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Contents

Protocols

Protocol

Hidden Workers in Aging Australia: Protocol of Intersectionality-Informed Mixed Methods Study

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Abstract

Background: Australians are living longer and are expected to remain in the workforce for longer; yet, many older adults struggle to secure employment despite being willing and able to work. A growing share of these individuals are "hidden workers," those underused in the labor market due to missed hours, long-term unemployment, or withdrawal from job seeking despite the capacity to work. This group reflects a global trend of aging yet underused workforces, and in Australia, they represent a significant proportion of the working-age population. Addressing the challenges of hidden workers is crucial, as their inclusion could help meet labor market demands, alleviate fiscal pressures of aging, and promote healthier, more equitable aging trajectories.

Objective: This intersectional mixed methods study has 3 overarching aims. First, to investigate how intersecting social identities (eg, age, gender, cultural background, health status, and caregiving responsibilities) shape hidden workforce participation and associated health outcomes among aging Australians. Second, to compare hidden workers with currently employed populations in order to identify health discrepancies between the 2 groups. Third, to explore the lived experiences of hidden workers, focusing on how intersecting and multiply disadvantaged identities impose additional burdens on employment outcomes and health status. Together, these aims will generate an integrated understanding of both structural and lived dimensions of hidden work, providing evidence to inform more equitable labor market and health policies.

Methods: This study uses an explanatory sequential mixed methods design to investigate the health, resources, and employment experiences of aging hidden workers in Australia. In phase 1, an online cross-sectional survey was administered to 1166 participants (696 hidden workers aged more than 45 years and 470 current workers), capturing variables on employment history, health, discrimination, workplace social capital, caregiving, and socioeconomic status. Validated instruments, including the Workplace Age Discrimination Scale, Intersectional Anticipated Discrimination Scale, and Workplace Social Capital Index, were incorporated to ensure reliability. Phase 2 will involve semistructured interviews with a purposive subsample (30 participants) identified from survey results, focusing on lived experiences of workforce exclusion and intersecting barriers. In phase 3, quantitative and qualitative findings will be integrated through triangulation and complementarity to provide a comprehensive understanding of hidden workers' challenges and assets, generating evidence to inform policy and stakeholder recommendations.

Results: As of September 2025, the online survey has been completed, phase 2 interviews are underway, and phase 3 integration is scheduled for completion by mid-2026.

Conclusions: This study will generate the first intersectional evidence on the health and employment challenges of hidden aging workers in Australia. These insights will inform tailored policy interventions that can support re-engagement, reduce inequities in health and well-being, and strengthen workforce participation. Ultimately, the findings will contribute to addressing skills shortages while promoting social and economic inclusion of aging Australians.

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KEYWORDS

employment; unemployment; aging workers; aging workers; hidden workers; intersectionality; health status disparities; mixed methods

Introduction

Aging Workforce and Hidden Workers

In this study, "aging workers" refers to adults aged 45 years and older, consistent with the Department of Employment and Workplace Relations (DEWR) definition of "mature-aged" [1]. Australians are living longer and expected to work for longer than ever before. With increased life expectancy and more years of disability-free living, aging Australians have both greater capacity and greater need to remain in the workforce [2]. Many express a desire to continue working or to increase their hours; however, despite decades of experience, aging job seekers often struggle to gain employment.

Maestas and Li [3] estimated that 13% of aging workers become discouraged workers or hidden workers, meaning those not actively seeking employment despite being willing and able to work, often due to repeated rejection or perceived lack of opportunities [4]. Moreover, many discouraged workers face age-based stereotyping and discrimination. Aging "hidden workers" reflect a global trend of an aging yet underused workforce [5].

Fuller et al [6] coined the term "hidden workers" to include 3 categories of labor underuse, namely "missing hours" (working one or more part-time jobs but willing and able to work full-time), "missing from work" (unemployed for a long time but seeking employment), and "missing from the workforce" (not working and not seeking employment but willing and able to work under the right circumstances). In Australia, hidden workers comprise approximately 22% of the population aged 15 years and older [7]. However, research has devoted far less attention to their drivers and characteristics compared to the unemployed [8].

