12 hours. The training program included two components: (1) knowledge enhancement regarding first aid, basic life support (BLS), AED use, AOC, and communication in emergencies, and (2) skill development, consisting of demonstrating and then returning to demonstrate first aid, BLS, AED use [15,23], AOC implementation, communication activities, and maritime transfer. Activities of this phase fell into one of the following categories:

- Activities focusing on knowledge development over two and a half lecture hours to educate on fundamental assistance issues, such as symptom assessment, requesting help (emergency call number 1669), and communicating with the emergency medical system
- Workshop activities (1 h) on basic communication and assistance tools connecting to the AOC system
- Activities to develop competency in initial assistance and maritime referrals, such as condition assessment, movement, communication, and symptom monitoring, with the sample divided into groups in initial assistance exercises of 4 hours and 30 minutes each
- Activities to restore knowledge and skills in simulations (4 h each) in week 30
- An AOC equipment setup activity, as supported by TELY 360, demonstrated how to integrate the equipment into marine patient referral systems. This satellite signal connection device is used to track coordinates and locations during patient transfers, a common practice in secondary and tertiary health service facilities in Thailand. In the context of remote islands, the AOC was the first contact that the island had with the mainland. In addition, AOC devices, including radios to coordinate patient details with the operation center at Donsak Hospital and camera equipment to monitor patient status and referral teams (eg, CHVs and family caregivers), can be installed on the subject when a ready-to-use referral is available. This technological integration is a crucial component that enables the destination hospital to guide the referral team on board the ship during patient transport. The AOC device was placed in a portable box (as shown in Figure 1), and a designated, ready-to-use storage point was established for emergency patient transport in key areas, as agreed upon by the community.

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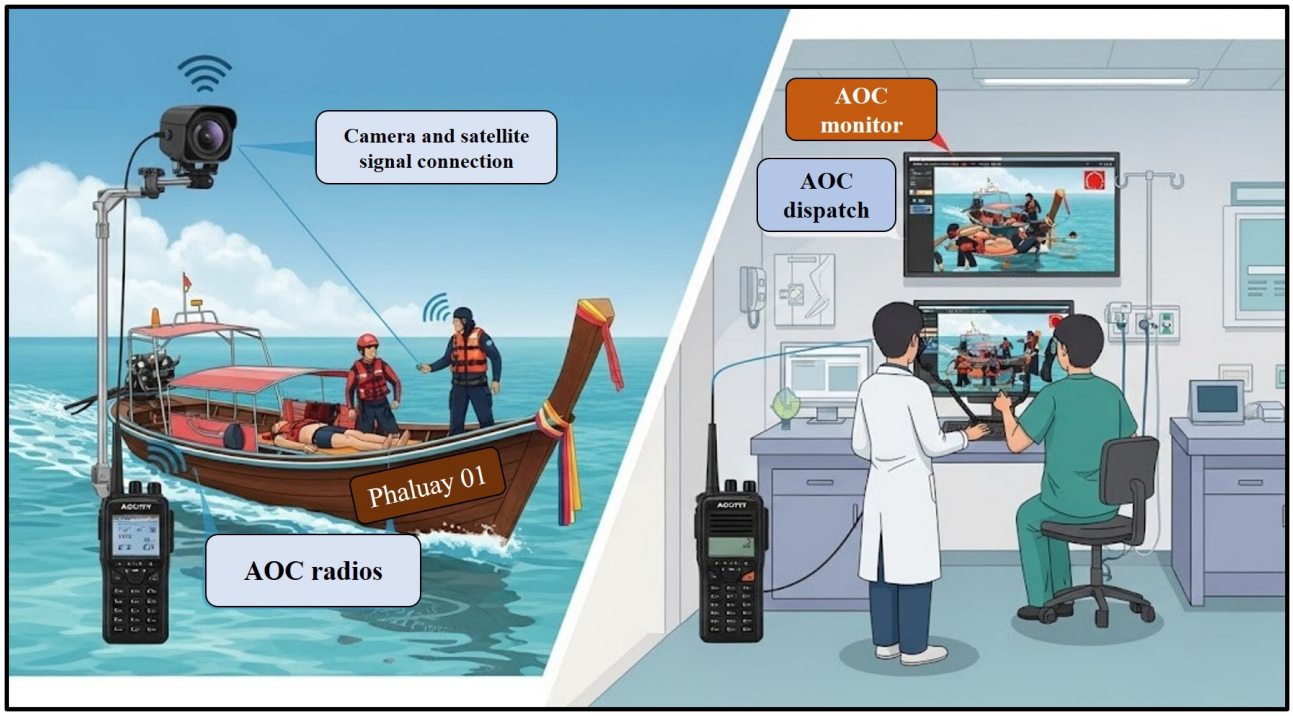
Figure 1. Ambulance operation center (AOC), generated using Google Gemini (artificial intelligence image generator), 2025 [24].



The second part of the research instruments used for data collection were demographic characteristic questionnaires, the questionnaire of knowledge measurement, and the questionnaire of skill measurement, which are described as follows.

Demographic characteristic questionnaires gathered data on the volunteers' age, occupation, and education level; number of experiences providing basic health care assistance to victims of accidents or emergency illnesses; experience in helping with marine patient transport; and BLS experience.

The researchers developed a multiple-choice knowledge measure of emergency assistance and marine patient transfer coordination competency among the CHVs based on a literature review of relevant research. Each question had 2 answer options ("yes" or "no"), with 1 point given for a correct answer and 0 points for a wrong answer. There were 15 questions, leading to possible total scores of 0 to 15 points. This questionnaire involved evaluating the situation, emergency notification, and first aid for patients who met with an accident in situations such as poisonous animal bites, hemostasis, basic immobilization, and BLS.

The researchers also derived a skill measure of emergency assistance and marine patient transfer coordination competency among CHVs based on a literature review. The measurement had a 3-level rating scale. The program instructors performed a skill assessment during practice activities by selecting 1 answer that matched each participant's practice status: a complete practice yielded 2 points, an incomplete practice 1 point, and nonpractice 0 points. Participants could receive a total score between 0 and 36 on this 18-item questionnaire. This skill measurement focused on symptom assessment, communication, first aid, and BLS.

To evaluate assistance competency and marine patient transfer coordination, the researchers further assessed the volunteers' total knowledge and practical skills scores, with scores ranging from 0 to 51 points.

Instrument Validity

Five qualified experts examined the research instruments to determine whether their content validity ratio values exceeded 0.99, except for the following exceptions: item 7 of the demographics instrument, item 2 of the knowledge measure, and items 4 and 8 of the skill measure. The experts provided improvements, and the researchers implemented them accordingly. Considering the questionnaires' content validity index (CVI) results, the knowledge measure had a CVI of 0.98, and the skill measure had a CVI of 0.97. The researchers then administered each questionnaire to a pilot group of 30 people with characteristics similar to the sample. The reliability of the knowledge measure was also examined using the Kuder Richardson 20, which yielded a value of 0.737, while the skill measure yielded a Cronbach α coefficient of 0.964.

Data Collection

This research, in particular, was conducted between March and October 2024. After receiving ethics committee approval, the researcher proceeded to recruit the sample group to participate in the research process for a total of 30 weeks. The sequence of the quasi-experimental research process is outlined in Figure 2.

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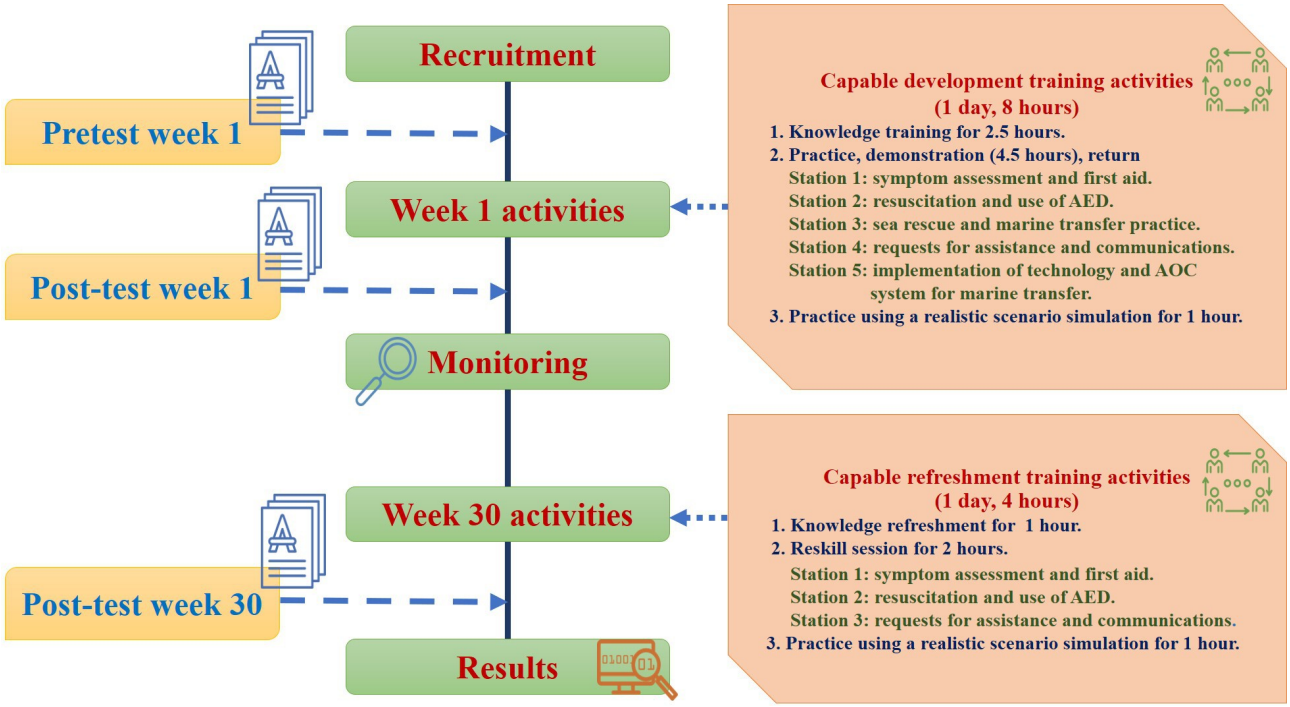
Figure 2. Data collection protocol. AED: automated external defibrillator; AOC: ambulance operation centers.



Data Analysis

The demographic data were analyzed using descriptive statistics such as frequency, mean, percentage, and SD. The inferential statistics repeated measures ANOVA and the Bonferroni test were used to compare the mean differences in emergency assistance and marine patient transfer coordination knowledge, skills, and competencies among the volunteers before and after training at week 1 and week 30, respectively, with statistical significance set at P=.05.

Ethical Considerations

This project was approved by the Human Research Ethics Committee of the Surat Thani Provincial Health Office (approval STPHO2023-318). The researchers followed the principles of the Belmont Report to ensure the protection of the volunteers regarding respect for persons, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) [25]. The volunteers received sufficient information before deciding to participate in the project and signing the consent form. The participants could withdraw from the project at any time without penalty or adverse effect. The participants' information, including names and initials, was anonymized. All results will be presented and published for academic purposes and will be deidentified. The data and materials relevant to the participants will be stored in a secure room and destroyed 5 years after the first day of data collection. The participants in this study received a cash payment of 100 Thai baht per person for their time. They were also provided with one lunch (120 Thai baht; an exchange rate of US $1=32.6 Thai baht is applicable) and two snack breaks (30 Thai baht each). The total value provided was 280 Thai baht per participant.

Results

From the preliminary analysis of the 30 CHVs, the sample group's information was complete, and the data from 25 cases were analyzed because of 5 participants withdrawing from the project for personal reasons. The results showed that the sample had an average age of 48.20 (SD 13.43) years, and most individuals worked as freelancers. Forty percent (10/25) were involved in CHV work, while the majority had no experience in emergency aid (17/25, 68%), as shown in Table 2.

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Table . Volunteer demographic data and emergency assistance experience (N=25).

Demographic data	Values
Career, n (%)	
Government officer	1 (4)
Farmer	3 (12)
Fisherman	1 (4)
Freelancer	10 (40)
State enterprises	2 (8)
Own business	8 (32)
Education level, n (%)	
Grade 6	15 (60)
Junior high school	4 (16)
Senior high school	3 (12)
Undergraduate	3 (12)
Role in the community, n (%)	
Community health volunteer	10 (40)
Community leader	2 (8)
Security officer	1 (4)
No specific role	12 (48)
Experience with emergency assistance, n (%)	
No	17 (68)
Yes	8 (32)
Age (y), range; mean (SD)	20-69; 48.20 (13.43)
Frequency of emergency assistance experience, range; mean (SD)	0-10; 1.52 (3.22)
Frequency of the marine patient transfer experience, range; mean (SD)	0-10; 1.53 (3.17)
Frequency of emergency calls experienced, range; mean (SD)	0-10; 0.64 (2.07)

A repeated measures ANOVA (n=25) revealed significant within-subject effects for all knowledge, skill, and competency. Knowledge scores increased significantly over time, $F_{(1, 24)}$=41.379, P<.001, with a large effect size (η^2p=.633; estimated mean, 95% CI 8.782 - 10.312). Skill scores change significantly, $F_{(1, 24)}$=58.532, P<.001, with a large effect size (η^2p=.709; estimated mean 95% CI 23.815 - 25.012). Competency scores also demonstrated significant improvement, $F_{(1, 24)}$=37.755, P<.001, with a large effect (η^2p=.611; estimated mean 95% CI 32.817 - 35.103), as shown in Table 3.

Table . The variance of the variable within the training group for knowledge, skill, and competency (N=25).

Variable	SS[a]	MS[b]	F test (df)	P value	η^2p [c]	95% CI
Knowledge (error)	66.667 (38.667)	66.667 (1.611)	41.379 (1, 24)	<.001[d]	0.633	8.782-10.312
Skill (error)	499.280 (204.720)	499.280 (8.530)	58.532 (1, 24)	<.001[d]	0.709	23.815-25.012
Competency (error)	126.960 (257.880)	126.960 (10.745)	37.755 (1, 24)	<.001[d]	0.611	32.817-35.103

[a]SS: type III sum of squares.

[b]MS: mean square.

[c] 2 : partial eta squared (effect size).

[d]Significant at P<.001.

The average scores on emergency assistance and marine patient transfer coordination knowledge before and after training, specifically at weeks 1 and 30, revealed that the CHVs' level of knowledge was significantly higher (P<.001). When comparing pairs using the Bonferroni method, the average knowledge score before week 1 and before the formal start of the knowledge training likewise showed a statistically significant increase (P<.001). Between week 30 (after the program took

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place) and before the knowledge training began, there was also a statistically significant increase (*P*<.001). However, following the trials in week 1 and week 30, there were no statistically significant differences (*P*=.39), as shown in Table 4.

Table . Average scores on emergency assistance and marine patient transfer coordination knowledge before and after training (N=25).

Time	Score, mean (SD)	Before training	Week 1, MD[a] (*P* value[b])	Week 30, MD (*P* value[b])	*P* value[c]
Before training	7.36 (2.039)	—[d]	3.52 (<.001)	3.04 (<.001)	<.001
Week 1	10.88 (2.369)	—	—	–0.48 (.39)	—
Week 30	10.40 (2.432)	—	—	—	—

[a]MD: mean differences (time 2 – time 1).

[b]Bonferroni test for pairwise comparisons.

[c]Repeated measures ANOVA for test of within-subject effects.

[d]Not applicable.

The average scores on emergency assistance and marine patient transfer coordination skills in weeks 1 and 30 in the CHVs were significantly higher (*P*<.001). When comparing pairs using the Bonferroni test in week 1 and before the training, the mean skill scores were statistically significantly different (*P*<.001). In week 30 and before the training, there was also a statistically significant difference in the skill level (*P*<.001). After the trials in weeks 1 and 30, the CHVs' average skill levels were significantly different (*P*=.005), as shown in Table 5.

Table . Average scores on emergency assistance and marine patient transfer coordination skills before and after training (*N*=25).

Time	Score, mean (SD)	Before training	Week 1, MD[a] (*P* value[b])	Week 30, MD (*P* value[b])	*P* value[c]
Before training	21.00 (1.871)	—[d]	3.92 (<.001)	6.32 (<.001)	<.001
Week 1	24.92 (1.631)	—	—	2.4 (.005)	—
Week 30	27.32 (3.579)	—	—	—	—

[a]MD: mean differences (time 2 – time 1).

[b]Bonferroni for pairwise comparisons.

[c]Repeated measures ANOVA for test of within-subjects effects.

[d]Not available.

The average scores on the CHVs' overall emergency assistance and marine patient transfer coordination competencies before and after training, specifically in weeks 1 and 30, showed a significantly higher competency mean score among the CHVs (*P*<.001). Upon pair comparison using the Bonferroni test, the competency mean scores at week 1 and before training showed a statistically significant difference (*P*<.001). After the experiment at week 30 and before training, the competency levels were statistically significantly different (*P*<.001). Weeks 1 and 30 were also statistically significantly different (*P*=.006), as shown in Table 6.

Table . Average scores on overall emergency assistance and marine patient transfer coordination competencies before and after training (N=25).

Time	Score, mean (SD)	Before training	Week 1, MD[a] (*P* value[b])	Week 30, MD (*P* value[b])	*P* value[c]
Before training	28.36 (0.568)	—[d]	7.44 (<.001)	9.36 (<.001)	<.001
Week 1	35.80 (0.590)	—	—	1.92 (.006)	—
Week 30	37.72 (0.908)	—	—	—	—

[a]MD: mean differences (time 2 – time 1).

[b]Bonferroni for pairwise comparisons.

[c]Repeated measures ANOVA for test of within-subjects effects.

[d]Not available.

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Discussion

Principal Results

In accordance with the research hypothesis, the CHVs' competency in providing emergency assistance and coordinating marine patient transfers after receiving this training will be statistically significantly higher than before the training (P<.05). The critical results indicate that there was a significant increase in the level of knowledge, skills, and competency in emergency assistance and marine patient transfer coordination from the first week after training to the 30th week.

Strengths and Limitations

This research's key strength is its integration of a new technology, AOC, into the training of CHVs. It also provides realistic scenarios based on community contexts gathered from community member recommendations. However, it may be limited by a lack of confidence in using the technology, which is new and exciting, among volunteers. This factor might inhibit this technology's full potential from being realized. Therefore, CHVs' technology competencies need to be developed regularly and continuously trained to eliminate their unconfident practice to prepare for the situations faced by people in the community. An additional constraint of this study was that participants were recruited via purposive sampling, which may limit external validity and introduce selection bias. Therefore, future studies should consider random, stratified, or cluster-based sampling for participant recruitment. Another limitation in this research needs to be addressed, specifically the gap between week 1 and week 30, during which no boosting activity was conducted, and it may affect their knowledge stability. Consequently, a further training program should consider incorporating booster activities via online sessions to monitor their knowledge and confidence in emergency illness assistance.

Comparison With Previous Work

The findings of this study are similar to previous research, which suggested that continuous training in BLS and first-aid skills helps trainees maintain better skills and competencies in the long term [26,27]. The results of this study reflect the effectiveness of the proposed training program in CHVs' continuous development, both in decision-making and practical skills, as well as their overall understanding of patient referral. This finding is consistent with a recent study by Pongtriang et al [15,23], who emphasized the importance of organizing continuous training programs and conducting long-term monitoring to encourage trainees to learn skills in-depth and maintain them for a longer period [28]. Indeed, competency levels can decrease significantly over time [29]. This result indicates that CHVs still require review and periodic knowledge updates [30] to be able to provide emergency assistance and transfer marine patients effectively. Another recent study highlighted that regularly restoring knowledge and skills helps slow down the rapid decline in competency levels that can occur after an initial training session [31]. Therefore, the findings of this study, where rehabilitation activities were held in week 30, effectively support long-term competency maintenance.

However, the study also revealed that the level of emergency assistance knowledge and skills among the CHVs was low overall. It is therefore important to raise awareness among nurses and other health officials of the need to study the context and background factors of people in their area to develop their potential [32], such as through the strategies tailored to this study. The recent study also suggests that considering the community context is an essential component in successful health development [33]. When analyzing the sample's background, it also became evident that the volunteers' education level was relatively low. Most participants had no experience assisting or responding to accidents and emergency illnesses. These factors contribute to insufficient knowledge and inadequate practices relevant to emergency assistance [34], making it crucial to maintain CHVs' knowledge and skills. This could be improved through government support for regular training on BLS and similar emergency issues [35].

Although Thai government legislation mandates that development initiatives take place at least once per year [36], inequity and insufficient development persist due to Phaluay Island's isolated location. This research finding aligns with a previous study, which identified several barriers to providing quality health care in rural communities [37] that require advanced care strategies, such as telehealth and satellite care, to close the health care gaps [38]. Our research incorporated digital technologies into a training program to continuously enhance the capabilities of the island's community members. This development can be considered a new approach to promoting prehospital care through technological support systems [39]. An improved referral system can also be achieved by enhancing the abilities of community volunteers to support their community's emergency care system. Using digital technology can aid communication, monitoring patient status [40], and facilitating the work of CHVs and family caregivers while transporting patients as well. Furthermore, the recent study supports that technology would be an advantage for community training in improving the competency of health care volunteers in the community [41]. Indonesia and the Philippines, similar to other Southeast Asian countries, encounter substantial challenges in marine health management, which necessitate the adoption of solutions, such as telemedicine systems [42]. In addition to technological interventions, the development of integrated national policies, including explicit legislation and dedicated funding for air and sea medical referrals, can address coordination barriers and reduce related costs [43]. Furthermore, strengthening community knowledge and attitudes through partnerships with local leaders may reduce delays in family decision-making and enhance understanding of health insurance systems [44].

Although previous studies have found the advantages of integrating technology to enhance people's potential holistically, our study found that unfamiliar technologies are challenging for volunteers, resulting in excitement and anxiety about using the equipment, which affects confidence in practice. These insights were drawn from the low level of practice scores in the first trial. In addition, the issue of communicating emergency medical incidents to the emergency dispatch staff revealed that a majority of participants in the sample group were not confident

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and were anxious about communicating important and necessary information relevant to an incident [45]. Therefore, training with a clear format to practice both the use of necessary technologies and effective communication [46], using a step-by-step framework that can be followed and practiced independently [47], will be an important part of building confidence in developing first-aid skills and communicating more effectively in emergency confrontations [48]. When considering the knowledge and skills development program of this research, which utilized the concept of situated learning theory [22] as a framework for organizing activities to develop volunteers, the theory focuses on learning in collaborative learning situations through team participation. It is considered a highlight that is consistent with the situation and learning the context [49] of the group to understand its limitations, including support and resources for assistance at the scene, leading to problem solving and helping patients and injured people with the realistic context and situation [50], such as applying natural tools or materials in the vicinity to immobilize and move, among others. Addressing this situation is particularly important for areas with limited access and insufficient health support [51]. The findings of this development are important for the further development of training programs to enhance the knowledge and skills of volunteers in the area, which are tailored to the local context and leverage technology connectivity. This encouragement enables tracking and support for people and caregivers during the transfer, ensuring the safest possible outcome.

Implications for Practice

Health care providers play a crucial role in establishing community training, which necessitates consideration of community context through community engagement, such as the limitations of a local health care system, the level of digital literacy of community residents, the level of social participation, and the issue of community needs of competencies development to effectively enhance the abilities of CHVs and develop an appropriate training program to maintain their knowledge and skills. In addition, due to its remote island location, similar to our study site around the world, there are several limitations to health care, support, and access to resources. With these limitations, community nurses and health providers could play an advocacy role by supporting the local people's need for emergency care system support with community health data and presenting to higher government agencies to encourage more attention to establish a policy-driven approach to health care accessibility [52]. In addition, the result of this study could be scaled up via provincial health offices to strengthen island-based emergency medical services in southern Thailand.

Conclusions

This study presented comparative findings on the competence, knowledge, and skills of local CHVs in providing first aid for emergency illnesses, accidents, and marine transfers of patients in a remote island area. This training program was developed based on the context, limitations, and stakeholder needs of Phaluay Island in southern Thailand. The training program utilized various methods that CHVs employ to prevent illness and attend to emergencies among the public. The findings revealed that the competence development program, which integrated digital technology to communicate with hospitals and monitor patients during rescue and transport to the destination hospital, can improve the CHVs' knowledge and skills in terms of assessing patient condition, requesting help in an emergency, communicating effectively, BLS, and AED use. The training can also assist with coordination and practices during patient transport for effective initial care. The results further demonstrated that the application of situated learning theory, the community context, and technology integration, with appropriate components, can improve the CHVs' competence and learning outcomes. However, to support the continuity and sustainability of competence in the long term, it is necessary to study development strategies that follow the changing context and relevant community factors. This may improve access to emergency medical services for local people and reduce the likelihood of disability and subsequent mortality.

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Data Availability

The datasets in this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

AED: automated external defibrillator
AOC: ambulance operation center
BLS: basic life support
CHV: community health volunteer
CVI: content validity index

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Clinical Barriers to Hands-Free, Eyes-Free Voice Input for Nursing Records: Field Usability Study

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Abstract

Background: Nursing records are essential for maintaining patient care quality but impose a substantial workload on nurses, thus contributing to burnout and diverting attention from direct care. Voice input technology enables hands-free and eyes-free documentation, allowing simultaneous patient care and record entry. Despite its potential, its adoption in clinical nursing practice remains limited owing to concerns about patient privacy, technical instability, and the complexity of entering structured data into electronic medical record interfaces. Furthermore, most previous studies have been conducted in simulation settings or have focused on post hoc dictation. Thus, the feasibility of true simultaneous documentation in real-world clinical environments remains largely unexplored.

Objective: This pilot study was designed to explore the feasibility of using hands-free and eyes-free voice input for concurrent nursing documentation in the highly structured clinical environment of a catheterization laboratory.

Methods: This study was conducted at Kyoto University Hospital using a mixed methods exploratory design. Eight cases of percutaneous transhepatic cholangiodrainage and transcatheter arterial chemoembolization were observed between December 2022 and January 2023. Five nurses participated in this study and documented intraoperative events using both traditional handwritten records and a prototype voice dialogue system comprising a smartphone (Google Pixel 6a) and wireless earphones (Pixel Buds Pro). Researchers observed the nurses' behavior in adjacent control rooms to minimize interference. Log data from voice input and the corresponding handwritten notes were compared to determine the proportion of events successfully captured. In addition, semistructured interviews and usability surveys were conducted to obtain qualitative feedback on usability, practicality, and perceived barriers.

Results: Voice input successfully recorded 40% to 100% of events during the preoperative and intraoperative phases, but only 0% to 12% during postoperative documentation. Observations and interviews revealed that the postoperative phase involved higher cognitive and communication demands, thereby making simultaneous voice documentation difficult. A significant barrier identified was the "social awkwardness" of interacting with the system; nurses reported feeling embarrassed when speaking loudly to activate the device and often stepped away from patients to record data, negating the benefit of concurrent entry. Concerns about disturbing patients or interrupting medical communication have also hindered use.

Conclusions: This pilot study identified two major barriers in applying concurrent voice input in clinical settings: (1) the instability and unreliability of using voice input as the sole recording method and (2) the conflict between voice interaction and the social dynamics of care. To overcome these, future implementations should consider visible devices to signal recording status, support for whisper recognition, and protocols for code words to handle sensitive information. Gradual implementation may reduce nurses' cognitive and psychological burdens. Further large-scale longitudinal studies are warranted to validate these strategies in routine nursing documentation.

(Asian Pac Isl Nurs J 2026;10:e71462) doi:10.2196/71462

KEYWORDS

feasibility study; workflow; catheterization laboratories; point-of-care documentation; mobile phone

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Introduction

Nursing records are not only essential documents of patients' conditions but also serve as key materials for evaluating the quality of care and ensuring patient safety [1,2]. Nurses and other health care professionals rely on nursing records to understand patient status and coordinate care. Therefore, nurses must update these records promptly and accurately. However, documentation accounts for a substantial proportion of nursing tasks—over 30% of the total working time in some reports [3-5]—and has been identified as a factor contributing to nurse fatigue and burnout [6-8]. Thus, reducing the documentation burden while maintaining accuracy and completeness has become a central issue in nursing practice and informatics research [9-12].

Voice input technology, which enables documentation through speech, has attracted attention as a possible solution to this challenge. If nurses could record information verbally while providing care, they would no longer need to allocate separate time for documentation after completing clinical tasks, potentially reducing total work time. In the future, task-oriented voice dialogue systems customized for nursing scenarios, integrating natural language processing and conversational artificial intelligence, may further support nurses by enabling hands-free and eyes-free sequential documentation. Such systems could allow nurses to make a query on the required data elements, receive prompts regarding missing information, and complete documentation through voice interactions in real time.

Voice input also holds promise for improving the documentation continuity in multitasking environments. Nursing work inherently involves frequent interruptions such as responding to patient calls, communicating with physicians, and handling sudden changes in patient conditions [13]. During such events, nurses often postpone documentation and must rely on memory until they find the time to record it. As record accuracy depends on memory, delayed entry increases the risk of omission or error [14,15]. From this perspective, the ability to document immediately and directly by voice, even when one's hands are occupied or while maintaining visual attention to the patient, offers an important potential advantage.

However, implementing voice input in clinical settings faces practical and ethical challenges, most notably ensuring a secure input environment that protects patient privacy [16]. Nurses are constantly on the move [3,17]; requiring them to relocate to a private area before dictating would reduce efficiency and negate the benefits of real-time documentation.

Previous studies that have applied speech-to-text technologies to nursing records have primarily used simulated patients or laboratory-based scenarios. Most of these studies have examined voice input for patient care documentation [18-21]. The study by Lee et al [22] reported its use for triage nurse documentation in emergency departments. However, evaluations in actual clinical settings remain limited. As speech recognition accuracy improves, studies have reported improvements in documentation accuracy [18,19], input speed [18,19,22], and nurses' acceptance and satisfaction [18,19]. Nevertheless, several challenges persist, including the incompatibility of voice input with the complex hierarchical structure of electronic medical records [19], potential interference with nurse-patient communication [20], and the need for training and associated costs [23].

As most of these studies were conducted under simulated conditions, privacy protection measures were not sufficiently addressed. Moreover, these studies generally assumed that nurses would perform voice input while viewing an electronic record interface, thereby overlooking the central benefit of hands-free and eyes-free documentation conducted concurrently with clinical tasks. To date, the feasibility of such real-time voice input in actual clinical settings has rarely been examined, highlighting the need for preliminary field-based investigations.

For hands-free and eye-free documentation to be applied in nursing practice, the clinical setting and type of records must be carefully selected. Situations involving highly variable information, such as patient complaints or subtle physical changes, are unsuitable for this approach. The conditions required for testing voice input include environments in which patient privacy can be adequately protected, and tasks follow standardized procedures with relatively predictable documentation content. In such cases, nurses are not required to deliberate over what to record, as the system is activated only when documentation is needed and returns to standby mode afterward. Moreover, as nurses frequently communicate with both patients and physicians, the system must distinguish between documented utterances and conversational speech.

Therefore, we selected nursing documentation from a catheterization laboratory as the focus of this pilot study. This environment satisfies several key conditions necessary for testing concurrent voice inputs. First, because only 1 patient was present in the room at a time, the major challenge of maintaining patient privacy during voice recordings was mitigated. Second, nursing activities in the catheterization laboratory follow a relatively standardized sequence: patient entry, time-out, procedure, completion, and exit, allowing nurses to document procedural progress, patient responses, and nursing interventions in chronological order. In this context, the variation in record content is smaller than in inpatient wards, where nurses document diverse and frequently changing care situations. Nurses can simply verbalize their observations and actions without the need to view or verify the input on the display. Furthermore, communication between patients and physicians is limited to essential exchanges, which minimize interference with the recording process.

Unlike simulation-based studies, which cannot fully reproduce real clinical tension, urgency, or workload, an in situ approach enables the observation of how voice input interacts with authentic clinical dynamics. Conducting investigations under carefully controlled conditions in actual clinical settings, while minimizing the burden on both patients and nurses, can yield valuable preliminary insights into practical barriers to implementation.

Therefore, this pilot study was designed to explore the feasibility of using hands-free and eyes-free voice inputs for concurrent nursing documentation within the highly structured clinical environment of a catheterization laboratory. Specifically, it

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aimed to examine (1) how nurses can use voice input during clinical tasks, (2) what contextual and technical barriers might arise, and (3) what conditions are necessary to facilitate integration into practice. As clinical contexts differ across settings, the findings are not intended to be generalized; rather, this preliminary study seeks to identify implementation challenges and provide foundational evidence to guide future large-scale investigations.

Methods

Overview of Nursing Operations

This pilot study was conducted in the catheterization laboratory at Kyoto University Hospital, Japan, where two procedures were selected as the study context: percutaneous transhepatic cholangiodrainage (PTCD) and transcatheter arterial chemoembolization (TACE).

These procedures were performed under local anesthesia by inserting an angiographic catheter through the femoral access. PTCD aims to drain bile, whereas TACE involves the administration of anticancer drugs and embolization of the hepatic artery. Both surgeries share several nursing procedures common to other interventional treatments and involve relatively simple, standardized documentation tasks. As these procedures are short and exhibit fewer fluctuations in patients' vital signs than cardiac or neurological angiographic interventions, they are considered appropriate for minimizing patient risk while allowing real-world investigation under routine conditions.

The catheterization laboratory environment typically maintains a noise level of 60 dB to 75 dB generated by fluoroscopy equipment, computer fans, air conditioning systems, and conversations among health care professionals. Each surgical procedure was performed by several physicians, radiologists, and a nurse. Nurses document observations, interventions, and vital data in short phrases and numerical entries, rather than lengthy descriptive texts. These records were written on a dedicated angiography nursing record sheet and kept in a binder that nurses carried during procedures to enable quick access and recording.

The surgical process is divided into three distinct phases: (1) preoperative phase: from preparation and patient entry to the start of the procedure, (2) intraoperative phase: from time-out to the end of the procedure, and (3) postoperative phase: from completion of the procedure until the patient exits the room.

Nurses' responsibilities during these phases can be broadly categorized into three domains: (1) direct patient care, (2) collaboration with ward nurses and documentation, and (3) assisting physicians, including instrument handling and medication administration. During the preoperative and postoperative phases, numerous tasks overlap within a short time (often less than 10 minutes), creating highly intensive work periods. Figure 1 summarizes the surgical progress and corresponding nursing tasks in each phase.

The nursing documentation in the catheterization laboratory included vital signs, procedural progress, fluid balance, puncture sites and indwelling devices, administration of analgesics and antiemetics, and postoperative instructions. Given the structured nature of these entries, the environment was deemed suitable for examining the feasibility of hands-free and eyes-free voice input without introducing additional patient risks.

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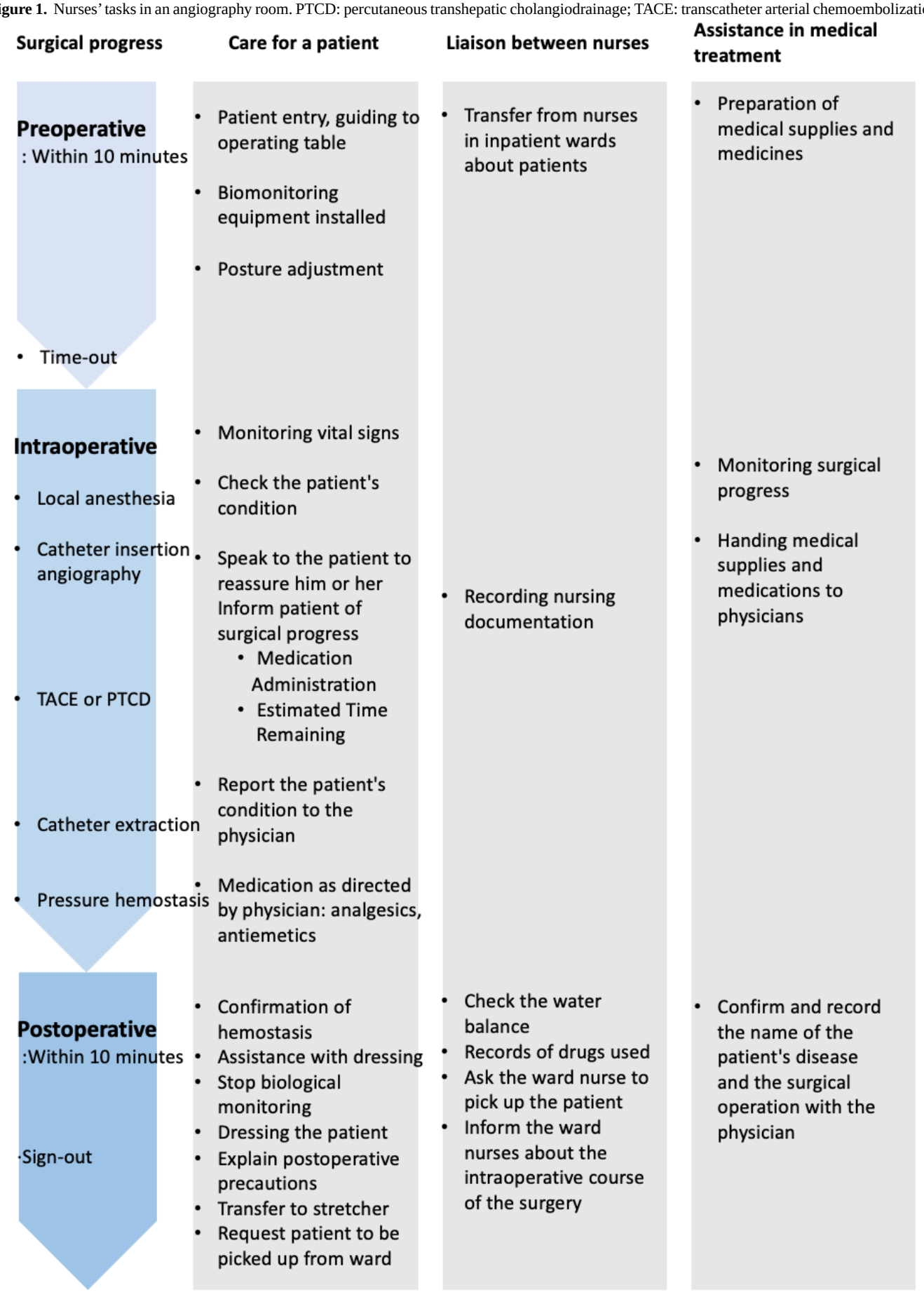
Figure 1. Nurses' tasks in an angiography room. PTCD: percutaneous transhepatic cholangiodrainage; TACE: transcatheter arterial chemoembolization.



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Study Design and Participants

This study adopted a mixed methods exploratory design to identify practical barriers and contextual factors influencing the use of voice input in clinical documentation. This study combined quantitative log data analysis with qualitative observations and interviews.

To ensure patient safety and minimize workflow disruption, the number of cases was limited. On the basis of feasibility and workload considerations, a sample size of ≥5 nurses was established as adequate for this pilot phase. Participants were nurses who had worked in the catheterization laboratory for at least 1 year and were familiar with both PTCD and TACE procedures. Only scheduled procedures were included; emergency cases were excluded to prevent patient risk and ensure stable observation conditions.

During the procedure, the nurses performed routine handwritten documentation while simultaneously using a voice input system to record equivalent information whenever possible. As handwritten records serve as official medical documentation, nurses were explicitly instructed to prioritize them over voice inputs to ensure completeness and patient safety.

The equipment setup was carefully designed to integrate the voice input device into the clinical workflow without interrupting surgical progress. All procedures were observed by the research team, who recorded the operational patterns, timing, and contextual conditions that affected the voice input performance.

System Setup

This study was conducted within a closed and secure hospital electronic medical record network in accordance with the institutional privacy and data protection policies. All devices used were dedicated exclusively to the study and operated only within this protected infrastructure. No patient-identifiable data were stored outside the hospital system or transmitted externally, thereby eliminating the risk of patient data leakage.

For this pilot study, we used Google Assistant, a voice-activated dialogue application with built-in note-taking functionality [24]. A Google Pixel 6a smartphone with Google Assistant preinstalled and offering stable voice control was used as the main recording device. A Pixel Buds Pro wireless earphone-microphone was selected owing to its lightweight design, comfort, and compatibility with radiation-protection goggles. Although earphones support ambient sound pass-through, only 1 earbud was used to ensure that the surrounding sounds could still be heard and to avoid any potential patient safety risks.

When the nurse said “OK Google,” Google Assistant was activated, followed by “Take a note,” prompting the response “What would you like to note?” The nurse then verbalized the desired record—for example, “The patient has entered the room.” Google Assistant replied, “The note has been saved,” completing the entry within approximately 10 to 15 seconds. The spoken data were immediately transcribed and stored as text in Google Keep. Although the application can also be launched manually from a smartphone, only voice activation was used in this study to maintain a hands-free operation.

Figure 2 illustrates the setup used for the voice input activation. The nurses wore standard protective gear, including radiation-proof clothing and goggles. A running pouch containing a smartphone and a wireless microphone was used for the voice input operation. The pouch was designed to fit securely onto the body, prevent interference with movement, and allow nurses to operate the device without removing it. As handwritten documentation remained in the official nursing record, the nurses also carried a traditional binder for handwritten entries.

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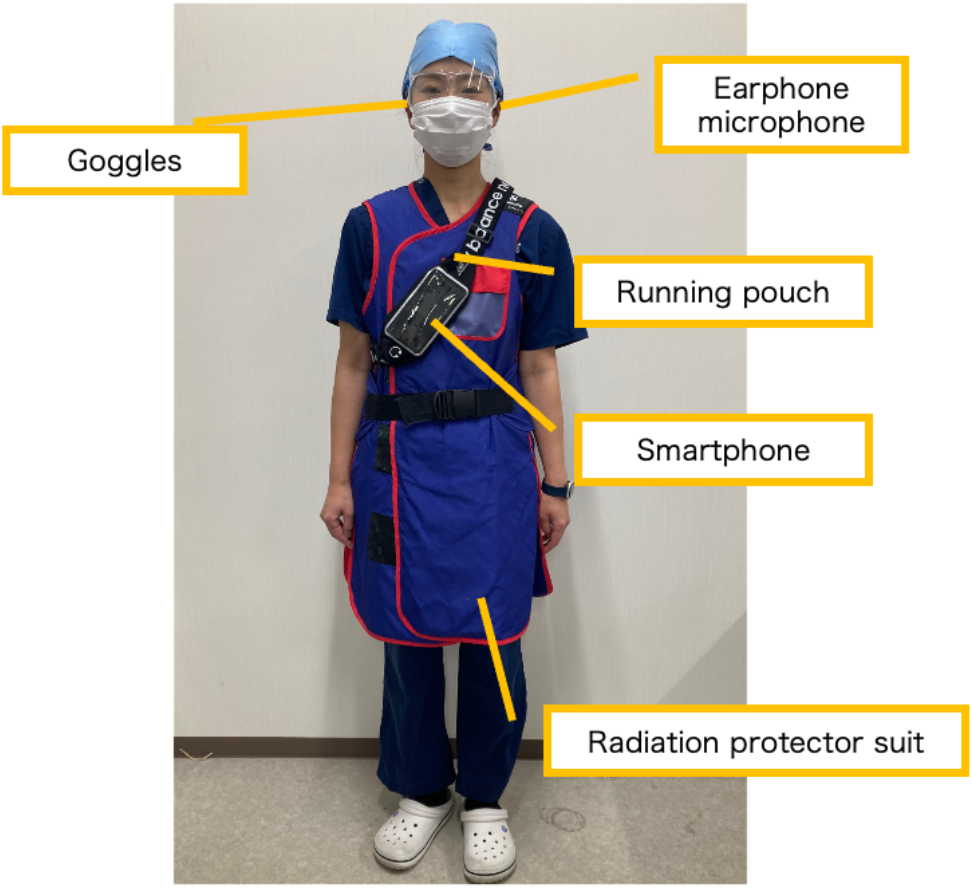
Figure 2. The equipment was prepared for nurses for voice activation.



Training Procedures

Before the study, the participants registered their voice profiles on a smartphone to enhance their speech recognition accuracy. They activated and interacted with Google Assistant to confirm system responsiveness and learn the appropriate voice volume for reliable activation. The nurses were instructed that each interaction should record a single item per dialogue turn and were trained on how to verify the recorded content on the smartphone screen, if necessary.

Data Collection Procedures

The target period for the voice input documentation ranged from patient entry to exit. To reduce workload during the study, vital signs and fluid balance data were excluded, allowing nurses to focus on narrating their procedural actions (what they did) rather than continuous physiological monitoring. The content to be recorded by voice input is assumed to correspond mainly to the "procedure progress" items shown in Figure 1.

For each case, the number of voice-input log entries was compared with the number of corresponding handwritten entries for the same phase. The ratio of voice input entries to handwritten events was calculated by setting the number of handwritten entries to 100. Each voice input log was cross-checked against the paper records to confirm that the events were successfully captured.

As the input accuracy of voice recognition systems has been partially validated in previous studies [19,20], this study did not reexamine transcription accuracy; instead, it focused on the feasibility and contextual barriers to real-time use.

Observation Procedures

To gain a contextual understanding of the environment, real-time observation of nurses' activities was used rather than video recordings. The research team observed nurses' behavior in an operations control room adjacent to the catheterization laboratory, from the patient's entry through to exit. An unstructured observation method, rather than a predefined checklist, was used. Observers recorded events and behaviors in free-text notes, focusing on how nurses interacted with the system and the contextual factors that influenced their use of voice input.

Each nurse's voice input memos saved to Google Keep were shared with the observer's account, allowing the observer to verify the timing of each voice input event in real time. The observers also noted the nurse's location and concurrent actions at the time of recording.

Usability Survey and Interviews

After each procedure, nurses participated in short face-to-face interviews regarding their experiences using the voice input system. Subsequently, a questionnaire using a 5-point Likert scale was distributed to collect structured feedback. The survey

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questions were developed with reference to established instruments such as the system usability scale. As this study aimed to identify barriers to system implementation in clinical settings, the questions were tailored to practical aspects and designed to facilitate participant response. Responses were collected online. Details of the items are provided in Multimedia Appendix 1: interview and questionnaire items.

Ethical Considerations

This study focuses on patient safety and confidentiality. The study protocol was reviewed and approved by the Kyoto University Graduate School and Faculty of Medicine Ethics Committee (approval number R3508). Before participation, the purpose and procedures of the study were explained to all nurses, patients, and attending physicians, and their consent was obtained. The collected data were deidentified and strictly managed in a secure environment. No financial compensation was provided to the health care professionals.

Results

Overview of Cases and Participants

Between December 2022 and January 2023, 8 patients were studied in the catheterization laboratory. The participating nurses were 1 male and 4 females (4 aged in their 40s and 1 in their 50s). Throughout the sessions, the system configuration did not exhibit any connectivity or stability problems. In all cases, nurses provided handwritten documentation as an official record while attempting voice input whenever feasible.

Ratio of Voice Input to Handwritten Records

Table 1 summarizes the case ID, assigned nurse, procedure duration, procedure type, number of voice input entries per case, number of handwritten entries on the record sheet, and percentage of voice input entries relative to handwritten entries.

In this pilot study, vital signs and fluid balance were intentionally excluded from voice input targets to reduce workload; target items spanned events from patient entry to exit (eg, admission or discharge times, catheter insertion, and administered medications). Although some procedures were lengthy, the number of recordable events was not necessarily proportional to the procedure time because longer durations often reflected extended physician operation times rather than increased nursing events.

Table . Experimental results.

Case	Nurse	Operating time (minutes)	Surgical procedure	Entries, n		VE/HW (%)
				VE[a]	HW[b]	
1	A	58	PTCD[c] catheter replacement	8	16	50
2	A	110	PTCD catheter replacement, liver biopsy	9	19	47
3	A	59	PTCD catheter replacement	7	15	46
4	B	123	Transjugular vein liver biopsy	10	22	45
5	B	40	PTCD catheter replacement	7	18	38
6	C	174	PTCD catheter implantation	22	29	75
7	D	144	TACE[d]	16	25	64
8	E	199	PTCD catheter implantation	9	22	40

[a]VE: voice entry.

[b]HW: handwritten .

[c]PTCD: percutaneous transhepatic cholangiodrainage.

[d]TACE: transcatheter arterial chemoembolization.

Phases Where Voice Input Was or Was Not Feasible

As shown in Figure 3, voice input captured 50% to 100% of the target items in the preoperative phase and 40% to 100% in the intraoperative phase, but only 0% to 12% in the postoperative phase.

Consistent with Figure 1, both the preoperative and postoperative phases involved dense task clustering within less than 10 minutes. While preoperative entries were often feasible by voice input, postoperative documentation was rarely recorded by voice, despite containing more items (eg, arterial palpation checks, puncture-site compression method, pressure-release

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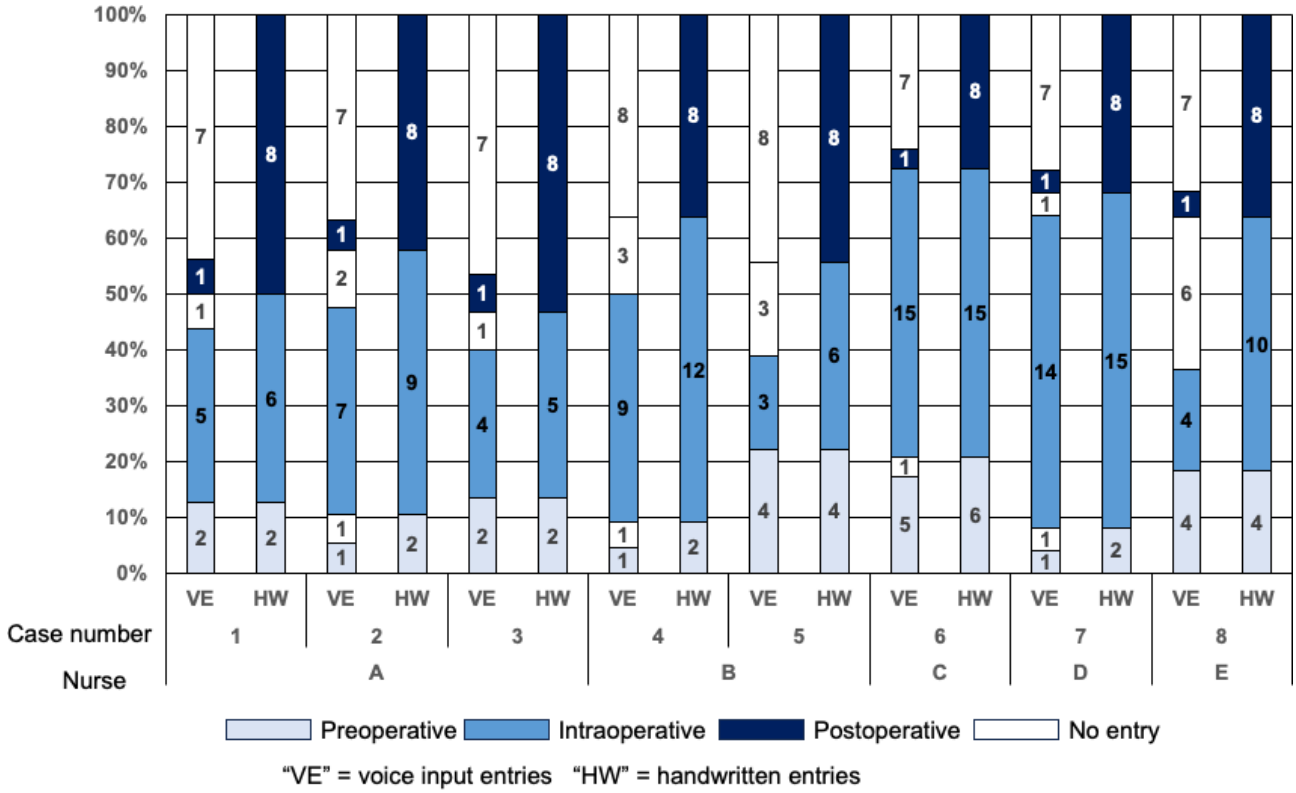
timing, and verification of procedural steps). In one case, the procedure was temporarily paused because of the patient's pain, and no voice input entry was created for this event.

Figure 3. Ratio of voice input to handwritten input in each phase.



Observational Findings on Nurses' Behavior

Across all cases, nurses sometimes used voice input while providing care, but they also frequently stepped away from the patient or physician during short intertask intervals to make voice input entries. As a result, the time stamp of voice entry does not always coincide with the actual care time. The nurses occasionally reviewed their smartphone entries when brief opportunities arose.

In one instance, when a patient reported pain during the procedure, the nurse administered analgesics and remained with the patient until stable; during this period, the medication name and dose were not recorded by voice input.

System Usability Survey

The response rate was 100%. Nurse A participated on 2 separate days (cases 1 and 3) and completed surveys for both; because the second participation did not involve prior training, the second-day response was excluded to avoid confounding, leaving 5 analyzed responses (Multimedia Appendix 2: distribution of nurses' responses to the poststudy Likert scale survey).

Wearing a single earbud did not interfere with the nursing tasks. However, nurses reported the need to speak aloud to activate the system, and several perceived the dialogue or processing speed to be insufficient for the clinical pace. The ratings for "difficulty inputting while working" and "confidence in voice input" were mixed. All participants agreed that technical support was required for practical use. The following interview comments further illustrate these tendencies: a button-based start might be preferable to voice wake-up; domain dictionaries could reduce recognition errors; with familiarity, hands-free narration (eg, reading out drainage amounts) might streamline tasks; recognition was often poor near electrocardiography monitors; a fixed smartphone placement might help; ear discomfort occurred with prolonged wear, suggesting other form factors for long procedures; speaking in a loud voice felt embarrassing; visible near-mouth devices (eg, smartwatch or handheld push-to-talk or intercom-style microphone) may be more acceptable; and potential use cases include night shifts or emergencies and intensive care unit or closed units.

Integrated Findings From Logs and Surveys

Two patterns were consistent across cases: (1) postoperative items were rarely captured by voice input and (2) nurses often moved away from others to make voice input entries. The chosen earbud microphone was lightweight, unobtrusive, and beneficial for comfort; however, because it was not visibly apparent, others could not tell when voice input was being used. Combined with occasional activation failures (necessitating louder speech), nurses sometimes felt compelled to speak suddenly and loudly, which appeared socially awkward. This likely contributed to the tendency to step aside from the input.

Perceived system responsiveness is also considered suboptimal for busy workflows. Although brief prestudy training was provided, all participants indicated that additional technical support (eg, troubleshooting, supplementary training, and device optimization) would be required for sustained, routine use.

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Discussion

Principal Findings

This pilot study examined the feasibility of hands-free and eyes-free voice input in real nursing workflows within a catheterization laboratory. Although the study focused on procedures with similar nursing tasks, the number of recorded voice input items varied by phase and content. These results suggest that the current voice dialogue system is not yet fully compatible with the realities of nursing workflows, and that nurses must constantly negotiate interactions with both the system and its surroundings. The following discussion considers the key barriers to the concurrent use of voice input and care tasks.

Task Complexity and Cognitive Load

Despite the high workload in the preoperative phase, the documentation content—such as "patient entry," "monitoring start," and "procedure start"—was relatively standardized and consistent across patients. As sudden changes in the patient's condition are uncommon, voice input is feasible for most items, resulting in a high input rate (50%-100%). During the intraoperative phase, voice input also achieved moderate to high rates (40% - 100%). This appeared to be related to the longer duration of this phase and fewer interactions between nurses, physicians, and patients, thereby providing brief moments suitable for voice-based recording.

In contrast, the postoperative phase showed extremely low input rates (0% - 12%). This period involves increased documentation and communication demands such as confirming postoperative instructions with physicians or explaining precautions to patients. Unexpected events, such as pain or unstable vital signs, often require immediate action. These conditions heighten nurses' cognitive load and necessitate flexible prioritization, leaving a limited capacity for voice input. Similar findings were reported in the study by Chen et al [25], which noted that a greater task complexity reduces the feasibility of speech-based documentation.

In an environment where privacy was protected, nurses could perform voice input simultaneously with their tasks for simple and standardized content. However, the conflict between system interaction and clinical tasks and the increasing complexity of tasks have made their use difficult. Although further training and system customization may improve usability over time, situations in which voice input is inappropriate or technically unreliable remain. Therefore, backup methods such as quick manual notes or onscreen edits should be available to ensure the completeness of documentation.

Context of Voice Input Use

Observations revealed that nurses often moved away from patients or physicians to provide voice input. This may reflect concerns about being interrupted or uncomfortable speaking aloud when others could not observe the interaction. Several nurses reported feeling embarrassed when they spoke loudly to activate the system. The inability of the system to recognize soft voices likely reinforces this behavior.

In one case, the nurse chose not to record the administration of analgesics while attending to a pain-experiencing patient. She expressed concern that saying aloud, "The patient is in pain and pain relief medication has been administered," might make the patient anxious. These findings highlight that voice input is not merely a technical act; it is also embedded in the social and emotional contexts of care. In some situations, verbalizing information is inappropriate or psychologically uncomfortable for both nurses and patients.

Prior studies [18-20] have mainly evaluated voice input as a point-of-care aid in which nurses looked at a screen while dictating. This approach focuses on efficiency within conventional input workflows. In contrast, this study explored simultaneous voice input during care, which allows documentation without diverting gaze or hands, but may also shift the nature of documentation toward something shared and audible to the patient. This difference implies that introducing voice input for concurrent care requires consideration of the context, interpersonal dynamics, patient perceptions, and system usability.

Both environmental and social support are required to facilitate acceptance. In the initial stages, cooperation between health care staff and patients is essential. Creating an environment in which nurses can use voice input comfortably without fear of misunderstanding or interruption is a key step toward sustainable integration.

Technical and Implementation Considerations

The findings suggest two primary barriers to real-time voice input in clinical settings: (1) the instability of relying solely on voice input as the main documentation method and (2) the gap between voice input and traditional input workflows. Therefore, several technical and environmental improvements are required to overcome these limitations. Microphones should detect lower-volume speech and ideally enable whisper-based recognition [26]. Custom wake words, faster response times, and the ability to enter multiple items in a single interaction could enhance efficiency. Additionally, context-sensitive "code words" or predefined phrases could allow nurses to record sensitive information discreetly when speaking near patients.

The microphone did not interfere with nursing tasks; however, it was found that having the device visible to others was preferable. Moreover, the potential physical effects of prolonged use should also be considered. The advantages and disadvantages of each device are listed in Table 2.

Making the input process more visible—for example, by using microphones attached to uniforms or earphones that illuminate when recording—could promote transparency and reduce discomfort. Smartwatches may also be practical for quick activation; however, some institutions restrict their use for hygiene reasons [27].

Nurses should communicate with patients and colleagues regarding voice input use. It is important for patients to understand that they can always talk to a nurse, even during the recording. Preoperative explanations can alleviate potential discomfort and encourage open communication. Voice input can also enhance safety during "*time-out* procedures [28], where

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audible confirmation of information benefits the entire surgical team. Beginning with such secure and cooperative contexts may help normalize technology.

Table . Advantages and disadvantages of each device.

Device type	Does not block the ears	Visibly worn	Compactness and lightness	Features
In-ear earphone- microphone	X	X	✔	The timing of input is difficult to share
Neck speaker	✔	✔	X	Sound is audible to the surrounding people
Open-ear type	✔	✔	✔	The ear-hook type may interfere with goggles
Headset (intercom type)	✔	✔	X	The ear-hook type may interfere with goggles
Smartwatch	✔	✔	✔	Wearing devices below the elbows is prohibited in some facilities

Future Directions and Practical Implications

On the basis of the pilot findings, three potential directions for future development were considered: (1)

Regardless of the approach, improvements in the device design, targeted training, and collaborative understanding among health care staff can reduce the psychological and operational burdens of voice input. Beginning with environments and content that foster safety and comfort and gradually expanding their use may allow nurses to adapt to the system more naturally.

Overall, this pilot study provided preliminary insights into the barriers and contextual factors affecting voice input in nursing documentation. While these findings are not generalizable owing to the limited sample size and controlled setting, they highlight the essential design, training, and social considerations for future large-scale evaluations.

Limitations

This study was conducted as a pilot investigation within a real clinical environment, with careful consideration of patient safety and minimization of the burden on participating nurses. Consequently, this study has several limitations that must be acknowledged.

First, the study was conducted in the catheterization laboratory of a single facility with a limited number of participants and a short study period. These constraints were intended to ensure clinical safety and avoid disrupting nursing workflows; however, they naturally limit the scope of interpretation.

Second, the input rate and nurses' experiences with voice input may vary depending on the type of procedure, facility characteristics, and organizational culture used. Broader multisite investigations are needed to confirm whether the findings observed here are consistent in other contexts.

Third, as the study was conducted alongside routine clinical duties, the nurses were not solely dedicated to voice input. They continued their official handwritten documentation, which comprised their primary records. Therefore, voice input was used as a supplementary capacity. The results may differ if nurses rely exclusively on voice input without concurrent handwritten notes.

Additionally, this study did not assess changes over time, for example, how input rates or usability perceptions might evolve with continued use and increased familiarity. Therefore, the observed outcomes should be interpreted as preliminary findings reflecting the early stages of the system introduction.

Despite these limitations, this pilot study offers valuable preliminary insights into the contextual and technical barriers to implementing hands-free and eyes-free voice inputs in real-world nursing settings. These findings provide practical guidance for future research on system refinement, workflow integration, and user adaptation under varying workload levels and interactions with other health care professionals.

Conclusions

This pilot study explored the feasibility of hands-free and eyes-free voice input in clinical settings within a catheterization laboratory. These results suggest that nurses were able to use voice input concurrently with their tasks in situations that imposed relatively low cognitive demands. Conducting the study in an actual clinical environment also revealed psychological factors such as tension, hesitation, and environmental constraints, which cannot be replicated in simulations.

In this preliminary stage, two major barriers to introducing voice input in clinical workflows were identified: (1) the instability of relying solely on voice input as the main documentation method and (2) the gap between new voice-based methods and conventional input practices.

To reduce nurses' cognitive and psychological burden, it is important to start with simple, low-risk documentation tasks and content that can be safely shared with other staff members or patients. Continued technical improvements, such as the recognition of softer speech and visual cues that indicate when the system is active, may further enhance its usability and acceptance.

Although limited in scope and duration, this pilot study provides preliminary insights into the contextual, technical, and human

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factors affecting the introduction of voice input in clinical practice. These findings serve as a foundation for future research aimed at developing safer, more adaptive, and context-sensitive systems for nursing documentation.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Poststudy survey for nurses.
[PNG File, 67 KB - apinj_v10i1e71462_app1.png]

Multimedia Appendix 2
Distribution of nurses' responses to the postexperiment Likert scale survey.
[PNG File, 139 KB - apinj_v10i1e71462_app2.png]

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Abbreviations

PTCD: percutaneous transhepatic cholangiodrainage
TACE: transcatheter arterial chemoembolization

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Cumulative High-Risk Pregnancy Complications and Stunting Risk in Indonesian Children Younger Than 5 Years: Retrospective Analysis Using the Developmental Origins of Health and Disease Framework

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Abstract

Background: Stunting affects 21.6% of Indonesian children younger than 5 years, with complications from high-risk pregnancies (HRPs) identified as a potential risk factor. The Developmental Origins of Health and Disease framework suggests that prenatal exposures may permanently alter physiological development and disease susceptibility later in life.

Objective: This study aimed to examine the cumulative effects of HRP complications on the risk of stunting in Indonesian children younger than 5 years while controlling for socioeconomic confounders.

Methods: A retrospective study was conducted in Sleman Regency, Indonesia, analyzing 450 children (300 children with stunting and 150 children without stunting) aged 12 to 59 months. Data were collected from maternal medical records, maternal and child health handbooks, and integrated health post reports. Multivariate logistic regression was used to adjust for socioeconomic confounders including maternal education, family income, and antenatal care (ANC) visits.

Results: Mothers of children with stunting had significantly higher rates of any HRP complications (206/300, 68.7% vs 48/150, 32%; *P*<.001). After adjustment, multiple HRP complications (≥2 conditions) showed the strongest association with stunting (adjusted odds ratio [aOR] 5.80, 95% CI 3.26 - 10.32), exceeding the risk associated with individual complications such as anemia (aOR 3.21, 95% CI 2.12 - 4.86) or preeclampsia (aOR 4.37, 95% CI 2.18 - 8.76). Maternal education (aOR 0.72, 95% CI 0.58 - 0.89), family income (aOR 0.68, 95% CI 0.52 - 0.89), and ANC visits (aOR 0.85, 95% CI 0.76 - 0.95) were identified as protective factors.

Conclusions: The dose-response relationship between cumulative HRP complications and stunting supports the Developmental Origins of Health and Disease hypothesis. Current ANC protocols emphasizing single risk factors may be insufficient. Integrated prenatal care addressing cumulative risks is essential for stunting prevention in Indonesia.

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KEYWORDS

pregnancy complications; maternal health; high-risk pregnancy; child nutrition disorders; stunting; Developmental Origins of Health and Disease

Introduction

Overview

Stunting, defined as height-for-age *z* score ≤−2 SDs below the World Health Organization (WHO) Child Growth Standards median [1], represents a chronic nutritional disorder reflecting failures in health, nutrition, and psychosocial care [2]. Globally, an estimated 149 million children younger than 5 years were stunted in 2023, with the burden disproportionately concentrated in low- and middle-income countries (LMICs) [3]. Indonesia reports one of Southeast Asia's highest stunting prevalence rates at 21.6% according to the 2023 National Nutritional Status Survey [4], though this masks significant regional disparities ranging from 7.2% in Bali to 39.4% in Central Papua [5]. Beyond short stature, stunting leads to irreversible cognitive deficits [6], reduced educational attainment, lower adult productivity, and intergenerational poverty perpetuation [7].

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This original research article aims to examine the cumulative effects of high-risk pregnancy (HRP) complications on the risk of stunting in Indonesian children younger than 5 years, applying the Developmental Origins of Health and Disease (DOHaD) framework.

The DOHaD hypothesis provides a critical framework for understanding stunting etiology. First, proposed by Barker (1990) and later expanded by Hanson and Gluckman (2015), this theory posits that environmental exposures during sensitive developmental windows have permanent effects. Recent reviews have increasingly emphasized that these effects are often the result of cumulative and synergistic exposures, rather than single insults [8], which forms the central hypothesis of our study. These exposures can alter physiological structure, metabolic programming, and disease susceptibility later in life [9,10]. Central to this concept is fetal programming, where prenatal insults such as those from HRP complications disrupt normal development [11]. In LMICs like Indonesia, where 48.9% of pregnant women experience anemia [12], the interplay between maternal nutritional status, HRP complications, and child growth outcomes represents a critical pathway [13].

HRP complications, including anemia, preeclampsia, gestational diabetes mellitus (GDM), heart disease, and asthma, expose fetuses to nutrient deprivation, hypoxia, oxidative stress, and inflammation [14]. Maternal nutrition plays a critical role in fetal development, with deficiencies in key nutrients including iron, folate, and protein contributing to both HRP complications and subsequent child stunting [15]. Recent evidence suggests these effects may be cumulative, with multiple HRP complications synergistically increasing stunting risk beyond individual conditions [16-18]. For instance, a mother with both anemia and preeclampsia may expose the fetus to combined insults that disrupt fetal programming more severely than either condition alone [19]. However, most research examines HRP complications in isolation, with limited studies assessing their combined effects on stunting in Indonesia [20].

Despite Indonesia's National Stunting Acceleration Strategy (2023‐2024), which emphasizes integrated nutrition interventions and antenatal care (ANC) strengthening, stunting prevalence remains above the WHO's significance threshold (>20%) [21]. Current ANC protocols primarily focus on identifying single risks such as anemia or preeclampsia [22], potentially overlooking pregnancies with overlapping complications that confer exponentially higher risk [23]. Furthermore, the role of socioeconomic confounders such as maternal education, family income, and health care access requires careful consideration to clarify the independent association between HRP and stunting [24].

This study addresses these gaps by doing the following:

1. Analyzing the comprehensive association between HRP history and stunting in Indonesian children younger than 5 years using contemporary international guidelines [22,25]
2. Controlling for key socioeconomic and health care–related confounders
3. Applying the DOHaD framework to interpret findings within Indonesia's public health context
4. Providing evidence for integrated prenatal care approaches that address cumulative risks rather than isolated complications.

Key Messages

The key messages for this study are as follows:

1. Cumulative maternal complications during pregnancy significantly increase the risk of stunting among children younger than 5 years.
2. Integrating maternal health monitoring into early child nutrition programs may help prevent intergenerational undernutrition.
3. Findings support the DOHaD framework, emphasizing the importance of prenatal care quality for child growth.
4. Strengthening ANC screening for HRPs could be an effective policy to reduce stunting prevalence in Indonesia.

Methods

Study Design

A retrospective analytical study was conducted in Sleman Regency, Yogyakarta Special Region, Indonesia, between January 2019 and December 2024. The design followed the life course epidemiology framework and employed the counterfactual framework of causation [26]. The methodology adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [27].

Setting

Sleman Regency had 2272 documented stunting cases in 2024. The study focused on 6 subdistricts (Sleman, Brebah, Mlati, Kalasan, Godean, and Tempel), accounting for 91.6% of the regency's stunting cases. Data were collected from the following:

1. Maternal medical records from public health centers
2. Maternal and child health (MCH) handbooks
3. Monthly integrated health post reports

Participants

The study population consisted of children aged 12 to 59 months registered in the district Integrated Nutrition Information System in 2024.

Eligibility Criteria

Inclusion criteria were as follows:

- Age 12‐59 months
- Complete MCH handbook with documented pregnancy history
- Complete medical records from prenatal care
- Complete anthropometric data

Exclusion criteria were as follows:

- Congenital anomalies
- Chronic diseases affecting growth
- Incomplete pregnancy history data
- Missing anthropometric measurements

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Sampling Strategy

A multistage cluster sampling method was used to obtain a representative sample of children aged 12 to 59 months in Sleman Regency. The process involved three stages.

Stage 1: Stratification of Subdistricts

Subdistricts were stratified based on the documented number of stunting cases:

- High burden: >400 stunting cases
- Medium burden: 200 - 400 stunting cases
- Low burden: <200 stunting cases

Stage 2: Random Selection of Subdistricts

Two subdistricts were randomly selected from each stratum:

- High: Sleman (634 cases) and Berbah (445 cases)
- Medium: Mlati (400 cases) and Kalasan (271 cases)
- Low: Godean (196 cases) and Tempel (135 cases)

Stage 3: Probability Proportional to Size Sampling

For the final stage, we established a comprehensive sampling frame consisting of all 150 active integrated health posts within the 6 selected subdistricts, based on the registry from the Sleman District Health Office. From this list, we used probability proportional to size sampling to randomly select 33 integrated health posts, where the probability of selection was proportional to the number of children aged 12 to 59 months registered at each integrated health post.

Within each of the 33 selected integrated health posts, a systematic random sampling technique was used to recruit participants. The monthly attendance register of children aged 12 to 59 months served as the sampling frame. We calculated a fixed sampling interval (k) and aimed to recruit approximately 30 eligible children from each integrated health post until the target initial sample size of 990 children was achieved (33 integrated health post×30 children/integrated health post≈990). This approach ensured that the final sample was proportional to the population distribution across the selected subdistricts and that the recruitment process was both systematic and random.

Participant Flow

A total of 990 eligible respondents were recruited from 6 subdistricts and 33 integrated health posts. However, due to incomplete data, 540 respondents were excluded. The final analytical sample comprised 450 children (300 children with stunting and 150 children without stunting).

Sample Size Calculation

Using the formula for estimating a proportion in a finite population (N=62,817, Z=1.96, p=0.50, e=0.046), a total sample size of 450 children was determined [28].

Variables

Dependent Variable

Stunting (height-for-age *z* score≤–2 SD; WHO 2006) is the dependent variable of the study.

Independent Variable

HRP complications (with timing of assessment) is the independent variable, including:

- Anemia: Diagnosed based on hemoglobin levels (Hb<11 g/dL) recorded during the first trimester (≤13 wk) and/or third trimester (≥28 wk) of pregnancy as documented in the MCH handbook, following WHO guidelines [22].
- Preeclampsia: Identified by new-onset hypertension (BP≥140/90 mmHg) with proteinuria occurring after 20 weeks of gestation as per routine ANC monitoring records, in line with American College of Obstetricians and Gynecologists guidelines [25].
- GDM: Diagnosed based on an abnormal oral glucose tolerance test (OGTT) result conducted between 24 and 28 weeks of gestation, using the International Association of Diabetes and Pregnancy Study Groups criteria [29].
- Heart disease: Documented preexisting or pregnancy-induced cardiac conditions diagnosed at any point during pregnancy and recorded in medical records, as defined by standard obstetric practice [25].
- Asthma: Physician-diagnosed asthma with exacerbations recorded during the pregnancy period in the MCH handbook or medical records, following the Global Initiative for Asthma report [30].
- HRP categorized as none, single, and multiple (≥2).

Confounding Variables

Maternal age, education, family income, ANC visits, iron consumption, maternal nutrition, and family size

Maternal Nutrition (Operational Definition)

Maternal nutritional status was assessed using prepregnancy or first-trimester BMI documented in the MCH handbook. BMI was calculated as weight in kilograms divided by height in meters squared (kg/m^2). For this study, "inadequate maternal nutrition" was defined as a BMI less than 18.5 kg/m^2 (underweight), as this represents a state of chronic undernutrition strongly linked to adverse pregnancy outcomes, following WHO classifications [31].

Data Collection and Quality Assurance

Data were collected through a rigorous three-step process to ensure validity and minimize bias: (1) medical record review for HRP history and maternal variables, (2) MCH handbook review for detailed pregnancy history and ANC visits, and (3) direct verification of anthropometric data at integrated health posts.

Quality Control and Measurement Validity

To ensure the highest data quality, a comprehensive quality assurance protocol was implemented.

- Training and standardization: All field staff responsible for data extraction and anthropometric measurements underwent a 3-day intensive training workshop prior to data collection. This included standardization exercises for both data abstraction and height measurement techniques, as recommended by the Demographics and Health Surveys Phase 8 Anthropometry Manual [32]. An inter-rater

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reliability assessment was conducted, showing high agreement (κ=0.89). A refresher training session was also held midway through the data collection period to prevent observer drift.

- Anthropometric measurement protocol: A child's height was measured using a Seca 213 microtoise (precision: 0.1 cm). Two measurements were taken and averaged if the difference was less than 0.5 cm. All procedures strictly followed WHO protocols [1].
- Instrument calibration: The Seca 213 microtoise was calibrated for accuracy daily before the first measurement using a standard calibrated measuring rod by the field supervisor. Any instrument deviating by more than 0.1 cm was immediately replaced, a critical step for ensuring measurement validity [33].

Statistical Analysis

Data were analyzed using Python (pandas 1.5.3, numpy 1.24.3, scipy 1.10.1; Integrated Development Environment). Descriptive statistics were presented as means with SD for continuous variables and frequencies with percentages for categorical variables. Bivariate analyses, including χ^2 tests for categorical variables and *t* tests for continuous variables, were conducted to examine the unadjusted associations between independent variables and stunting, reporting unadjusted odds ratios (OR) with 95% CI. A multivariate logistic regression model was developed to determine the independent association between HRP complications and stunting while controlling for confounders. All identified confounding variables (maternal age, education, family income, ANC visits, iron tablet consumption, maternal nutrition, and family size) were entered into the model simultaneously using a forced entry method. The model fit was assessed using the Hosmer-Lemeshow goodness-of-fit test, Nagelkerke R^2, and the area under the receiver operating characteristic curve. A 2-tailed *P* value less than .05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Ethics Committee Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada (Ref: KE/FK/0825/EC/2025). All data were anonymized to protect respondents' privacy and confidentiality. Since this study was using retrospective data, informed consent was not needed. The study was conducted in accordance with the Declaration of Helsinki [34] and relevant bioethical principles [35].

Results

Participant Flow

The participant selection process is detailed in Figure 1. From an initial pool of 990 children recruited from the selected integrated health posts, a total of 540 children were excluded due to incomplete data. The primary reasons for exclusion were incomplete anthropometric measurements (n=400) and incomplete pregnancy history data (n=140), which were treated as mutually exclusive categories. This resulted in a final analytical sample of 450 children (300 children with stunting and 150 without stunting).

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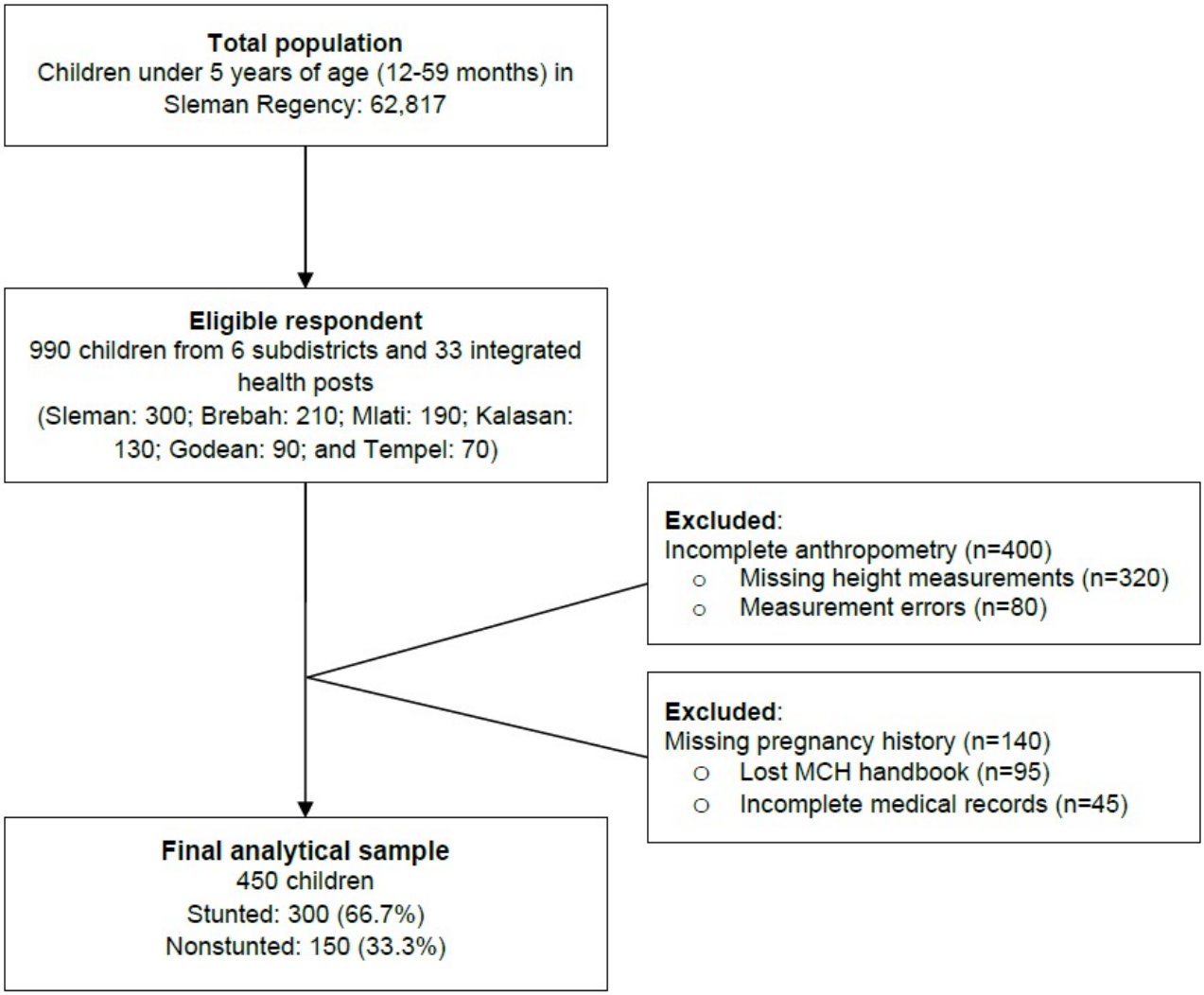
Figure 1. Flow diagram of participant selection in Sleman Regency, Indonesia. MCH: maternal and child health.



Characteristics of Study Participants

The final sample of 450 children was drawn from 6 subdistricts, with the number of participants from each stratum being proportional to the documented stunting cases (high: Sleman and Berbah; medium: Mlati and Kalasan; and low: Godean and Tempel). The distribution of children with and without stunting across these subdistricts was comparable (*P*=.87). The characteristics of the study participants are presented in Table 1.

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Table . Comparison of child and maternal characteristics between children with stunting (n=300) and those without stunting (n=150) in Sleman Regency, Indonesia.

Variable and category	Children with stunting (n=300)	Children without stunting (n=150)	*P* value
Child characteristics			
Age (mo), mean (SD)	34.8 (12.9)	34.1 (12.6)	.43
Sex, n (%)			.68
Female	142 (47.3)	74 (49.3)	
Male	158 (52.7)	76 (50.7)	
Maternal characteristics			
Education, n (%)			<.001
No education	15 (5.0)	3 (2.0)	
Elementary school	35 (11.7)	8 (5.3)	
Junior high school	85 (28.3)	18 (12.0)	
Senior high school	149 (49.7)	99 (66.0)	
College/university	16 (5.3)	22 (14.7)	
Family income (IDR[a]), n (%)			<.001
Low (<1.5 million)	187 (62.3)	52 (34.7)	
Medium (1.5 - 3 million)	89 (29.7)	68 (45.3)	
High (>3 million)	24 (8.0)	30 (20.0)	
ANC[b] visits, n (%)			<.001
<6 visits	98 (32.7)	21 (14.0)	
≥6 visits	202 (67.3)	129 (86.0)	
Iron tablets, n (%)			<.001
<90 tablets	176 (58.7)	48 (32.0)	
≥90 tablets	124 (41.3)	102 (68.0)	
Maternal nutrition, n (%)			<.001
Inadequate	193 (64.3)	43 (28.7)	
Adequate	107 (35.7)	107 (71.3)	
Family size, n (%)			<.001
≤4 members	98 (32.7)	89 (59.3)	
>4 members	202 (67.3)	61 (40.7)	

[a]US $1=16,740.00 IDR.

[b]ANC: antenatal care.

Table 1 presents participant characteristics and the sampling process. The mean age was 34.6 (SD 12.8) months, with no significant difference between stunted (34.8, SD 12.9 mo) and nonstunted (34.1, SD 12.6 mo) groups (*P*=.43). Gender distribution was similar (158/300, 52.7% male in stunted group vs 76/150, 50.7% in nonstunted group; *P*=.68). Significant differences were observed in maternal education (*P*<.001), family income (*P*<.001), ANC visits (*P*<.001), iron supplementation (*P*<.001), maternal nutrition (*P*<.001), and family size (*P*<.001).

Prevalence of HRP Complications

Table 2 shows the prevalence of HRP complications. Any HRP complication was significantly higher among mothers of children with stunting (206/300, 68.7% vs 48/150, 32%; *P*<.001). Anemia was the most common complication (145/300, 48.3% vs 34/150, 22.7%, *P*<.001), followed by preeclampsia (46/300, 15.3% vs 6/150, 4%; *P*<.001). A clear dose-response relationship was observed: children exposed to multiple HRP complications had 6.71 times higher odds of stunting (OR 6.71, 95% CI 3.54 - 12.72).

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Table . Prevalence of individual and cumulative high-risk pregnancy (HRP) complications among mothers of children with and without stunting, with unadjusted odds ratios (ORs) for stunting.

HRP component	Children with stunting (n=300)	Children without stunting (n=150)	Unadjusted OR (95% CI)	*P* value
Any HRP, n (%)	206 (68.7)	48 (32.0)	4.67 (3.10 - 7.04)	<.001
Individual complications, n (%)				
Anemia (Hb[a]<11 g/dL)	145 (48.3)	34 (22.7)	3.17 (2.10 - 4.78)	<.001
Preeclampsia	46 (15.3)	6 (4.0)	4.33 (1.83 - 10.24)	<.001
Gestational diabetes	28 (9.3)	7 (4.7)	2.07 (1.01 - 4.25)	.05
Heart disease	12 (4.0)	2 (1.3)	3.08 (0.68 - 13.94)	.09
Asthma	18 (6.0)	5 (3.3)	1.86 (0.69 - 5.01)	.16
Number of HRP complications, n (%)				
None	94 (31.3)	102 (68.0)	Reference	—[b]
One complication	132 (44)	36 (24.0)	3.98 (2.49 - 6.36)	<.001
Two or more complications	74 (24.7)	12 (8.0)	6.71 (3.54 - 12.72)	<.001

[a]Hb: hemoglobin.

[b]Not applicable.