At the same time, companies are struggling to find people with skills and competencies [9]. A total of 64% of HR leaders say their companies are struggling with skills shortages; yet, only 4% of employers have any formal plan to keep aging workers in the workforce [10]. Barriers for hidden workers include skill mismatch, digital exclusion, health constraints, caregiving duties, and discriminatory hiring practices. Inflexible work arrangements exacerbate these challenges, especially for those managing care or health conditions [6]. Given these conditions, retaining and re-engaging aging workers offers an important solution to both skill shortages and the health benefits associated with meaningful work [11-13].

Therefore, better understanding and addressing the hidden workers among aging populations is important because they represent an underused economic resource that can offset the fiscal pressures of population aging [3]. At the same time, they are a systemically excluded group with notable implications for inequitable health and well-being trajectories associated with labor market discrimination [14].

Health Inequalities

Research shows that both unemployment and underemployment harm mental and physical health. Unemployment can leave lasting "scarring" effects on individuals' careers—including reduced wages, diminished job quality, lower aspirations, and fewer long-term achievements—even decades after the initial job loss [15]. Underemployment also affects psychological well-being, with people reporting poorer mental health and reduced life satisfaction, which can in turn impact overall health outcomes [16-18].

For aging jobseekers, the impact is amplified. According to one study [9], Australians aged 55 years and older experience median unemployment durations more than twice those of people aged 25-44 years. Prolonged unemployment erodes financial security, increases social isolation, and harms both physical and mental health, ultimately reducing re-employment prospects and life satisfaction [19].

Addressing these issues requires a systems approach that transcends individual job-search interventions. Coordinated action across employment, health, housing, and social protection systems is essential to reduce the structural barriers that sustain labor-market detachment. Age discrimination remains a major impediment to re-employment [20]. Aging interacts with race, gender, and class to shape unique "career-capital" trajectories [21-23], while organizational cultures and recruitment practices often perpetuate negative stereotypes—portraying aging workers as costly, less adaptable, or technologically resistant [24,25]. Such biases reinforce exclusion, deepen health inequalities, and constrain healthy aging.

Thus, understanding the health consequences of labor underuse among aging hidden workers—and how these are compounded by intersecting inequalities—is vital for equitable aging and workforce policy.

Intersectional Disadvantage

Intersectionality provides a framework for understanding how multiple social identities—such as age, gender, ethnicity, health, and caregiving—combine to create unique patterns of disadvantage. Aging hidden workers are not a homogeneous group but experience interlocking systems of exclusion that shape both their employment and health trajectories [6,26].

Research highlights that aging intersects with other forms of inequality—such as race, gender, and class—to shape individualized career-capital pathways that accumulate advantage or disadvantage across the life course. For instance, women's careers are more frequently interrupted by caregiving, leading to reduced lifetime earnings, superannuation, and access to employer-sponsored training [27-29]. Migrant and racialized aging workers often experience credential discounting and language-based discrimination, which restrict entry into professional occupations and limit career progression [30,31].

Class position also affects the capacity to invest in continuous learning, digital upskilling, and health resources that underpin employability in later life [6]. Over time, these intersecting inequalities produce differentiated career-capital trajectories. While some aging adults can leverage accumulated skills and networks to remain employable, others face compounded exclusion that intensifies their risk of becoming hidden workers [23].

ABS (Australian Bureau of Statistics) has recently published potential worker statistics that show there are 1.7 million potential workers who are willing to work but can't [9]. Many of these individuals—particularly aging carers, migrants, or people with chronic conditions—no longer self-identify as job seekers due to discouragement, yet they remain part of the hidden workforce. Addressing this evidence gap is critical for designing equitable, targeted policy interventions.