Bivariate and Multivariate Analysis

Table 3 presents bivariate and multivariate analysis results. After adjustment for all confounders, anemia (adjusted OR [aOR] 3.21, 95% CI 2.12 - 4.86), preeclampsia (aOR 4.37, 95% CI 2.18 - 8.76), and gestational diabetes (aOR 2.85, 95% CI 1.42 - 5.72) remained significantly associated with stunting. Children exposed to multiple HRP complications showed a 5.8-fold increased risk (aOR 5.80, 95% CI 3.26 - 10.32). Among confounders, maternal education (aOR 0.72, 95% CI 0.58 - 0.89), family income (aOR 0.68, 95% CI 0.52 - 0.89), and ANC visits (aOR 0.85, 95% CI 0.76 - 0.95) were independently protective (Figure 2).

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Table . Bivariate and multivariate logistic regression analysis of factors associated with stunting in children aged 12 - 59 months (n=450)[a].

Variable	Unadjusted OR[b] (95% CI)	*P* value	aOR[c] (95% CI)	*P* value
HRP[d] complications				
Anemia (Hb[e]<11 g/dL)	3.17 (2.10 - 4.78)	<.001	3.21 (2.12 - 4.86)	<.001
Preeclampsia	4.33 (1.83 - 10.24)	<.001	4.37 (2.18 - 8.76)	<.001
Gestational diabetes	2.07 (1.01 - 4.25)	.05	2.85 (1.42 - 5.72)	.003
Heart disease	3.08 (0.68 - 13.94)	.09	2.63 (0.57 - 12.14)	.22
Asthma	1.86 (0.69 - 5.01)	.16	1.74 (0.63 - 4.79)	.29
Number of HRP complications				
None	Reference	—[f]	Reference	—
One complication	3.98 (2.49 - 6.36)	<.001	3.45 (2.14 - 5.56)	<.001
Two or more complications	6.71 (3.54 - 12.72)	<.001	5.80 (3.26 - 10.32)	<.001
Confounding factors				
Maternal age (per year increase)	0.98 (0.94 - 1.02)	.34	1.01 (0.96 - 1.06)	.73
Maternal education (per level increase)	0.65 (0.52 - 0.81)	<.001	0.72 (0.58 - 0.89)	.003
Family income (per category increase)	0.58 (0.45 - 0.75)	<.001	0.68 (0.52 - 0.89)	.005
ANC[g] visits (per visit increase)	0.79 (0.71 - 0.88)	<.001	0.85 (0.76 - 0.95)	.006
Iron tablet consumption (<90 vs ≥90)	3.01 (2.03 - 4.47)	<.001	1.21 (0.75 - 1.95)	.43
Maternal nutrition (inadequate vs adequate)	4.47 (2.98 - 6.71)	<.001	1.34 (0.81 - 2.21)	.25
Family size (per person increase)	1.42 (1.23 - 1.64)	<.001	1.08 (0.92 - 1.27)	.34

[a]Model fit statistics: Hosmer-Lemeshow test: χ^2=6.84, *P*=.55; Nagelkerke R^2=0.412; area under receiver operating characteristic curve 0.812. Key finding: Multiple HRP complications (≥2) showed the strongest association with stunting (aOR 5.80), exceeding individual risks like anemia (aOR 3.21) or preeclampsia (aOR 4.37).

[b]OR: odds ratio.

[c]aOR: adjusted odds ratio.

[d]HRP: high-risk pregnancy.

[e]Hb: hemoglobin.

[f]Not applicable.

[g]ANC: antenatal care.

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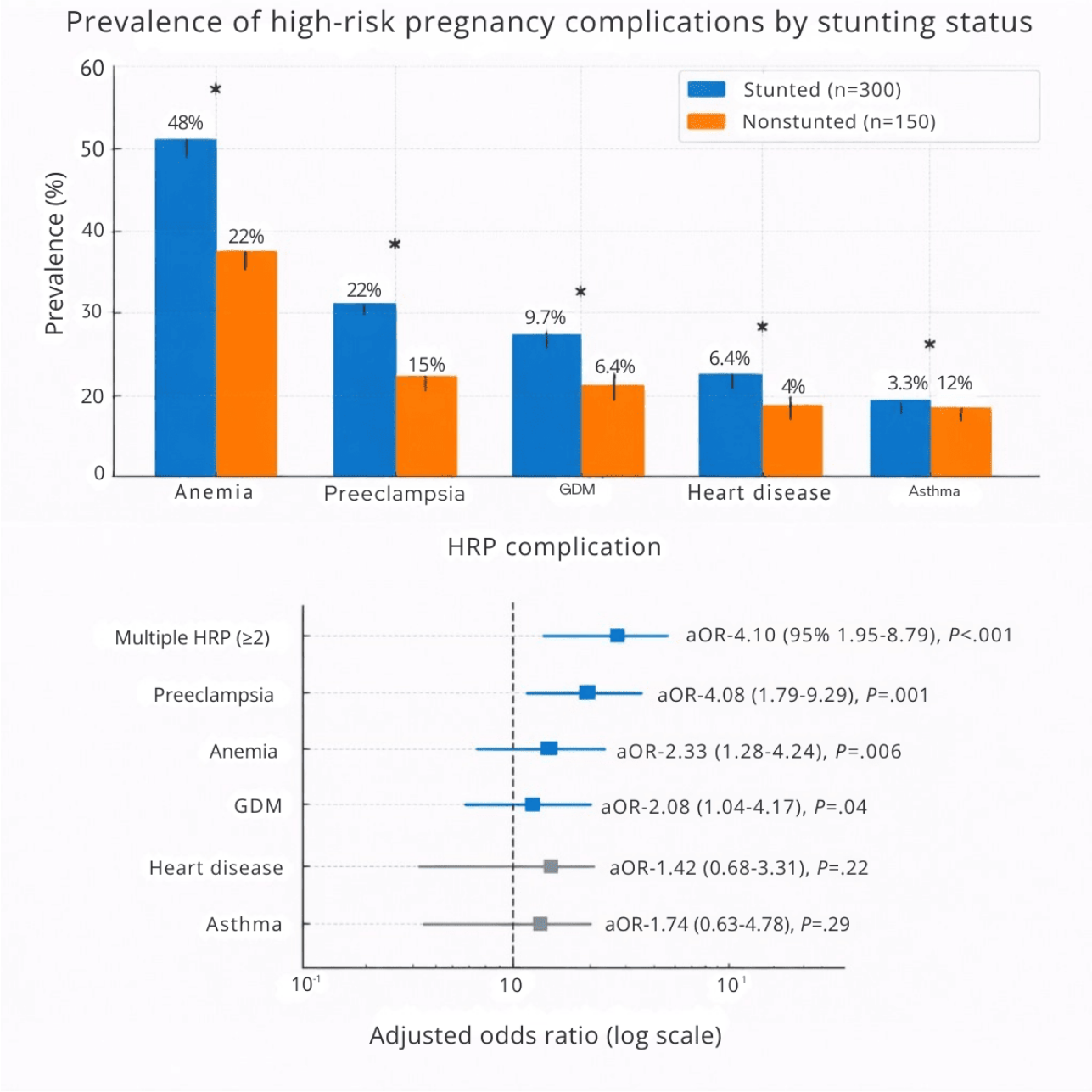
Figure 2. Adjusted odds ratios (aOR) from multivariate logistic regression showing the association between high-risk pregnancy (HRP) complications and stunting. Error bars represent 95% CIs. GDM: gestational diabetes mellitus.



Model Fit Statistics

The multivariate model showed good fit (Hosmer-Lemeshow test: χ^2=6.84, *P*=.55; Nagelkerke R^2=0.412; area under receiver operating characteristic curve=0.812) with no multicollinearity (all variance inflation factor <2.5).

Discussion

Main Findings and Theoretical Implications

This study provides compelling evidence that the cumulative burden of HRP complications, rather than isolated conditions, is the most powerful prenatal factor associated with stunting in Indonesian children. Our finding of a dose-response relationship, where exposure to two or more HRP complications increased stunting risk nearly 6-fold (aOR 5.80), offers strong empirical support for the DOHaD hypothesis [16]. Critically, our findings extend the DOHaD framework by demonstrating that it is not merely the presence of a single prenatal insult but the synergistic interaction of multiple simultaneous exposures that most profoundly disrupts fetal programming and elevates disease risk later in life [10,11,16]. This challenges the current ANC paradigm in Indonesia, which predominantly focuses on identifying and managing single risks like anemia or preeclampsia, potentially overlooking pregnancies with overlapping complications that confer substantially higher risk.

While anemia and preeclampsia remained significant independent predictors, their impact must be contextualized within the broader landscape of cumulative risk. Anemia (aOR 3.21) was the most prevalent single complication in our study (48.3% in the stunted group), consistent with Indonesia's high national maternal anemia burden of 48.9% [12]. However, its

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effect size was substantially lower than that of multiple HRP exposures. Similarly, preeclampsia (aOR 4.37), while strongly associated, was also outpaced by the combined risk. These findings indicate that isolated management of single risks during ANC may miss HRPs with overlapping complications, underscoring the need to understand the synergistic biological pathways that make the cumulative effect so profound.

Biological Mechanisms of Cumulative Risk

Our finding that multiple HRP complications exponentially increase stunting risk suggests synergistic biological effects rather than a simple additive model. According to the DOHaD framework, the fetus adapts to the intrauterine environment. However, multiple simultaneous stressors can overwhelm these adaptive mechanisms, leading to permanent alterations in developmental programming. Several interconnected pathways likely explain this phenomenon. First, placental dysfunction serves as a central hub. Conditions like preeclampsia directly impair placental blood flow, a process increasingly understood through specific placental biomarkers that predict adverse outcomes [36], leading to fetal hypoxia and nutrient restriction. When combined with maternal anemia, which reduces the oxygen-carrying capacity of the blood, the placenta's ability to deliver oxygen and nutrients is severely compromised, amplifying fetal growth restriction [19]. Second, oxidative stress and inflammation are common final pathways for many HRP complications. Preeclampsia, GDM (through hyperglycemia), and anemia (through hypoxia-reperfusion injury) all independently increase the production of reactive oxygen species. The concurrent presence of these conditions creates a pro-inflammatory and prooxidant intrauterine environment that can damage developing fetal tissues and disrupt metabolic programming [37]. Finally, the combined metabolic disruption is critical. For instance, a fetus exposed to both maternal anemia (nutrient deprivation) and GDM (excess glucose) receives conflicting and damaging signals, forcing it to adapt to both scarcity and toxicity simultaneously. This metabolic dissonance can have a more profound impact on endocrine and cardiovascular system development than either condition alone, setting the stage for postnatal growth faltering and stunting [38].

Role of Socioeconomic and Health Care Factors

While the biological mechanisms explain the heightened vulnerability from cumulative HRP exposures, our analysis also identified key protective factors. Maternal education (aOR 0.72), family income (aOR 0.68), and ANC visits (aOR 0.85) were significantly associated with reduced stunting risk. However, their modest effect sizes reveal a complex reality and highlight the limitations of current interventions. This complexity is further illustrated by the shifting significance of iron tablet consumption and maternal nutrition. Both showed strong associations in bivariate analysis but lost significance after adjustment for socioeconomic confounders, suggesting their effects are largely mediated by upstream factors like education and income [26]. It appears that mothers with higher education and greater resources are better equipped to maintain adequate nutrition and adhere to supplementation, positioning these socioeconomic conditions as more fundamental determinants of child growth [3,14]. This finding underscores that interventions focusing solely on nutrient provision or increasing ANC visit frequency, without addressing the underlying socioeconomic context, are likely to have limited long-term impact on stunting prevention.

Strengths

This study has several methodological strengths. First, the large, representative sample with rigorous multistage cluster sampling enhances external validity. Second, comprehensive adjustment for socioeconomic and health care confounders strengthens our analytical approach. Third, the use of contemporary international guidelines [22,25] for HRP diagnosis ensures methodological rigor and comparability. Fourth, triangulation of multiple data sources minimizes misclassification bias. Fifth, the application of advanced statistical methods with appropriate model fit assessment ensures the robustness of our findings.

Limitations

Despite these strengths, several limitations must be acknowledged. Our interpretation of the findings is constrained by the study's retrospective observational design and data sources, which also impact the generalizability of our results.

- Study design and causality: The retrospective, cross-sectional nature of our analysis limits our ability to establish temporality and infer direct causality. While we have identified strong and statistically significant associations, we cannot confirm that the observed HRP complications directly caused stunting, only that they are robustly linked within the DOHaD framework.
- Potential for selection bias: A significant limitation is the exclusion of 540 participants (54.5% of the initial sample) due to incomplete data. This raises a substantial risk of selection bias. It is plausible that mothers and children excluded from the analysis faced greater socioeconomic challenges or more severe health complications, which could lead to an overestimation of the effect sizes reported. Future research should implement more robust data collection strategies to minimize exclusions and ensure findings are more generalizable.
- Data constraints and unmeasured mediators: Our reliance on secondary data from medical records and MCH handbooks, while practical, is subject to potential inaccuracies in documentation. Furthermore, we could not assess the severity or gestational timing of HRP complications, which may have differential impacts. Critically, our dataset did not include key perinatal and postnatal mediators such as birth weight, gestational age, and breastfeeding practices that are central to the DOHaD framework. Consequently, we are unable to quantify the indirect effects of HRP and can only report the total effect, not the specific direct and indirect pathways. For instance, birth weight and gestational age are critical outcomes of a complicated pregnancy and are themselves strong predictors of stunting [7]. Similarly, breastfeeding practices (eg, exclusivity and duration) can be influenced by maternal health and are a major determinant of postnatal growth [7]. Future research should aim to integrate these perinatal and postnatal variables to provide a more complete

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understanding of the DOHaD mechanisms in this context [9].

- Generalizability of findings: This study was conducted in Sleman Regency, a region with relatively high development indices and health care access compared to many high-burden areas in Indonesia, such as Central Papua [5,39]. Therefore, while the fundamental biological relationship between cumulative HRP and stunting is likely universal [10], the specific prevalence and effect sizes observed may not be directly generalizable to less-resourced settings. Our findings are most directly applicable to similar regencies in Java, and they serve as a crucial call for further research in more diverse contexts.

Implications for Policy and Practice

Our findings align with studies from other LMICs showing strong associations between maternal HRP and child stunting. A recent systematic review by Beal et al [20] reported similar effect sizes for anemia and preeclampsia in Indonesian children. However, our study adds significant value by being the first to examine multiple HRP complications simultaneously, demonstrating their synergistic cumulative effect while controlling for a comprehensive set of confounders using contemporary international guidelines [22,25].

The Indonesian context presents unique challenges and variations. In our study area of Sleman, anemia prevalence was high (48.3%), yet the national stunting burden shows stark disparities, from 7.2% in Bali to 39.4% in Central Papua [4,5], a pattern where the latest analyses confirm that socioeconomic factors remain a primary driver of stunting nationally [13,40]. This complex landscape, characterized by a dual burden of malnutrition and epidemiological transition, underscores why a single-risk approach is insufficient. Our analysis demonstrates that cumulative risk assessment better predicts stunting in this diverse environment.

Given this robust evidence, our findings have direct and critical implications for MCH policy in Indonesia. The current single-risk-focused ANC paradigm is insufficient to address the complex, cumulative risks we have identified. We recommend the following actionable shifts:

- Revise ANC protocols to incorporate cumulative risk assessment: National guidelines should be updated to include a cumulative risk scoring system. Pregnancies with two or more identified HRP complications should be automatically flagged as “very high risk” and prioritized for intensive, integrated management involving both obstetricians and nutritionists.
- Integrate MCH services: To break the intergenerational cycle of malnutrition, health information systems must be linked. A mother’s history of cumulative HRP complications should trigger targeted postnatal follow-up for her infant, including enhanced growth monitoring and nutritional support, regardless of the infant’s initial anthropometric status.
- Strengthen health system capacity: Addressing cumulative risk requires a well-trained and empowered workforce. Investment in training for ANC providers to identify, manage, and counsel patients with multiple complications is essential. This includes training on the DOHaD framework to enhance their understanding of the long-term implications of prenatal care quality.

Strengthen health system Capacity: Addressing cumulative risk requires a well-trained and empowered workforce. Investment in training for ANC providers to identify, manage, and counsel patients with multiple complications is essential. This includes training on the DOHaD framework to enhance their understanding of the long-term implications of prenatal care quality.

By adopting a cumulative risk framework aligned with the DOHaD hypothesis, Indonesia can accelerate progress toward reducing stunting and breaking the cycle of intergenerational malnutrition.

Research Recommendations

Prospective cohort studies are needed to establish temporality and explore mediating pathways in the HRP-stunting relationship. Implementation research on integrated HRP-stunting prevention programs could identify effective delivery strategies. Finally, exploration of biological mechanisms could advance our understanding of developmental programming and identify novel intervention targets.

Conclusion

In conclusion, this study provides compelling evidence that the cumulative burden of HRP complications is the most powerful factor associated with stunting in Indonesian children. While individual complications remain significant, their impact is substantially lower than that of cumulative exposures. This challenges the current single-risk-focused ANC paradigm and highlights the urgent need for a shift toward integrated, cumulative risk management strategies. Such a paradigm shift, aligned with the DOHaD framework, is essential for effectively breaking the intergenerational cycle of malnutrition in Indonesia.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to respondents’ privacy but are available from the corresponding author on reasonable request.

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Authors' Contributions

Conceptualization: WW
Methodology: WW
Writing – original draft: WW
Data analysis: WW
Data curation: HMR
Formal analysis: HMR
Investigation: HMR
Writing: HMR
Review and editing: WW, HMR

Conflicts of Interest

None declared.

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Abbreviations

ANC: antenatal care
aOR: adjusted odds ratio
DOHaD: Developmental Origins of Health and Disease
GDM: gestational diabetes mellitus
HRP: high-risk pregnancy
LMICs: low- and middle-income countries
MCH: maternal and child health
OR: odds ratio

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STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
WHO: World Health Organization

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Development of Sarcopenia Management Systems for Former Homeless Older Adults Residing in Supportive Housing: Mixed Methods Study

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Abstract

Background: Former homeless older adults represent a highly vulnerable population facing substantial community health challenges, including an elevated risk of sarcopenia due to compounded health and social disadvantages. Developing a context-specific management system is crucial for enhancing early detection, prevention, and care within supportive housing settings.

Objective: This study aimed to develop and evaluate the feasibility of a sarcopenia management system for former homeless older adults in Thailand.

Methods: mixed methods design was used, consisting of three phases: (1) development, (2) implementation, and (3) preliminary evaluation testing. The development phase engaged 18 stakeholders and 32 focus group participants (former homeless older adults and staff) through 2 rounds of consultation. The system was subsequently implemented and preliminarily evaluated for feasibility, perceived quality, perceived benefits, and user satisfaction.

Results: Through qualitative methods and a systematic review, a context-specific sarcopenia management system was developed for former homeless older adults. The system comprised five core components screening, classification, management, follow-up, evaluation and was integrated into routine care processes involving multidisciplinary staff and homeless volunteers within a supportive housing setting. The system was subsequently implemented and preliminarily tested among 116 former homeless older adults living in a supportive housing facility in Thailand. Preliminary findings indicated good feasibility and acceptability of the system. The perceived quality of the system achieved a mean score of 2.6 (SD 0.48), while perceived benefits were rated at 3.8 (SD 0.40). Overall satisfaction with system use and implementation processes achieved mean scores of 2.8 (SD 0.41) and 2.72 (SD 0.79), respectively, indicating high user satisfaction.

Conclusions: This study presents the first context-sensitive sarcopenia management system specifically developed for former homeless older adults in supportive housing in Thailand. The system was well accepted and shows promise for strengthening early detection, prevention, and management of sarcopenia in community-based housing settings.

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KEYWORDS

sarcopenia; homelessness; older adults; supportive housing; community health systems; Thailand

Introduction

Sarcopenia has become a pressing public health concern amid global population aging, characterized by a progressive and generalized loss of skeletal muscle mass and function [1]. This condition not only heightens the risk of physical disability [2,3] and frailty [4] but is also linked to adverse outcomes such as falls [5], fractures [6], hospitalization [7], and mortality [8]. Previous studies have identified age, low physical activity, malnutrition [9], and poor diet quality [10] as major risk factors for sarcopenia.

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Among vulnerable populations, former homeless older adults residing in supportive housing represent a group in whom the prevalence of sarcopenia is likely underestimated and inadequately addressed. Prolonged exposure to poverty, multimorbidity [11], chronic diseases [12,13], persistent health disparities, and limited access to health care services place individuals with a history of homelessness at substantially elevated health risks [14,15]. As a result, this population experiences accelerated aging and premature morbidity, often being classified as older adults at approximately aged 50 years, which is markedly earlier than the general population, typically defined as 60‐65 years, depending on national criteria [16]. This premature aging trajectory contributes to profound health inequities, increased vulnerability to sarcopenia, and a heightened risk of early mortality from largely preventable or manageable conditions [12,17]. Notably, the average age at death among individuals with lived experience of homelessness is approximately 51.6 years, nearly 2 decades younger than that observed in other socioeconomically deprived populations [18].

Despite this elevated vulnerability, sarcopenia among former homeless older adults frequently remains underrecognized and inadequately managed, particularly within supportive housing settings where health and social care resources are constrained. In community-based environments, early identification of sarcopenia is often limited by limited access to body composition assessment tools, such as bioelectrical impedance analysis (BIA), which reduces the feasibility of conventional diagnostic approaches. To address these practical challenges, the Asian Working Group for Sarcopenia (AWGS) 2019 introduced the concept of possible sarcopenia to facilitate early screening and timely intervention in nonclinical and resource-limited settings [19].

Although community-oriented screening frameworks such as the AWGS criteria are available, screening alone is insufficient to address the complex and ongoing needs of formerly homeless older adults. What remains largely absent is a structured, integrated management system that translates early identification into coordinated prevention strategies, personalized interventions, and sustained follow-up within supportive housing contexts. The lack of such a system limits the ability of health and social care providers to deliver proactive, consistent, and context-appropriate care, thereby perpetuating avoidable functional decline and health inequities in this underserved population. Accordingly, there is a critical need to develop a context-sensitive sarcopenia management system tailored to the realities of supportive housing settings. Such a system has the potential to strengthen early detection, support timely and individualized interventions, and promote functional independence and well-being among former homeless older adults. Therefore, this study aimed to develop and evaluate a sarcopenia management system for former homeless older adults residing in a supportive housing facility in Thailand.

Methods

Study Design

This study used an embedded mixed-methods design [20] to develop and evaluate a sarcopenia management system for former homeless older adults residing in a supportive housing facility in Thailand. The design was selected to support system development within a real-world institutional context, where health care delivery is shaped by organizational structures, staff-led processes, and resident dependency. Qualitative and quantitative components were integrated across three sequential phases: system development, implementation, and preliminary evaluation. Qualitative methods were used to explore contextual needs, operational challenges, and stakeholder perspectives, informing the design and refinement of system components. Quantitative methods were subsequently applied to assess the feasibility, acceptability, and perceived performance of the developed system during pilot implementation [21]. The overall development and evaluation process was guided by Donabedian's framework [22], which conceptualizes health care quality through interrelated dimensions of structure, process, and outcomes. This framework provided a systematic approach to designing a context-sensitive management system that aligns organizational resources and care processes with measurable outcomes relevant to sarcopenia prevention and management in supportive housing settings. Purposive sampling was used to select the supportive housing facility and to recruit participants across 2 groups. For the preliminary evaluation phase, former homeless older adults aged 50 years or older who had resided in the facility for at least 6 months were eligible for inclusion. Individuals with cognitive impairment, defined as a Chula Mental Test (CMT) score below 15, or those unable to provide written informed consent, were excluded. For the system development phase, stakeholders, including administrators, staff, first-aid personnel, and support staff aged 18 years or older with proficiency in Thai, were recruited purposively from 6 of the 7 dormitories within the facility. The study was conducted at a government-operated supportive housing facility in Nonthaburi Province, Thailand, which provides shelter, basic health care, and rehabilitation services for individuals experiencing homelessness.

Study Procedure

This study was conducted between March 2024 and March 2025 and followed a 3-phase, embedded mixed-methods approach comprising system development, implementation, and preliminary evaluation. The study procedure was designed to integrate evidence from systematic reviews, previously published qualitative findings, and stakeholder engagement to develop and test a context-sensitive sarcopenia management system for former homeless older adults residing in supportive housing. Purposive sampling was used to recruit participants who met the predefined eligibility criteria for each study phase.

Phase 1: System Development

Phase 1 focused on developing the sarcopenia management system using multiple sources of evidence, including 2 previously published systematic reviews and 1 qualitative study.

First, findings from 2 systematic reviews were synthesized to inform system priorities and intervention selection [23,24]. The first review identified key personal and health-related factors associated with sarcopenia among older adults in Thailand, including BMI, waist circumference, type 2 diabetes mellitus, mild cognitive impairment, and depression [23]. These findings

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informed risk identification and screening priorities within the system. The second review examined the effectiveness of protein supplementation combined with resistance exercise for sarcopenia rehabilitation in community settings and demonstrated improvements in muscle mass and strength [24]. These findings guided the selection of intervention components suitable for implementation in supportive housing.

Second, the development process was informed by previous qualitative findings [21]. This qualitative inquiry explored lived experiences, perceptions, and contextual challenges related to sarcopenia among former homeless older adults, as well as perspectives of staff involved in their care. Key themes highlighted barriers to sarcopenia prevention and management, including limited health knowledge, constrained physical activity opportunities, nutritional challenges, and structural limitations within institutional care settings. These qualitative insights provided critical contextual understanding that complemented the systematic review evidence and directly informed the design and contextual adaptation of the system components [21].

Third, stakeholder engagement was integrated into the development process. In this study, stakeholders were defined as administrators, general staff, first aid staff, chefs, and homeless volunteer representatives who were former homeless residents serving in caregiving and supervisory roles within each dormitory. Thirty stakeholders participated in 2 structured meetings to validate system components, identify feasible care processes, and refine implementation strategies. This phase established the system's framework, building on insights from the prior qualitative study, particularly the 2 overarching themes, "Insufficiency" and "The Price of Plenty" [21]. Accordingly, the implementation plan emphasized practical and context-sensitive strategies to promote dietary protein intake, oral health, and physical activity engagement. Sustainable food-based protein strategies included Nile tilapia cultivation and soy milk production, alongside resistance exercise training as the core physical activity component.

Phase 2: System Implementation

Phase 2 involved implementing the sarcopenia management system in supportive housing. Implementation activities included three major components: (1) Training for sarcopenia screening, (2) implementing sarcopenia screening and classification, and (3) implementing interventions.

1. Training for sarcopenia screening: This process involved engagement of 18 staff members and 12 homeless volunteers. There were 2 main training sessions, including assessment of the 5-item Mini Sarcopenia Risk Assessment (MSRA) and measurements of calf circumference, handgrip strength, and gait speed. The research team also developed educational materials, including resistance exercise demonstration videos, and provided training on sarcopenia screening and exercise techniques.
2. Implementing sarcopenia screening and classifying sarcopenia risk and possible sarcopenia according to the AWGS 2019 criteria. This part recruited 116 older adults aged 50 years and above who had resided in supportive housing for at least 6 months and met the inclusion criteria for independence in Activities of Daily Living and stable chronic physical or mental health conditions. Impaired cognitive function, as defined by a CMT score below 15, was excluded. Screening and classification of sarcopenia risk and possible sarcopenia were then conducted according to the AWGS 2019 criteria.
3. Implementing interventions, including resistance exercise, Nile tilapia cultivation, and soy milk as locally feasible strategies to improve access to affordable dietary protein.

Participants engaged in a supervised resistance exercise program for 8 months, 5 days per week, with each session lasting approximately 45 minutes. The exercise program was led by trained staff and supported by instructional videos to ensure safe and consistent implementation. Participants also received nutritional support through soy milk supplementation. A hands-on demonstration was conducted to guide participants through each step of soy milk production. Soy milk was prepared and provided once per month for 8 consecutive months and served after resistance exercise sessions as a locally available dietary protein source. In addition, 2 former homeless older adult volunteers were assigned as tilapia cultivation leaders and were responsible for daily fish care, basic maintenance, and coordination with staff for harvesting and distribution to older adults and other former homeless older adults. Nile tilapia cultivation was maintained continuously for 8 months, and the fish were harvested periodically and prepared as meals, serving as a sustainable, locally available source of dietary protein to support the sarcopenia management program.

Phase 3: Preliminary Evaluation

The preliminary evaluation phase included 116 homeless older adults, similar to Phase 2. Based on system implementation processes, the preliminary evaluation included perceived benefits, perceived quality, and satisfaction of the sarcopenia management system as assessed by staff members and former homeless older adults. Findings from this phase were used to inform the refinement of system components and assess readiness for broader application.

The development process for the sarcopenia management system, through stakeholder engagement, for homeless older adults in supportive housing, is illustrated in Figure 1.

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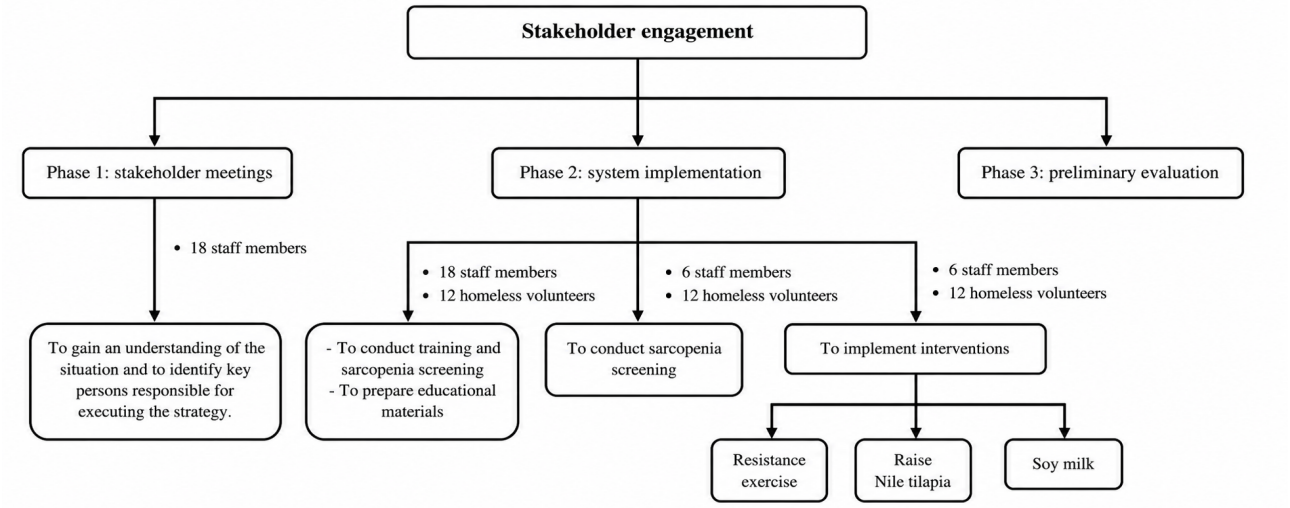
Figure 1. Development process of the sarcopenia management system.



Setting

This study was conducted at a supportive housing facility located in Nonthaburi Province, Thailand. The facility serves as a pivotal institution for vulnerable populations from both Nonthaburi and Bangkok. It was purposively selected because of its central role in addressing homelessness, particularly in Bangkok, which reports one of the highest rates of homelessness in the country. The supportive housing operates as a closed and structured system that provides temporary shelter, basic health care, and rehabilitation services for individuals experiencing homelessness, vagrancy, begging, or posthospital discharge. Its primary mission is to prepare former homeless individuals for reintegration into their families and communities while addressing their immediate physical, psychological, and social needs.

Organizational Structure and Dormitory Arrangement

Administratively, the facility is organized under a hierarchical management structure comprising 1 head administrator, administrators, first aid staff members, 11 general staff members, and chefs, all of whom support daily operations and resident care. The facility is divided into 7 dormitories that accommodate residents based on functional status and daily activity patterns.

For the purposes of this study, 6 of the 7 dormitories were included in stakeholder engagement, focus group discussions, and implementation activities. Dormitory 7 was excluded because it primarily housed older adults who regularly worked outside the facility and spent substantial portions of the day away from the home. As a result, former homeless people in this dormitory had limited exposure to routine institutional care processes and intervention activities. To ensure contextual consistency and relevance to the sarcopenia management system, data collection and implementation activities were therefore conducted in the remaining 6 dormitories.

Research Instruments

The research instruments used in this mixed-methods study included both qualitative and quantitative tools, applied across the 3 phases. In phase 1 (system development), qualitative data were collected through stakeholder consultations using semistructured guiding questions to identify priorities and refine system components. In phase 2 (system implementation), quantitative instruments were used for participant screening and sarcopenia assessment and classification, including the CMT, Barthel ADL Index, Modified MSRA, calf circumference, handgrip strength, gait speed, and BIA when feasible. Qualitative feedback from stakeholders was also obtained during implementation through structured consultations and brief semistructured interviews to support process evaluation and system refinement. In phase 3 (preliminary evaluation), researchers developed quantitative questionnaires to assess perceived benefits, quality, and satisfaction with the sarcopenia management system.

Screening Tools for Participant Recruitment

The following instruments were used as eligibility screening tools to assess cognitive function and functional status prior to enrollment in the study. Participants who did not meet the predefined criteria were excluded.

1. The CMT, developed by Jitaphankul [25], was used to assess cognitive function disorders among former homeless older adults. The test comprised 13 items with 19 possible answers, yielding scores ranging from 0 to 19. Each item was scored as 0 for an incorrect response and 1 for a correct response. A score of less than 15 on the CMT indicated the presence of a cognitive function disorder. In this study, participants were required to achieve a CMT score of 15 or higher to advance to the next phase of the research. For those who scored below 15, their information was shared with stakeholders for further assessment and follow-up.
2. The Barthel ADL Index, developed by Jitaphankul [26], was used to evaluate ability to perform daily activities. This index consisted of ten questions, with a total score ranging from 0 to 20. Each score reflected a specific level of dependence, providing valuable insights into the participants' functional abilities. Scores between 0 and 4 indicated total dependence, while scores from 5 to 8 represented severe dependence. Participants who scored between 9 and 11 were classified as having moderate to severe dependence, whereas those scoring between 12 and 20 were considered minimally dependent.

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Instruments for Early Detection and Classification of Sarcopenia

The identification and classification of sarcopenia in this study were based on the AWGS 2019 criteria [19]. In the supportive housing setting, screening and classification primarily focused on identifying sarcopenia risk and possible sarcopenia using calf circumference, handgrip strength, and gait speed. BIA was incorporated into the management algorithm as a confirmatory assessment for suspected sarcopenia or severe sarcopenia when feasible or when referral to health care services was indicated. According to the system classification, participants were categorized into three groups: green (no sarcopenia risk), yellow (case finding or possible sarcopenia), and red (sarcopenia or severe sarcopenia). The selected assessment tools are established methods recommended by the AWGS 2019 criteria and are widely used in older adult populations to assess sarcopenia risk, muscle strength, physical performance, and muscle mass [19].

1. Screening tool for identifying sarcopenia risk: the researchers used the Modified MSRA, a 5-item instrument initially developed by Rossi et al [27]. The 5 items have possible scores ranging from 0 to 34, and a total score < 30 indicates a risk of sarcopenia. The MSRA assessment includes the following five components: (1) age, (2) the number of hospitalizations in the last year, (3) the level of physical activity, (4) regular meal consumption, and (5) weight loss in the last year. The questionnaires were translated from English to Thai by Akarapornkrailert (2020). The content validity index (CVI) for the MSRA 5-item questionnaire was established at 1.0 [28].
2. The screening tool for identifying possible sarcopenia was based on the criteria of the AWGS 2019 [19]. These assessments involve measuring calf circumference, handgrip strength, and gait speed. Sarcopenia management is based on the surveillance, maintenance, and reversal classification. The insights from the qualitative part guide the development of a management program combined with a thorough review of relevant literature as follows: (1) the green group refers to older homeless adults who are not at risk of developing sarcopenia following the use of MSRA assessment, (2) the yellow group refers to older homeless adults identified as case-finding or possible sarcopenia following CC assessment, handgrip strength assessment, and gait speed assessment, and (3) the red group refers to older homeless adults diagnosed with sarcopenia and severe sarcopenia.
    1. Calf circumference was measured using a standard tape with 1 millimeter precision. Participants sat with their knees bent at 90 degrees while the tape was placed around the widest part of the calf, parallel to the floor, and pulled taut. The measurement was recorded in centimeters, with values <34 cm for men and <33 cm for women indicating a case finding.
    2. Muscle strength was measured using a digital handgrip dynamometer, calibrated to ISO standards. Participants sat comfortably and gripped the dynamometer with their dominant hand, keeping the elbow at 90 degrees and the arm away from the trunk. After exerting maximal force, the test was performed twice, and the highest value was recorded in kilograms (kg). Handgrip strength below 28 kg for men and 18 kg for women indicated low muscle strength.
    3. Physical performance was assessed by measuring walking speed over a 6-meter distance using a stopwatch and a tape measure. The researcher first demonstrated walking at a normal pace, then participants stood at the starting point. On the “start” signal, the timer began and stopped when the participant reached the end. The time taken to walk 6 meters was recorded in seconds. Walking speed was calculated as distance/time (eg, 6 meters / 9 s=0.67 m/s). A walking speed ≤1 m/s indicated low physical performance.

Instruments for Preliminary Evaluation of the Sarcopenia Management System

These instruments were used to assess the quality, perceived benefits, and satisfaction associated with the sarcopenia management system among former homeless older adults and stakeholders.

1. Demographic and health questionnaire for older homeless adults: the questionnaire was developed from literature reviews by researchers. There are questions, including age, gender, years of homelessness among former homeless older adults in supportive housing, education level, the presence and type of chronic diseases, and nutritional status, which were assessed using the Short Form Mini Nutritional Assessment (MNA-SF). Additional health-related information included weight loss, smoking status, history of falls, and physical activity levels.
2. Benefits of the sarcopenia management systems questionnaire: the questionnaire was developed by the researchers based on an extensive review of relevant literature and was designed to assess the perceived benefits of the sarcopenia management system. The instrument included items addressing the benefits of sarcopenia screening, follow-up, maintenance, and reversal, as well as the overall benefits of the service. Participants rated each item on a 4-point Likert scale: excellent, good, fair, and needs improvement. In addition, an open-ended question was included to elicit participants’ opinions and suggestions on the system’s benefits. The Content Validity Index (CVI) was 1.00.
3. Quality of sarcopenia management systems questionnaire: the questionnaire was developed by researchers based on an extensive review of relevant literature and was designed to assess the quality of the sarcopenia management system. The instrument included domains related to process quality, staff quality, and overall service quality. Participants rated each item on a 3-point Likert scale: beyond expected, as expected, and below expected. In addition, an open-ended question was included to allow participants to provide comments and suggestions on the system’s quality. The CVI was 1.00.
4. Satisfaction of the sarcopenia management systems questionnaire: the questionnaire was developed by researchers based on an extensive review of relevant literature and was designed to assess the satisfaction of staff members and former homeless older adults following their

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use of the sarcopenia management system. The instrument included domains related to satisfaction with staff providing services, satisfaction with facilities, and overall service satisfaction. Participants rated each item on a 3-point Likert scale: beyond expected, as expected, and below expected. In addition, 1 open-ended question was included to elicit participants' opinions and suggestions regarding the system. The CVI was 1.00.

Data Analysis

Data were organized and analyzed separately for each phase. In phase 1 (system development), findings from 2 previously published systematic reviews and 1 qualitative study were synthesized narratively and integrated with data from stakeholder consultations to inform the design and contextual adaptation of the sarcopenia management system. Qualitative data from stakeholder consultations were summarized according to key themes related to system priorities, feasibility, and implementation strategies. In phase 2 (system implementation), process-related qualitative feedback obtained from structured consultations and brief semistructured interviews was reviewed and summarized to support ongoing refinement of the system. Quantitative screening and assessment data were used descriptively to classify participants according to the AWGS 2019 criteria and guide individualized management. In phase 3 (preliminary evaluation), the researchers analyzed data using SPSS 21.0 (Mahidol University). First, the raw data were reviewed, and the data entry process was checked for missing values and inconsistencies by performing frequency analysis to ensure data quality. Next, the sarcopenia screening (including calf circumference, gait speed, handgrip strength, and appendicular skeletal muscle index [ASMI]) was analyzed using descriptive statistics, including frequency, percentage, mean (SD), and range. The efficiency of the sarcopenia service system was evaluated using two questionnaires: one assessing the benefits of the service and the other evaluating its quality, both using frequency and percentage analyses. Finally, satisfaction with the sarcopenia service system was analyzed in a similar manner, using frequency and percentage.

Ethical Considerations

In this research study, human research ethics were considered and approved by the research committee of the Faculty of Medicine at Ramathibodi Hospital, Mahidol University (approval number MURA2024/64). The primary researcher introduced herself with the research authorization letter and requested permission to collect data from the Department of Social Development and Welfare. Data collection was conducted strictly in accordance with ethical principles, with the researcher explaining the study's objectives and the steps involved to participants. Participants were informed of their right to withdraw from the study at any time, without needing to provide a reason. Additionally, all data were kept confidential unless the participant authorized its disclosure. To ensure privacy, participants were assigned fictitious names, and identifying information was not shared. Audio recordings, transcripts, and coding were stored in a locked cabinet, and all data were deleted after the research process was completed. Only the findings were published, and all data were destroyed 1 year after publication.

Results

In phase 1, based on prior systematic reviews [23,24] and qualitative findings [21], and AWGS 2019 criteria, the sarcopenia management system (Figure 2) was developed to promote multidisciplinary collaboration among administrators, staff, and health professionals and to ensure early detection and ongoing care for older adults in supportive housing facilities. The sarcopenia management system comprises five core components: screening, classification, management, follow-up, and evaluation. Screening tools include assessments of the 5-item MSRA and health-related factors, including BMI, waist circumference, type 2 diabetes and other noncommunicable diseases, mild cognitive impairment, depression, calf circumference, handgrip strength, and gait speed, among older adults residing in supportive housing. Classification was then made into three risk levels: green (no risk), yellow (possible sarcopenia), and red (sarcopenia or severe sarcopenia), each linked to specific management strategies. A follow-up assessment for sarcopenia was scheduled 12 weeks after completion of the management program through education, structured resistance exercise, and nutritional interventions. In addition, annual rescreening was conducted to monitor long-term outcomes and progression.