In summary, the literature underscores that aging hidden workers represent both an underused economic resource and a systemically excluded population whose marginalization carries significant social and health costs. Addressing their exclusion is not merely a matter of fairness but also essential for maintaining workforce sustainability and reducing fiscal pressures associated with population aging. In the Australian context, meaningful progress requires a coordinated, systems-level response that goes beyond individual employability programs to integrate employment services, health care, housing, and social protection policies. However, despite clear evidence of need, little is known about the distinct circumstances of aging jobseekers, carers, and people with health conditions who have withdrawn from the labor market due to discouragement. Closing this evidence gap through intersectional and mixed methods research is therefore critical to developing targeted, evidence-based interventions that can reduce health inequities, support re-engagement, and restore opportunity structures for Australia's aging workforce.

Aims and Objectives

The aims and objectives are as follows:

1. Aim: to examine how intersecting social identities shape labor-market participation and health outcomes among aging hidden workers in Australia.
2. Objectives: (1) quantify disparities between hidden and active workers, (2) identify determinants of health and employment inequalities, and (3) explore lived experiences and assets among intersectionally marginalized hidden workers.

Theoretical Framework: The Intersectionality-Based Hidden Workers' Health Inequality Framework

The Intersectionality-based Hidden Workers Health Inequality Framework (IHHIF) guides the conceptual and analytic approach of this study. The framework integrates principles of intersectionality [27,32-34], social determinants of health [35], labor-market discrimination [6,20,23,26], and behavioral theories related to self-efficacy and aging-work motivation [36,37] to explain how employment exclusion shapes health outcomes among aging hidden workers.

IHHIF conceptualizes labor-market exclusion as the product of interacting structural and identity-based mechanisms rather than isolated individual factors. Structural determinants—such as labor policies, welfare regulations, employer practices, digital access, and socioeconomic conditions—create material and institutional constraints that influence workers' opportunities. These structural forces intersect with social identities, including age, gender, ethnicity, migration background, class, disability, and caregiving roles, producing cumulative and patterned disadvantages over the life course.

The framework positions cognitive–behavioral mediators—such as perceived discrimination, self-efficacy, outcome expectations, and aging-related beliefs—as the mechanisms through which structural inequities become embodied and affect health, agency, and employment behaviors. These mediators are shaped not only by personal experiences but also by societal narratives about older workers, stereotypes about productivity, and the intersectional burdens of racialization, gendered care roles, or chronic illness.

IHHIF is designed to capture how hidden workers navigate the labor market.

Observable outcomes:

1. Structural determinants (policies, systems, and contexts)
2. Intersecting identities (age×gender×ethnicity×class×health status)
3. Cognitive–behavioral processes (motivation, confidence, and expectations)
4. Health and employment outcomes (physical, mental, social, and economic)
5. Assets and protective factors (social capital, community support, retraining, and resilience)

Interact Dynamically Over Time to Shape Hidden-Worker Trajectories

By grounding this study in IHHIF, the framework enables a multilevel, intersectional, and mixed methods analysis that aligns quantitative patterns with lived experiences. It guides the identification of inequities, the interpretation of mechanisms underlying those inequities, and the development of targeted, contextually informed policy and practice recommendations to support aging hidden workers' re-engagement and well-being.

Methods

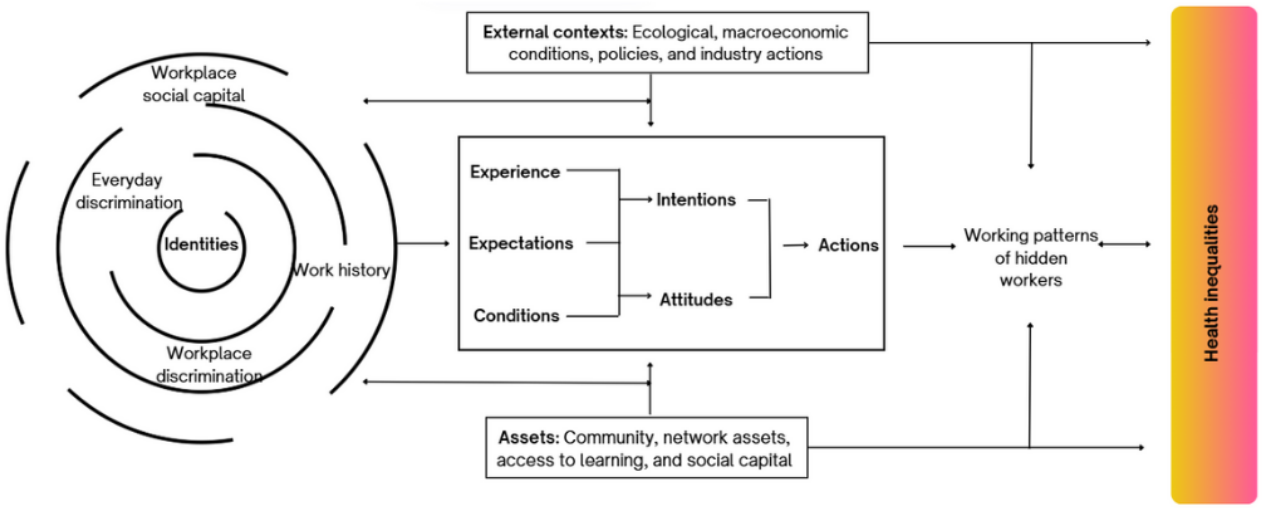
Data Collection: Mixed Methods Research Process