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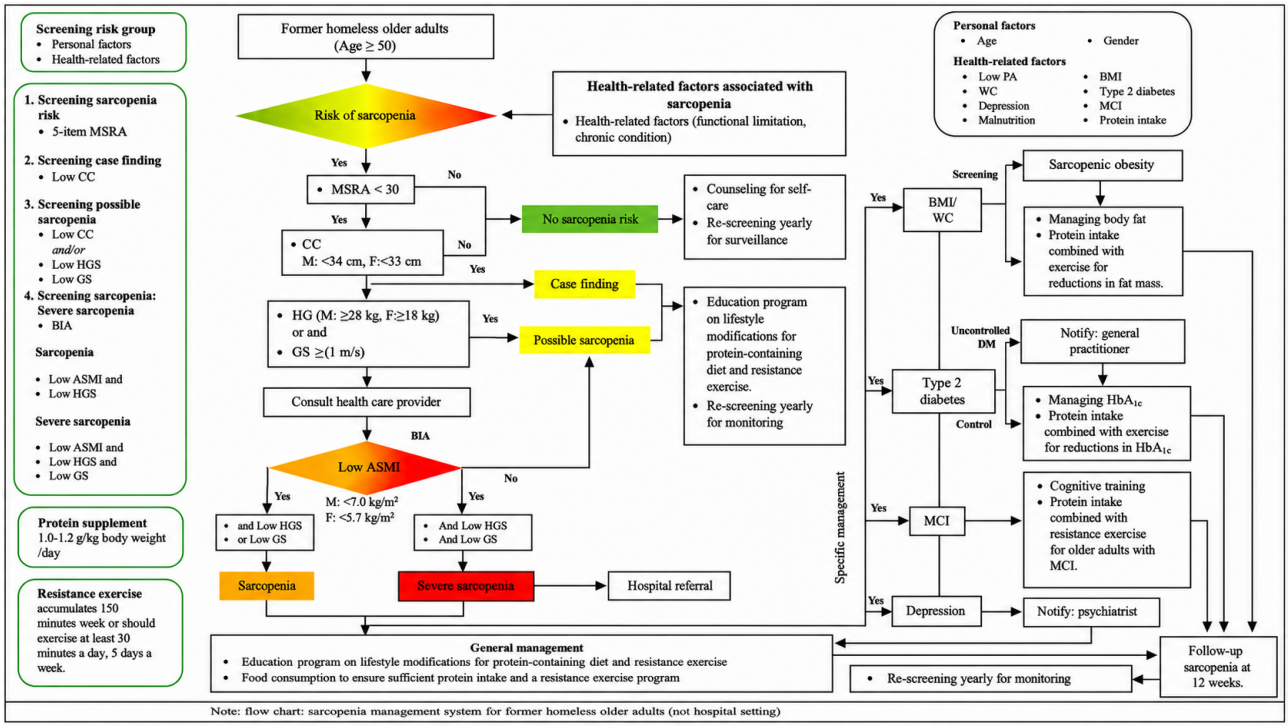
Figure 2. Flowchart of sarcopenia screening and management in supportive housing. ASMI: appendicular skeletal muscle mass index; BIA: bioelectrical impedance analysis; CC: calf circumference; DM: diabetes mellitus; GS: gait speed; HGS: handgrip strength; HbA_{1c}: glycated hemoglobin; MCI: mild cognitive impairment; MSRA: Mini Sarcopenia Risk Assessment; PA: physical activity; VC: vital capacity; WC: waist circumference.



In phase 2, the sarcopenia management system was implemented with the involvement of 30 stakeholders, including 1 head administrator, 2 administrators, 2 first-aid staff, 11 general staff members, 2 chefs, and 12 homeless volunteer representatives. Their ages ranged from 25 to 58 years, with most (13/18, 72.2%) between 41 and 60 years. The gender distribution was balanced (9/18, 50% male; 9/18, 50% female). The mean duration of employment was 8.22 (SD 7.73) years, with two-thirds (12/18, 66.7%) having worked for more than 5 years. Over half (10/18, 55.5%) held a bachelor's or graduate degree, while 38.9% (7/18) had completed secondary education, and 5.6% (1/18) held a diploma. Similarly, the 12 homeless volunteer representatives had ages ranging from 36 to 73 years, with a mean age of 49.42 (SD 10.40) years. Most (8/12, 66.7%) were aged 18-49 years and were male (8/12, 66.7%). The mean duration of residence in the home for the destitute was 8.22 (SD = 7.73) years, with over half (7/12, 58.3%) having lived there for 1-3 years. One-third (4/12, 33.3%) had no formal education.

A total of 116 former homeless older adults also participated in phase 2. Their age ranged from 50 to 83 years, with a mean of 59.1 (SD 7.8) years. The majority were aged 50 - 59 years (70/116, 60.3%), and more than half were male (77/116, 66.4%). Regarding the duration of former homeless older adults in the supportive housing, 55.2% (64/116) had resided there for 1 - 3 years. Regarding educational attainment, nearly half of the participants completed primary school (57/116, 49.1%). Most older adults (101/116, 87.1%) reported having at least 1 chronic illness, including psychiatric disorders (71/116, 61.2%), hypertension (37/116, 31.9%), dyslipidemia (28/116, 24.1%), and type 2 diabetes (15/116, 12.9%). Regarding nutritional status, 51.7% (60/116) of participants had Short Form (MNA-SF) scores less than 12, indicating malnutrition or risk of malnutrition. Recent weight loss was reported by 15.5% (18/116) of participants, 62.9% (73/116) reported a history of smoking, while 28.4% (33/116) reported a history of falls. Regarding physical activity levels, 64.6% (75/116) were classified as sedentary, while 32.8% (38/116) engaged in moderate physical activity.

The calf circumference among participants ranged from 25.5 to 42.8 cm, with a mean of 31.51 (SD 3.16) cm. The majority of participants (93/116, 80.2%) had normal calf circumference, while 19.8% (23/116) had low calf circumference. Handgrip strength ranged from 5.8 to 42.6 kg, with a mean of 19.82 (SD 7.23) kg. Based on established cut-off values, 77.6% (90/116) of participants were classified as having low handgrip strength, whereas 22.4% (26/116) had normal handgrip strength. Gait speed ranged from 3.27 to 22.45 m/s, with a mean of 7.56 (SD 3.41) m/s. Over half of the participants (73/116, 62.9%) demonstrated normal gait speed, while 37.1% (43/116) had low gait speed.

Regarding sarcopenia risk, 19.8% (23/116) of participants were classified as having no sarcopenia risk (green zone), while 80.2% (93/116) were classified in the yellow zone through case finding. Overall, 78.4% (91/116) of participants met the AWGS 2019 criteria for possible sarcopenia. Participants in both the green and yellow zones performed resistance exercise and consumed Nile Tilapia and soy milk.

In phase 3, a preliminary evaluation was conducted to assess the sarcopenia management system's efficiency, perceived benefits, quality, and satisfaction. Perceived benefits were high for both older adults and staff. Former homeless older adults rated system benefits with a mean of 3.8 (SD 0.4), while staff rated benefits slightly higher (mean 3.9, SD 0.3), indicating

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shared recognition of the system's efficiency. The perceived quality of the sarcopenia management system among former homeless older adults achieved a mean score of 2.6 (SD 0.5). Similarly, staff rated system quality at a mean of 2.6 (SD 0.53), reflecting consistent perceptions between users and providers. Satisfaction with system processes and procedures was rated similarly (mean 2.6, SD 0.53). Overall satisfaction after system implementation was 2.8 (SD 0.4), and satisfaction with specific procedures was 2.7 (SD 0.8). These results indicate high satisfaction levels, confirming that the sarcopenia management system was both efficient and acceptable. Feedback from participants and staff suggested future refinements should focus on expanding physical activities, providing regular training, and improving follow-up monitoring for long-term sustainability.

Discussion

Principal Findings

This study developed and implemented a context-sensitive sarcopenia management system tailored to former homeless older adults residing in supportive housing in Thailand. Using a mixed-methods approach guided by the Donabedian framework, the system integrated structural readiness, care processes, and outcome evaluation to address sarcopenia within a constrained institutional environment. The findings demonstrate that the system is feasible, acceptable, and responsive to the specific needs of this vulnerable population.

The preliminary evaluation demonstrated that the sarcopenia management system was successfully implemented in a supportive housing setting, with 78.4% (91/116) of participants identified as having possible sarcopenia according to the AWGS 2019 criteria, and all participants completed the resistance exercise and nutritional interventions. Both formerly homeless older adults and staff reported high perceived benefits, good quality, and high satisfaction, supporting the feasibility and acceptability of the system [29].

System Development and Contextual Relevance

The design of the sarcopenia management system reflects alignment with international clinical and public health recommendations, including those of the AWGS and European Society for Clinical Nutrition and Metabolism (ESPEN) [19,30], which emphasize early detection, resistance exercise, and adequate protein intake as core strategies for sarcopenia prevention and management. In this study, 78.4% (91/116) of participants met the criteria for possible sarcopenia [29], highlighting the substantial burden of early-stage sarcopenia in this vulnerable population and underscoring the importance of timely screening and intervention. All participants completed the resistance exercise and nutritional interventions, supporting the feasibility of implementing evidence-based sarcopenia management within supportive housing settings where resources and access to professional health services are limited. Consistent with previous evidence, integrating resistance exercise and nutritional support within the system supports muscle strength and functional maintenance among older adults [31]. Importantly, this study extends existing evidence by demonstrating how these interventions can be operationalized within supportive housing settings where resources, autonomy, and access to professional health services are limited.

The incorporation of community-based nutritional initiatives, including Nile tilapia cultivation and locally sourced soy milk for protein supplementation, represents a culturally appropriate and sustainable adaptation to the Thai supportive housing context. These strategies are supported by published evidence from this population indicating that malnutrition and low BMI are important factors associated with possible sarcopenia [29]. This approach directly addresses food security and nutritional access, which are critical social determinants of sarcopenia among former homeless older adults. Consistent with previous evidence, higher dietary quality and adequate protein intake are strongly associated with improved physical performance and functional outcomes in older adults [32,33]. The high ratings for perceived benefits, service quality, and satisfaction further suggest that these strategies were acceptable to both participants and staff and could be integrated into routine care practices. By embedding these strategies within existing community resources, the system demonstrates potential for long-term sustainability and scalability within community health settings.

In addition to alignment with AWGS and ESPEN recommendations [19,30], the developed sarcopenia management system is conceptually consistent with the World Health Organization's Integrated Care for Older People (ICOPE) framework [34]. ICOPE emphasizes the preservation of intrinsic capacity, particularly mobility, vitality, and nutrition, as key domains for preventing functional decline in older adults [34]. The system's focus on early sarcopenia screening, resistance exercise, nutritional support, and monitoring of functional status reflects core ICOPE principles and illustrates how intrinsic capacity-oriented care can be operationalized within supportive housing settings for former homeless older adults.

Structural and Process Improvements Within Supportive Housing

Prior to system implementation, the supportive housing facility lacked standardized sarcopenia screening procedures and staff capacity for early identification and management. Similar challenges have been documented in other geriatric and community-based care settings, where fragmented care pathways and limited geriatric expertise compromise care quality and efficiency [35]. Mixed-methods evidence further emphasizes that the absence of structured systems and role clarity undermines preventive care delivery for older adults [35].

The implemented system addressed these gaps by introducing validated screening tools, structured protocols, and clear role delineation, enabling nonmedical staff to participate in sarcopenia prevention. In this study, 18 staff members and 12 homeless volunteers were trained to conduct sarcopenia screening and support resistance exercise and nutritional interventions, demonstrating the feasibility of task-sharing within a resource-limited setting. Reviews of sarcopenia management emphasize that multidisciplinary and multicomponent approaches are necessary to effectively address sarcopenia, as single-domain interventions are often insufficient [36,37]. By integrating screening, exercise, and nutrition into routine workflows, the present model demonstrates a pragmatic,

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system-level innovation that enhances efficiency without requiring additional specialist resources.

Process evaluation findings indicate that integrating screening, exercise, and nutrition into existing daily routines enhanced feasibility and adherence. All participants completed the resistance exercise and nutritional interventions, and both staff and former homeless older adults reported high perceived benefits, good service quality, and high satisfaction with the system. Stakeholder engagement and role clarification facilitated coordination across staff groups and supported consistent care delivery. These findings align with prior research demonstrating that integrated, multidisciplinary approaches improve implementation fidelity and health outcomes in long-term care environments [38,39].

Efficiency Perceived Benefits, Quality, and Satisfaction

The preliminary evaluation demonstrated that the sarcopenia management system was feasible and well accepted among former homeless older adults residing in supportive housing. Participants and stakeholders reported high perceived benefits, good service quality, and high satisfaction, particularly regarding early detection of sarcopenia, structured follow-up, and strategies to maintain or reverse sarcopenia. These findings suggest that the system was effective in establishing a practical and organized approach to sarcopenia management within a resource-constrained institutional setting. The incorporation of nutritional interventions, including Nile tilapia cultivation and soy milk supplementation, may have contributed to these favorable perceptions by addressing modifiable nutritional factors associated with possible sarcopenia in this population [29]. The perceived benefits and high satisfaction reported by participants may be partly explained by the system's relevance to addressing important functional vulnerabilities, including falls, mobility limitations, and loss of independence, which are common among former homeless older adults and are recognized as major consequences of sarcopenia [1,31].

Sarcopenia is a well-established risk factor for falls, functional decline, and loss of independence among older adults [1]. In the present supportive housing population, a substantial proportion of residents reported a history of falls (33/116, 28.4%), underscoring the high baseline risk and vulnerability of this group. Consistent with previous evidence, sarcopenia has been identified as an independent risk factor for falls, with fall risk increasing progressively from possible sarcopenia to sarcopenia, highlighting the importance of early screening and management for fall prevention in older adults [40].

Among populations with a history of homelessness, fall risk is further compounded by poor physical functioning, balance impairment, multimorbidity, and prolonged exposure to adverse living conditions. Prior studies among former homeless older adults living in permanent supportive housing report high fall prevalence associated with markedly impaired mobility and physical resilience [41,42]. Global falls prevention guidelines emphasize the importance of structured assessment, strength-based exercise, and mobility monitoring to reduce fall risk [43]. Systematic reviews further support the role of exercise interventions in improving muscle strength and reducing fall-related outcomes among older adults with sarcopenia [44]. By integrating routine sarcopenia screening, physical performance assessment, resistance exercise, and nutritional strategies, the developed system addresses key modifiable determinants associated with falls. Although falls were not assessed as a primary outcome in this preliminary evaluation, the system may contribute to fall prevention by promoting early detection, resistance exercise, nutritional support, and maintenance of mobility and functional capacity in this high-risk population.

Innovation, Quality, and Responsiveness of Care

From an innovation perspective, this study differs from most existing sarcopenia interventions, which typically focus on isolated components delivered in clinical or research settings [24,31,36,37]. The proposed model represents a system-level innovation by embedding sarcopenia management into routine supportive housing workflows and enabling delivery by nonspecialist staff. This approach addresses gaps identified in prior geriatric care research, where the lack of integrated pathways and the overreliance on specialist services limit real-world applicability [35,37]. Participants also reported high satisfaction with the sarcopenia management system, reflecting positive perceptions of the screening process, exercise and nutritional components, staff support, and overall service delivery. Stakeholders similarly rated the system's quality favorably, indicating that the program was well integrated into routine care and contributed to improved coordination, communication, and documentation.

High satisfaction and perceived benefits among both former homeless older adults and staff indicate that the sarcopenia management system was user-friendly and acceptable within the institutional context. Beyond individual-level benefits, the system contributed to improved care coordination, documentation, and communication among staff, reflecting strengthened process quality. In line with the Donabedian framework [21], improvements in structural readiness and care processes were associated with positive implementation outcomes, supporting the relevance of system-based approaches to sarcopenia management in vulnerable populations. All participants completed the resistance exercise and nutritional interventions, further supporting the system's responsiveness and acceptability in the supportive housing setting.

Equity, Sustainability, and Public Health Implications

The findings suggest that a structured, context-sensitive sarcopenia management system has the potential to enhance early detection, prevention, and coordinated care for institutionalized and socially marginalized older adults. By combining evidence-based interventions with locally adapted strategies, including resistance exercise, Nile tilapia cultivation, and soy milk supplementation, the system offers a practical model for supportive housing and similar community-based care settings. If implemented at scale, such systems may help maintain functional independence, reduce preventable disability, and improve equity in geriatric health services. The approach is consistent with national healthy aging priorities and the World Health Organization ICOPE framework, which emphasizes functional ability and integrated, person-centered care.

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From a public health perspective, the system advances equity by extending preventive geriatric care to former homeless older adults, a population that has historically experienced limited access to coordinated health services and a high burden of functional vulnerability. In this study, 78.4% (91/116) of participants met the criteria for possible sarcopenia [29], underscoring the substantial unmet need for early identification and intervention in this underserved population. Integrated care models targeting intrinsic capacity have been shown to improve functional outcomes and support sustainable healthy aging strategies [45]. Multidisciplinary care pathways for fall prevention further underscore the importance of coordinated system-level approaches to addressing functional decline among high-risk populations [46].

By integrating care processes into existing institutional routines and using locally adapted nutritional strategies, the system supports sustainability in resource-constrained settings by minimizing reliance on external specialist resources and strengthening staff capacity within supportive housing facilities.

Strengths and Limitations

This study is among the first to develop and pilot a sarcopenia management system specifically for former homeless older adults residing in supportive housing. The use of a Donabedian-guided mixed-methods design strengthened methodological rigor by linking structural conditions, care processes, and outcomes. Extensive stakeholder involvement enhanced feasibility, acceptability, and real-world applicability. However, the study was conducted in a single facility, and the sample size was limited to a preliminary feasibility and acceptability assessment. Long-term outcomes and cost-effectiveness were not evaluated. Future studies should use multisite designs with longitudinal follow-up to assess sustainability, effectiveness, and economic implications. In addition, potential confounding factors, such as age, nutritional status, physical activity, and comorbidities, were not statistically controlled due to the preliminary design and descriptive analytical approach. Future studies should include larger samples and apply multivariable analyses to examine the effects of the sarcopenia management system while controlling for these factors.

Conclusions

This study demonstrated the feasibility and acceptability of a context-sensitive sarcopenia management system for former homeless older adults residing in supportive housing in Thailand. By integrating evidence-based screening, resistance exercise, and nutritional support within an institutional care framework, the system addressed both clinical and social dimensions of sarcopenia management in a highly vulnerable population. The findings suggest that this structured, stakeholder-supported approach may strengthen early detection and coordinated care and support the maintenance of functional ability and independence for older adults in supportive housing settings. Further research is warranted to evaluate long-term effectiveness, sustainability, scalability, and cost-effectiveness prior to broader implementation.

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: PW, NP, TJ, KK, AS, KJ
Methodology: PW, NP, TJ, KK, AS
Investigation: PW
Supervision: NP
Data curation: PW, NP, TJ
Formal analysis: PW
Writing – original draft: PW
Validation: PW, NP, KK, AS, KJ
Writing – review and editing: PW, NP
Project administration: PW, NP
Clinical expertise: AS, KJ

Conflicts of Interest

None declared.

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Abbreviations

AWGS: Asian Working Group for Sarcopenia
BIA: bioelectrical impedance analysis
CMT: Chula Mental Test
CVI: content validity index
ESPEN: European Society for Clinical Nutrition and Metabolism

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ICOPE: Integrated Care for Older People
MSRA: Mini Sarcopenia Risk Assessment

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Experiences of Persons With Disabilities Regarding Home Adaptation and Assistive Products in a Rural Community of Northern Thailand: Qualitative Study

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Abstract

Background: Chiang Mai Province, located in northern Thailand, is a well-known tourist destination. Its rural areas are characterized by mountainous and valley landscapes, where residents primarily engage in agricultural activities and maintain traditional ways of life rooted in Northern Thai culture. However, persons with disabilities in rural areas of Chiang Mai face significant challenges in enhancing their quality of life and well-being. Home adaptations and assistive products are essential for these individuals, as they facilitate daily activities and improve overall living conditions. To address the needs of persons with disabilities in these communities effectively, it is crucial to gather insights and perspectives that reflect their everyday experiences.

Objective: This study aimed to explore the experiences of persons with disabilities, focusing on the needs and obstacles they encounter in accessing home adaptation and using assistive products.

Methods: A qualitative approach was used for this study. Individual interviews were conducted with 11 persons with disabilities residing in rural communities of the Doilor Subdistrict in Chiang Mai, Thailand. The data were analyzed using thematic analysis.

Results: Five themes emerged: (1) financial and personal burdens of home adaptations, (2) living with safety risks in the home environment, (3) the need for assistive products aligned with individual health conditions and contexts, (4) challenges in accessing mobility support and essential services, and (5) emotional impact and sociocultural support.

Conclusions: The findings indicate that persons with disabilities in rural northern Thailand encounter multifaceted barriers to enhancing their mobility and adapting to their home environments. More effort is needed to enhance home modification support, integrate assistive products, and provide transportation accessibility that promotes community inclusion for persons with disabilities. This study highlights the influence of organizational priorities on community practice and the need for person-centered practice to ensure that modifications lead to meaningful outcomes valued by persons with disabilities in the future.

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KEYWORDS

persons with disabilities; home adaptations; assistive products; rural community; occupational therapy

Introduction

Background

In 2024, Thailand had approximately 2.18 million persons with disabilities, with 51.96% (1,136,174/2,186,769) being male and 48.04% (1,050,595/2,186,769) being female. The most common types of disabilities are physical or mobility disabilities (1,106,553/2,186,769, 50.60%), visual impairment (177,999/2,186,765, 8.43%), and intellectual disabilities (150,688/2,186,765, 6.86%). Most of them have graduated primary school (1,400,625/2,186,765, 64.05%) and live in rural areas, with the highest proportions residing in the Northeast (879,081/2,186,765, 40.20%) and North (508,423/2,186,765, 23.25%) regions [1]. While the employment of persons with disabilities is low, the ratio of employees with disabilities to no disabilities is approximately 1:100 [2]. The National Statistical Office (NSO) and the United Nations Children's Fund reported that in 2022, the total population of persons with disabilities was 4,192,291 or 6% of the entire Thai population. This represents a significant increase from 5.5% in 2017 [3]. Although the Empowerment of Persons With Disabilities Act and the National Development Plan for the Empowerment of Persons With Disabilities (Fifth Edition) aim to support all persons with disabilities, the national committee established by this legislation provides only state aid to Thai citizens with identification and disability cards [4].

According to the 2022 report by the NSO Thailand, 99.1% (2,134,137/2,153,519) of persons with disabilities can access

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universal health care services under national welfare schemes. However, only 42.6% (917,399/2,153,519) are registered for disability certification, indicating that 57.4% (1,236,119/2,153,519) do not receive formal financial support and resources [5]. Additionally, 4.1% (88,294/2,153,519) are unable to access required medical treatment, 9.2% (198,123/2,153,519) require rehabilitation services, and 16.6% (357,484/2,153,519) lack essential prosthetic or assistive devices, equivalent to approximately 696,000 individuals. The most commonly unmet needs included canes, wheelchairs, forearm crutches, hearing aids, and eyeglasses [5]. Rural-urban disparities in access to services for persons with disabilities in Thailand remain insufficiently quantified in the studies. Nonetheless, reports from the NSO Thailand found that persons with disabilities in rural areas experience significant support gaps, including long travel distances and limited availability of health care professionals and services. Given Thailand's geographic landscape, rural areas are likely to have fewer rehabilitation facilities and assistive product providers per capita [5]. Consequently, individuals experiencing significant hardship are often underrepresented in national surveys. For example, ethnic hill tribe populations living in remote forest and mountainous areas, as well as individuals born in rural communities without Thai citizenship, are frequently overlooked and may be unable to obtain disability cards, thereby limiting their access to services and support [6].

In Thailand, it is a predominantly Buddhist country, with approximately 93% of the population adhering to this faith [7]. Thai Buddhist culture is deeply rooted in the practice of merit making, which is based on the fundamental beliefs of karma (human actions) and destiny. The concept of karma, or the belief that actions in a previous time or past life influence one's current circumstances and future, is a central tenet of Thai Buddhism [8]. Health and illness in Buddhism reflect interdependence and cause-and-effect relationships in life. Moreover, the Thai Buddhist belief that "doing good will get good, doing bad will get bad" has influenced the cultural understanding of disability [9]. They believe that this legacy is inherited from devil karma and the sins of past lives. This belief leads to the view that disability is a personally earned tragedy, embodying faults accumulated in past or present lives. This cultural perspective often results in sympathy or mercy toward disabled people, while societal responsibility for ensuring their rights is overlooked [10]. Hence, the stigma surrounding disability in Thai society was found to hinder access to opportunities for persons with disabilities, particularly in rural areas.

In rural areas of Chiang Mai, Northern Thailand, vernacular stilt housing constitutes a distinctive regional architectural style that is deeply embedded in local sociocultural practices and ways of life. These dwellings are typically characterized by elevated structures, designed to reduce exposure to ground-level cold and moisture, reflecting adaptive responses to the local environmental context. These dwellings commonly incorporate architectural features such as external stair access, steeply pitched roofs, and detached sanitation facilities located at a distance from the main house for practical and hygienic purposes [11]. Moreover, road infrastructure and public transportation in rural Northern Thailand demonstrate marked spatial disparities between lowland and upland areas. In upland areas, road infrastructures remain uneven and inadequate. Many villages are on narrow concrete or unpaved roads that become impassable during the rainy season, limiting access to health care, education, and economic opportunities. In contrast, lowland areas have found well-developed, all-weather roads with reliable links to urban centers. Public transportation in upland areas is not available, with residents depending primarily on private vehicles, highlighting persistent inequities in transportation access [12].

Home adaptation and the use of assistive products can help persons with disabilities overcome challenges in daily activities, promoting greater independence and a better quality of life [13]. However, persons with disabilities encounter limited access to health care support services, such as home adaptations and assistive devices. There is an urgent need to enhance national policies to improve these services [14]. Additionally, the lack of specific guidelines for housing adaptations hinders the implementation of policies aimed at improving the quality of life for persons with disabilities [15]. Furthermore, persons with disabilities in rural areas often face distinct challenges that differ from those experienced by persons with disabilities in urban settings. These unique challenges are influenced by various cultural and contextual factors, which can hinder the full implementation of policies or limit the advocacy for the rights of persons with disabilities [16]. Living with a disability in rural areas can be a challenging experience because various factors can significantly impact the quality of life of those affected. The geographic environment and the lack of infrastructure, transportation, specialized health care, and rehabilitation services in rural areas can create significant barriers to independence, social integration, and overall well-being for persons with disabilities [17].

Literature Review

Home adaptations refer to modifications made to the built environment to enhance safety, accessibility, and usability for older adults and persons with disabilities [18]. They are widely recognized as effective interventions that support independent living and reduce reliance on formal or informal caregiving [19,20]. In aging societies, the home environment plays a critical role in enabling families to manage care demands, with appropriate design and modifications contributing to reduced care needs and improved functioning within community settings [21]. Such adaptations often involve structural and environmental changes, including the installation of ramps, accessible pathways, and the integration of assistive products to support daily activities [22].

Assistive products, as defined by the World Health Organization, are "any product, instrument, equipment or technology adapted or specially designed to improve the functioning of a person with disability" [23]. The use of assistive products is associated with reduced inequalities, enhanced productivity, and increased participation in daily life among older adults and persons with disabilities [24]. More broadly, assistive technology, encompassing both products and related services, plays a vital role in promoting health, independence, and dignity, enabling individuals to engage more fully in educational, occupational, and social domains.

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Access to home adaptations and assistive products in low-resource settings is shaped by a complex interplay of environmental, economic, and social factors. Evidence from rural South India highlights persistent barriers, including social stigma associated with disability, high costs of assistive devices, and limited availability of essential supplies, all of which restrict equitable access to rehabilitation services [25]. Similarly, the study on persons with intellectual disabilities indicates that limited awareness of assistive products, combined with insufficient funding mechanisms and a lack of proactive assessment by health professionals, further constrains appropriate utilization of these technologies [26]. Collectively, these findings suggest that both structural and knowledge-related barriers play a critical role in limiting access to home adaptations and assistive products.

Beyond access, the design of the home environment itself is a key determinant of independence and successful community reintegration. Studies emphasized that incorporating accessible housing features such as step-free entrances, walk-in showers, and ground floor living spaces can facilitate smoother transitions from hospital to home and reduce the need for costly retrofitting [27]. Furthermore, evidence from intervention studies demonstrates that home modification programs can significantly enhance community participation among individuals with mobility impairments, with reported increases in social and recreational engagement following improvements in home usability [28]. However, the sustainability of these benefits remains a concern, as gains in participation may diminish over time without ongoing support.

In the Thai context, similar challenges are evident, particularly in rural and underserved areas. Previous studies have consistently reported limited access to assistive devices, environmental modifications, and broader health care support services for persons with disabilities [29-31]. These limitations are compounded by gaps in disability registration systems and low uptake of disability-related benefits, reflecting broader systemic and policy-level constraints [32]. Although community-based home modification programs in Thailand have reported positive outcomes such as reduced activity limitations and enhanced quality of life, the underlying problems and access barriers remain insufficiently understood. This gap is particularly evident in geographically remote areas of northern Thailand, where limited accessibility continues to constrain in-depth exploration. It is crucial to identify the actual needs of persons with disabilities regarding home adaptations and assistive products to improve their quality of life, particularly in rural areas of Thailand.

The Doilor subdistrict, located in Chiang Mai Province, provides a representative example of a rural agricultural community in northern Thailand. The area comprises 26 villages with a total population of 12,227 people, the majority of whom (approximately 70%) are engaged in agriculture, including the production of longan, rice, cantaloupe, tomato, and pumpkin [33]. In 2024, there were 738 persons with disabilities in this subdistrict, accounting for approximately 6% of the total population [34]. The geographic and socioeconomic characteristics of this community may further influence access to home adaptations and assistive product services.

Previous studies in Thailand showed evidence that predominantly focused on service provision, policy implementation, and measurable outcomes. Consequently, there remains a limited understanding of how persons with disabilities, particularly in rural communities, perceive, access, and use these supports in their everyday lives. This gap is further compounded by insufficient attention to contextual factors, such as geographic isolation, seasonal transportation barriers, and local sociocultural conditions, which may significantly shape service accessibility and usability. This issue is particularly pronounced in rural northern Thailand, where access to services may differ substantially from urban areas and other regions of the country.

Addressing this gap, this study aims to explore the perspectives and lived experiences of persons with disabilities in the Doilor community regarding home adaptations and assistive products, with a specific focus on identifying barriers and unmet needs that influence their occupational engagement within home and community environments. By generating contextually grounded insights, the findings are expected to inform the development of targeted, locally relevant, and sustainable strategies to promote service provision and ultimately enhance the quality of life for persons with disabilities in rural northern Thailand.

Methods

Study Design

A descriptive qualitative approach [35] was conducted to investigate the experiences and perspectives of persons with disabilities toward home adaptation and assistive products. The research design, methodology, and methods were carefully aligned to ensure rigor and analytical depth [36].

Ethical Considerations

The study obtained ethics approval from the Ethics Committee of the Faculty of Associated Medical Sciences, Chiang Mai University (reference AMSEC-65EX-030). Prior to participation, all individuals provided written informed consent, which was obtained from the participants' legally authorized representatives prior to the study. Each participant recieved US $10 and a small gift as compensation for thier time. Interviews were audio-recorded, transcribed verbatim, and lasted approximately 1 hour. The research process was systematically documented, and transcripts were reviewed by the research team. Pseudonyms were assigned to ensure participant confidentiality.

Participants and Recruitment

The participants were recruited on the basis of the following criteria: (1) possession of a disability identification card, (2) household registration in the Doilor subdistrict, (3) older than 18 years, (4) ability to communicate and experience home adaptations and assistive products, and (5) willingness to participate in the interview. To recruit participants, the research team disseminated advertisements over a 2-month period. These advertisements were placed in key locations within the Doilor subdistrict, including at a subdistrict health-promoting hospital, community halls, and the Doilor Community Rehabilitation Center, which is part of the Subdistrict Administrative Organization. The sample size was guided by the concept of

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information power as described by Malterud et al [37], whereby the adequacy of participants is determined by the relevance and data saturation in relation to the study aims and questions. Accordingly, we planned to recruit approximately 8 - 12 participants who met the inclusion criteria. Individuals who expressed interest after seeing the advertisements were then contacted by the research team and assessed for eligibility based on the predefined criteria.

Interview Procedure

The interview guide was developed based on a review of relevant literature and aligned with the study aims. An iterative process was used to refine the interview protocol, including pilot interviews conducted prior to data collection to ensure alignment between the study context, participant selection, and interview procedures. Participants for the pilot phase were purposively selected to reflect the characteristics of the target population, and the preliminary interview guide was designed to capture key concepts relevant to the study. Prompts were incorporated to facilitate in-depth responses when needed. Feedback from pilot participants and the pilot process informed further refinement of the semistructured interview guide.

In addition, the interview guide was designed with a primary focus on exploring barriers and challenges related to the use of home adaptations and assistive products, which have influenced the nature of the findings. However, participants were also provided with opportunities to share their experiences and facilitators where relevant, and these were considered during data analysis to ensure balanced representation. The first author (AK) received training in qualitative interviewing techniques prior to data collection. Face-to-face individual interviews were conducted by the first author. This included a 45- to 60-minute mock interview conducted in a private setting, which served both as a skills assessment and as an opportunity to receive feedback. All interviews were conducted face-to-face, typically in participants' homes, to promote comfort and create a relaxed environment conducive to open sharing.

Furthermore, the research team comprises occupational therapy researchers with extensive experience in home adaptations and assistive products in Northern Thailand. Their professional backgrounds and prior engagement with persons with disabilities may have influenced data collection and interpretation. To address this, reflexive practices, including memo writing and regular team discussions, were used throughout the research process to enhance credibility and minimize potential bias. A purposive sampling strategy was used to recruit individuals with lived experience in using home adaptations and assistive products, based on predefined inclusion criteria. Participant characteristics are described in detail to enhance transparency and reproducibility. The semistructured interview questions are presented in Textbox 1.

Textbox 1. Examples of interview questions.

Questions

1. Have you ever modified your home or environment? If so, who helped you with the modifications (family, government, foundation, or private sector)? What modifications did you make? Please tell us about your experience.
2. What are the challenges you have faced in modifying your home or environment? What are the obstacles that have prevented you from making the changes you want?
3. If you had the opportunity to make further modifications to your home or environment, what would you change and why?
4. What assistive products do you use (nonslip mats, wheelchairs, hearing aids, adjustable beds, canes, walkers, wheelchairs, shower chairs, turning pillows, air mattresses, etc)? How have these products helped you? Please share your experiences with us.
5. What are the barriers or difficulties you have faced in using assistive products?
6. If you had the opportunity to choose new assistive products, what would you choose and why?

Data Collection

Data collection occurred between December 2023 and February 2024 to generate in-depth qualitative insights. Participants who met the inclusion criteria were recruited. Semistructured interview guidelines were used, and interviews were scheduled at a time and location convenient for participants, typically conducted face-to-face by a trained researcher.

Data Analysis

The interview data were analyzed using thematic analysis [38]. The process involved 3 researchers (HA, JG, and PM) and 2 research assistants (PT and SS) and followed a 6-step analytical procedure. First, transcripts were read multiple times to achieve familiarization and to develop a comprehensive understanding of participants' experiences using home adaptations and assistive products. Initial notes were recorded during this stage. Second, meaningful units of text (eg, phrases or sentences) were identified and coded. Two researchers (HA and PM) independently conducted initial coding for each transcript to capture diverse interpretive perspectives. A consensus-based approach was subsequently applied, with regular meetings held to compare codes, resolve discrepancies, and refine code definitions. Third, codes were systematically organized into categories and then grouped into potential themes by identifying patterns and relationships across the dataset. For example, codes such as "I don't have enough money" and "I have no income" were grouped under the subtheme "Insufficient financial resources," within the main theme "Financial and personal burdens of home adaptation." Fourth, main themes and subthemes were reviewed and refined to ensure that they accurately represented the data and aligned with the research questions. Investigator triangulation was applied throughout this stage, with multiple researchers involved in reviewing, comparing, and discussing emerging interpretations to enhance

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credibility. Fifth, themes were clearly defined and named to reflect their underlying meanings. Finally, the results of the analysis were reported in a written extract of the stories revealed by the analysis process.

Hence, the first and second authors (AK and HA) developed the initial version of the coding that contained the list of codes, subthemes, and main themes, which was then reviewed by the research team. Differences in interpretation were discussed and resolved through iterative team discussions, and the coding framework was refined accordingly. Participant quotations were anonymized using identification codes to ensure confidentiality.

Regarding translation, all interviews were transcribed verbatim in Thai, and coding and theme development were conducted in the original language to preserve meaning. Following the completion of the analysis, the finalized codes, themes, and illustrative excerpts were translated into English [39]. The translations were verified by 2 bilingual experts to ensure linguistic and conceptual accuracy [40]. These revisions improve the transparency, coherence, and rigor of the analytical process.

Rigor and Trustworthiness

The evaluation of credibility, transferability, dependability, and confirmability followed the methodology outlined by Hanson et al [41]. Triangulation was used to ensure credibility. This method included interviews with 11 participants who offered diverse perspectives. The interviews were conducted following a structured protocol to maintain consistency. Transferability was assured by providing a thorough description of the sample, setting, interview questions, and findings. Additional information was made accessible to future researchers upon request to facilitate understanding and to apply the findings in different contexts.

Dependability was established through rigorous practices such as multiple researchers independently analyzing the data, peer-debriefing sessions where insights were discussed, and member checking to validate themes with participants. These steps ensured that the study's conclusions were grounded in the data collected. Confirmability was achieved through accurate documentation: all interviews were recorded and transcribed, and researchers held regular meetings to discuss coding and thematic analysis. A final decision-making meeting involved all the researchers to ensure transparency and coherence in the findings, allowing external scrutiny and validation of the study's interpretations. To support interpretation and analysis, a trustworthiness audit trail was established by the research team, ensuring transparency and traceability of decisions made throughout the research process [42].

Results

Overview

Eleven persons with disabilities agreed to participate (3 male and 8 female participants), and all of them signed consent forms before participating in the study. Pseudonyms were used to protect their identity. The demographic characteristics of the participants are presented in Table 1.

Table . Demographic characteristics of the participants in the individual interviews.

Participants	Sex	Age (years)	Cause of mobility disabled	Work status	Living situation
Tida	Female	70	Lumbar spondylolisthesis	Unemployed	Resident with family
Nawat	Male	50	Above-knee amputation	Farmer/Freelance	Resident with mother
Malee	Female	62	Congenital deformities of the hands and feet	Farmer/Freelance	Resident with siblings
Suchitra	Female	68	Below-knee amputation	Vegetable vendor	Owner and live alone
Yupin	Female	61	Ischemic stroke (left hemiplegia)	Unemployed	Resident with husband
Petchara	Female	54	Ischemic stroke (left hemiplegia)	Unemployed	Resident with family
Intira	Female	57	Ischemic stroke (left hemiparesis)	Unemployed	Resident with family
Nissa	Female	72	Lumbar spondylolisthesis	Farmer/Freelance	Resident with family
Mukda	Female	90	Femur fracture repair	Farmer/Gardener	Resident with sons
Anada	Male	76	Ischemic stroke (right hemiparesis)	Farmer/Gardener	Resident with family
Boonchu	Male	53	Hemorrhagic stroke (left hemiplegia)	Unemployed	Resident with family

Five themes arose from the analysis of the interview data: (1) financial and personal burdens of home adaptations, (2) living with safety risks in the home environment, (3) the need for assistive products aligned with individual health conditions and

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contexts, (4) challenges in accessing mobility support and essential services, and (5) emotional impact and sociocultural support. These themes are presented with illustrative quotes (names are pseudonyms).

Theme 1: Financial and Personal Burdens of Home Adaptations

Persons with disabilities often face major hurdles in achieving full mobility and independence both at home and in their communities. In the rural areas of northern Thailand, persons with disabilities face unique challenges due to financial limitations. Furthermore, the participants' situations highlight the insufficiency of government aid to cover both basic living expenses and necessary home modifications or assistive devices. In Tida's account, she independently made necessary modifications, underscoring the challenges and costs involved in improving her daily living conditions, as she states:

> *I had to handle this home modification on my own, without any help from the government. Yet, the changes have truly made my daily life much easier.* [Tida]

Intira's interview highlighted significant structural issues within her home that created challenges and safety risks when she used her bathroom. This underscores the difficulties in navigating various areas of the home due to these constraints, which necessitate personal effort and often incur substantial costs to resolve, as she states:

> *My home has some structural problems, such as narrow and high entryways to the bathroom, which make it hard to access and increase the risk of accidents. The bathroom is important to us, so my family and I put in the effort to replace the toilet and redo the floor ourselves.* [Intira]

Petchara's interview illustrates the direct impact of limited financial resources on her ability to address her home modification needs, despite receiving multiple sources of government aid. This highlights a broader issue where government support is inadequate to cover both basic living expenses and the additional costs of modifying living spaces to accommodate specific needs, as the following quote reveals:

> *I do not have enough money to make changes to my home. I get 800 baht a month from disability benefits, plus 300 baht from government aid. I also get 700 baht from old age benefits, so that is 1,800 baht a month in total. I need to use this money for food and bills.* [Petchara]

Like Petchara, Yupin highlights the financial struggles of relying solely on disability and older adult allowances with little extra income. This situation presents a challenge for those with limited resources, as these allowances fall short of covering essential home improvements and daily living equipment, as she states:

> *Right now, I don't have any income from work and mostly rely on disability allowances. My husband's income from agricultural labor isn't enough to help us modify our home or buy the assistive equipment we need.* [Yupin]

The financial burden of home modifications and necessary equipment is significant for individuals. Tida's situation illustrates the limited government support, which provided a toilet without covering additional equipment costs. This highlights a common issue where incomplete government assistance forces individuals to shoulder substantial expenses, as she states:

> *Even though the government gave me a toilet, I had to pay for the installation and other necessary equipment myself, which ended up costing a lot.* [Tida]

Nissa's account underscores the high costs of renovating essential areas such as the toilet and bathroom. Many labor costs are prohibitively expensive, illustrating the gap between the need for home modifications and available financial support, as the following statement reveals:

> *The big problem is that I don't have enough money to renovate my toilet and bathroom. Construction and hiring workers are expensive, and the labor cost is approximately 400-500 baht a day. Unfortunately, I can't afford these expenses.* [Nissa]

Theme 2: Living With Safety Risks in the Home and Environment

The adaptations needed within the home, such as proper lighting, structural modifications, and assistive devices, ensure safety and comfort. The safety hazards present in the home environment include inadequate modifications and poor conditions.

In Nissa's interview, she emphasized the need for broader home renovations to increase accessibility and improve daily living conditions. She highlights the importance of modifications such as replacing low squat toilets with higher ones and installing grab bars to address specific needs, as she recounts:

> *I really want to renovate my house, especially the toilet and bathroom, to make my daily life easier. The toilet I have is now too low, so it is uncomfortable for me to use. I need a new, taller toilet that works better for me.* [Nissa]

Similarly, Nawat's account highlights the benefits of installing grab bars for added support and stability. This shows how grab bars can promote safer movement and greater independence at home, reducing the risk of falls and injuries. He states:

> *If I got grab bars, it would be way better. It would give me extra support and stability, making it easier to stand up and move around safely, especially in the bathroom where it is easy to slip and fall.* [Nawat]

Petchara's account highlights the high-risk areas in her home and the surrounding environment, particularly the rough pathways with holes and bumps that promote falls. It emphasizes the challenges faced by mobility aid users and the urgent need for pathway improvements to ensure safety, as she recounts:

> *The pathways around here are really rough, with lots of holes and bumps. Yesterday, I was using my walker and almost fell because of it.* [Petchara]

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Intira's case highlights safety concerns related to poor lighting and high steps within the home. This finding illustrates the difficulties and risks associated with navigating the home environment without adequate lighting and support, leading to frequent falls and the need for home modifications to improve safety and accessibility, as she states:

> *It is tough to move around my house safely without good lighting. I have fallen a few times because the steps are too high and there's nothing to hold onto.* [Intira]

Tida's account emphasizes the importance of installing grab bars in key areas of the home, such as the bathroom, to increase stability and prevent falls. Grab bars provide essential support for individuals with mobility issues, helping them maintain balance and safely maneuver within their environment. This adaptation is a simple yet effective measure for enhancing safety and independence within the home, as she recounts:

> *A grab bar would truly help with my stability and safety, especially in the bathroom where it's easy to slip. Right now, I feel truly unsteady getting in and out of the shower or using the toilet because there's nothing to hold onto. The floors can be slippery, and I often lose my balance. Installing grab bars would give me the extra support I need to move around more confidently and safely, reducing the risk of falls.* [Tida]

Theme 3: The Need for Assistive Products Aligned With Individual Health Conditions and Contexts

This study addresses how health issues related to disabilities significantly affect individuals' daily activities. This highlights the physical challenges, such as pain and weakness, that necessitate aids and therapeutic interventions. The shared experiences illustrate how these conditions can limit independence and require modifications in daily routines to maintain functionality.

Health conditions associated with functional impairments directly affect physical, psychological, and social capacities, thereby increasing the need for additional support and assistive products. Mukda's account illustrates how leg pain and difficulty walking limit her mobility, reduce functional ability, and necessitate assistance in daily activities, as she states:

> *I have been dealing with some health problems, such as truly bad pain in my legs and I have a hard time walking. It has been tough because leg pain makes it hard to get around and do everyday things.* [Mukda]

In Boonchu's experience, this highlights the severe impact of a stroke on physical abilities and the recovery process. The use of a walker and cane, along with therapy, represents a crucial adaptation for regaining independence. This underscores the need for specific mobility aids and therapeutic support to address the challenges posed by serious health events such as strokes, as he states:

> *After my stroke, I struggled with a lot of weaknesses. However, thanks to therapy and practicing with a walker and cane, I have regained more independence in my daily activities.* [Boonchu]

The challenges and adjustments needed to transition to specific aids, such as wheelchairs, canes, and grab bars, are significant. Anada's experience captures the difficulties individuals face when moving from a cane or walker to a wheelchair, highlighting the physical and psychological adaptations required owing to limitations with the previous aid, as described:

> *I cannot use a cane because I found it too heavy and hard to manage. After hip surgery, I used a walker, but it is very hard to stand up and use it. Therefore, I have had to stop using it altogether. I'm hoping to start using a wheelchair and practice with it until I get the hang of it.* [Anada]

Malee's account highlights the significant benefits of an electric wheelchair for an individual's independence and mobility. It emphasizes how a wheelchair can transform daily activities, providing a sense of freedom and comfort that other mobility aids may lack, as she recounts:

> *I used to have an electric wheelchair, which was very good and allowed me to go far. I even went to buy food near the three-way intersection in the village. Currently, wheelchairs are broken and cannot be fixed. If I got a new electric wheelchair, I could help myself more, as it gives me freedom and comfort.* [Malee]

Theme 4: Challenges in Accessing Mobility Support and Essential Services

Access to motorized wheelchairs and other mobility aids significantly improves independence and quality of life. However, individuals face financial and practical challenges in accessing facilities and services because of mobility constraints.

Malee shared her experience of how using a wheelchair improved her sense of independence and quality of life. It highlights the contrast between life with and without a motorized wheelchair, emphasizing the newfound freedom to perform daily activities and engage in social interactions without relying on others, as she states:

> *When I had a motorized wheelchair for two years, I felt a whole new level of independence compared to not having one. This wheelchair made life much easier. I could go outside, go shopping, and visit my grandkids. It was incredibly convenient.* [Malee]

Intira reflects on the proactive efforts of individuals seeking additional mobility aids, such as canes and wheelchairs, to enhance their mobility and accessibility. This highlights the ongoing challenges faced by those with mobility issues and her determination to improve her situation through appropriate assistive devices, as she states:

> *Now I am looking to get a cane and a wheelchair to help with my mobility. The cane gives me more stability and support when walking, especially on uneven ground. The wheelchair will give me a reliable way to get around, allowing me to move more freely and comfortably at home and in the community.*

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> *Having these mobility aids is key for me to manage daily tasks with less difficulty and reduce the strain of walking long distances.* [Intira]

Tida highlighted the financial challenges of modifying facilities to accommodate her mobility constraints. This underscores the gap between the basic facilities provided by the government and the additional costs individuals must bear to make these facilities fully accessible and functional for client needs, as she recounts:

> *The government provided a toilet, but I had to pay for the installation and extra equipment myself, which was expensive.* [Tida]

Suchitra indicates the daily inconvenience and discomfort experienced by individuals who do not have adequate bathroom facilities that suit their mobility needs. It emphasizes the necessity for specialized equipment, as she states:

> *Currently, I sit on the toilet seat to shower, which is not very convenient. Having a shower chair that suits me would make bathing much more comfortable.* [Suchitra]

Theme 5: Emotional Impact and Sociocultural Support

Anxiety and fear of falling, along with dependence on others due to mobility issues, significantly impact mental health. In rural areas, individuals often rely on family and community support for essential mobility aids and daily assistance. Additionally, there is a need for support from local governments and agencies to facilitate home improvements and access to assistive devices.

Anxiety and fear are experienced by individuals with mobility issues when they are navigating uneven surfaces. Suchitra's account emphasizes the emotional stress related to the risk of falling, which can significantly limit outdoor mobility and independence, as she states:

> *I'm scared of falling when I walk, and it is truly hard if the ground outside is uneven and there's nothing to grab onto.* [Suchitra]

In her interview, Tida reflected on the broader mental health impacts of living with mobility constraints, especially the constant fear of falling and the need for assistance. These factors contribute to increased stress, anxiety, and a sense of helplessness, as she recalls:

> *I'm scared of falling, and not being able to move around freely without help has truly affected my mental health.* [Tida]

Like Nissa, the account illustrates the psychological relief and improved mental well-being that she anticipates from using assistive devices such as wheelchairs. This highlights the importance of mobility in reducing dependence on others and enhancing personal freedom and quality of life.

> *Having a wheelchair would truly boost my mobility. I could get around on my own and go to different places without having to rely on others to carry me. It would give me more freedom and make everyday activities a lot easier.* [Nissa]

Boonchu's reflection highlights the influence of Thai cultural beliefs in karma (rebirth and cycles), suggesting an acceptance of disability as a consequence of actions in a past life. Additionally, Buddhist values of compassion, combined with a collectivist social structure, foster mutual support within the community, particularly for persons with disabilities, as he states.

> *I truly believe in Karma. Sometimes I feel like I'm being punished for a previous life, especially since my health issues and trouble walking make it so hard to get a job. Luckily, my nephew is here to help me out. I have great neighbors, too. They help me get food from the market and never charge me a thing, simply because we treat each other like family as taught in Buddhism.* [Boonchu]

Within the context of community support, Suchitra's account highlights the role of the Subdistrict Administration Organization in providing essential aids, such as canes and walkers, to support individuals in their daily activities. This assistance enables the participant to engage in productive tasks, such as selling vegetables on the market, as she states:

> *The staff at the local government office gave me a tripod cane and a walker to help me get to the fresh market to sell vegetables.* [Suchitra]

Petchara's account highlights the need for organizational support, such as local government organizations, to help people with disabilities improve their homes. This underscores the reliance on these organizations to enhance living conditions and accommodate the specific needs of those with disabilities, as she states:

> *I'm looking for help from organizations such as the SAO (Subdistrict Administrative Organization) and PAO (Provincial Administrative Organization) to assist people with disabilities like me in improving our homes and living conditions.* [Petchara]

As reflected in the aforementioned quotes, persons with disabilities often rely on government assistance, indicating that existing resources and support are insufficient to meet their needs, particularly in rural areas.

Discussion

Principal Findings

This study provides context-specific insights into the challenges faced by persons with disabilities in the rural Doilor community of Chiang Mai, Thailand, in relation to home adaptations and assistive products. While previous research has identified common barriers, our findings extend this knowledge by illustrating how geographic isolation, seasonal accessibility, and limited local infrastructure interact to shape everyday experiences of accessing and using these supports in a rural Northern Thai context. Consistent with prior studies, participants expressed a strong need for accessible home adaptations but faced significant financial constraints, despite partial support from local government programs. Viripiromgool et al [43] highlighted that financial barriers disproportionately affect marginalized populations in rural Thailand, while Szanton et al

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[44] noted limitations in formal funding systems for home modifications. Building on these findings, our study demonstrates how persons with disabilities actively navigate these constraints through a combination of limited governmental support, out-of-pocket payments, and reliance on informal community and family networks. This dynamic interplay between formal and informal support systems represents an important contribution to this study.

Semeah et al [45] reported comparable costs between rural and urban settings, with rural users incurring slightly lower expenses for bathroom modifications. Our study revealed that the cost of home modifications even in rural areas has increased due to the rising prices of construction materials and high labor costs. Furthermore, it indicates that financial pressures are more pronounced in geographically remote areas. According to Goddard et al [46], home adaptations were perceived to enhance safety, reduce physical effort, and promote independence and psychological well-being. However, our findings emphasize that these benefits remain unevenly accessible due to contextual and structural constraints. Despite these efforts, significant challenges remain, as participants and their family members continue to express concerns about how to ensure safety and effectively improve the functioning and well-being of persons with disabilities.

Addressing mobility challenges and the need for assistive products remains a critical issue. Giesbrecht et al [47] reported higher unmet needs among wheelchair users, including greater reliance on assistance and increased financial burden, while Vanderschuren et al [48] emphasized the role of structural and environmental barriers in limiting accessibility. Extending these perspectives, our study found that the assistive products should be matched to individual health conditions, functional abilities, and environmental contexts. This highlights the need for context-sensitive, person-centered approaches to assessment and provision, particularly in resource-limited rural settings. While Burns et al [49] and Sukkay and Upala [50] highlighted structural inadequacies in housing, these studies demonstrated how these limitations are compounded by local socioeconomic constraints and limited support systems, resulting in persistent safety risks such as falls despite awareness of the need for safer environments. Our findings extend previous studies by offering a context-specific understanding of how persons with disabilities in rural northern Thailand experience not only safety risks within the home but also challenges related to their surrounding environmental conditions and landscape.

In relation to mobility and service support, although previous studies have identified gaps in policy, service provision, and training [51-53], our study contributes new insight into how these systemic gaps are experienced in practice in rural settings. Specifically, we highlight the lack of repair and maintenance services, as illustrated by participants' difficulties in maintaining essential mobility devices. Consistent with Madanhire et al [54], who highlighted the challenges faced by wheelchair users in rural areas, where rough, uneven terrain and poor road systems make it difficult for conventional wheelchairs to function effectively, our study reflected not only infrastructural limitations but also the mismatch between assistive products and the rural environment.

In addition, home adaptations are known to improve safety and reduce fall risk [55]. The study showed that it was significantly reduced 3 months after housing adaptations in the intervention group, but this effect did not persist for 6 months. Home adaptations alone were not sufficient to significantly reduce falls or near-falls. The study suggests that additional interventions are necessary to address clients' activity limitations and improve fall-related outcomes. Our findings reveal that fear of falling and dependence on family support persist even after modifications are implemented. Hence, this study suggests that environmental adaptations alone may be insufficient, highlighting the need for comprehensive, person-centered interventions that integrate both physical provision and psychosocial support.

Importantly, this study provides novel insights into the sociocultural context. In Thailand, persons with disabilities frequently encounter social stigma and discrimination, which limit their employment opportunities. Aroonsrimorakot et al [56] reported that negative societal perceptions of persons with disabilities, often viewing them as burdensome or incapable, significantly contribute to these challenges, reinforcing barriers to both employment and participation. Consequently, limited access to job opportunities exacerbates feelings of insecurity and unease. These barriers are further intensified by difficulties in accessing workplaces, particularly among individuals with mobility impairments, which contribute to increased psychological stress [57]. Consistent with these findings, some participants in our study reported, "Right now, I don't have any income from work and mostly rely on disability allowances." This reflects restricted employment opportunities and a resulting dependence on government financial support.

Persons with disabilities may face limited access to employment opportunities, partly because societal perceptions in Thailand often view them as less capable of fulfilling work-related roles than individuals with no disabilities. Consistent with Jantasara [58], the societal belief that disability results from past misdeeds, prevalent in a predominantly Thai culture, further complicates the situation, making it difficult for persons with disabilities to find equitable opportunities in the workforce. However, our findings highlight the important role of sociocultural context. Cultural beliefs, including karma, Buddhist values, and a collectivist community, significantly shape how persons with disabilities accept their condition, develop coping strategies, and access support. These influences are less explicitly addressed in previous studies. Moreover, our findings demonstrate that neighbors and villagers in rural communities are often willing to accommodate and support persons with disabilities. This underscores the importance of understanding how persons with disabilities interpret and respond to disability within their local sociocultural context in rural Thailand.

Furthermore, the Ministry of Social Development and Human Security of Thailand offers subsidies for home modifications for older people and persons with disabilities. Eligible persons with disabilities can receive home assessments and improvements worth up to 40,000 Baht (US $1119) [59]. Provincial administrative organizations and local governments or subdistrict municipal offices are responsible for evaluating and making home adaptations, including installing assistive

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devices to meet the specific needs of individuals to help them engage in meaningful activities [60]. Our findings indicate that persons with disabilities rely on support from agencies and local government to improve their quality of life. This underscores a gap between policy and practice in rural areas, where limited funds and resources, fragmented service delivery, and inadequate implementation reduce effectiveness.

In 2023, the Economic and Social Commission for Asia and the Pacific [61] reported that Thailand has made progress in aligning national legislation with international frameworks on the rights of persons with disabilities, with notable improvements in accessibility, employment, and living standards. The involvement of organizations with persons with disabilities has been crucial in driving these legislative changes. However, persistent challenges remain, including limited interministerial coordination and the absence of systematic monitoring mechanisms.

Limitations

This study was conducted within a single subdistrict, the Doilor community, representing a relatively limited group of persons with disabilities residing in a specific rural context. As a phenomenological inquiry, the study aimed to explore the lived experiences of persons with disabilities in relation to the use of home adaptations and assistive products within their everyday environments. While this qualitative approach enables an in-depth understanding of participants' experiences grounded in their contextual realities, the findings may have limited transferability to other geographic or sociocultural settings. Future research should consider adopting longitudinal designs to examine the sustained and evolving impact of home adaptations and assistive products on the quality of life and occupational participation of persons with disabilities. Such approaches would allow for a more comprehensive understanding of how users' experiences, needs, and adaptation processes develop over time within their social and environmental contexts.

Conclusions

In summary, the experiences of persons with disabilities in rural communities in northern Thailand are multifaceted and influenced by various factors, such as financial limitations and insufficient governmental support, the home environment and safety concerns, relevant assistive devices related to disabled conditions, home adaptations, and access to assistive products. The challenges faced by persons with disabilities in these communities include barriers to accessing health care services, home modifications, and assistive products, as well as lower well-being associated with impairments. The findings suggest the need for comprehensive support systems and interventions to improve the quality of life for persons with disabilities in rural areas.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

AK and PM contributed to the study conceptualization, methodology, and project administration. AK, HA, JG, and PM conducted data collection, reference management, and data analysis. AK and PM drafted the manuscript. AK, HA, JG, and PM contributed to the interpretation of findings, manuscript review, and editing. All authors contributed to all stages of the research process, approved the final manuscript, and accept responsibility for the accuracy and integrity of the work.

Conflicts of Interest

None declared.

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Abbreviations

NSO: National Statistical Office

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Digital Health Technology Use by Vietnamese Americans: Cross-Sectional Study

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Abstract

Background: Digital health technologies (DHTs), including mobile health (mHealth) apps and online medical records, are increasingly being used to support self-management and communication with health care professionals among the general population across the United States. However, few studies have explored whether cultural, privacy, and sociodemographic factors may influence DHT adoption among Vietnamese Americans specifically.

Objective: This cross-sectional study aimed to explore DHT use, barriers to adoption, and their associations with social determinants, such as age, sex, social support, and mental health concerns, among Vietnamese Americans.

Methods: Data were collected from a sample of Vietnamese American adults (n=304) through surveys assessing DHT engagement, confidence in medical record security, and social and psychological factors. Descriptive statistics and inferential analyses, including 2-tailed *t* tests and chi-square tests, were used to examine differences across demographic groups.

Results: Many participants had engaged with mHealth tools (253/304, 83.2%), including using mobile devices for health tracking (185/302, 60.9%), and health care professional discussions (194/301, 64.5%). Online medical records were reported to be widely available (230/304, 75.7%), with a large proportion of the participants (182/227, 80.2%) accessing them at least once in the past year. Privacy concerns were a key barrier to using online medical records, with 40.5% (17/42) of nonusers citing security fears, and 26.6% (81/304) reporting withholding health information from health care professionals. The main reasons participants did not access online medical records (45/304, 14.8%) were that they preferred to speak to health care professionals directly (31/44, 70.5%) or did not perceive a need to access their online medical records (30/43, 69.8%). There were no statistically significant differences in sociodemographic characteristics between DHT users and nonusers. There were statistically significant differences in the levels of social support of participants who had varying levels of confidence in the security of their medical records ($F_{2,301}$=10.19; P<.001; η^2=0.063). A greater proportion of male participants reported distrust (ie, being “not confident” in the security of their medical records) than female participants (χ^2_2=20.8; P<.001), indicating a significant association between sex and confidence level.

Conclusions: While DHT adoption is high among Vietnamese Americans, privacy concerns remain a major barrier to full use of online medical records. Health care professionals and public health initiatives should focus on improving trust in medical record security, incorporating culturally tailored education on the benefits of digital health, and leveraging social media and mHealth tools to optimize patient engagement. Developing stronger family and community support may facilitate the adoption of DHTs.

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KEYWORDS

digital health technologies; health information technologies; cyber security; trust; social support; cultural competency; Asian Americans; diabetes mellitus

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Introduction

Background

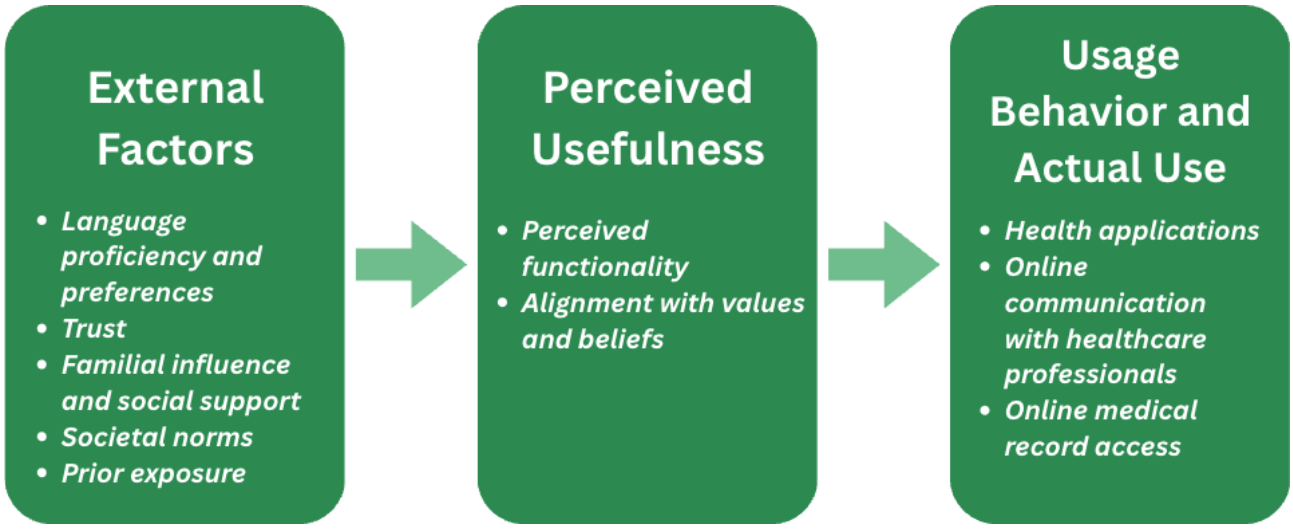
The rapid advancement of digital health technologies (DHTs) has revolutionized the way health care is delivered and accessed, including mobile health (mHealth) apps, wearable devices, and telemedicine platforms for the general population across the United States [1,2]. These technologies play significant roles in helping manage chronic health conditions, promote preventive care, and improve communication between patients and health care professionals (eg, physicians, nurses, and registered dieticians) among diverse specialties and settings [2]. DHTs, such as mobile phone–based systems and apps, have been shown to be highly effective to lower health care costs [3]. Despite growing DHT use, more than 75% of Asian Americans reported not using these technologies, and they are half as likely as non-Hispanic White individuals to search for health information online [4,5]. Among all Asian Americans, Vietnamese Americans comprise the fourth largest Asian ethnic subgroup nationally [6], yet Vietnamese Americans continue to be an underrepresented population in DHT use and adoption research. Existing studies in this population have been largely qualitative, focused on COVID-19 screening and vaccination; there have been no survey-based studies quantitatively assessing DHT use or its predictors among Vietnamese Americans [7-9]. Vietnamese Americans face unique challenges in health care access, including limited English proficiency, cultural stigma surrounding certain health conditions, and reliance on family-centered decision-making, all of which may affect how they engage with digital health tools [10,11]. There is a paucity of research focusing specifically on Vietnamese Americans, whose cultural beliefs, language preferences, and social dynamics may significantly influence their acceptance of DHTs [10]. Previous studies have also highlighted that trust and privacy concerns are significant barriers to the adoption of DHTs [12,13].

Therefore, the purpose of this study was to explore DHT use among Vietnamese Americans: including mHealth engagement, online medical record adoption, and key barriers to use. This study also assessed potential factors impacting DHT engagement among Vietnamese Americans, such as age, sex, social support, and privacy concerns.

Theoretical Framework

This exploratory study is guided by the extended technology acceptance model (TAM2) to assess the perceived usefulness and actual use of health-related technology by Vietnamese Americans (Figure 1) [14]. TAM2 has been successfully applied to health care technologies, patient portals, mHealth apps, and telehealth, particularly among populations for whom social influence, trust, and accessibility strongly influence technology use [15-17]. In alignment with TAM2, this research explored factors influencing technology adoption, such as language proficiency, trust in health care professionals, family opinions, community norms, and exposure to digital tools through peers or ethnic media. Perceived usefulness indicates facilitators to actual use. Use behaviors, including real-world engagement with DHTs (eg, frequency of online medical records access, health-tracking apps use, and digital patient–health care professional communication), are eventually shaped by both external and contextual factors.

Figure 1. Simplified technology acceptance model for digital health technology use in Vietnamese Americans. Adapted from Venkatesh and Davis [14].



Methods

Overview

This paper presents findings from a secondary analysis of a cross-sectional survey study conducted by a coauthor (APN) between November 2023 and March 2024. The methodology for this study has been previously described in detail [18]. Vietnamese Americans are the fourth most populous Asian population in the United States, with the largest concentrations in California, Texas, Washington, Florida, and Georgia [19]. The study included persons who self-identified as Vietnamese American and were aged 18 years or older. Because of the purpose of the original study, interested persons were excluded if they did not have high risk for diabetes (based on a score of 5 or more on the American Diabetes Association Diabetes Risk Test [20]) or a current diagnosis of prediabetes or diabetes.

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Initial recruitment efforts were conducted locally at in-person community events in the Dallas-Fort-Worth-Arlington metropolitan area and nationally online through professional nursing organizations and social media groups. Additional participants were referred through snowball sampling. Quota sampling was used to ensure sufficient Vietnamese-language responses for scale validation (ie, at least 10 participants per item on the survey with the highest item count). Bilingual researchers, including the principal investigator and a trained assistant, conducted eligibility screening and data collection in the participant's choice of either English or Vietnamese language to ensure delivery consistency.

Ethical Considerations

The study received institutional review board approval from Baylor University (IRBNet ID 2018067‐5) and was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants prior to data collection, including consent for future analyses. Participant confidentiality was protected through secure data storage and deidentification, with access restricted to authorized researchers and findings reported in aggregate form.

Measures

The PhenX Toolkit (version 41.5, August 18, 2022) was used as a base for measurement selection in this study [21]. Data collection was conducted in the participant's choice of English or Vietnamese, and the survey was translated from English to Vietnamese using a cross-cultural adaptation process with initial translations done by a bilingual team member and back-translations done by a certified translation company. Pretesting of translations passed through cognitive interviewing. An expert panel reviewed translations prior to and during validation testing. Participants had the choice of completing the survey face-to-face on paper, by interview, or online by interview or using Qualtrics. Interviews were performed by either the principal investigator or the trained research assistant, both of whom were bilingual.

The primary measure used in this secondary analysis of DHT use over the past 12 months was the Health Information National Trends Survey (HINTS) 2018, cycle 2 [22]. The psychometric properties of the HINTS survey have been evaluated by the National Cancer Institute on a question-by-question basis through expert review and cognitive validity [23,24]. HINTS includes 16 core items, several of which include multiple subitems and built-in skip patterns based on participants' prior responses (Multimedia Appendix 1). HINTS topics include tablet, smartphone, or electronic device use; internet use (eg, social media, online forums, and YouTube); and online medical records access. Most HINTS items have yes or no response options regarding how participants use DHT. As applicable, the HINTS items also include a third "not applicable" or "don't know" response option (eg, the item that asks if participants had shared health information from either an electronic monitoring device or smartphone with a health care professional within the 12 months). One HINTS item asks about the confidence level that safeguards, including technological factors, are in place to protect privacy with 3 ordered response options. For participants who had been offered online access to their medical records, items asked who offered this access, how many times the records were accessed, and the usefulness of the records for monitoring health.

Mental health risks were measured with 4 domains of the *DSM-5* (*Diagnostic and Statistical Manual of Mental Disorders* [*Fifth Edition*]) self-rated level 1 cross-cutting symptom measure for anxiety, depression, sleep disturbance, and substance abuse, where a rating of 2 or greater on any 5-point Likert scale item within the domain indicated a risk for that condition. The anxiety, depression, and substance abuse domains, with 2 to 3 items each, have been shown to be internally consistent and valid measures of psychopathology, with a strong sensitivity greater than 0.83 in community settings [25,26]. The sleep domain only consists of 1 item. Collectively, the *DSM* items used in this study demonstrated acceptable reliability (Cronbach α=0.72).

Health literacy was measured by the 18-item Short Assessment of Health Literacy; scores of 14 or less indicate limited health literacy [27]. The Short Assessment of Health Literacy demonstrated acceptable reliability (Cronbach α=0.78). Social support was measured with the total score of 19 five-point Likert scale items from the Medical Outcomes Study (MOS) social support survey, where high scores indicate more support [28]. The MOS social support survey demonstrated good reliability (Cronbach α=0.97). Sociodemographic data such as age, sex, educational level, and household income were also collected.

Data Analyses

Data were analyzed using SPSS (version 29; IBM Corp). Descriptive statistics were used to describe the sample characteristics and DHT use by Vietnamese Americans. Chi-square tests were used to examine associations between categorical variables where expected counts per cell were at least 5. Independent-samples 2-tailed *t* tests were used to compare mean scores of continuous or ordinal variables when the data were normally distributed, as demonstrated by histograms. Mann-Whitney *U* tests were used when the data for continuous or ordinal variables were not normally distributed.

One-way ANOVAs were also used to assess differences in means across 3 or more groups, for example, comparing social support scores across varying levels of confidence in medical record security. A 2-tailed $P<.05$ was considered statistically significant. Subsequent post hoc test options depended on whether homogeneity of variance was met (Tukey or Sidak post hoc tests) or violated (Games-Howell post hoc test).

Results

This sample was diverse in age and income, with a mean age of 52.86 (SD 16.37) years and mean household income of nearly US $100,000 (Table 1). The youngest participant was 18 years old and the oldest participant was 85 years old. There were more female participants and highly educated (247/300, 82.3% had completed at least some college education) participants. Most participants reported proficient English language proficiency (228/277, 82.3%) and demonstrated proficient health literacy (256/304, 84.2%). There were no statistically significant

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differences in sociodemographic characteristics of DHT users versus nonusers.

Table . Sample characteristics and digital health technology (DHT) use[a].

Characteristics	Total sample	DHT use	*P* value[b]
Age (y), mean (SD; range)	52.86 (16.37; 18 - 85)	52.53 (16.55; 18 - 85)	.16
Sex: Male, n (%)[c]	118 (39.1)	108 (38)	.14
Educational level, n (%)[d]			.52
High school or less	53 (17.6)	51 (18.1)	
Some college or bachelor's degree	184 (61.3)	173 (61.3)	
Graduate degree or higher	63 (21)	58 (20.6)	
Household income (US $)[e]			.93
<50,000	106 (40)	98 (39.4)	
50,000-99,999	57 (21.5)	54 (21.7)	
100,000-149,999	39 (14.7)	38 (15.3)	
≥150,000	63 (23.8)	59 (23.7)	
Health insurance: yes[f]	156 (88.6)	267 (94)	.06
English proficiency: well or very well[g]	228 (82.3)	213 (81.9)	.51
First generation immigrant[h]	247 (81.5)	205 (81.3)	.87
Percentage of life in the United States, mean (% SD; range)	79.7 (19.22; 16-100)	79.8 (19.33; 16-100)	.57
Health literacy level: proficient, n (%)[i]	256 (84.2)	241 (94.1)	.92
Mental health risks ≥2, n (%)[i]	138 (45.4)	130 (45.5)	.93
Social support, mean (SD; range)	73.44 (16.11; 19 - 95)	73.78 (15.80; 19 - 95)	.14

[a]Health literacy was measured by the Short Assessment of Health Literacy, where higher scores indicate higher health literacy levels, with scores ≥14 indicating a proficient health literacy level. Social support was measured by the Medical Outcomes Study Social Support Survey, where higher scores indicate more support.

[b]*P* values represent tests of association between each characteristic and DHT use (user vs nonuser), not comparisons with the total sample.

[c]Total sample: n=302; DHT use: n=284.

[d]Total sample: n=300; DHT use: n=282.

[e]Total sample: n=265; DHT use: n=249.

[f]Total sample: n=301; DHT use: n=284.

[g]Total sample: n=277; DHT use: n=260.

[h]Total sample: n=303; DHT use: n=252.

[i]Total sample: n=304; DHT use: n=286.

Table 2 presents findings from the HINTS survey. Most participants (289/304, 95.1%) used at least 1 type of DHT in the past year. Many participants (242/304, 79.6%) had used their smartphone or tablet for facilitating discussions with their health care professionals, health tracking, or informing their health decisions. A little more than half of the participants (156/302, 51.7%) had used other health-tracking devices.

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Table . Digital health technology use by Vietnamese Americans.

	Value, n (%)
Any digital health technology tools used within the last 12 months (n=304)	289 (95.1)
Online medical records—general	
Online medical records awareness (n=304)	230 (75.7)
Accessed online medical records at least once in the past year (n=227)	182 (80.2)
Reports online medical records are at least somewhat useful for monitoring health (n=172)	165 (95.9)
Top 3 components of online medical records identified	
Physician visit summary (n=170)	154 (90.6)
Health or medical problem list (n=169)	144 (85.2)
Immunization history (n=171)	145 (84.8)
Top 5 most helpful functions in online medical records	
Fill forms or paperwork related to health care (n=183)	136 (74.3)
Message health care professional (n=182)	122 (67)
Request refill of medications (n=183)	104 (56.8)
Help with deciding how to treat an illness or condition (n=183)	103 (56.3)
Download health information (n=183)	102 (55.7)
Sent online medical information to (n=183)	
Another health care professional	73 (39.9)
Family or caretaker	57 (31.1)
Health service or app	51 (27.9)
Top 2 reasons for not accessing online medical records	
Prefer to speak to health care professional directly (n=44)	31 (70.5)
Did not feel the need to use online records (n=43)	30 (69.8)
Privacy concerns due to online medical records and information withholding	
Nonusers citing security fears (n=42)	17(40.5)
Withheld health information from health care professionals due to privacy concerns (n=304)	81 (26.6)
Health-related uses for smartphones and tablets	
Health care professional discussions (n=301)	194 (64.5)
Health tracking (n=302)	184 (60.9)
Health decisions (n=303)	154 (50.8)
Other health-tracking devices (n=302)	
Used nonphone or nontablet device for health tracking in the past 12 months (eg, Fitbit, glucose meter, or blood pressure monitor)	156 (51.7)

Many participants reported having an online medical record (182/227, 80.2%). Most participants who accessed their online medical records (165/172, 95.9%) reported that online medical records were at least somewhat useful. The top 3 most helpful functions of their online medical records were for filling out forms or paperwork, messaging health care professionals, and requesting medication prescription refills.

The top 3 reasons participants gave for not accessing online medical records were that they preferred to speak to their health care professionals directly, did not feel the need to use online records, and that they reported a lack of trust in the privacy safeguards of online medical records. A total of 40.5% (17/42) of nonusers expressed concern about the security of their health data online. More than one-quarter of all respondents (81/304, 26.6%) even reported withholding information from their health care professionals due to those privacy concerns.

There were statistically significant differences in the levels of social support of participants who had varying levels of confidence in the security of their medical records ($F_{2,301}$=10.19; P<.001; η^2=0.063). Participants who were very confident (mean 77.70, SD 13.45) scored significantly higher than those who

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were somewhat confident (mean 71.94, SD 15.54; *P*=.005) and those who were not confident (mean 65.85, SD 21.80: *P*=.003). The difference between somewhat confident and not confident participants was not statistically significant (*P*=.19). A greater proportion of male participants reported distrust (ie, being "not confident" in the security of their medical records) than female participants (30/118, 25% vs 17/184, 9%; χ^2_2=20.8; *P*<.001), indicating a significant association between sex and confidence level.

The following nonsignificant trends were found: (1) a smaller proportion of participants with 2 or more mental health risks reported being very confident in the security of their medical records than those with 1 or no mental health risks (45/119, 32.6% vs 74/119, 44.6%; χ^2_2=5.3; *P*=.07), (2) a larger proportion of participants who reported using tablets or smartphones for health-related reasons also reported receiving disparate care than participants reporting no reported disparate care (53/58, 91% vs 144/173, 83%; χ^2_1=2.3; *P*=.13), and (3) a larger proportion of participants who did not report proficiency in the English language also reported that they were not confident in the security of online medical records compared with participants who reported proficiency in the English language (11/49, 22% vs 32/228, 14%; χ^2_2=4.6; *P*=.10).

Discussion

Key Findings

The key findings of this study include the high overall DHT engagement of Vietnamese Americans, and a key facilitator was that most participants found DHT to be useful. While DHT adoption was high among Vietnamese Americans in this study, privacy concerns remained a major barrier to full use. There were also interesting demographic and psychosocial differences linked to DHT perceptions and use related to sex and social support.

Privacy Concerns

Digital divides [29] may deepen if we do not address concerns related to the security of personal health information. For some participants, these concerns ran so deep that they reported withholding information from their health care providers. The proportion of participants who withheld information from their health care professionals in this present study was greater than that reported in other studies [30]. Withholding information can lead to missed diagnoses and delayed treatment, increasing health care inequities for populations such as the Vietnamese Americans [31]. Likewise, the likelihood of withholding personal health information decreases when there is a perceived high quality of care [32]. Although AI offers transformative potential for DHTs by enabling personalized, predictive, and context-aware interventions [33], there is uncertainty regarding how this will further impact the confidence that Vietnamese Americans have in the security of their protected health information online, such as demographic information, physical or mental health conditions, and care provided.

The collectivist cultural values common among Vietnamese Americans [11] must also inform how DHTs are promoted and explained. Tailoring DHT messaging in culturally and linguistically appropriate ways, such as offering Vietnamese-language tutorials, community testimonials, and intergenerational success stories, can improve resonance and reduce perceived risks. These messages should also acknowledge and support collective decision-making norms within families and communities, an often-overlooked factor in digital health adoption in Asian communities [34]. By addressing these specific cultural needs and values, health care professionals can provide more effective and meaningful persuasion in promoting DHT systems.

Recommended strategies to improve privacy, security, and trust in DHTs include compliance with data privacy regulations, robust security measures, and the provision of personalized and digital health care services [35,36]. Building trust in DHT systems among Vietnamese Americans should begin with targeted privacy education that clearly explains how DHTs protect personal health information. Nurses are well-positioned to lead efforts to address patients' privacy concerns and build trust in DHT systems. For example, a systematic review concluded that DHT was a feasible, effective, and acceptable method for reducing hemoglobin A_{1C} levels in individuals with prediabetes or diabetes, especially when there is timely and responsive personalized coaching by a dedicated health care professional [37].

Social Support

Participants in this present study who expressed high confidence in the security of their online medical records had significantly stronger social support. This finding suggests that social connectedness may play a role in shaping perceptions of digital privacy and trust, potentially influencing willingness to engage with health technologies. Nurses and public health practitioners can collaborate with trusted community figures and influencers to codevelop campaigns that highlight the safety and usefulness of DHTs in culturally relevant ways. Those with high social support may also feel more confident navigating online systems through help from others [38]. One study suggested that interventions promoting patient engagement via electronic health record portals should incorporate in-person technical support, which may overcome barriers related to privacy and security concerns [2].

While patient-facing strategies are crucial, health care provider behaviors remain a powerful driver of DHT adoption [32]. Health care providers' endorsement and active promotion of the DHT tools' benefits can significantly influence patient adoption and sustained use of digital systems. Nurses can serve as digital health ambassadors, reinforcing how technologies enhance patient–health care provider communication, improve care continuity, and facilitate timely access to health data.

Sociodemographic Factors

Although the present study found no statistically significant differences between DHT users and nonusers, these participants had a relatively high mean household income of nearly US $100,000, and the majority also had proficient health literacy and reported accessing their patient portal at least once in the past year.

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Other studies have shown that sociodemographic factors such as household income, English language proficiency, and health literacy may impact DHT use. Nearly half of low-income, limited English proficient Vietnamese Americans from the Lee et al [39] study reported using the internet; but only 28% reported using the internet to log in to access their patient portal. On the other side of the spectrum, Tuitert et al [40] noted that DHT use was higher in participants with a higher income. Studies have also linked limited language proficiency with low health literacy [41]. Limited health literacy has also been associated with difficulty accomplishing tasks on their patient portals (eg, finding their treatment plans) and more basic computer barriers (eg, difficulty using a mouse) [42].

One possible implication of the findings from this study is that higher income, English literacy, and health literacy levels may reduce barriers, such as limited access to devices, unstable internet connectivity, and difficulty navigating online health systems. Greater financial resources may also facilitate ownership of multiple internet-enabled devices and access to paid, higher-speed internet services, while proficient health literacy may enhance users' ability to locate, understand, and apply health information from digital platforms [42,43]. Taken together, these findings support the notion that digital health adoption is closely linked to broader social determinants of health and that interventions aimed at increasing patient portal use in Vietnamese American communities must address not only technology design but also structural and educational barriers that disproportionately affect lower-income, limited English proficient populations.

Limitations

While this study drew from a relatively large and diverse Vietnamese American sample, it may be subject to sampling bias due to convenience and snowball sampling. Also, while validated tools and dual-language data collection were used, self-reported data are not as reliable because they may be subject to recall or social desirability bias. For example, the HINTS survey does not ask participants to specify which electronic health record systems or patient portal platforms they had used, which limits the interpretation of findings regarding system-specific features and security perceptions. Furthermore, no formal adjustments for multiple comparisons were applied, and potential confounders were not controlled for, given the exploratory nature of this study,

Conclusions

This study suggests that for Vietnamese Americans, the digital divide is no longer primarily about access, but about trust and meaningful engagement. Although DHT use is widespread, persistent concerns about privacy and data security limit full use and may even compromise care when patients withhold information. These findings highlight the need to shift digital health efforts toward building trust, improving transparency, and delivering culturally responsive communication. Trust in digital systems is shaped not only by technology but also by social support, cultural values, and health care provider relationships, underscoring the importance of community-informed and health care provider–led interventions.

As digital health continues to expand, especially with emerging technologies such as AI, ensuring that systems are trusted, inclusive, and aligned with patient values will be critical to preventing new forms of inequity. Ultimately, advancing digital health equity will depend not just on who adopts these tools but on how confidently and effectively they are used.

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Data Availability

Data may be made available upon reasonable request by contacting the principal investigator (APN).

Authors' Contributions

Conceptualization: APN
Formal analysis: WK
Funding acquisition: WK, APN
Visualization: RQ

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Writing—original draft: RQ, JT, NN, LBG, AL, WK, APN
Writing—review and editing: APN

Conflicts of Interest

APN serves on the Editorial Board for the Asian Pacific Islander Nursing Journal.

Multimedia Appendix 1
Operationalized constructs of the extended technology acceptance model from sections B and D of the Health Information National Trends Survey (HINTS).
[DOCX File, 18 KB - apinj_v10i1e83091_app1.docx]

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Abbreviations

DHT: digital health technology

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***DSM-5*:** *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*
HINTS: Health Information National Trends Survey
MOS: Medical Outcomes Study
TAM2: extended technology acceptance model

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Differential Association of Inflammation With Pain and Physical Function in Knee Osteoarthritis by Race Focusing on Non-Hispanic Whites and Asian Americans: Pilot Study in Florida

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Abstract

Background: The current body of work has not yet addressed the potential racial differences in the relationship between systemic inflammation and knee osteoarthritis (OA) symptoms, including pain and physical function.

Objective: This pilot study aimed to investigate this association specifically among non-Hispanic Whites and Asian Americans.