This is a cross-sectional mixed methods approach to develop a rich understanding of study participants' mental and physical health, coping strategies, access to resources, and informal and formal support for employment access. We will explore relevant assets and strengths for hidden workers and examine variations through the lens of intersectionality. Analyses, outputs, and dissemination plans will be planned to inform new findings to key stakeholders.

The study is an explanatory sequential mixed methods design in which a quantitative element is used first and followed by a qualitative component contingent on and informed by the initial

quantitative results. Preliminary findings from the quantitative analysis will inform later phases of qualitative data collection, and hypotheses derived from qualitative analysis will be tested in the quantitative component. A value of this design is that it enables researchers to further explore the nuances and mechanisms that explain the quantitative results [38]. The project will have 3 phases of gathering different resources. Figure 1 provides an overview of the steps taken in the data collection and analysis.

Figure 1. Intersectionality-Based Hidden Workers Health Inequality Framework (IHHIF).



The explanatory sequential mixed methods design integrates quantitative survey data with qualitative interviews to provide a comprehensive understanding of aging hidden workers' employment and health experiences.

Phase 1: Online Survey

The first phase will comprise an online cross‐sectional survey administered to both hidden and nonhidden workers using the QuestionPro platform from December 2024 to March 2025. This platform provided access to a large, diverse participant pool across all Australian states and territories, enabling recruitment that captures variation in demographic, socioeconomic, and employment characteristics [39]. The survey is designed to ensure representativeness where possible and to capture key variables relevant to employment status, work history, health, and caregiving responsibilities. The full survey is included in the Multimedia Appendix 1 to ensure transparency and support replicability.

The questions will be used to (1) examine the circumstances and lived experiences for hidden workers, particularly those facing multiple and intersectional forms of marginalization (eg, cultural and linguistic diversity, disability, and agism), (2) discern the differences of attitudes, behavior, and health status between hidden and nonhidden workers, with a focus on their perspectives, challenges, and opportunities related to labor market participation. The questionnaire was pilot-tested with 30 participants to assess clarity, length, and skip-logic prior to launch. Participants were recruited through QuestionPro's Australian panel (stratified by age, gender, and state) and included community partners (libraries and senior associations) to ensure diversity.

The total sample for the survey is 1166 participants, where 696 are selected as hidden workers aged more than 45 years, and 470 are currently in the workforce. A total sample of 1166 affords ~±4.4% precision for group proportions, detects 6-7 pp differences in prevalence at 80% power, supports multivariable regression with adequate events per variable, and provides sufficient stability for latent class analysis–based subgroup identification and subsequent policy targeting—meeting both statistical power and policy-interpretability needs.