Methods: We cross-sectionally analyzed 40 community-dwelling participants aged 50 - 70 years with self-reported knee OA pain, including 20 non-Hispanic Whites and 20 Asian Americans. Knee OA symptoms were assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and physical function subscales. The serum levels of C-reactive protein (CRP), tumor necrosis factor-alpha (TNF-α), and interleukin-10, as systemic inflammatory markers, were measured. Univariate and multivariable analyses, using stepwise linear regression models, were conducted to examine the correlation between these inflammatory markers and OA symptoms, with systematic adjustment for age.

Results: In non-Hispanic Whites, the above inflammatory markers did not correlate with knee pain or physical function. In Asian Americans, bivariate analyses revealed that CRP and TNF-α levels were associated with worse WOMAC pain scores (r=1.325, P=.041; and r=2.418, P=.036, respectively), and CRP levels were also linked to worse WOMAC physical function scores (r=4.950, P=.035). Multivariate analyses confirmed the association of CRP levels with both worse WOMAC pain (β=1.328, P=.046) and physical function (β=4.974, P=.034) scores in Asian Americans.

Conclusions: CRP may be a clinically relevant marker for knee OA symptoms, specifically in Asian Americans; however, caution is warranted owing to the exploratory nature of this study. Future research is set to benefit from leveraging a larger sample, incorporating additional inflammatory markers, and including racially diverse samples to validate and augment these findings.

Trial Registration: Clinicaltrials.gov NCT02512393; https://www.clinicaltrials.gov/study/NCT02512393

(Asian Pac Isl Nurs J 2026;10:e75086) doi:10.2196/75086

KEYWORDS

Asian Americans; inflammation; knee osteoarthritis; pain; physical function

Introduction

Background

Knee osteoarthritis (OA) is one of the leading causes of pain, daily living impairments, and disability in people aged ≥45 years. Although local inflammation aggravates OA joint pathologies, systemic inflammatory markers are also elevated in OA, especially in the presence of symptoms such as pain and reduced physical function [1,2]. Notwithstanding, the evidence remains controversial. The pooled results of a meta-analysis indicated a weak correlation between serum C-reactive protein (CRP) levels and knee OA pain [1]. Other studies have identified no significant association between serum CRP levels and knee OA pain or physical function [3,4]. A recent systematic review also reported conflicting associations of other markers, such as interleukin (IL)-6, with pain scores in patients with knee OA [5].

Several researchers argue that inconsistent evidence regarding the relationship between inflammation and knee OA symptoms is attributable to sex-specific differences [6-8]. However, considerably less attention has been focused on the possibility of racial/ethnic disparities in these relationships. Racial/ethnic minority groups, owing to systemic inequities and environmental challenges, may develop a different inflammatory fingerprint than their non-Hispanic White counterparts (ie, epigenetics) [9]. They are also disproportionately susceptible to chronic knee OA pain [10-12]. Nonetheless, most studies on inflammation and knee OA symptoms have failed to specify the racial

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composition of their samples, predominantly included non-Hispanic White participants, or adopted typical approaches that report average effects from race/ethnicity-adjusted analyses, possibly obscuring crucial dissimilarities. Overlooking such differences potentially hinders the development of personalized approaches to analgesic care and interventions that improve physical function, ultimately impeding efforts to reduce pain inequities across groups.

To our knowledge, no study has elucidated the potential racial/ethnic differences in the relationship between systemic inflammatory markers and knee OA symptoms. Only recently, Overstreet et al [13] found that the expressions/profiles of biomarkers underlying inflammation associated with chronic low back pain-related outcomes (ie, pain interference, pain at rest, and movement-evoked pain) differed between non-Hispanic Whites and non-Hispanic Blacks.

Study Aim

This pilot study investigated the relationship between inflammation and knee OA symptoms (ie, pain and physical function) by race. Specifically, we compared non-Hispanic Whites to Asian Americans. Asian Americans constitute a rapidly growing minority yet have been underrepresented in knee OA research, despite emerging evidence indicating that they experience greater knee OA symptoms than non-Hispanic Whites [10,11]. This underscores the critical importance of studying this population.

Methods

Study Design and Participants

This cross-sectional analysis used baseline data from a randomized controlled trial (RCT) registered at clinicaltrials.gov (NCT02512393) to assess the efficacy of transcranial direct current stimulation (tDCS) in mitigating knee OA pain. The parent trial employed a double-blind, sham-controlled, parallel-group design, in which participants were randomly assigned to receive either active tDCS (n=20) or sham tDCS (n=20). Participants underwent daily 20-minute stimulation sessions for 5 consecutive days. Additional details regarding the design and procedures of the parent RCT are reported elsewhere [14,15]. At baseline, a total of 40 individuals with self-reported knee OA pain (20 non-Hispanic Whites and 20 Asian Americans) were recruited in North Central Florida between September 2015 and August 2016. Prior to the intervention, participants completed comprehensive baseline assessments, including demographic characteristics, clinical measures, knee OA pain severity, physical function, and relevant biological factors. The breadth and depth of these baseline data provided a robust foundation for the present cross-sectional analyses.

Recruitment was conducted through a combination of posted flyers, email advertisements, and community-based outreach efforts at local clinics, hospital-based outpatient services, and community centers. Flyers and electronic announcements described the study purpose, eligibility criteria, and contact information for the research team. Interested individuals contacted the study staff and were provided with additional information about the study. Some participants were recruited via direct referral from treating clinicians in outpatient settings. Potential participants then underwent a standardized screening process, which included an initial telephone screening followed by an in-person eligibility assessment to confirm the inclusion and exclusion criteria prior to enrollment.

Because the present analyses were conducted using baseline data from a parent RCT, the eligibility criteria reflected those of the parent trial rather than being tailored specifically for the current secondary analysis. Participants were eligible if they were aged 50 - 70 years; reported unilateral or bilateral knee OA pain according to the American College of Rheumatology criteria [16,17]; were able to speak and read English; were willing to be randomly assigned to either the intervention or control group; were available to complete five consecutive daily tDCS sessions and weekly follow-up phone assessments for 3 weeks; had no plans to change pain-related medication regimens during the study period; had no contraindications identified through the tDCS safety screening questionnaire (eg, epilepsy) [18]; and were willing and able to provide written informed consent prior to enrollment. Exclusion criteria ensured that participants did not have concurrent medical conditions that could confound OA-related outcomes or coexisting diseases that could hinder protocol completion. Thus, the following were the exclusion criteria: (1) having undergone prosthetic knee replacement or non-arthroscopic surgery on the affected knee, (2) a serious medical illness, such as uncontrolled hypertension, heart failure, or a recent history of acute myocardial infarction, (3) peripheral neuropathy, (4) systemic rheumatic disorders, such as rheumatoid arthritis, systemic lupus erythematosus, and fibromyalgia, (5) alcohol or substance abuse, (6) cognitive impairment, defined as a Mini-Mental Status Exam score of 23 or lower, (7) a history of brain surgery, tumor, seizure, stroke, or intracranial metal implantation, (8) pregnancy or lactation, and (9) hospitalization for a psychiatric illness within the past year.

Measurement

The collected basic characteristics included age, sex (male vs female), marital status (partnered vs unpartnered), BMI (kg/m^2), and Kellgren–Lawrence (KL) radiographic grade (0 - 1 vs 2 - 4), pain catastrophizing, and negative affect. The study assessed pain catastrophizing using the pain catastrophizing scale (PCS), a 13-item measure designed to evaluate catastrophic thinking related to pain across three dimensions: rumination, magnification, and helplessness [19,20]. Each item was scored on a 5-point Likert scale ranging from “not at all” (0) to “all the time” (4). The PCS demonstrated adequate internal consistency, with subscale alphas ranging from 0.66 to 0.87 (α for all items=0.87) [19], and its sensitivity to psychosocial interventions for chronic pain has been well established [21]. Negative affect was assessed using the 10-item negative affect subscale of the Positive and Negative Affect Schedule (PANAS-NA) [22]. Respondents are asked to rate on a 5-point scale (1 = “very slightly or not at all”; 5 = “extremely”) their agreement with 10 descriptors of negative affect (afraid, ashamed, distressed, guilty, hostile, irritable, jittery, nervous, scared, and upset). The PANAS has been validated and

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demonstrates reliability, with an alpha coefficient range of .84 to .87 for negative affect [23].

Knee OA Symptoms: Knee OA Pain and Physical Function

Knee OA pain and physical function were measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and physical function subscales, where higher scores indicate greater pain and physical functional disability [24]. The pain subscale includes 5 items on a 5-point Likert scale (0 being none to 4 being extreme) measuring the pain severity during walking, climbing stairs, sleeping, resting, and standing. The participants' responses to the pain questions were summed up to derive an aggregated score of pain intensity (range 0 - 20). The physical function subscale asks patients to rate the degree of difficulty in accomplishing 17 activities of daily living on a 5-point scale (0 being none to 4 being extreme). The participants' responses were aggregated to produce a composite score of functional disability (range 0 - 68). The subscales in WOMAC demonstrate reliability and validity in evaluating knee OA in patients [24,25].

Inflammatory Markers

In this study, we also gathered data regarding the following inflammatory markers: CRP, tumor necrosis factor-alpha (TNF-α), IL-1β, IL-6, and IL-10. Owing to substantial missing data (45.0% - 80.0%), we excluded IL-1β and IL-6 from the current analysis. In the original study [15], blood samples were obtained prior to treatment initiation (ie, tDCS) on day 1 and after completing the fifth treatment on day 5. For our analysis, we utilized pre-treatment data acquired on day 1. Blood was drawn into ethylenediaminetetraacetic acid plasma tubes. Samples were inverted five times and stored on ice until further processing. Within 30 min of being collected, samples were centrifuged at 1600×*g* and 4°C for 15 min, aliquoted, and immediately stored in a −80°C freezer.

The plasma samples underwent solid-phase extraction using an Oasis™ Hydrophilic–Lipophilic-Balanced (30 mg) 96-well plate along with a vacuum manifold (Waters Corp.), according to the manufacturer's protocol. Briefly, the plate was conditioned with acetonitrile and equilibrated twice with 0.1% trifluoroacetic acid (TFA) in high-performance liquid chromatography (HPLC)-grade water. Samples were acidified with 1% TFA (1:1) and loaded onto the plate. The plate was washed thrice with 0.1% TFA in HPLC-grade water. The samples were eluted in 60% acetonitrile/40% HPLC-grade water/0.1% TFA and dried in a Savant AES1010 Automatic Environmental SpeedVAC® w/VaporNet Radiant Cover (Thermo Fisher Scientific). Thereafter, they were reconstituted using the original sample volume in assay buffer.

Plasma CRP levels were measured in duplicate using enzyme-linked immunosorbent assays, following the manufacturers' instructions (cat# DCRP00, R&D Systems, Minneapolis, MN; cat# ADI-900 - 071, Enzo Life Sciences, Inc., Farmingdale, NY, respectively). For CRP, the average intra- and interassay CV values were <10.0% and <7.0%, respectively. TNF-α and IL-10 plasma levels were measured in triplicate using a commercial multiplex immunoassay kit (cat# HCYTMAG-60Kl; MilliporeSigma, Burlington, MA) and analyzed using the MILLIPLEX® Analyzer 3.1 xPONENT® System (Luminex Corporation) . Data acquisition was accomplished using the same system and data analysis performed via MILLIPLEX® Analyst Software. Intra- and interassay CVs were <19.0% for all markers.

Statistical Analysis

Descriptive and comparative statistics were employed to determine sample characteristics. As the inflammatory markers were not normally distributed, log transformation was applied to mitigate skewness. When missing data were present (CRP, n=4), listwise deletion was performed, resulting in a streamlined dataset for analysis. Race-stratified analyses were conducted owing to an observed interaction between race and certain inflammatory markers, such as CRP (data not shown). We examined the relationships between BMI and each inflammatory marker, aiming to circumvent possible collinearity (since adiposity proves to be significantly associated with systemic inflammation), and specifically investigated their associations with knee OA symptoms. Multivariable linear regression models were used in the main analysis of each outcome.

Explanatory variables included age, sex, marital status, BMI, and KL radiographic grade, all of which potentially affect both inflammation and knee OA symptoms [26,27]. Pain catastrophizing and negative affect were also considered because of their relation to knee OA symptoms [28-30]. Candidate variables comprised those with $P<.200$ in bivariate analyses: single-factor analysis of variance in cases of variance equality, the Kruskal–Wallis test for qualitative variables, and the simple linear regression test for quantitative variables. Multivariable analysis based on stepwise selection at an alpha value of .05 was conducted to preserve the most relevant variables in the model and distinguish those independently associated with the outcomes. In all multivariable models, systematic adjustment for age was performed. Finally, we conducted diagnostic tests to ensure that the multivariable models satisfied linear regression model assumptions. All statistical analysis was carried out using R Studio (version 4.0.2; R Foundation for Statistical Computing) [31].

Ethical Considerations

The Institutional Review Board (IRB) of the University of Arizona considers investigators engaged in research if (1) they interact with participants for research purposes; (2) they have access to identifying study information; (3) they obtain informed consent from research participants; or (4) the University of Arizona directly receives part of federal funds for the study (ie, the University of Arizona is the prime awardee). If none of the above are true, then the researchers would not require IRB approval. Thus, this secondary analysis of deidentified data from an existing RCT was determined to be exempt from IRB review. Informed written consent was obtained from all participants in the parent trial, and participants were compensated for their time and participation.

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Results

Table 1 presents the characteristics of the participants by race. The groups differed in terms of age, BMI, KL radiographic grade, and pain catastrophizing. Asian American participants were significantly younger than non-Hispanic White participants (mean [SD] 54.80 [7.74] vs 65.10 [7.41] years; *P*=.001) and had a lower BMI (mean [SD] 25.02 [3.59] vs 27.98 [3.28] kg/m²; *P*=.001). A greater proportion of Asian Americans had lower KL radiographic grades (0‐1) compared with non-Hispanic Whites (80% vs 25%; *P*=.001). Asian American participants also reported higher pain catastrophizing scores than non-Hispanic White participants (mean [SD] 1.33 [1.25] vs. 0.31 [0.74]; *P*=.004). There were no significant differences between the groups in the levels of CRP, TNF-α, and IL-10, or in any WOMAC subscales (*P*>.05).

Table . Comparison of basic characteristics, inflammatory markers, and WOMAC[a] subscale scores between non-Hispanic Whites and Asian Americans (n=40).

Variables	Non-Hispanic Whites (n=20)	Asian Americans (n=20)	*P* value
Age (years), mean (SD)	65.10 (7.41)	54.80 (7.74)	.001[b]
Sex, n (%)			.205
Male	12 (60)	7 (35)	
Female	8 (40)	13 (65)	
Marital status			.127[c]
Married/partnered	13 (65)	18 (90)	
Nonmarried/unpartnered	7 (35)	2 (10)	
Body mass index, kg/m^{2,} mean (SD)	27.98 (3.28)	25.02 (3.59)	.001[b]
Kellgren-Lawrence radiographic grade (grade 0‐1)			.001[c,b]
Grade 0‐1	5 (25)	16 (80)	
Grade 2‐4	15 (75)	4 (20)	
Pain catastrophizing scale score, range: 0‐6; mean (SD)	0.31 (0.74)	1.33 (1.25)	.004[b]
Negative affect scale score, range: 10‐50, mean (SD)	14.00 (4.29)	20.15 (9.02)	.165
Inflammatory markers, mean (SD)			
C-reactive protein, ng/nl	2295.27 (3002.13)	1001.12 (898.91)	.114
Tumor necrosis factor-α, pg/ml	10.33 (5.56)	7.51 (3.67)	.067
Interleukin-10, pg/ml	8.38 (5.27)	6.78 (3.69)	.273
Clinical pain measures, mean (SD)			
WOMAC pain, range: 0‐20	4.90 (2.61)	4.40 (2.74)	.559
WOMAC physical function, range: 0‐68	16.50 (9.86)	13.6 (9.95)	.361

[a]WOMAC: Western Ontario and McMaster Universities Osteoarthritis.

[b]Significant results.

[c]Fischer exact test.

Table 2 presents the relationships between BMI and inflammatory markers by race. Pearson correlation analyses showed no statistically significant associations between BMI and log-transformed CRP, TNF-α, or IL-10 in either non-Hispanic Whites or Asian Americans (all *P*>.05). Similarly, ANOVA analyses revealed no significant differences in inflammatory marker levels across BMI categories in either group. These findings indicate that BMI was not strongly correlated with inflammatory markers in this sample and did not raise major concerns about multicollinearity in subsequent analyses, as shown in Table 2.

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Table . Relationships between BMI and inflammatory markers by race (n=40).

	Non-Hispanic Whites (n=20)			Asian Americans (n=20)		
	log(CRP)[a], ng/nl	log(TNF-α)[b], pg/ml	log(IL-10)[c], pg/ml	log(CRP), ng/nl	log(TNF-α), pg/ml	log(IL-10), pg/ml
Pearson correlation coefficient	0.179	−0.079	−0.190	0.364	0.292	0.218
P value	.507	.740	.421	.115	.212	.356
18.5≤BMI<25[d], mean (SD)	7.49 (1.53)	2.22 (0.59)	2.01 (0.71)	6.13 (0.91)	1.79 (0.62)	1.74 (0.64)
25≤BMI<30[e], mean (SD)	6.75 (0.54)	2.20 (0.33)	1.97 (0.71)	7.11 (0.79)	1.97 (0.38)	1.74 (0.33)
BMI≥30[f], mean (SD)	7.73 (0.73)	2.26 (0.64)	1.87 (0.82)	6.71 (1.07)	2.22 (0.57)	2.11 (0.67)
ANOVA *P* value	.194	.971	.929	.096	.551	__[g]

[a]CRP: C-reactive protein.

[b]TNF-α: tumor necrosis factor-alpha.

[c]IL-10: interleukin-10.

[d]Non-Hispanic Whites (n=5), Asian Americans (n=11).

[e]Non-Hispanic Whites (n=9), Asian Americans (n=7).

[f]Non-Hispanic Whites (n=6), Asian Americans (n=2).

[g]not applicable.

Table 3 presents the results of bivariate and multivariable analyses in both non-Hispanic Whites and Asian Americans. In non-Hispanic Whites, both analyses indicated that only pain catastrophizing was associated with worse WOMAC pain score and WOMAC physical function score (*P*<.050). In Asian Americans, bivariate analysis indicated that CRP and TNF-α levels were associated with a worse WOMAC pain score (*r*=1.325, *P*=.041; *r*=2.418, *P*=.036, respectively), while the CRP level was also related to a worse WOMAC physical function score (*r*=4.950, *P*=.035). In multivariable analysis adjusting for age, only the CRP level was associated with a worse WOMAC pain score (β=1.328, *P*=.046) and a WOMAC physical function score (β=4.974, *P*=.034) in Asian Americans. Of note, the IL-10 level was not significantly associated with WOMAC pain or physical function scores in either non-Hispanic White or Asian American participants in bivariate or multivariable analyses.

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Table . Bivariate and multivariable analyses (n=40).

	Non-Hispanic Whites (n=20)								Asian Americans (n=20)							
	WOMAC[a] pain				WOMAC physical function				WOMAC pain				WOMAC physical function			
	Bivariate analysis		Multivariable analysis		Bivariate analysis		Multivariable analysis		Bivariate analysis		Multivariable analysis		Bivariate analysis		Multivariable analysis	
	r	*P* value	β (SE)[b]	*P* value	*r*	*P* value	β (SE)	*P* value	*r*	*P* value	β (SE)	*P* value	*r*	*P* value	β (SE)	*P* value
Age	−0.133	.101	−.062 (0.058)	.304	−0.170	.592	.048 (0.283)	.868	0.030	.724	.032 (0.076)	.683	0.278	.360	.284 (0.266)	.300
Sex	0.043	.378	—[c]	—	0.108	.157	—	—	0.027	.488	—	—	0.001	.921	—	—
Marital status	0.037	.414	—	—	0.004	.802	—	—	0.013	.637	—	—	0.000	.931	—	—
BMI	0.211	.259	—	—	0.682	.335	—	—	0.029	.872	—	—	−0.144	.828	—	—
KL[d] radiographic grade	0.087	.207	—	—	0.002	.860	—	—	0.006	.754	—	—	0.001	.897	—	—
Pain catastrophizing	2.548	<.001[e]	2.370 (0.572)	.001[e]	7.115	.013[e]	7.252 (2.764)	.018[e]	0.478	.345	—	—	1.395	.449	—	—
Negative affect	−0.068	.631	—	—	−0.720	.167	—	—	0.130	.053	—	—	0.279	.269	—	—
log(CRP)[f], ng/nl	−1.035	.157	—	—	−2.789	.283	—	—	1.325	.041[e]	1.328 (0.616)	.046[e]	4.950	.035[e]	4.974 (2.157)	.034[e]
log(TNF-α)[g], pg/ml	−0.115	.930	—	—	−2.613	.596	—	—	2.418	.036[e]	—	—	6.716	.118	—	—
log(IL-10)[h], pg/ml	−0.861	.395	—	—	−4.158	.273	—	—	1.134	.349	—	—	2.297	.604	—	—

[a] WOMAC: Western Ontario and McMaster Universities Osteoarthritis.

[b] SE: standard error.

[c] not applicable.

[d] KL: Kellgren-Lawrence.

[e] Significant results.

[f] CRP: C-reactive protein.

[g] TNF-α: tumor necrosis factor-alpha.

[h] IL-10: interleukin-10.

Discussion

Principal Findings and Comparison With Previous Works

This pilot study investigated whether differences in the relationship between inflammation and knee OA symptoms (pain and physical function) exist between non-Hispanic Whites and Asian Americans. Our adjusted analyses indicated that the CRP level persists as a clinically relevant marker for both knee OA pain and functional disability in Asian Americans. The findings emphasize that inflammatory underpinnings of knee OA symptoms potentially vary among specific racial groups, echoing the results of Overstreet et al [13], which focused on patients with chronic low back pain.

However, interpretation needs caution. The proportion of individuals with early-stage knee OA (KL radiographic grade 0 - 1) significantly differed between the two groups, with 25% and 80% of non-Hispanic Whites and Asian Americans falling into this category, respectively. Evidence suggests that in early-stage knee OA, inflammation is a major reason why

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patients seek medical assistance in outpatient departments, and anti-inflammatory treatment may be more effective during this stage; in contrast, in late-stage knee OA, pain may not primarily originate from inflammation but rather from other sources that require further investigation [32], a phenomenon corroborated by our study. Furthermore, in the current study, men constituted 60% and 35% of the non-Hispanic White and Asian American samples, respectively. Although this sex composition was not statistically significant, a previous study has reported sex-specific relationships exhibiting weaker associations of CRP and TNF-α with knee pain among men [7]; this possibly, in part, explains our insignificant findings for non-Hispanic Whites.

The findings wherein no relationships were established between inflammatory markers and knee OA symptoms among non-Hispanic Whites aligns with an earlier study predominantly based on non-Hispanic White samples [3]. However, it contrasts with results reported by Zhu et al [33], who found serum CRP to be cross-sectionally and longitudinally associated with knee pain in patients with knee OA, as well as with other research reporting significant associations between knee OA pain and TNF-α [7,34,35]. Nonetheless, direct comparisons are challenging owing to the unknown racial composition of these studies, our pilot study's cross-sectional nature characterized by small sample sizes, varying socioeconomic and clinical characteristics across the study populations, and the multidimensional nature of pain assessed using various tools across the studies.

Notably, the IL-10 level was not associated with knee OA symptoms in either non-Hispanic White or Asian American participants. IL-10 is an anti-inflammatory cytokine that regulates immune homeostasis and may slow the progression of knee OA [36]. Several studies in knee OA have reported null or negative associations between IL-10 levels and clinical pain and function [7,37,38]. Imamura et al [37] found no relationship between serum IL-10 levels and WOMAC pain scores in individuals with painful knee OA and sensitization. Perruccio et al [7] reported that higher serum IL-10 levels were associated with lower WOMAC pain scores, regardless of sex. Similarly, Zhu et al [38] examined longitudinal associations between inflammatory and metabolic markers and WOMAC outcomes and found that an IL-10–related component, characterized by predominantly anti-inflammatory markers, was negatively associated with WOMAC pain and function scores. Yet, none of the aforementioned studies examined racial differences in the associations between IL-10 and knee OA symptoms, limiting comparisons with the present findings and underscoring the need for future research that explicitly considers race.

As health care practices in the United States shift toward precision and targeted medicine, considering demographic factors that potentially influence mechanistic processes is imperative [13]. We acknowledge that our pilot investigation may not have immediate clinical implications. However, our race-specific findings may inform health care providers that treatments chiefly developed based on data from non-Hispanic Whites may not provide optimal analgesic care for Asian Americans and suggest that the future development of novel OA treatment approaches may ultimately vary according to race, depending on the therapeutic target.

Based on our findings, future studies involving larger samples are required to validate our results and facilitate more advanced modeling (eg, with mediators/moderators) to augment current knowledge. In addition, future studies may substantially benefit from leveraging a larger pool of biomarkers that could be analyzed as possible correlational factors for knee OA symptoms. Simultaneously, several studies [5,39], including our own, have relied on a single marker as a measure of inflammatory status; however, recognizing that the inflammatory system is complex and involves multiple feedback mechanisms is indispensable. For example, a study by Zhu et al [38] attempted to address these issues by examining the patterns of 19 different inflammatory markers and adipokines derived from principal component analysis and subsequently exploring their association with knee OA symptoms. Future studies should ascertain whether these associations differ across racial/ethnic groups and also include individuals from other racial/ethnic minority groups, such as non-Hispanic Blacks and Hispanics.

Limitations

This pilot study has certain limitations. First, as this study represents a secondary, cross-sectional analysis of baseline data from a parent RCT, both the study design and the measures available for analysis were determined by the objectives of the parent trial rather than the specific aims of the current study. In addition, the sample size was defined by the feasibility-oriented goals of the parent pilot trial, rather than by statistical power considerations for the present secondary analysis. As such, the findings should be interpreted as exploratory. These design features may also introduce potential sources of bias, including selection bias related to the original eligibility criteria and measurement bias due to reliance on pre-specified baseline assessments. Second, the findings may not be generalizable as they are based on an extremely small convenience sample from a specific region. Furthermore, owing to the small sample size, we could not account for or control heterogeneity within racial groups (ethnicity). Third, the presence of unknown or unmeasured confounding factors, such as the use of nonsteroidal anti-inflammatory drugs, comorbid conditions, psychosocial factors like depression or anxiety, and synovial inflammation, cannot be ruled out. Fourth, the cross-sectional design hindered our ability to determine the directionality of the relationships between variables. Finally, our study was limited by the number of biomarkers assayed.

Conclusions

This pilot study provides pioneering evidence of race-specific relationships between inflammatory markers and knee OA symptoms among non-Hispanic Whites and Asian Americans. Based on our findings, racial/ethnic differences in this context warrant further exploration, with potential implications for the formulation of personalized strategies for managing knee OA symptoms.

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The authors attest that there was no use of generative artificial intelligence (AI) technology in the generation of text, figures, or other informational content of this manuscript.

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Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

CL and CKK were responsible for the conception or design of the work. HA contributed to the acquisition of the data. CL and CKK were involved in the analysis and interpretation of the data, as well as drafting the work. CKK and HA revised the manuscript critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the work.

Conflicts of Interest

HA is the Editor-in-Chief of *Asian/Pacific Island Nursing*. CKK reports consulting relationships with TLC, AposHealth, Kolon Tissue Gene, Express Scripts, Levicept, Enlivex, Pleryon, Avalor, GSK, Moebius Sun, Xalud, and Novartis. CNW's institution has received research grants from Amgen, Cumberland Pharmaceuticals, Novartis, Lilly, AbbVie, UCB, Pfizer, Artiva, and Bristol Myers Squibb.

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Abbreviations

CRP: C-reactive protein
IL-10: interleukin-10
KL: Kellgren–Lawrence
OA: osteoarthritis
PANAS: Positive and Negative Affect Schedule
PCS: Pain Catastrophizing Scale
SE: standard error
TNF-α: tumor necrosis factor-alpha
WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

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Personal Agency Support Questionnaire in Acute Psychiatric Inpatients: Development and Instrument Validation Study

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Abstract

Background: Promoting personal agency may reduce perceived coercion and facilitate recovery in acute psychiatric care. However, no patient-reported tool currently exists to evaluate support for personal agency in this setting.

Objective: This study aimed to develop a patient-reported tool (the Personal Agency Support Questionnaire [PASQ]) to assess perceived support for personal agency and to evaluate its psychometric properties among inpatients in acute psychiatric wards.

Methods: We used a literature review and focus group interviews to generate a pool of items for the questionnaire, which was then refined using cognitive interviews and a pretest. We evaluated the construct validity, internal consistency, and test-retest reliability of the newly developed PASQ using a cross-sectional survey of inpatients in acute psychiatric wards. This study was conducted in collaboration with individuals who have lived experiences of mental illness.

Results: We analyzed data from 109 respondents (response rate: 109/178, 61.2%; mean age: 52.9, SD 16.9 years; women participants: 59/109, 54.1%; diagnosed with schizophrenia: 61/109, 56%). The 10-item PASQ demonstrated excellent convergent validity and acceptable discriminant validity. Internal consistency was high (Cronbach α=0.92), and test-retest reliability was moderate (intraclass correlation coefficient 0.68).

Conclusions: This PASQ is a valuable tool for assessing personal agency support in acute psychiatric wards, demonstrating promise for both clinical use in acute psychiatric wards and clinical research.

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KEYWORDS

inpatients; mental disorders; mental health; personal autonomy; psychometrics; surveys and questionnaires

Introduction

Acute psychiatric wards provide rapid treatment to stabilize the symptoms of individuals whose acute mental health challenges cannot be fully managed by community services [1]. Because acute psychiatric symptoms temporarily influence cognitive processes and impair behavioral control [2,3], involuntary treatment and behavioral restrictions are sometimes used to ensure safety [4]. Although many inpatients experience therapeutic benefits from psychiatric hospitalization, it is often a negative experience, with previous studies indicating a high frequency of traumatic events [5,6] that affect patients' well-being and self-worth [7,8]. This increased distress caused by inpatient stays can lead to the subsequent avoidance of mental health services [6].

The psychiatric care system in Japan has one of the largest numbers of psychiatric beds globally (approximately 319,000), and a long average length of stay (263.2 d) remains a persistent concern [9]. To address this issue, the government has been promoting a shift from long-term hospitalization to community-based care, making the role of acute psychiatric wards—which emphasize short-term stabilization of acute symptoms—increasingly important [10]. Almost half of patients occupying these beds are there involuntarily, and Japanese acute wards use restrictive treatments at significantly higher rates than other countries [11,12]. Key strategies for addressing this urgent issue include minimizing the use of restrictive practices and enhancing staff awareness of the importance of supporting patients' personal agency [5].

Personal agency is defined as an individual's ability to control their own lives, pursue their goals [13,14], and perceive a sense of ownership of their own behavior [15]. It incorporates concepts such as intentionality, forethought, self-reactivity, and self-reflectiveness and operates through cognitive, motivational,

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affective, and choice processes [13]. Personal agency has been conceptualized as encompassing both intrinsic (internal states of being, such as self-confidence and self-awareness) and instrumental (ways of acting, such as goal-directed decision-making and behavioral control) agency [16,17]. This framework builds upon prior conceptualizations of agency, such as Kabeer's distinction between "power within" and "power to" [18].

Personal agency is conceptually related to other key concepts in psychiatric care, such as autonomy, empowerment, and personal recovery. Autonomy is commonly understood as acting in line with one's own values in psychiatry [19] and is regarded as an outcome achieved through processes that constitute personal agency [13,19,20]. In mental health services, support for autonomy emphasizes the promotion of self-determination, with shared decision-making highlighted as a contemporary approach [21,22]. Empowerment is a process by which individuals gain greater control over the decisions and actions that affect their health [23], encompassing both personal agency and broader social and environmental transformation [24]. Personal recovery refers to living a fulfilling life despite experiencing psychiatric symptoms [25] and represents a comprehensive framework in which personal agency is a central driving force that facilitates the recovery process [26-28]. In acute psychiatric care, symptoms and safety requirements often limit the extent to which higher-order processes, such as autonomy and empowerment, can be expressed [19,29]. In contrast, personal agency remains a central mechanism within the recovery process regardless of symptom severity or treatment phase [26-28,30]. Therefore, clarifying how personal agency is supported in daily care is particularly important in acute settings. Personal agency plays a crucial role in reducing feelings of coercion and involuntariness during hospitalization [8]; moreover, it contributes to patient engagement in care and long-term recovery [31,32].

Despite its importance, there are currently no tools available to assess support for personal agency from the patient's perspective. In acute settings, understanding how patients perceive the support they receive and how their voice is reflected in clinical practice is essential for maintaining a balance between safety and patients' personal agency and ultimately fostering care that supports their recovery. Therefore, the aim of this study was to develop and validate the Personal Agency Support Questionnaire (PASQ) as a practical checklist-type questionnaire, rather than a psychometric scale that measures latent constructs, that captures patient-perceived support for personal agency in acute psychiatric settings.

Methods

Overall Design

This study was conducted within acute psychiatric care settings, where supporting personal agency is especially relevant and challenging owing to acute symptoms, rapid clinical decision-making, and safety needs. It consisted of 3 phases. The development and psychometric evaluation of the PASQ were guided by the COSMIN (Consensus-Based Standards for the Selection of Health Measurement Instruments) checklist, which provides international standards for studies on measurement properties of health-related instruments (Checklist 1).

In phase 1, we conducted a literature review and focus group interviews to generate an item pool for the new questionnaire. Subsequently, we conducted cognitive interviews to refine these items.

In phase 2, we conducted a pretest to verify whether the questionnaire items were appropriate for the target group and evaluate the likely responses.

In phase 3, we evaluated the validity and reliability of the PASQ by a cross-sectional survey of inpatients in acute psychiatric wards. Reporting of phase 3 followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for observational studies [33] to ensure methodological rigor and transparent reporting (Checklist 1).

Phase 1: Developing an Initial Item Pool and Cognitive Interview

In phase 1, we conducted a literature review and focus group interviews guided by best-practice recommendations for item pool generation [34]. We referred to existing patient-reported scales assessing various factors, such as recovery, empowerment, and autonomy, that had demonstrated reliability and validity for evaluating individuals with mental illness. From these scales, we incorporated the perspectives of research collaborators with lived experience of mental illness and extracted items according to 3 criteria: (1) the support aligned with personal agency; (2) the support included only the direct experiences of patients' interactions with staff, rather than support provided by hospitals or services; (3) the support focused on foundational aspects of personal agency relevant to acute psychiatric care, rather than directly targeting long-term social participation or self-actualization.

Through team discussions, we grouped items that met these criteria according to similarity in meaning to reduce redundancy and organize the item pool.

In parallel, focus group interviews were conducted with individuals who had experienced acute psychiatric hospitalization within the past 10 years. Participants were recruited from welfare service centers and nonprofit organizations in the Kansai region of Japan using convenience sampling (this approach was used primarily because of existing collaborative networks and logistical feasibility). The focus group interviews aimed to identify support that contributed to personal agency during acute hospitalization. Data collection and analysis were conducted iteratively and concurrently to capture diverse narratives, including unspoken perspectives and differing patterns. For the analysis, we focused on the experiences that were commonly identified as support for personal agency across participants, taking into account differences in backgrounds and experiences. These experiences were integrated and organized according to similarity.

Based on these findings, semantically redundant items were removed or integrated. Through collaborative discussions with our research collaborators with lived experience of mental illness, we selected items that supported personal agency while

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also considering the psychological burdens and contextual constraints of acute psychiatric settings. During this process, we examined how each support type was perceived and its effectiveness in acute contexts. For example, for the item of "information provision," participants stated that "too much information can be confusing, and it is more important to understand what is happening now and what to do next." Upon reflection of such views, the item was refined to ensure that it evaluated whether information was provided at a time and in a manner that patients could understand and accept.

Content validity was examined collaboratively alongside four research collaborators with lived experience of mental illness and one clinical expert. All reviewed each item for clarity, relevance to support for personal agency, and appropriateness for acute psychiatric contexts. A cognitive interview was then conducted with one of the focus groups to confirm that the instructions and item wording could easily be understood.

Phase 2: Pretest

In phase 2, we conducted a pretest with 20 people from 2 acute wards of a psychiatric hospital. One of these wards later participated in the main survey in phase 3 in May 2024. The pretest involved assessing the extent of the burden on questionnaire respondents and identifying items that were frequently left unanswered or often received identical responses.

Phase 3: Evaluation of the Questionnaire

Setting and Participants

To evaluate the validity and reliability of the PASQ, we conducted a cross-sectional survey among inpatients in 6 acute psychiatric wards across 2 psychiatric hospitals in Japan. The hospitals were selected using convenience sampling. Coincidentally, both hospitals were accredited by the Japan Council for Quality Health Care, which ensured a more structured and higher-quality treatment environment compared with many other psychiatric facilities in Japan.

Inpatients were included in this study if they met the following criteria: (1) they had been hospitalized for at least 1 week during their current stay; (2) the attending psychiatrist had confirmed that their mental state and treatment would not be affected by participation in the research; and (3) they were aged 18 years or older. We excluded inpatients who (1) were in isolation or physically restrained; (2) were primarily being treated for a physical illness; and (3) had a diagnosis of dementia or intellectual disability. Nursing managers in each ward identified eligible patients admitted during the study period (from May to September 2024). The first author explained the study to each participant and obtained their informed consent. The estimated required sample size for phase 3 was 100 participants, in accordance with the COSMIN (Consensus-Based Standards for the Selection of Health Measurement Instruments) checklist [35], which provides international guidelines for measurement studies.

Data Collection Procedures

The first author distributed paper-based self-administered questionnaires to each participant. If requested, the first author read the questions aloud or completed responses on the participants' behalf, using only the exact wording of the items without providing additional explanations to minimize response bias. Participants were informed that their responses would remain confidential, would not affect their treatment, and would never be disclosed to the hospital staff involved in their care. They could either return the questionnaire to the first author directly or seal it in an envelope and place it in the ward's collection box to ensure privacy.

Measures

The Personal Agency Support Questionnaire

The PASQ is a newly developed tool for assessing perceived support for personal agency even under restricted environments, including acute psychiatric care settings. It is rated on a 5-point Likert-type scale (0="not at all" to 4="very much"). A higher score indicates higher perception of the support for personal agency. As it assesses it in a checklist-like manner, it is not expected to be normally distributed. The Japanese version of the scale is provided in Multimedia Appendix 1.

The Japanese Version of Brief INSPIRE (Brief INSPIRE-J)

Given that personal agency is considered a central mechanism supporting personal recovery, and recovery-oriented support is conceptually linked to personal agency, we used the Brief INSPIRE-J to assess convergent validity. It is a shortened, 5-item version of the INSPIRE measure. Each item corresponds to 1 aspect of the concept of personal recovery (connection, hope, identity, meaning and purpose, and empowerment) and is rated on a 5-point Likert-type scale (0="not at all" to 4="very much") [36]. A higher score indicates greater satisfaction of the service user with the professional support they received in their recovery-oriented practice. The validity and reliability of Brief INSPIRE-J have been confirmed in Japan (Cronbach $\alpha \geq 0.82$) [37]. In this study, the Brief INSPIRE-J exhibited high internal consistency, with a Cronbach α of 0.92.

The Japanese Version of the Kessler 6-Item Psychological Distress Scale

Because the psychological distress scale assesses internal emotional states [38], while the PASQ measures the perception of support, these 2 scales are theoretically assumed to assess conceptually distinct constructs. Therefore, we used the Kessler 6-item Psychological Distress Scale (K6) to examine divergent validity. The K6 comprises 6 items that ask respondents how frequently they have experienced symptoms of psychological distress. It is rated on a 5-point Likert-type scale (0=none of the time to 4=all the time) [38], with higher scores indicating a greater likelihood of the respondent having experienced distress. The Japanese version demonstrated equivalent screening performance to that reported for the original English versions (the area under the receiver operating characteristic curve 0.94, 95% CI 0.88 - 0.99) [39]. For K6 in this study, Cronbach α=0.80, indicating good internal consistency.

Statistical Analysis

First, we conducted a descriptive analysis to examine the distribution of responses. Convergent validity was assessed assuming a significant and positive correlation with Brief INSPIRE-J; divergent validity was examined assuming an

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insignificant correlation with K6. The Shapiro-Wilk test demonstrated that the PASQ had a nonnormal distribution; therefore, Spearman's rank correlation coefficients, 95% CI, and *P* values were calculated. Correlation coefficients were interpreted based on Akoglu [40] as follows: 0.00 - 0.19: none/very weak; 0.20 - 0.39: weak; 0.40 - 0.59: moderate; 0.60 - 0.79: strong; and 0.80 - 1.00: very strong.

We calculated Cronbach α coefficients to measure internal consistency, with a value of 0.70 or higher considered sufficient [41]. We also calculated Cronbach α after removing each item and item-to-total correlations, which indicated how well each item aligned with the overall construct. In addition, to prevent inflation of the correlation value, we calculated corrected interitem correlations and the correlation between each item and the sum of the others. Item-to-total correlation and corrected interitem correlations of 0.30 or higher were considered acceptable [42], suggesting that the item contributed well to the overall reliability of the PASQ.

We assessed test-retest reliability in targeting 20 participants over approximately 2 weeks. This interval was established based on previous research, assuming that the memory and experience of the first response would not influence the second response and that little would change between responses. We calculated the intraclass correlation coefficients (ICCs) between the 2 time points to examine test-retest reliability. ICC values were classified as poor (<0.50), moderate (0.50 - 0.75), good (0.75 - 0.90), or excellent (>0.90), in line with Koo and Li [43]. Because the PASQ was developed as a short assessment questionnaire in a checklist manner, following previous studies [44,45], we did not perform factor analysis.

All statistical analyses were performed in *R* (Version 4.4.1; R Core Team) [46]. We used the psych [47] and tidyverse [48] packages for descriptive statistics and reliability analyses and the psych [47], lavaan [49], and irr [50] packages for ICCs. A *P* value of <.05 was considered statistically significant (2-tailed test).

Patient and Public Involvement

Because this research focused on patients' subjective experiences, 4 individuals who had experienced acute psychiatric admissions were involved as research collaborators throughout this study. They advised on the clarity and comprehensibility of item wording and the survey procedures to ensure that the items reflected patients' lived experiences during acute psychiatric hospitalization. Their feedback led to some of the items being revised to better reflect perceived support that is responsive to the individual's sense of readiness and current mental state. This patient and public involvement process followed ethical guidelines and adhered to the principles of meaningful involvement [51]. The study collaborators received a 5000 Japanese yen (US $31.60) gift card as a token of appreciation for attending 2 or 3 meetings.