The decision to have 45 years as our age cutoff is based on the Australian context. While there exist discrepancies between definitions of "mature aged" across different countries and various organizations, the DEWR defines 'mature age' to include persons aged more than 45 years [1]. Including 45- to 54-year-olds captures midlife transitions preceding traditional "older" thresholds, aligning with mature-age category and international definitions used by ILO (International Labour Organization) and OECD (Organisation for Economic Co-operation and Development [1]). This will be the first attempt to use the survey to ask 2 groups (currently working and hidden workers), enabling us to discern, for the first time, the differences in work expectations and perceptions toward their later working lives. This would allow the researcher to identify the composition of groups with single and multiple social disadvantages, which in turn would inform the population groups for the in-depth interview (phase 2). These questions are multiple-choice, simple-answer, and scale questions. The survey is anonymous, and participants can leave the survey anytime. It is expected to take approximately 15-20 minutes to complete.

Various measures of the discrimination index will be collected. The 45 years and older are exposed to accumulated lifelong discrimination and inequality. Until recently, few studies had explicitly investigated discrimination based on multiple social identities or positions [40,41]. Recent development on tools to identify intersectional discrimination, the Intersectional Anticipated Discrimination Scale [42] is a useful tool to understand the exposure to discrimination of hidden workers aged more than 45 years. We have integrated the questions into

the survey together with the validated Workplace Age Discrimination Scale (WADS) [43]. These instruments were selected for their ability to capture multidimensional and intersectional experiences of discrimination and will be complemented by demographic variables (eg, gender, ethnicity, country of birth, education, employment history, income, and household structure) to allow analysis of intersectional effects.

Workplace Social Capital (WSC) is defined as a workplace resource that concerns employees' perceptions regarding trust, reciprocity (cognitive WSC), and network interactions (structural WSC) that exist both among peers (bonding WSC) and among individuals across different hierarchical levels or organizations (bridging WSC) [44-46]. WSC is an important indicator to understand the relationship between relational aspects and an individual's attitudes toward entering/re-entering the workforce. The validated WSC index will be used in this survey [47]. Together, these validated measures and contextual variables provide a robust methodological framework for multivariate and intersectional analyses. Furthermore, all instruments have demonstrated strong psychometric properties in aging worker populations, with internal consistency (Cronbach α) typically exceeding 0.80, ensuring reliability for this study cohort [32].

Phase 2: Interview

The qualitative phase will be informed by the survey results from phase 1, in line with the explanatory sequential mixed methods design. Based on the quantitative findings from phase 1, a purposive subsample of approximately 30 participants will be invited to take part in in-depth qualitative interviews (September 2025-February 2026). The final number was determined by the need to ensure representation of key intersectional subgroups identified in the quantitative analysis (eg, combinations of minoritized status, condition or impairment, and citizenship status) and to reach thematic saturation.

From Facebook (Meta Platforms, Inc) advertisements, we will be recruiting participants to approximately reflect the characteristics of the aging populations facing multiple and intersecting barriers to entering or re-entering the workforce. The semistructured interview guide will be developed and piloted with 1-2 participants to refine questions. Semistructured interviews will be conducted via Zoom (Zoom Communications Inc). Zoom recordings are stored temporarily on the La Trobe University–approved encrypted cloud. Files are downloaded within 24 hours, deleted from the cloud, and retained on the university's secure server. Access is restricted to the lead researcher and one authorized data manager under institutional data-handling agreements.

We will recruit interview participants from advertisements or links distributed through a range of platforms and networks, as well as through local lay coresearchers. We will rely on participant self-identification of citizenship status and condition or impairment. Posters, advertisements, and snowball sampling will target those who lack resources or technology to be recruited via online messages. They can contact us by telephone or email.

Respondents can choose to have their interviews by remote video methods, lasting approximately 60-90 minutes, by telephone, or in person (where feasible) to accommodate varying access needs. Interviews will be recorded and professionally transcribed. Attention will be given to making the interviews fully accessible and inclusive, and all researchers will be vigilant to the participant's needs, such as requiring frequent breaks. All potential participants will be informed about the study in plain English (read to them if needed) and told that interviews will be in English by default. Plain-English language consent forms are provided to ensure that participants are able to give fully informed consent. The interview guide will be informed by the survey results (phase 1) and will cover the same key domains (Table 1), with flexibility to explore emergent themes.