Ethical Considerations

Because this study involved acute psychiatric inpatients, certain considerations were applied to the recruitment of participants. Attending psychiatrists could restrict the first author from approaching patients to explain the study, if such contact could negatively impact patients' treatment. The first author, who had no clinical or organizational role at the hospitals, explained the study to individual patients privately, without staff present. The voluntary nature of participation, the absence of any effect on treatment, and confidentiality were explained both verbally and in writing, and written informed consent was obtained from all patients. To ensure privacy, data were anonymized in a linkable manner to allow for consent withdrawal. Personal identifiers were stored separately. Data were managed on a password-protected computer and in a locked cabinet. No compensation was provided to participants. The study was approved by the Ethics Committee of the Kobe University Graduate School of Health Sciences and the Graduate School of Medicine at Kyoto University (approval 1172 and R4367), as well as the Ethics Committee of the participating hospital (approval 2024 - 1).

Results

Phase 1: Developing an Initial Item Pool and Cognitive Interview

From the 330 items extracted from existing patient-reported measures, 94 items were selected according to item-selection criteria and grouped according to similarities (eg, respect for strengths and values, support for coping with difficulties, and assistance with decision-making). Focus group interviews were conducted with 12 individuals. Over 8 sessions, commonly reported experiences of support for personal agency in acute settings were identified, such as feeling safe, the ability to express thoughts openly, and the ability to make choices based on recovery level. By integrating insights from both the literature review and the focus group interviews, 10 items were selected, and consensus was reached among the researchers and research collaborators on all items, including their wording and clarity. The cognitive interview confirmed that all items could be easily understood by patients. The instructional texts were revised to ask respondents to reflect on the support received throughout their entire hospitalization and to rate support provided by all staff members in the ward rather than specific individuals.

Phase 2: Pretest

The pretest was conducted with 21 participants from 2 wards. Although 4 participants required assistance (eg, reading support), all completed the questionnaire within approximately 5 minutes. No missing data or extreme response biases were observed.

Phase 3: Evaluation of the Questionnaire

Study Participants

During the recruitment period, we explained the study to 113 of 178 eligible inpatients. Four participants did not return their questionnaires, but the remaining 109 (response rate 61.2%) provided responses and were included in the analysis. Of these 109 participants, 14 (12.8%) requested assistance with either reading the questions or writing their answers. There were no missing values for the main variables. Participant characteristics are presented in Table 1. Over half of the participants (59/109, 54.1%) were women. The overall mean age of participants was 52.9 (SD 16.9) years. Schizophrenia was the most common

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diagnosis (62/109, 56%), followed by mood disorders (32/109, 29.4%).

Table . Demographic and clinical characteristics of respondents[a].

Variables	Values (N=109)
Age (y), mean (SD)	52.9 (16.9)
Duration of illness (y), mean (SD)	18.9 (15.9)
Length of current hospitalization (d), mean (SD)	36.4 (30.9)
Gender, n (%)	
Women	59 (54.1)
Men	50 (45.9)
Diagnosis, n (%)	
Schizophrenia	61 (56.0)
Mood disorders	32 (29.4)
Substance abuse	7 (6.4)
Anxiety disorder	4 (3.7)
Developmental disability	4 (3.7)
Epileptic psychosis	1 (0.9)
Type of hospitalization at the time of admission, n (%)	
Involuntary hospitalization for medical protection	66 (60.6)
Voluntary hospitalization	34 (31.2)
Involuntary hospitalization	7 (6.4)
Emergency hospitalization	2 (1.8)
Type of hospitalization at the time of the survey, n (%)	
Involuntary hospitalization for medical protection	56 (51.4)
Voluntary hospitalization	49 (45.0)
Involuntary hospitalization	4 (3.7)
Number of previous admissions to a psychiatric hospital, n (%)	
None	24 (22.9)
One	10 (9.5)
Two or more	71 (67.6)

[a]Subsample sizes vary for some variables because of missing responses (n=107 for age, n=105 for number of previous admissions to a psychiatric hospital, and n=99 for duration of illness).

Distribution of the Responses

Table 2 and Figure 1 illustrate the distribution of the responses to each item of the PASQ. Responses were generally skewed toward the higher categories (“quite a bit” and “very much”), with a median score of 3 for all items. Mean scores ranged from 2.48 (SD 1.29) to 2.93 (SD 1.21). A high proportion of respondents (almost 70%) answered “quite a bit” or “very much” to the following items: “Medical staff respect me as a person (75/109, 68.8%),” “Medical staff are involved so that I have a feeling of safety (77/109, 70.6%),” and “Medical staff provide support so that I can handle trouble (76/109, 69.7%).” Although these 3 items and item 6 demonstrated ceiling effects, they were retained to maintain content validity. In contrast, less than 60% of participants answered “quite a bit” or “very much” to the following items: “Medical staff try to understand the reason for my actions (63/109, 57.8%),” “Treatment and care are in line with what I want and the way I wish to be (63/109, 57.8%),” and “Medical staff share future treatment plans and expectations with me (62/109, 56.9%).”

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Table . Personal Agency Support Questionnaire item responses and item-to-total correlations (N=109).

Item[a]	Mean (SD)	Median (IQR[b]; range)	Cronbach α when item is deleted[c]	Item-to-total correlation[d]	Corrected Interitem correlation[e]
1	2.83 (1.21)	3 (2; 0-4)	0.92	0.65	0.57
2	2.76 (1.18)	3 (2; 0-4)	0.91	0.78	0.72
3	2.93 (1.21)	3 (2; 0-4)	0.91	0.71	0.64
4	2.84 (1.16)	3 (2; 0-4)	0.91	0.81	0.76
5	2.61 (1.25)	3 (2; 0-4)	0.92	0.63	0.54
6	2.70 (1.32)	3 (2; 0-4)	0.91	0.75	0.67
7	2.48 (1.29)	3 (1; 0-4)	0.91	0.79	0.73
8	2.62 (1.35)	3 (2; 0-4)	0.91	0.80	0.74
9	2.51 (1.41)	3 (2; 0-4)	0.91	0.81	0.75
10	2.67 (1.31)	3 (2; 0-4)	0.90	0.84	0.79

[a]The wording of each item is presented in Figure 1.

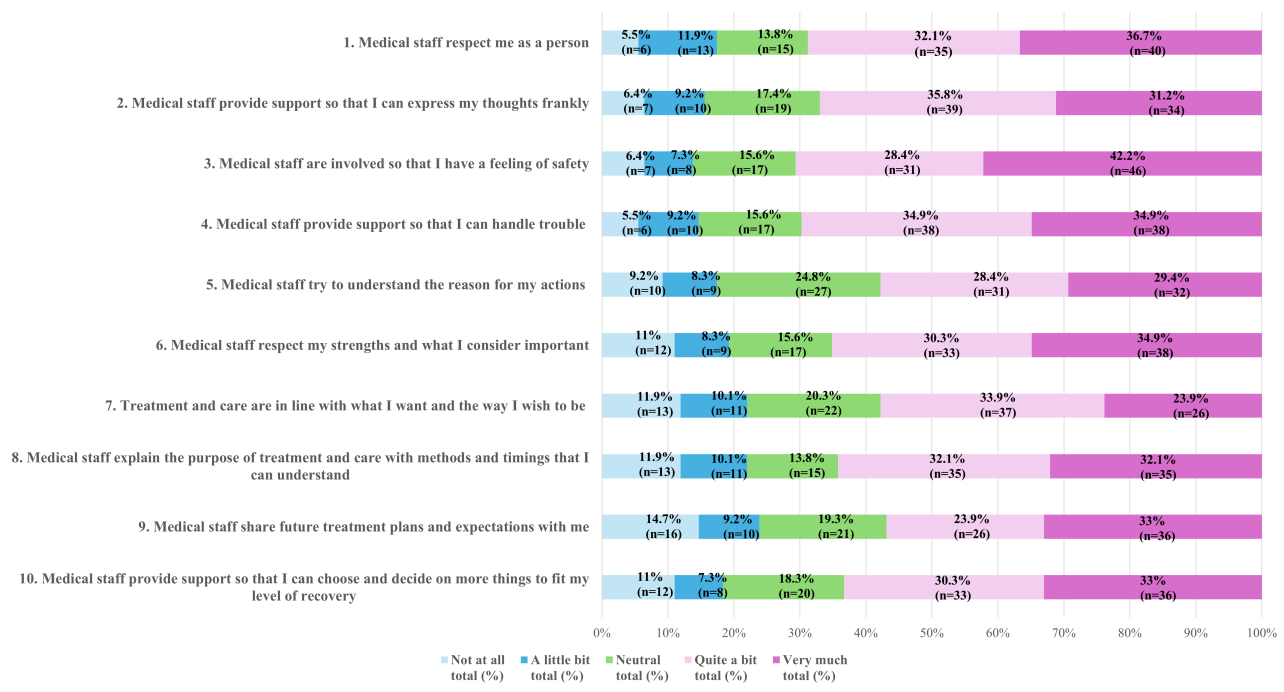
[b]IQR: interquartile range.

[c]Cronbach α when item is deleted: reliability coefficient of the scale if the respective item is removed.

[d]Item-to-total correlation: correlation between the item and the total scale score excluding that item.

[e]Corrected interitem correlation: average correlation between the item and all other items.

Figure 1. Distribution of responses to the Personal Agency Support Questionnaire items (N=109). Bars represent the percentage of participants selecting each response option on a 5-point Likert scale: not at all, a little bit, neutral, quite a bit, and very much.



Convergent and Divergent Validity

We found significant positive correlations between the total PASQ and total Brief INSPIRE-J scores (ρ=0.75, 95% CI 0.63 - 0.85; *P*<.001). There were significant weak and negative correlations between the total PASQ and total K6 scores (ρ=−0.32, 95% CI −0.49 to −0.13; *P*<.001).

Reliability

The total score of the PASQ demonstrated sufficient homogeneity of all items, with a Cronbach α coefficient of 0.92. No single item substantially reduced the internal consistency, with Cronbach α coefficients ranging from 0.90 to 0.92 when each item was removed. Item-to-total correlations ranged from 0.63 to 0.84, indicating strong associations between each item and the overall scale, while corrected interitem correlations ranged from 0.54 to 0.79, suggesting adequate interitem relatedness without excessive redundancy. The ICC value for the total score was 0.68 (95% CI 0.37-0.86; n=21), indicating moderate test-retest reliability.

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Discussion

Key Findings and Interpretation

The newly developed PASQ assesses patients' perceptions of the support for their personal agency. Although some participants required assistance to complete the survey, most were able to respond appropriately independently. This suggests that the PASQ is feasible for use in acute psychiatric wards. It also exhibited adequate convergent validity, acceptable divergent validity, good internal consistency, and moderate test-retest reliability among inpatients in acute psychiatric wards in Japan.

Although there are existing scales assessing support for similar concepts related to personal agency, such as empowerment and personal recovery [52-54], the PASQ is the first scale developed to evaluate support for personal agency. Several items generated from our study shared similarities with existing tools, such as the Health Care Climate Questionnaire, which assesses professionals' support for patients' autonomy [55]. Given that the Health Care Climate Questionnaire does not specifically assess care for patients with mental illness or acute care, the similarities observed between these tools suggest that there are fundamental elements involved in supporting patient personal agency, regardless of the type or stage of illness. However, each item of the PASQ reflects fundamental support elements in acute psychiatric wards. For example, the items related to a feeling of safety and respect reflect the importance of relational safety in acute psychiatric care, as highlighted in previous studies [56-58]. Support aligned with personal values, as captured by several items, contributes to self-understanding and a sense of consistency [59]. Furthermore, providing appropriate information and stage-appropriate choices, as addressed by other items, supports the regaining of control [8].

The relatively high scores for items related to a sense of safety and respect suggest that the psychiatric facilities prioritize these aspects during the acute phase of care. However, comparatively lower scores for items "Medical staff try to understand the reason for my actions," "Treatment and care are in line with what I want and the way I wish to be," and "Medical staff share future treatment plans and expectations with me" may reflect the challenge in supporting patients to participate in their treatment during the acute phase, despite its importance for personal agency [8,59,60].

PASQ and Brief INSPIRE-J scores exhibited a significant and strong correlation, confirming convergent validity. This finding supports the proposition that personal agency is key to promoting personal recovery [26-28]. The weak but significant negative correlation between PASQ and K6 did not support our hypothesis. However, this finding is consistent with previous studies, which found a negative relationship between personal agency and psychological distress [61,62]. It is therefore possible that perceived support for personal agency may be slightly associated with the extent of anxiety or depression, supporting the distinction between these concepts and the discriminant validity of the PASQ.

The PASQ exhibited high internal consistency, indicating sufficient homogeneity. Cronbach α values remained stable when items were deleted, suggesting limited redundancy. Item-to-total correlations were moderate to high, confirming that each item contributed meaningfully to the total score and that item deletion was not warranted. However, the moderate test-retest reliability suggests that the PASQ may not be entirely stable over time. This could be attributed to the rapid fluctuations in patients' conditions in acute psychiatric settings [63] during the 2-week interval or the slightly smaller sample size in this study.

Limitations and Strengths

This study has 2 main limitations. First, it was conducted at only 2 psychiatric hospitals, both of which provide relatively high-quality care. This may explain the relatively high scores observed, suggesting that our findings may not be generalizable to a broader range of clinical settings. Differences in staffing levels, staff training and attitudes, collaboration with community services, and the physical environment may all affect how support for personal agency is provided and perceived. Future research should therefore examine the applicability and validity of the PASQ in more diverse psychiatric settings. Second, the test-retest reliability was not excellent, with wide 95% CIs, which may reflect changes in patient symptoms and the care context during the 2-week interval; a shorter interval with a larger sample size might be more appropriate for acute psychiatric settings. Despite these limitations, this study is valuable as the first to develop a questionnaire for assessing perceived support for personal agency in acute psychiatric wards. It is also strengthened by the involvement of individuals with lived experience of acute psychiatric hospitalization, who helped to ensure that the PASQ reflects users' perspectives in acute settings.

Implications for Nursing Practice

The PASQ offers a practical approach to enable medical staff to understand how patients perceive support for personal agency in acute psychiatric wards and to apply these perspectives to clinical practice. Nurses, who work most closely with patients, face the challenge of maintaining a balance between delivering treatment, ensuring safety, and supporting patients' agency [64]. The PASQ may be helpful for nurses to gain an understanding of patients' subjective experiences and guide individualized care. Future studies could explore the use of the PASQ in staff training, interprofessional education, collaborative care planning in acute settings, and routine clinical reflection to enhance therapeutic engagement and communication. Furthermore, although the PASQ was developed and validated in acute settings, it may also be relevant in other contexts where agency may be compromised, such as long-term psychiatric hospitalization or trauma-related experiences. Future research should explore its applicability in such settings.

Conclusion

In this study, we developed and validated the PASQ, a patient-reported questionnaire that assesses perceived support for personal agency in acute psychiatric inpatients. The questionnaire demonstrated adequate convergent validity, acceptable divergent validity, good internal consistency, and moderate test-retest reliability. The PASQ shows promise as a

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valuable tool for both clinical practice in acute psychiatric wards and future clinical research.

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Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: TK
Data curation: TK, MS
Formal analysis: TK
Funding acquisition: TK
Methodology: TK, RC, YH
Project administration: TK
Supervision: RC, YH, and MS
Writing – original draft: TK
Writing – review & editing: RC, YH, and MS

Conflicts of Interest

None declared.

Multimedia Appendix 1
Personal Agency Support Questionnaire (PASQ), Japanese version.
[PDF File, 335 KB - apinj_v10i1e83366_app1.pdf]

Checklist 1
STROBE and COSMIN checklists.
[PDF File, 421 KB - apinj_v10i1e83366_app2.pdf]

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Abbreviations

COSMIN: Consensus-Based Standards for the Selection of Health Measurement Instruments
ICC: intraclass correlation coefficient
K6: Kessler 6-item Psychological Distress Scale
PASQ: Personal Agency Support Questionnaire
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Association Between Parental Smoking Status and Adolescent Mental Health: Population-Based Study

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Abstract

Background: Adolescents' mental health problems significantly affect their long-term psychological and physical health. Although peer influence grows during adolescence, parental influence remains critical. Parental smoking is associated with behavioral problems in adolescents.

Objective: This study aimed to investigate the association between parental smoking, particularly maternal smoking, and adolescents' mental health outcomes in South Korea, as research in this area is limited.

Methods: We analyzed data from the nationwide Korea National Health and Nutrition Examination Survey from 2012 to 2017. A total of 2761 adolescents were included in the final analysis after excluding those with missing data. We used ANOVA and chi-square tests to compare adolescents' and parents' baseline characteristics and mental health. In addition, multiple logistic regression analyses were conducted to examine the association between parental smoking status and adolescents' mental health.

Results: Our logistic regression analyses revealed that mothers' current smoking habits were significantly associated with their adolescents' cognitive stress (odds ratio [OR] 1.65, 95% CI 1.06 - 2.56), experiences of melancholy (OR 2.09, 95% CI 1.20 - 3.65), and suicidal ideation (OR 2.39, 95% CI 1.17 - 4.88). Furthermore, adolescents whose mothers were current smokers and had cognitive stress demonstrated higher cognitive stress (OR 2.09, 95% CI 1.12 - 3.90), melancholy (OR 2.27, 95% CI 1.10 - 4.71), and suicidal ideation (OR 2.74, 95% CI 1.21 - 6.23) than those whose mothers were not smokers and had no cognitive stress.

Conclusions: Efforts to improve adolescents' mental health require considering their mothers' smoking status and stress levels. This highlights the need to develop programs to enhance adolescent mental health, manage maternal stress, and promote smoking cessation.

(Asian Pac Isl Nurs J 2026;10:e73588) doi:10.2196/73588

KEYWORDS

parental smoking; adolescent mental health; suicidal ideation; melancholy; cognitive stress

Introduction

Adolescence is a critical period for the development and maintenance of social and emotional habits that are important for mental health [1]. Mental health issues during adolescence have considerable long-term impacts on one's physical and psychological status, with parental behaviors playing a critical role in this developmental stage [2], including in school connectedness [3,4], emotional and physical health [5], substance misuse [6], and suicide-related injury risk [7,8]. Therefore, prevention and early intervention are essential for effective mental health management and improved social outcomes [9].

Several variables affect the mental health of children and adolescents, including school-, peer-, and family-related factors [10]. However, there is renewed interest in family-related factors that affect children's mental health. In particular, the relationship between parental and children's mental health requires further verification and support [11].

Researchers have identified several parental health-risk behaviors as predictors of poor mental health in children. Parental smoking, particularly maternal smoking, is associated with internalizing and externalizing behavioral problems in children [12-14]. Maternal smoking has been linked to mental health issues in children, including symptoms of melancholy, anxiety, and suicidal ideation [15]. Parental smoking is associated with the initiation and regular use of smoking among children and adolescents [16]. The direct effects of smoking on children and adolescents may be attributed to an induced biological vulnerability to the addictive properties of nicotine, whereas the indirect effects may be driven by nicotine-induced behavioral problems in childhood [17].

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A systematic review and meta-analysis showed that compared with smoking cessation, continued smoking was associated with increased depression, stress, and poor overall mental health [18]. However, to our knowledge, no studies have examined the association between parental smoking (as reported by parents) and adolescents' mental health in Asian cultures. Furthermore, as Asian cultures are more receptive to men engaging in smoking than women, societal acceptance of female smoking remains low despite increasing smoking rates in women [19]. In South Korea, the prevalence of depression among adolescents reached 20.3% in 2021, and smoking remains a significant public health concern, with 4.5% of high school students reporting current use [20]. These high rates of mental health issues and smoking highlight the urgent need to understand the family-related factors influencing adolescent well-being in this cultural context.

We expected that parents' sex and smoking status would have differential effects on the mental health outcomes of adolescents. This study examined the association between parental smoking, with a particular focus on maternal smoking, and adolescent mental health in the South Korean cultural context. The current findings will contribute to a more nuanced understanding of these relationships.

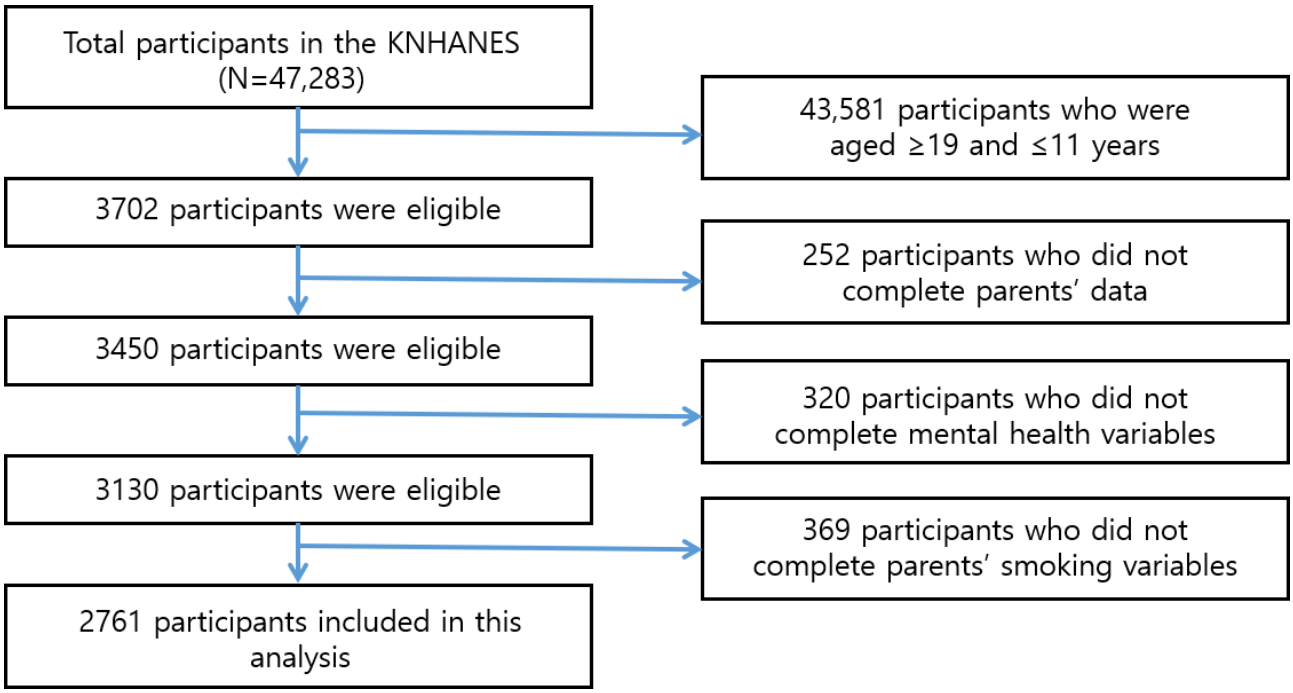
Methods

Study Design and Population

This study analyzed data from the Korea National Health and Nutrition Examination Survey (KNHANES), a cross-sectional, nationally representative survey conducted by the Korea Centers for Disease Control and Prevention from 2012 to 2017. The survey used a stratified multistage probability sampling design to draw a sample representative of the entire South Korean population. The KNHANES included health interviews, health behavior surveys, nutrition surveys, and health examinations.

Of the 47,283 participants enrolled in the KNHANES between 2012 and 2017, we included those aged 12 - 18 years (n=3702). Participants with missing parental (n=252), mental health (n=320), or parental smoking (n=369) variables were excluded. Finally, we examined the data of 2761 adolescents enrolled in the KNHANES (Figure 1).

Figure 1. Schematic depicting the study population. KNHANES: Korea National Health and Nutrition Examination Survey.



Research Variables

Baseline Characteristics

We recorded the following baseline characteristics of adolescents: age, sex, household and personal income levels, smoking status, and alcohol consumption. In addition, we recorded the following baseline parental characteristics: age, education level, current economic activity, BMI, waist circumference, smoking status, and alcohol consumption.

We classified household and personal income based on equivalent income,

average monthly household incomenumber of family members, designating values reflecting the lowest 25% as the first quartile, and the subsequent 3 levels (25% each) as the second, third, and fourth quartiles. We categorized parental education levels as "below university graduation" and "university graduate or higher." We organized current economic activity as "yes" or "no" to represent whether parents were currently employed or unemployed. We classified smoking status according to whether participants currently smoked. We considered participants who consumed more than 30 mL of alcohol per day as heavy drinkers.

Well-trained examiners performed anthropometric measurements during the study period. We acquired measurements for height and waist circumference to the nearest

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0.1 cm using a portable stadiometer (Seca 225, Seca) and a calibrated ruler (Seca 200, Seca) after exhalation and from the narrowest point between the lower borders of the ribcage and the iliac crest. We measured weight to the nearest 0.1 kg using a calibrated balance-beam scale (GL-6000‐20; G-tech). All instruments were calibrated regularly to ensure measurement accuracy, and inter-rater reliability tests were conducted periodically to minimize measurement bias. We calculated BMI as weight divided by height squared (kg/m^2).

Smoking Status

Smoking status was assessed using the question, "Are you currently smoking?" Participants could respond with "I smoke every day," "I smoke sometimes," "I smoked in the past, but I don't smoke currently," or "not applicable." We classified participants' smoking status as "current smoker," "ex-smoker," or "never smoked," with "current smoker" including "every day or occasional smoking."

Mental Health

The mental health variables included cognitive stress, experiences of melancholy, and suicidal ideation. The following questions were developed and reviewed by a panel of experts for epidemiological research, ensuring their validity as single-item questions. For cognitive stress, we classified the responses of "I feel very stressed," "I feel stressed a lot," and "I feel a little stressed" as "yes" and the response of "I hardly feel stressed" as "no." We determined whether participants experienced melancholy based on the question, "Have you felt sad or depressed for at least 2 consecutive weeks within the last year to the extent that it disturbed your daily life?" To this, participants could answer "yes" or "no." We assessed suicidal ideation using the question, "Have you thought of committing suicide in the last year?" The possible responses included "yes" and "no."

We did not measure "experiences of melancholy" as a parental mental health variable in this study; however, we measured the difference in adolescents' mental health based on whether their parents were diagnosed with depression. We defined participants as being diagnosed with depression if they responded "yes" to the question, "Have you ever been diagnosed with depression by a doctor?"

Statistical Analysis

We used the SAS survey procedure (version 9.3; SAS Institute Inc) to run a complex sample design and analyze the survey data. Mean and SE values were used to represent continuous variables, and mean percentage and SE values were used to represent categorical variables. We used an ANOVA and the chi-square test to compare the baseline characteristics and mental health variables of adolescents and parents. Subsequently, we performed multiple logistic regression analyses to evaluate the association between adolescents' mental health variables and differences in parental smoking status. We examined the odds ratios (ORs) and 95% CIs after adjusting for age, sex, smoking status, alcohol consumption, and household income. In addition, we examined the ORs and 95% CIs in the association between adolescents' mental health and mothers' current smoking status and cognitive stress.

Ethical Considerations

The original data for the KNHANES were collected after being approved by the institutional review board of the Korea Centers for Disease Control and Prevention. Written informed consent was obtained from all participants prior to the original data collection. As this study is a secondary analysis using publicly available and deidentified data, it was determined to be exempt from a separate institutional review board review (number 1041078-202106-HRSB-172-01). No compensation was provided to participants for this specific analysis.

Results

Adolescents' Mental Health According to Adolescents' and Parents' Baseline Characteristics

Table 1 shows adolescents' mental health according to their baseline characteristics and mental health variables, along with those of their parents.

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Table . Adolescents' mental health according to adolescents' and their parents' baseline characteristics (N=2761).

Variables	Cognitive stress			Experience of melancholy			Suicidal ideation		
	No (n=2059)	Yes (n=702)	*P* value	No (n=2536)	Yes (n=225)	*P* value	No (n=2600)	Yes (n=161)	*P* value
Adolescents									
Age (years), mean (SE)[a]	15.1 (0.05)	15.31 (0.08)	.02	15.12 (0.04)	15.52 (0.14)	.007	15.15 (0.04)	15.1 (0.16)	.73
Sex (male), mean % (SE)[b]	54.28 (1.19)	47.32 (2.10)	.005	53.78 (1.07)	38.69 (3.85)	<.001	53.47 (1.06)	37.24 (4.51)	<.001
House-hold income (lowest Q1), mean % (SE)	9.27 (0.95)	10.76 (1.40)	.34	9.43 (0.85)	12.03 (2.52)	.27	9.32 (0.81)	14.89 (4.01)	.09
Current smoker (yes), mean % (SE)	13.55 (0.90)	21.70 (1.91)	<.001	14.83 (0.86)	24.31 (3.35)	.001	14.98 (0.85)	25.84 (4.41)	.003
Heavy drinker (yes), mean % (SE)	31.93 (1.28)	41.48 (2.19)	<.001	32.61 (1.18)	53.36 (4.19)	<.001	33.38 (1.17)	49.83 (4.28)	<.001
Mothers									
Age (years), mean (SE)	44.15 (0.13)	44.62 (0.19)	.03	44.25 (0.12)	44.48 (0.35)	.52	44.26 (0.11)	44.41 (0.47)	.75
Education (≥ universi-ty), mean % (SE)	39.53 (1.55)	38.81 (2.32)	.77	39.62 (1.47)	36.32 (3.64)	.39	40 (1.44)	29.27 (4.10)	.02
Current economic ac-tivity (yes), mean % (SE)	66 (1.47)	63.2 (2.25)	.26	65.79 (1.34)	59.68 (3.99)	.12	65.29 (1.33)	65.15 (4.68)	.98
BMI (kg/m^2), mean (SE)	23.24 (0.09)	23.54 (0.17)	.10	23.29 (0.09)	23.58 (0.3)	.35	23.3 (0.09)	23.61 (0.38)	.42
Waist cir-cumference (cm), mean (SE)	77.2 (0.25)	77.99 (0.46)	.11	77.36 (0.24)	77.81 (0.76)	.56	77.38 (0.24)	77.66 (0.94)	.77
Current smoker (yes), mean % (SE)	4.19 (0.61)	7.5 (1.24)	.006	4.66 (0.57)	9.16 (2.20)	.009	4.69 (0.56)	10.32 (3.24)	.02
Heavy drinker (yes), mean % (SE)	5.69 (0.71)	6.91 (1.27)	.36	5.71 (0.66)	9.24 (2.42)	.09	5.88 (0.66)	7.93 (2.65)	.39
Cognitive stress (yes), mean % (SE)	25.34 (1.41)	33.95 (2.16)	.001	26.42 (1.22)	39.78 (3.59)	<.001	26.69 (1.18)	40.64 (4.80)	.002

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Variables	Cognitive stress			Experience of melancholy			Suicidal ideation		
	No (n=2059)	Yes (n=702)	*P* value	No (n=2536)	Yes (n=225)	*P* value	No (n=2600)	Yes (n=161)	*P* value
Diagnosis of depression (yes), mean % (SE)	3.89 (0.52)	5.21 (0.93)	.16	4.07 (0.48)	5.94 (1.79)	.23	4.1 (0.48)	6.25 (2.30)	.27
Fathers									
Age (years), mean (SE)	47.01 (0.15)	47.54 (0.23)	.04	47.11 (0.14)	47.41 (0.42)	.49	47.16 (0.14)	46.82 (0.53)	.54
Education (≥ university), mean % (SE)	50.72 (1.89)	45.87 (2.90)	.10	49.87 (1.81)	45.76 (4.69)	.38	49.89 (1.78)	43.87 (5.69)	.29
Current economic activity (yes), mean % (SE)	94.51 (0.88)	95.07 (1.15)	.66	94.67 (0.83)	94.39 (1.76)	.88	94.88 (0.77)	90.93 (4.25)	.24
BMI (kg/m^2), mean (SE)	24.89 (0.11)	24.70 (0.16)	.28	24.84 (0.10)	24.88 (0.26)	.90	24.84 (0.10)	24.99 (0.35)	.67
Waist circumference (cm), mean (SE)	86.12 (0.28)	86.19 (0.45)	.88	86.13 (0.27)	86.26 (0.65)	.84	86.09 (0.26)	86.85 (0.97)	.45
Current smoker (yes), mean % (SE)	42.95 (1.69)	46.15 (2.79)	.30	43.93 (1.59)	41.35 (4.40)	.58	44.11 (1.53)	37.34 (5.62)	.24
Heavy drinker (yes), mean % (SE)	25.46 (1.42)	28.86 (2.37)	.17	26.16 (1.36)	27.68 (4.01)	.71	26.78 (1.34)	18.17 (3.77)	.046
Cognitive stress (yes), mean % (SE)	29.03 (1.56)	32 (2.48)	.27	29.90 (1.44)	28.03 (3.87)	.65	29.6 (1.43)	32.3 (5.15)	.60
Diagnosis of depression (yes), mean % (SE)	2.07 (0.50)	0.42 (0.30)	.01	1.65 (0.41)	1.92 (1.15)	.81	1.73 (0.42)	0.68 (0.68)	.34

[a]Mean (SE) values represent continuous variables.

[b]Mean percentage (SE) values represent categorical variables.

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Table . Adolescents' mental health and maternal smoking status (N=2761).

Maternal smoking status	Cognitive stress			Experience of melancholy			Suicidal ideation		
	Mean % (SE)	Model 1[a], OR[b] (95% CI)	Model 2[c], OR (95% CI)	Mean % (SE)	Model 1[a], OR (95% CI)	Model 2[c], OR (95% CI)	% Mean (SE)	Model 1[a], OR (95% CI)	Model 2[c], OR (95% CI)
Never smoked	24.33 (1)	1 (ref[d])	1 (ref)	7.82 (0.63)	1 (ref)	1 (ref)	5.53 (0.53)	1 (ref)	1 (ref)
Ex-smoker	35.19 (5.17)	1.72 (1.08-2.75)	1.63 (1.04-2.59)	10.52 (3.07)	1.45 (0.74-2.85)	1.32 (0.68-2.55)	10.23 (3.20)	1.97 (0.93-4.18)	1.74 (0.80-3.78)
Current smoker	37.83 (5.19)	1.88 (1.20-2.95)	1.65 (1.06-2.56)	15.07 (3.71)	2.09 (1.20-3.65)	1.64 (0.93-2.89)	12.39 (3.84)	2.39 (1.17-4.88)	1.72 (0.88-3.38)

[a]Model 1: adjusted for adolescents' age and sex.

[b]OR: odds ratio.

[c]Model 2: adjusted for adolescents' age, sex, household income, current smoking status, and heavy drinking status.

[d]ref: reference.

Regarding adolescents' cognitive stress, we found significant differences according to their age (P=.02), sex (P=.005), current smoking status (P<.001), and heavy drinking status (P<.001); maternal age (P=.03), current smoking status (P=.006), and cognitive stress (P=.001); and paternal age (P=.04) and diagnosis of depression (P=.01).

For adolescents' experiences of melancholy, we observed significant differences according to their age (P=.007), sex (P<.001), current smoking status (P=.001), and heavy drinking status (P<.001), as well as maternal current smoking status (P=.009) and cognitive stress (P<.001). No significant associations were found for the paternal variables.

Suicidal ideation showed significant differences according to adolescents' sex (P<.001), current smoking status (P=.003), and heavy drinking status (P<.001); maternal education level (P=.02), current smoking status (P=.02), and cognitive stress (P=.002); and paternal heavy drinking status (P=.046).

Association Between Adolescents' Mental Health and Parental Smoking Status

Table 2 presents the association between adolescents' mental health and maternal smoking status. In Model 1 of the logistic regression analysis, we adjusted for adolescent age and sex. In Model 2, we adjusted for adolescent age, sex, smoking status, alcohol consumption, and household income. The analysis revealed that maternal smoking status was significantly associated with adolescents' cognitive stress and melancholy (P=.03). The ORs for adolescents' cognitive stress were 1.72 (95% CI 1.08 - 2.75) and 1.63 (95% CI 1.04 - 2.59) in Models 1 and 2, respectively, in the group with mothers who were ex-smokers; the ORs were 1.88 (95% CI 1.20 - 2.95) and 1.65 (95% CI 1.06 - 2.56) in Models 1 and 2, respectively, in the group with mothers who were current smokers. The OR for adolescents' experience of melancholy was significant in Model 1 at 2.09 (95% CI 1.20 - 3.65) only in the group with mothers who were current smokers. In addition, the OR for adolescents' suicidal ideation was significant in Model 1 at 2.39 (95% CI 1.17 - 4.88) only in the group with mothers who were current smokers. Paternal smoking was not significantly associated with adolescents' mental health.

Association Between Adolescents' Mental Health and Mothers' Current Smoking Status and Cognitive Stress

Figure 2 shows the association between adolescents' mental health and mothers' current smoking status and cognitive stress. We classified mothers into 4 groups depending on their current smoking status and cognitive stress: Group A (reference group) for mothers who were "not current smokers and without cognitive stress," Group B for mothers who were "not current smokers but with cognitive stress," Group C for mothers who were "current smokers but without cognitive stress," and Group D for mothers who were "current smokers with cognitive stress." The significant ORs were 1.36 (95% CI 1.06 - 1.75) in Group B and 2.09 (95% CI 1.12 - 3.90) in Group D for adolescents' cognitive stress, and 1.59 (95% CI 1.11 - 2.27) in Group B and 2.27 (95% CI 1.10 - 4.71) in Group D for adolescents' experiences of melancholy.

However, adolescents' suicidal ideation was significant for only Group D (OR 2.74, 95% CI 1.21 - 6.23). Figure 2 shows that adolescents' mental health ORs in Group D (current smokers with cognitive stress) were higher than those in Group A (reference group).

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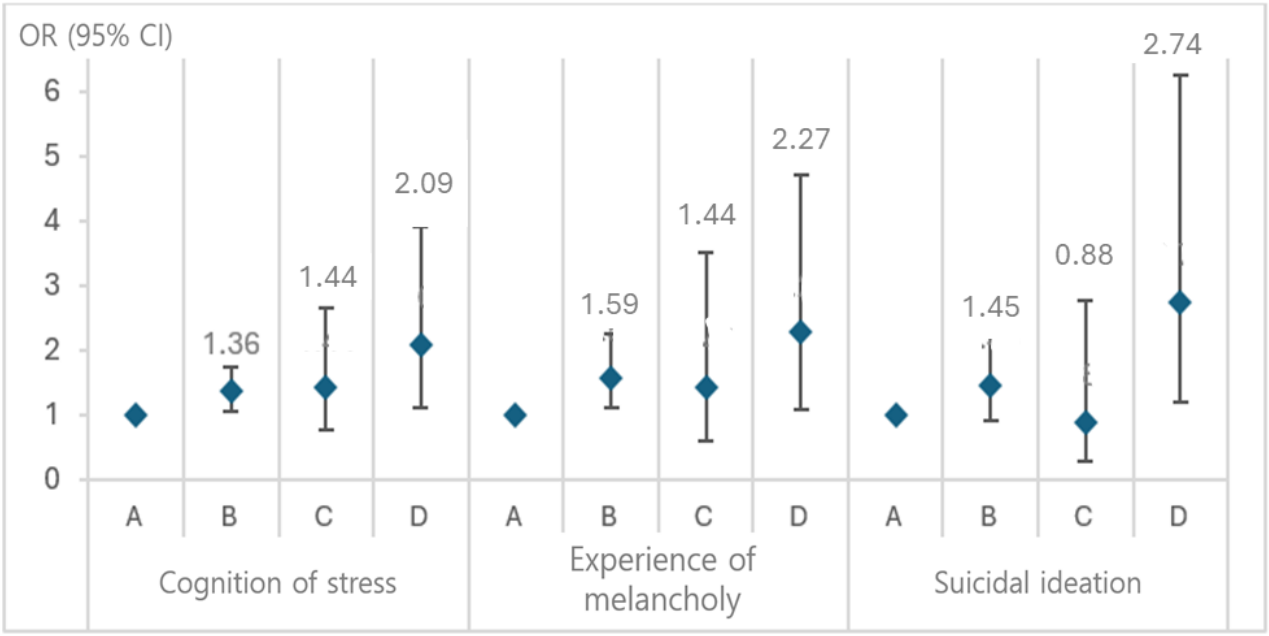
Figure 2. Association between adolescents' mental health and mothers' current smoking status and cognitive stress (N=2761). OR: odds ratio.



Discussion

Principal Findings

This study examined the association between parental smoking status and the mental health of their adolescents in South Korea, specifically focusing on cognitive stress, melancholy, and suicidal ideation. Furthermore, we analyzed these factors separately for mothers and fathers to identify any differences in the effects.

We observed a significant relationship between adolescents' cognitive stress and their parents' age and current smoking status. As parents age and their physical aging progresses, their employment stability may decrease; in addition, they often have to care for their own older parents. This can expose their children to various stressful situations [21]. In addition, mental health problems such as parental depression can negatively affect children's cognitive health. However, strengthening protective factors across various areas of adolescents' lives may help prevent psychological health problems among adolescents [22]. Therefore, researchers should use multiple approaches to improve parental mental health and reduce perceived stress among adolescents.

Mothers' current smoking status and cognitive stress influenced their adolescents' experiences of melancholy, whereas fathers' smoking status had no such significant effect. Parent–child communication is related to adolescents' life satisfaction, with their relationships with mothers having a particularly strong influence on girls [23]. In contrast, adolescent aggression and depressive symptoms were associated with increased mother-adolescent conflict [24]. In South Korean culture, the mother-child relationship is notably close [25], which may explain why mothers have a stronger influence on their adolescents' mental health than fathers. The observed effects of maternal smoking could also be influenced by prevailing social norms. In many Asian cultures, women who smoke may be perceived as violating traditional norms, leading to moral judgments (eg, viewed as less respectable, lacking self-control, or not family-oriented). This social stigma can indirectly affect adolescents' mental health through social pressure, family reputation concerns, or community gossip.

Reiss et al [26] analyzed data from the German National Health Interview and Examination Survey for children and adolescents, revealing that children of parents with higher education levels had fewer mental health problems in response to stressful life situations than their peers. Moreover, Guerrero et al [27] reported that the children of parents with lower education levels required interventions to address their risk of developing mental health problems due to stressful situations. These results echo those of our study, as parents' level of education can create high expectations for their children to study or go to school. In addition, the expression of conflict can be attributed to differences in one's future goals.

Maternal smoking and cognitive stress consistently had significant effects on adolescents' mental health, as mothers' smoking status was associated with their adolescents' cognitive stress, melancholy, and suicidal ideation. Adolescents whose mothers were current smokers and experienced stress exhibited higher cognitive stress, melancholy, and suicidal ideation than those whose mothers did not smoke or experience stress. Amrock and Weitzman [28] analyzed data from the National Health Interview Surveys in the United States to examine the mental health of children aged 4 - 17 years and identified a negative effect of parental mental health and sex on adolescent mental health. However, our study found that only maternal cognitive stress significantly affected adolescents' cognitive stress, melancholy, and suicidal ideation. This could be because in South Korea, mothers are primarily responsible for raising their children; thus, their mental health may have a more significant influence on their children than that of their fathers. Moreover, in a study comparing mothers' child-rearing stress in the United States and South Korea, South Korean mothers showed substantially higher stress levels than did American mothers [29].

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Lee et al [30] found that adolescents' mental health was significantly associated with maternal mental health and smoking status but not with paternal mental health. This difference may be because fathers often display cooperative and constructive problem-solving behaviors that adolescents tend to emulate. However, their focus on problem-solving may reduce emotional engagement, making interactions feel less supportive than the warmth typically provided by mothers [31]. Moreover, maternal depression can impair mother-child attachment and elevate maternal stress, leading to diminished nurturing behaviors. This creates a stressful home environment, potentially resulting in developmental challenges and emotional difficulties for adolescents [32]. Children may develop psychological symptoms as a result of receiving insufficient support during challenging moments, thereby necessitating the consideration of parental mental health [33]. By addressing parents' needs through family support programs, health professionals can improve the mental and behavioral health of adolescents as well as the happiness and nurturing nature of parents. Such family support programs can be a part of treatment and prevention [34].

Stress is a significant risk factor for smoking, as individuals often smoke to reduce stress [35]. In South Korea, the negative perception of women smoking likely means that the actual number of female smokers is substantially higher than the officially reported smoking rates [36]. Therefore, women may be more likely to smoke in personal spaces, such as their homes, than in public areas; therefore, children may be more likely to be exposed to their mothers' smoking.

Our findings provide valuable evidence supporting the influence of parental smoking on adolescents' mental health. However, this study has some limitations. First, our cross-sectional design limits causal interpretation. We analyzed data from the nationwide KNHANES; therefore, the results are associative rather than causative, restricting our ability to confirm causal relationships between parental smoking and adolescent mental health outcomes. Second, this study focused exclusively on South Korean adolescents and parents; therefore, the results may not apply to populations in different cultural or social environments, and their generalizability may be limited. Finally, the accuracy of self-reported parental smoking status remains a potential issue. The cultural stigma surrounding women engaging in smoking in South Korea may lead to the underreporting of mothers' smoking behaviors. Future research should consider a wider range of variables and interaction effects to provide a more comprehensive analysis of the factors affecting adolescent mental health and strengthen the understanding of these relationships across cultural contexts. In addition, future studies should incorporate longitudinal data to better understand the causality of these variables.

Limitations and Recommendations

The cross-sectional design of our study limits the ability to establish causality, while the self-reported nature of data presents a risk of underreporting, especially for maternal smoking due to cultural stigma. We recommend that future research use longitudinal data to better understand the causal relationships between variables. In addition, we suggest incorporating diverse measurement methods and standardized mental health scales to overcome the limitations of single-item, self-reported data.

Conclusions

We examined the relationship between parental smoking status and the mental health of adolescents in South Korea and found a significant association between adolescents' mental health and mothers' current smoking status. Moreover, maternal stress has a substantial association with their adolescents' well-being. We recommend programs to support mothers in managing their stress without having to rely on smoking and to quit smoking, as this can lead to improvements in their children's mental health. Therefore, systematic support at the national and domestic levels is required. Future research should explore additional factors affecting both parents' and adolescents' mental health.

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Conflicts of Interest

None declared.

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Abbreviations

KNHANES: Korea National Health and Nutrition Examination Survey
OR: odds ratio

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COVID-19 Knowledge, Anxiety, and Access to Voluntary Counseling and Testing Among People With HIV During the COVID-19 Pandemic: Cross-Sectional Study

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Abstract

Background: The COVID-19 pandemic caused significant disruption in health care services. Many essential services were delayed by health care facilities, including voluntary counseling and testing (VCT) services for people living with HIV. There were many reports of interruption in HIV testing, antiretroviral therapy (ART) initiation, and also ART access for people living with HIV during the pandemic. Patients were unable to attend follow-ups and acute care visits due to fear and anxiety. This situation also caused stress for people living with HIV.

Objective: This study aimed to determine the level of COVID-19 knowledge, anxiety, and access to VCT services for people living with HIV.

Methods: This cross-sectional, correlational study was conducted with 200 participants at 1 public hospital in Samarinda (n=140, 70%) and 1 public hospital in South Jakarta (n=60, 30%), Indonesia, from August 2022 to April 2023. Sampling was done using convenience methods and predefined inclusion criteria. Data collection included a demographic information form, COVID-19 knowledge questionnaire, the Coronavirus Anxiety Scale, and a questionnaire assessing access to health services.

Results: Both COVID-19 knowledge (odds ratio 11.246, 95% CI 11.246; *P*=.001) and anxiety (odds ratio 2.258, 95% CI 2.216; *P*=.03) had a positive and significant relationship with access to health services. A multivariate analysis showed that the most influential factor affecting access to VCT services was knowledge (*P*=.001; B=2.289).

Conclusions: This study highlights the need for enhanced support and education for people living with HIV or AIDS regarding their knowledge of and anxiety related to COVID-19, particularly considering their vulnerabilities. To ensure compliance with health protocols in future pandemics, it is crucial to improve access to health care services. One key recommendation is to enhance the VCT service system, especially for people living with HIV or AIDS, during public health emergencies such as the COVID-19 pandemic. Additionally, services such as telemedicine and telehealth should be further developed to allow people living with HIV or AIDS to receive ART without the need for in-person hospital visits.

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KEYWORDS

COVID-19 knowledge; voluntary counseling testing; anxiety; health service; people living with HIV; antiretroviral therapy; ART

Introduction

HIV is a significant global public health issue. People living with HIV require long-term treatment to achieve and maintain a good quality of life. The COVID-19 pandemic posed substantial global public health challenges and disrupted HIV testing and reporting worldwide [1]. In 2023, approximately 42.3 million people were living with HIV globally, of whom 28.9 million were receiving antiretroviral therapy (ART). These individuals require regular clinical monitoring and follow-up in HIV health care settings. However, during the pandemic, health care services were disrupted, including those serving people living with HIV. Access to HIV testing services was limited during the pandemic, and many people living with HIV were reluctant to visit health care facilities due to fear of COVID-19 infection [2]. People with chronic health conditions, such as HIV, may experience increased stress because of their heightened vulnerability to COVID-19 [3]. A study conducted in Hong Kong found that reduced contact with the LGBT (lesbian, gay, bisexual, and transgender) community during the COVID-19 pandemic was strongly associated with difficulties

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in accessing HIV services [4]. Several studies have highlighted the negative impact of the COVID-19 pandemic on HIV services for people living with HIV [4-6]. For example, a qualitative study in southwest Uganda [6] reported that COVID-19–related restrictions prevented patients from accessing HIV testing services. The pandemic also disrupted efforts to control the HIV epidemic by affecting the management of HIV care and continuity of access to ART. Concerns were raised regarding challenges in ART initiation and retention in care, fear of COVID-19 exposure, ART supply chain disruptions, and the potential increase in HIV incidence due to secondary transmission from individuals with detectable HIV loads [7]. Furthermore, the provision of HIV services to socially marginalized groups was particularly affected, exacerbating existing vulnerabilities.

During pandemics, access to health care services is often compromised. Even prior to the COVID-19 pandemic, factors such as stigma, acceptance of lifelong treatment, financial constraints related to distance and transportation, gender, and education level influenced access to voluntary counseling and testing (VCT) services [8]. Several studies have reported that COVID-19 disrupted HIV services, including HIV testing and access to ART medications. This disruption is particularly concerning because people living with HIV require continuous follow-up care and consistent ART to suppress viral replication and maintain viral load suppression. Therefore, ensuring uninterrupted access to ART remains essential [9-11]. The aim of this study was to examine the relationship between COVID-19 knowledge, anxiety, and access to VCT among people living with HIV during the COVID-19 pandemic.

Methods

Study Design, Population, and Sample

This study used a cross-sectional survey design and was conducted at 2 HIV outpatient hospitals: 1 in Jakarta and 1 in Samarinda, East Kalimantan, Indonesia. These public hospitals offer comprehensive HIV services, including HIV testing, ART, and VCT services for people living with HIV. Data collection was carried out from July 2022 to April 2023. The minimum required sample size was 140 (using the Slovin formula); however, 200 respondents were successfully recruited. The eligibility criteria are shown in Textbox 1.

Textbox 1. Participant eligibility criteria.

Inclusion criteria

- Confirmed diagnosis of HIV
- Aged ≥18 years
- Ability to provide written responses to the study questionnaire
- Adequate level of consciousness and responsiveness as assessed by the Glasgow Coma Scale (GCS)

Exclusion criteria

- Individuals without an HIV diagnosis
- Aged <18 years
- Individuals unable to provide written responses
- Those who were not adequately responsive based on the GCS assessment

Data Collection Tools

The instruments used in this study included a COVID-19 knowledge questionnaire [12], the Coronavirus Anxiety Scale [13], and a questionnaire assessing access to VCT services [14]. In addition, a demographic questionnaire was used to collect data on participants' characteristics, including age, gender, marital status, education level, place of residence, and COVID-19 infection status.

The COVID-19 knowledge questionnaire assessed participants' knowledge and attitudes toward COVID-19 using a 5-point Likert scale. For each of the 6 statements, respondents indicated their level of agreement as "strongly disagree," "disagree," "undecided," "agree," or "strongly agree." The final section of the questionnaire assessed preventive practices through 5 items related to behaviors such as (1) attending large social gatherings; (2) visiting crowded places; (3) avoiding cultural practices such as handshaking; (4) practicing social distancing; and (5) washing hands after sneezing, coughing, blowing the nose, or being in public places.

The Coronavirus Anxiety Scale consists of 5 items measuring anxiety symptoms related to COVID-19. Respondents rated how frequently they experienced each symptom over the past 2 weeks using a scale ranging from "not at all" to "almost every day." The items assessed symptoms such as (1) feeling dizzy, lightheaded, or faint when exposed to news about COVID-19; (2) difficulty falling or staying asleep due to thoughts about COVID-19; (3) feeling paralyzed or frozen when exposed to information about COVID-19; (4) loss of appetite when thinking about COVID-19; and (5) nausea or stomach discomfort triggered by thoughts about COVID-19.

The access to VCT services questionnaire was modified to include 7 items measured using a Guttman scale with dichotomous (yes or no) response options. The items assessed access-related experiences during the pandemic, including routine VCT service visits, difficulty finding time to collect medication, distance barriers, the ability to obtain medication

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through alternative means (eg, online or delivery services), financial constraints, increased treatment costs, and fear of stigma when visiting VCT services.

Statistical Analysis

All data were edited, coded, and entered into SPSS (version 25; IBM Corp) for analysis. Descriptive statistics were used to summarize respondents' demographic characteristics. Univariate analysis was conducted for all variables to examine frequency distributions and percentages. Before carrying out bivariate analysis, a normality test was performed on the independent and confounding variables. The Kolmogorov-Smirnov test was applied because the sample size exceeded 50 (N=200). The results indicated that the data were normally distributed (P>.05). Bivariate analysis was performed using the chi-square test to examine the relationships between the study variables. Subsequently, multivariate analysis was conducted using logistic regression to identify the variables that exerted the most significant influence on the dependent variable. The level of statistical significance was set at 95% CI (α=.05). A P value of <.05 was considered statistically significant, leading to rejection of the null hypothesis (H_0), whereas a P value >.05 indicated failure to reject the null hypothesis.

Ethical Considerations

Ethics approval for this study was obtained from the Ethics Committee of the Faculty of Nursing, University of Indonesia (KET-146/UN2.F12.2.1/PPM.00.02/2023) and from the Ethics Committee of the Hospital in Samarinda (362/KEPK-AWS/X/2021). Participation was voluntary. Prior to participation, all respondents provided written informed consent. Participants were provided with a written information sheet explaining the study procedures, objectives, potential benefits, possible risks, and their rights and obligations as research participants.

Results

Characteristics of Respondents

Table 1 shows the sociodemographic characteristics of the respondents and their access to voluntary counseling and HIV testing. A majority of the respondents were men (n=122, 61%) and were aged <40 years (146/200, 73%). Regarding educational attainment, 103 (51.5%) respondents had completed high school. Additionally, 54% (n=108) of the respondents were married and resided in Samarinda. More than 80% (n=160) of participants had never been diagnosed with COVID-19. No significant associations were found between respondents' demographic characteristics and access to VCT services.

Table . Correlation between respondent characteristics based on age, gender, education, marital status, domicile, COVID-19 infection, and access to voluntary counseling and testing (VCT; N=200).

Characteristics	Access to VCT		
	Respondents, n (%)	Odds ratio (95% CI)	*P* value
Age (years)		0.572 (0.302 - 1.086)	.11
<40	146 (73)		
>40	54 (27)		
Gender		0.869 (0.491 - 1.537)	.73
Man	122 (61)		
Woman	78 (39)		
Education		0.757 (0.308 - 1.862)	.70
High (senior high school-university)	22 (11)		
Low (elementary-high school)	178 (89)		
Marital status		1047 (0.592 - 1.851)	.99
Single	77 (38.5)		
Married	108 (54)		
Divorced	15 (7.5)		
Domicile		0.18 (0.004 - 0.077)	.001[a]
Samarinda	140 (70)		
Jakarta	60 (30)		
COVID-19 infection		0.47 (0.226 - 0.978)	.06
Yes	37 (18.5)		
No or never	163 (81.5)		

[a]*P*<.05.

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Level of Knowledge and Attitudes

Table 2 reports COVID-19 knowledge and anxiety in the respondents. More than half of the respondents demonstrated a high level of COVID-19 knowledge (112/200, 56%). The majority of respondents reported low levels of anxiety related to COVID-19 (122/200, 61%). A slight majority (106/200, 53%) of respondents indicated that their access to VCT services was good.

Table . Frequency distribution based on COVID-19 knowledge and anxiety in people living with HIV.

Variables	Access to VCT[a] services		*P* value
	Respondents, n (%)	Odds ratio (95% CI)	
COVID-19 knowledge		11.246 (5789-21.848)	.001[b]
High	112 (56)		
Low	88 (44)		
Anxiety		2.216 (1.242 - 3.955)	.01[b]
No	122 (61)		
Yes	78 (39)		

[a]VCT: voluntary counseling and testing.

[b]*P*<.05.

Findings of the Logistic Regression Analysis

Table 3 shows that among the variables examined, only COVID-19 knowledge and COVID-19 anxiety were significantly associated with access to VCT services. COVID-19 knowledge was identified as the most influential factor affecting access to VCT services.

Table . The relationship among variables with access to voluntary counseling and testing services.

Research variables	B	*P* value	Odds ratio (95% CI)
Age (years)	−0.245	.56	0.783 (0.341 - 1.798)
Gender	0.156	.70	1169 (0.522 - 2.617)
Education	−0.266	.64	0.767 (0.252 - 2.335)
COVID-19 status	−0.514	.25	0.598 (0.247 - 1.446)
Marital status	−0.421	.25	0.656 (0.317 - 1.358)
COVID-19 knowledge	2289	.001[a]	9.861 (4.916 - 19.778)
COVID-19 anxiety	0.815	.02	2258 (1.106 - 4.612)

[a]*P*<.05.

Discussion

Principal Findings

The results of this study demonstrated a significant association between COVID-19 knowledge and access to VCT services (*P*=.001). This finding indicates that higher levels of COVID-19 knowledge are associated with improved access to comprehensive health care services, including VCT services. Although limited studies have specifically examined the relationship between COVID-19 knowledge and access to VCT services, previous research has identified several contributing factors to the use of VCT services, including adequate knowledge of HIV, strong motivation to maintain health, and psychological responses such as stress and anxiety related to COVID-19. In addition, increased levels of depression and anxiety and disruptions in health care access were reported during the pandemic, particularly among women with chronic illnesses and ethnic minority groups who experienced significantly more appointment cancellations during lockdown periods [15]. Similarly, a study by Sitopu and Ndrudu [16] in Medan reported that only 50.6% of patients with good knowledge accessed VCT services.

Knowledge is a critical determinant of health-related behavior, including the use of VCT services [17]. People with adequate knowledge of COVID-19 may be more proactive in seeking HIV-related services to maintain their health. In this study, respondents with lower levels of anxiety were more likely to access VCT services. This may be associated with adequate COVID-19 knowledge, which could reduce anxiety levels. More than half of the respondents demonstrated adequate knowledge regarding preventive measures against COVID-19, such as wearing masks, frequent handwashing, and practicing social distancing. Additionally, information regarding COVID-19 was widely disseminated via social media platforms, such as WhatsApp and Instagram, increasing public access to health information.

During the COVID-19 pandemic, health care systems were significantly disrupted. The crisis exacerbated existing social

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inequalities and shifted health care priorities toward the treatment of patients with COVID-19. Consequently, people living with HIV faced barriers to accessing essential services, including VCT. These findings highlight the need for greater attention to the use of mass media, both print and electronic, during the COVID-19 pandemic. It is essential to disseminate information about HIV or AIDS services and VCT service access, as well as to organize seminars and workshops on these topics. These initiatives can help increase knowledge related to HIV or AIDS. Furthermore, additional studies should analyze other potential factors influencing individuals' willingness to participate in VCT. Identifying stronger predictors of knowledge, such as stigma toward HIV/AIDS, can provide valuable insights and create greater opportunities for intervention. By addressing these factors, we can develop targeted strategies to overcome the challenges faced in accessing HIV services [18].

In a survey conducted among residents of Wuhan, China, during the early COVID-19 outbreak (January 31-February 2, 2020), 17% of respondents reported experiencing moderate to severe depression, while 29% reported moderate to severe anxiety [19]. People living with HIV expressed anxiety during the pandemic regarding their treatment processes, particularly concerning the availability of ART and VCT services. This concern is significant because the immune systems of people living with HIV, which may not have improved, could have increased their risk of illness. However, it is important to note that there is no evidence indicating an increased risk of COVID-19 in people living with HIV [20].

Importantly, in this study, most of the participants reported low levels of anxiety regarding COVID-19. This suggests that adequate knowledge about COVID-19 may lead to reduced symptoms of anxiety. Consequently, this can increase access to VCT services during the pandemic. A study by Jayani and Eureka [21] on 34 people living with HIV showed a significant relationship between the level of knowledge and the level of stress experienced during the COVID-19 pandemic. Strengthening knowledge by providing education to people living with HIV throughout the pandemic was essential for this at-risk group, not only in relation to adherence to ART but also for complying with health protocols during the pandemic [21].

The anxiety experienced by people living with HIV during the COVID-19 pandemic is consistent with previous research [3], which found that people living with HIV experience anxiety and depression due to their illness, as they are at risk of death because of low immunity. This condition is further exacerbated by the COVID-19 pandemic, during which people living with HIV are at a higher risk of contracting the virus. Research findings also indicate that government-imposed restrictions disrupted treatment services. Although health care providers offered remote services in the form of telehealth, many people living with HIV were constrained by limited resources.

Psychological pressure during the COVID-19 pandemic was also experienced by people living with HIV. In addition to facing social stigma, they struggled to live in uncertain circumstances caused by the pandemic [19]. One of the most effective interventions to reduce anxiety is coping through social support, such as support from a partner or family members [18]. This finding is consistent with the results of this study, in which the majority of respondents received support from their family. Spouses also played an important role in assisting with ART collection at health facilities, reducing the need for people living with HIV to leave their homes during the COVID-19 pandemic [22]. Married people living with HIV tend to receive positive social support from their partners, which helps them cope with the challenges of a pandemic. The anxiety experienced by people living with HIV regarding their health was intensified by the COVID-19 pandemic, during which they were considered a high-risk group due to compromised immune systems. It can therefore be concluded that anxiety related to COVID-19 can influence people living with HIV in accessing VCT services because of their perceived vulnerability to illness. It is recommended that VCT service providers enhance and expand access to services for people living with HIV and address resource-related barriers to ensure continuity of treatment and maintain their quality of life [23].

Implications and Limitations

Adequate knowledge about COVID-19 and reduced symptoms of anxiety during the pandemic were significantly associated with access to VCT services. It is essential to integrate COVID-19 health education with social media platforms such as WhatsApp and Instagram to increase awareness. This approach may enable people living with HIV to access health care services with less concern about contracting COVID-19. Furthermore, similar strategies can be applied to various health topics to enhance the quality of life of people living with HIV. Our sample was relatively younger and more likely to be married. Although this may limit the generalizability of the findings to older people living with HIV in Indonesia, the results suggest that individuals with higher education, younger age, and greater exposure to information through social media tend to experience lower levels of anxiety and demonstrate better health outcomes.

Conclusions

This study highlights the need for enhanced support and education for people living with HIV or AIDS regarding their knowledge of and anxiety related to COVID-19, particularly considering their vulnerabilities. To ensure compliance with health protocols in future pandemics, it is crucial to improve access to health care services. One key recommendation is to enhance the VCT service system, especially for people living with HIV or AIDS, during public health emergencies such as the COVID-19 pandemic. Additionally, services such as telemedicine and telehealth should be further developed to allow people living with HIV or AIDS to receive ART without the need for in-person hospital visits.

Furthermore, VCT service providers should offer targeted education and support to individuals who experience difficulties in accessing health care services. Addressing the challenges faced by people living with HIV or AIDS, particularly those arising from anxiety related to the COVID-19 pandemic, is crucial to ensuring continuity of care and improving overall well-being.

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Authors' Contributions

SY contributed to the conceptualization and methodology of the study. SSA was responsible for data collection, references, and data analysis. ANZ responsible for data analysis and drafting manuscript. RZH was responsible for data analysis and discussion. RK was involved in both the conceptualization and data analysis. All authors were accountable at each stage of the study and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ART: antiretroviral therapy
LGBT: lesbian, gay, bisexual, and transgender
VCT: voluntary counseling and testing

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Effect of a Culturally Based Intervention Model on Infant Weight and Maternal Perceptions of Breastfeeding Adequacy Following Caesarean Section: Quasi-Experimental Study

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Abstract

Background: The breastfeeding coverage rate (that is, the number of mothers reached by breastfeeding programs) in several regions in Indonesia, including Banten and West Java, is still below the actual rate of breastfeeding nationwide. The breastfeeding coverage rate is influenced by mothers' condition after childbirth, particularly among mothers who have had a caesarean section. Support from partners, family, and close friends also has a large influence on the continuation of exclusive breastfeeding.

Objective: This study aims to identify the effectiveness of a culturally based intervention and its effect on mothers' perceptions of breast milk adequacy and the weight of newborns after caesarean section.

Methods: This study used a quasi-experimental design involving 116 respondents who were grouped into control and intervention groups. Pre- and postintervention measurements were taken using the Perceived Insufficient Milk scale (r=0.976) and calibrated baby weight scales. Paired t tests were used for the analysis.

Results: There was a significant increase in perception of breast milk adequacy and newborn weight in the intervention group compared to the control group. The intervention also increased the odds of perceiving breastfeeding as "very sufficient" by 2.53 times (odds ratio 2.53, 95% CI 1.36-4.73) after controlling for culturally held myths regarding breast milk insufficiency and family support.

Conclusions: This model could be applied as an alternative intervention by health care personnel, especially nurses, to support postpartum mothers who have undergone a cesarean section.

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KEYWORDS

baby weight; cesarean section; culturally based intervention; perception of breastfeeding

Introduction

Caesarean birth is one of the most-chosen delivery methods due to its advanced technology. A recent study reported that the proportion of caesarean births increased from 16.72% to 21.50% from 1998 to 2021, and it is projected to increase to nearly 29% by 2030 [1]. Maternal requests for caesarean section are associated with beliefs that recovery is painless and that it is the safest way to give birth, and these requests are also associated with traumatic previous birth experiences [2]. At the regional level, Asia has had the highest increase in recent years, with an average yearly increase of 6.4%. This increase is related to health care facility capacity, availability of resources, clinical management protocols, area of residence, maternal education, and economic status [1,3,4]. In Indonesia the increase in caesarean sections was approximately 10% from 2007 to 2017 [3]. This is due to an increasing number of pregnancy complications necessitating planned termination of pregnancy as well as increasingly advanced technology [4]. Unskilled health care workers, a lack of proper health infrastructure, and insufficient obstetric care are related to the increase in the decision to undergo a caesarean section. Sometimes, there are concerns related to vaginal appearance after vaginal birth, that is, that it will loosen the labia and decrease spousal satisfaction during sex; to minimalize this effect, mothers choose caesarean delivery [5]. Caesarean delivery increases the use of formula feeding in the hospital and delays the early initiation of breastfeeding. A previous study showed that after caesarean delivery, babies had a low breastfeeding rate, especially at 6 months post partum, due to lack of milk production, physical discomfort, and lack of support from the family [6,7]. Mothers

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undergo caesarean sections under general anesthesia, which delays the initiation of breastfeeding. Moreover, prelacteal feeding is reported as being associated with suboptimal initial breastfeeding [8]. Previous research has also found that mothers who undergo caesarean sections are less informed regarding the benefits of breastfeeding than mothers who give birth vaginally [7].

In Indonesia, exclusive breastfeeding remains a public health challenge, including in West Java and Banten. Recent evidence from West Java reported that only 58.3% of mothers practiced exclusive breastfeeding, with early initiation of breastfeeding achieved by 57.8% of mothers [9]. Maternal knowledge, education, self-efficacy, and early initiation of breastfeeding were identified as key determinants of exclusive breastfeeding. In Lebak, Banten, breastfeeding-related beliefs and cultural practices remain prevalent, with 60% of respondents demonstrating such beliefs [10]. Together, these findings suggest that breastfeeding outcomes in these regions are influenced not only by biological factors but also by maternal perceptions, cultural beliefs, and early postpartum experiences. Such challenges may be more pronounced among post-caesarean mothers, who are at higher risk of delayed breastfeeding initiation and perceived breast milk insufficiency, underscoring the need for targeted and culturally based interventions.

Culture is recognized as a key component in breastfeeding, but it is relatively underexplored, with considerable variation among ethnic groups [11]. There is little literature providing guidance on which cultural components need to be identified and considered in the design and development of interventions. Independent variables related to social and cultural significance must be explored to identify differences in cultural elements, such as values and behaviors. Dodgson et al [12] found 4 patterns of influence on breastfeeding behavior in society: local culture and customs, messages received by the mother, life experiences, and social support. The influence of culture on breastfeeding determines whether programs will be successful in specific areas or ineffective in others [13,14].

Another factor influencing breastfeeding and the sustainability of exclusive breastfeeding is support from people in the mother's immediate environment. Previous research conducted by Budiati et al [15] found that the habits of and recommendations from close family members, as well as a lack of partner support, influenced exclusive breastfeeding among post-caesarean mothers in the Cibinong area of West Java. This study aims to identify the experience of husbands and family members in navigating the culture surrounding exclusive breastfeeding in post-caesarean mothers.

Methods

Overview

This was a quasi-experimental study with 116 respondents who were grouped into control and intervention groups. Respondents were recruited using consecutive sampling at 2 locations: Lebak, Banten, and Cimanggis, Bogor. Eligible participants were postpartum mothers starting from the seventh day after delivery. Four questionnaires were used to evaluate the effectiveness of the intervention through quantitative analysis: questionnaire A covered respondent data and characteristics; questionnaire B covered breastfeeding and infant weight data on the first day and on the seventh day after the intervention (assessment of feeding practices used a 24-hour recall question); questionnaire C evaluated maternal knowledge of exclusive breastfeeding practices (Cronbach α=0.801); and questionnaire D, which has been previously used and validated by Budiati et al [15] (validity coefficient=0.976), assessed the perception of the adequacy of breastfeeding (Multimedia Appendix 1). The Perceived Insufficient Milk (PIM) instrument [16] and calibrated baby weight scales were also used.

The culturally based intervention was developed during the model development stage based on an initial analysis and literature review. A culturally sensitive intervention module was created as a reference for post-caesarean mothers, husbands, families, and local health care volunteers. The intervention was implemented through training and assistance for mothers and families to support breastfeeding practices in a culturally appropriate manner. The modules covered breastfeeding benefits and content, breast care, proper attachment, lactation management, family empowerment and support, the role of health workers, and the involvement of community, traditional, and religious leaders. The intervention aimed to improve breastfeeding practices and breast milk adequacy, reflected in infant weight gain.

Data were analyzed using the Kolmogorov-Smirnov test, unpaired and paired *t* tests, and logistic regression.

Ethical Considerations

Ethical approval for this research was obtained from the Faculty of Nursing Ethics Committee at the University of Indonesia (296/UN2.F12.D/HKP.02.04/2018). All participants provided written informed consent prior to enrollment. Participants were not offered any compensation for their participation in this study.

Model Development

The culturally based intervention model was developed based on a stage 1 analysis and literature study. This model then became a reference for mothers, husbands, their families, and local health care volunteers. Training and assistance were provided to the mothers and families in implementing culturally sensitive care after caesarean delivery to promote breastfeeding practices, which we expected would result in increased breast milk production and adequate infant weight.

Modules

The modules shown in Figure 1 were developed during the stage 1 analysis to explain the benefits of breast milk, breast care during breastfeeding, proper attachment during breastfeeding, and breastfeeding management. Other modules addressed transcultural care and the role of the community in supporting post-caesarean mothers.

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Figure 1. Modules developed for the culturally based breastfeeding intervention for post-caesarean mothers.

Eligibility Criteria

Participants were included if they were post-caesarean mothers who had given birth to a full-term baby with a weight ≥2500 grams and an Apgar score ≥8, were living with their spouse at the same residence, and were able to write and communicate verbally and non-verbally. Mothers with a critical medical condition that required emergency intervention and who could not fully participate in the research process were excluded.

Intervention

The culturally based intervention was carried out in 3 sessions of 60 minutes each. Training and assistance were scheduled 3 times for local health care volunteers, 3 times for family members, and 2 times for professional health care workers. A pretest was conducted at the first intervention session and repeated at the final session as a posttest to evaluate intervention outcomes. Meanwhile, the control group received conventional postpartum care delivery by health care professionals following the national maternal and child health reference (Buku Kesehatan Ibu dan Anak/KIA booklet) without any additional cultural components.

Results

The results of this study include the respondents' characteristics, breastfeeding outcomes, and factors associated with breastfeeding adequacy.

Table 1 shows that most respondents had a secondary education level and low family income. The control and intervention groups were generally homogeneous, except for family income (P=.02). Common myths related to breastfeeding identified in this study included beliefs that colostrum is harmful and should be discarded, that breast milk alone is insufficient to satisfy a newborn, and that caesarean delivery permanently impairs milk production. Family members frequently reinforced these beliefs by encouraging early formula supplementation when the infant appeared fussy or when the mother expressed uncertainty about her milk supply.

As shown in Table 2, the median maternal age and breastfeeding knowledge scores were comparable between the intervention and control groups, indicating homogeneity between groups (P>.05).

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Table . Distribution of respondent characteristics (n=116).

Variable		Intervention group, n (%)	Control group, n (%)	Total, n (%)	*P* value
Education level					.78
	High	19 (32.7)	16 (27.6)	35 (30.2)	
	Middle	32 (55.2)	32 (55.2)	64 (55.1)	
	Basic	7 (12.1)	10 (17.2)	17 (14.7)	
	Total	58 (100.0)	58 (100.0)	116 (100.0)	
Family income					.02
	High	27 (46.6)	19 (32.8)	46 (39.7)	
	Low	31 (53.4)	39 (67.2)	70 (60.3)	
	Total	58 (100.0)	58 (100.0)	116 (100.0)	
Breastfeeding experience					.83
	Ever experienced	26 (44.8)	33 (56.9)	59 (50.9)	
	Never experienced	32 (55.2)	25 (43.1)	57 (49.1)	
	Total	58 (100.0)	58 (100.0)	116 (100.0)	
Culturally held myths					.62
	Supported	22 (37.8)	26 (56.9)	48 (41.3)	
	Not supported	36 (55.2)	32 (43.1)	68 (58.7)	
	Total	58 (100.0)	58 (100.0)	116 (100.0)	
Family support					.45
	Good	18 (31.1)	22 (37.8)	40 (34.5)	
	Bad	40 (68.9.)	36 (55.2)	76 (65.5)	
	Total	58 (100.0)	58 (100.0)	116 (100.0)	
Skin to skin contact					.44
	Yes	0 (0)	0 (0)	0 (0)	
	No	58 (100.0)	58 (100.0)	116 (100.0)	
	Total	58 (100.0)	58 (100.0)	116 (100.0)	

Table . Distribution of respondent characteristics among the two groups (n=116).

Group		Median (IQR)	Range	95% CI	*P* value
Age (years)					.54
	Intervention (n=58)	26.50 (21-32)	17 - 39	27.14 - 29.78	
	Control (n=58)	30 (24-36)	18 - 42	30.03 - 33.26	
Knowledge (score)					.78
	Intervention (n=58)	84.27 (69.71-98.83)	41.76 - 100	78.00 - 85.66	
	Control (n=58)	85.50 (71.39-99.61)	43.56 - 100	79.72 - 85.26	

Table 3 shows the distribution of breast milk production in the intervention and control groups before and after the culturally based intervention. Before the intervention, there was no significant difference in breast milk production between the intervention and control groups (*P*=.57), indicating comparable baseline conditions. After the intervention, a significant difference in breast milk production was observed between the two groups (*P*<.001). In the intervention group, the proportion of mothers who perceived their breast milk as “very adequate” increased markedly, from 46.6% before the intervention to 82.8% after the intervention. In contrast, the control group decreased in the “very adequate” category (from 54.8% to 41.4%), with most respondents moving to the “adequate” category. These findings indicate that cultural based intervention had a significant effect on improving perceived breast milk production among post-caesarean mothers.

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Table . Breast milk production and infant weight before and after the intervention (n=116).

Breast milk production	Intervention group, n (%)	Control group, n (%)	Total, n (%)	*P* value[a]
Before intervention				.57
Not adequate	9 (15.5)	10 (17.0)	19 (16.3)	
Adequate	22 (37.9)	16 (28.2)	38 (33.2)	
Very adequate	27 (46.6)	32 (54.8)	59 (48.5)	
Total	58 (100.0)	58 (100.0)	116 (100.0)	
After intervention				<.001
Not adequate	1 (1.7)	7 (0)	1 (0.9)	
Adequate	9 (15.5)	34 (58.6)	43 (37.1)	
Very adequate	48 (82.8)	24 (41.4)	72 (62.0)	
Total	58 (100.0)	58 (100.0)	116 (100.0)	

[a]Paired *t* test.

Table 4 presents a comparison of infant weight before and after the culturally based intervention in both the intervention and control groups. In the control group, there was no significant change in infant weight before and after the intervention period (*P*=.56). Conversely, in the intervention group, infant weight increased significantly after the intervention (*P*=.001). The mean increase in infant weight in the intervention group was 185.60 (SD 119.64) grams, which was significantly higher than the change observed in the control group. These results demonstrate that the culturally based intervention contributed to a significant improvement in infant weight gain during the early postnatal period.

Table . Change in infant weight (n=116).

		Weight (grams), mean (SD)	Weight (grams), mean difference (SD)[a]	95% CI	*P* value[b]
Control group			–17.32 (203.05)	(–36.54 to 67.20)	.56
	Before	3204.89 (385.03)			
	After	3187.57 (413.62)			
Intervention group			185.60 (119.64)	(–147.06 to –84.15)	.001
	Before	3256.63 (365.04)			
	After	3442.23 (369.07)			

[a]Independent *t* test.

[b]Kolmogorov Smirnov test.

There were significant improvements in perceived breast milk production and infant weight before and after the intervention in the intervention group (P=0.001 and P<0.001, respectively). In contrast, no significant changes were observed in the control group (P=0.56) . Moreover, a comparison of infant weight change between the intervention and control groups demonstrated a statistically significant difference (P=0.001) , indicating that infants in the intervention group experienced greater weight gain than those in the control group.

As shown in Table 5, family support, culturally held myths, income, and the culturally based intervention had *P* values <.25; these variables were thus used in multivariate modeling.

Table 6 shows that the strongest way to increase breast milk production and infant weight was the culturally based intervention (odds ratio 2.53; 95% CI 1.36-4.73) after controlling for belief in culturally held myths and family support.

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Table . Bivariate analysis results.

Variable	*P* value
Age	.69
Family support	.08[a]
Breastfeeding experience	.36
Belief in culturally held myths	.08[a]
Education	.46
Work	.76
Income	.24[a]
Knowledge	.24
Culturally based intervention	<.001[a]

[a]*P* value <.25 (used in multivariate modeling).

Table . Logistic modeling.

Variable	B	SE	Wald	*df*	P value	Odds ratio (95% CI)
First model						
Income[a]	0.525	1.720	0.93	1	.76	1.691 (0.06 - 49.22)
Breastfeeding knowledge[a]	0.420	1.584	0.70	1	.79	1.522 (0.07 - 33.95)
Belief in culturally held myths	–1.395	0.351	15.806	1	.001	0.248 (0.13 - 0.49)
Culturally based intervention	–1.375	0.339	16.494	1	<.001	0.253 (1.13 - 0.49)
Family support	0.419	0.325	1.664	1	.20	1.521 (0.80 - 2.86)
Constant	–0.511	1.384	0.136	1	.71	—[b]
Second model						
Culturally based intervention	0.928	0.319	8.450	1	.004	2.530 (1.36 - 4.73)
Myth	0.722	0.509	2.015	1	.16	2.059 (0.76 - 5.58)
Family support	0.751	0.516	2.114	1	.15	2.119 (0.77 - 5.83)
Constant	–0.365	0.517	0.499	1	.48	0.694

[a]Income and breastfeeding knowledge were excluded from the second model following backward elimination due to *P* values exceeding the retention threshold (*P*>.25).

[b]Not applicable.

Discussion

Principal Findings

The majority of respondents in this study did not perform skin-to-skin contact, even though it is the first step in successful breastfeeding. This is consistent with research indicating that the caesarean process is associated with delays in both skin-to-skin contact and lactogenesis [7,8,17,18]. Disruption to the lactogenesis process can be influenced by the effects of decreased oxytocin secretion or stress in mothers who have undergone a caesarean section, resulting in decreased breast milk production in the mother [19,20].

According to Budiati and Setyowati [21], although mothers may have good knowledge, they still face many environmental obstacles to practicing the desired behavior. Also, many mothers may recognize the benefits of exclusive breastfeeding, but they are constrained by sociocultural barriers, such as a lack of family support, gender roles, traditional customs, and body image [22].

Our culturally based intervention combined several modules proven to affect breast milk adequacy and infant weight. This is in line with previous research on a baby-friendly hospital initiative that combined two or more strategies, finding that it was sustainable in different hospitals and in the community [23].

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Indonesian culture is based on kinship, and mothers' decisions about breastfeeding are often influenced by the people around them, such as their own mothers, parents-in-law, and husbands [22]. Thus, subjective norms are also a key component of successful breastfeeding [24,25]. Breastfeeding control refers to a mother's self-confidence and ability to practice breastfeeding.

During the model development stage, preliminary qualitative findings revealed that mothers initially desired exclusive breastfeeding but felt helpless and deferred to family members who introduced formula milk when breast milk appeared insufficient or the infant was fussy. This is consistent with previous research that mentioned how social influence affects mothers' decisions to breastfeed during the first 3 days after delivery [26]. That study showed that social norms or influence come from family, neighbors, and close relatives. These people's beliefs can unintentionally influence the mother's beliefs. If the family, neighbors, or close relatives feel that the mother should breastfeed exclusively, then she will do so. Conversely, mothers who receive opposing social pressure share the same perceptions as the people around them [27].

The results of this study showed that the average weight of infants in the intervention group differed before and after the culturally based intervention. This is in line with previous research regarding the effectiveness of breastfeeding education on infant weight and breastfeeding mothers' self-efficacy [28,29]. Other research on low-birth-weight infants highlighted that health education combined with peer support could increase maternal confidence and infant weight through the implementation of "kangaroo mother" care (ie, increased skin-to-skin contact) and lead to increased breastfeeding [30].

The findings of this study highlight the important role of cultural and social factors in shaping exclusive breastfeeding practices. This is consistent with findings from Herawati et al [10], who reported that breastfeeding beliefs and cultural factors significantly influenced exclusive breastfeeding success in Banten and West Java. These results suggest that cultural influences on breastfeeding may vary across regions, depending on local beliefs, family structures, and social dynamics.

Furthermore, the results align with a global scoping review by Badanta et al [31], which demonstrated that cultural beliefs and social norms strongly affect women's breastfeeding behaviors. Common cultural perceptions, such as beliefs regarding the quality of breast milk or the value of colostrum, as well as family and social pressures, were identified as barriers to exclusive breastfeeding. By integrating culturally based approaches into the intervention, this study supports the growing evidence that breastfeeding promotion strategies should not focus solely on health education but also address underlying cultural beliefs and social contexts.

Limitations

A limitation of this study was that several participants dropped out due to health problems after being exposed to COVID-19. In addition, there were confounding factors, such as self-efficacy, nutrition, and the use of galactagogues by mothers, that were difficult to control and may have affected the adequacy of breast milk production.

Implications

Providing a program that combines several strategies to promote breastfeeding among mothers can increase exclusive breastfeeding, especially among mothers who have undergone a caesarean delivery. Our culturally based intervention could be applied in health care facilities, such as community health centers (*puskesmas*) and hospitals, as a first-line strategy in the care of pregnant women. In addition to medical practices, care and cultural interventions are factors that affect mothers' decisions in choosing a delivery method. Culturally based interventions are often overlooked by health care workers, and developing new guidance and policies will increase mothers' awareness of exclusive breastfeeding practices, especially among post-caesarean mothers.

Conclusion

This quasi-experimental study was designed to evaluate the effectiveness of a culturally based intervention to increase breast milk adequacy and infant weight. The intervention increased the odds of perceiving breastfeeding as "very sufficient" by 2.53 times (odds ratio 2.53, 95% CI 1.36-4.73), after controlling for belief in breastfeeding myths and family support, compared to mothers who did not receive the intervention. The intervention improved mothers' and family members' capacity to differentiate evidence-based breastfeeding practices from culturally held myths, resulting in more informed and supportive family engagement during the post-caesarean recovery period.

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Data Availability

The data sets and materials used for this study are accessible upon reasonable request to the principal investigator.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaires created by the authors and used in the study.
[PDF File, 191 KB - apinj_v10i1e75203_app1.pdf]

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