Table 1. Variables collected from the survey on hidden workers.

Variables	Hidden workers	Current workers
Actions		
Job search undertaken	✓	✓
Engaged in learning	✓	✓
Adapted climate impact mitigation strategies	✓	✓
Intentions		
Willing to work	✓	
Attitudes		
Degree of discouragement	✓	
Passive or active job seekers	✓	
Attitudes to learning	✓	✓
Work history		
Work history	✓	✓
Workplace discrimination	✓	✓
Workplace social capital	✓	✓
Health and well-being		
Long-term health conditions	✓	✓
Subjective health status	✓	✓
Mental health well-being	✓	✓
Quality of life indicators	✓	✓
Everyday discrimination index	✓	✓
Conditions		
At-risk living conditions	✓	✓
Childcare needs	✓	✓
Other caregiving needs	✓	✓
Household living arrangement	✓	✓
Household income	✓	✓
External contexts		
Impact of the COVID-19 pandemic	✓	✓
Housing crisis	✓	✓
Supportive workplace policies	✓	
Assets		
Social capital (support networks)	✓	✓
Access to learning	✓	✓
Community assets	✓	✓

Prior to data collection, the interview guide will be pilot tested with 2-3 participants representative of the target population to ensure clarity, cultural appropriateness, and relevance. Feedback from the pilot will be used to refine question wording, sequence, and prompts. This approach will provide the qualitative phase that effectively expands upon and contextualizes the statistical patterns identified in the quantitative analysis.

The data will be retained for 5 years, and only the lead researcher will have access to the raw data. They will be asked about work and family biographies, their experience in the labor market, barriers to entering the job market, and health. Transcripts will be deidentified by removing names and potentially identifiable information before being analyzed thematically using NVivo qualitative software (Lumivero [33]), following Braun and Clarke's [34] 6-phase framework for thematic analysis.

Data Analysis: Quantitative Analysis

A descriptive statistical summary will be provided. More in-depth analysis will be conducted using Stata 18 (StataCorp LLC [48]), incorporating all variables in the dataset to address the research questions:

1. How do outcomes, including resource access, quality of life, physical and mental health, and social networks, and their trajectories differ between aging hidden workers and aging nonhidden workers across subgroups defined by minoritized status, condition or impairment, and citizenship status, as well as intersectional combinations of these characteristics?
2. To what extent are differences in outcomes and trajectories between aging hidden and nonhidden workers associated with healthy aging indicators?
3. What individual, structural, and contextual factors contribute most to between- and within-group disparities in outcomes and trajectories among aging workers?

Data analysis will be conducted in 3 stages, aligned with the research questions. For RQ1, descriptive statistics will compare key outcomes between aging hidden and nonhidden workers, followed by multiple regression models incorporating interaction terms (eg, group×minoritized status, condition or impairment, and citizenship) to assess intersectional effects. For RQ2, healthy aging indicators will be added to the models to examine their explanatory role in observed group differences. For RQ3, we will apply inequality decomposition techniques (eg, Blinder–Oaxaca) and variable importance ranking to quantify the contribution of individual, structural, and contextual factors to between- and within-group disparities.

Latent class models will be estimated via generalized structural equation modeling in Stata 18 using Akaike Information Criterion and Bayesian Information Criterion and entropy for class enumeration. Blinder–Oaxaca decompositions will quantify between-group disparities. Variable-importance ranking will use dominance analysis and Shapley Additive Explanations values derived from random forest models.

The final analytic sample comprised 1166 respondents. Missing data were assessed using Stata. Overall item nonresponse across core outcomes and exposures was low (typically <3%). Higher missingness observed in certain modules reflected structural missingness from survey branching (ie, respondents not eligible for those items). Analyses will be conducted within the appropriate universe for each item; structural missings will not be imputed. Where item nonresponse for a key variable exceeds ~5% among eligible respondents, we will perform multiple imputation under missing at random (with auxiliary variables) and compare against complete-case results, alongside prespecified missing not at random pattern-mixture sensitivity checks.

Qualitative Analysis

Theoretical approach

The qualitative phase will apply the IHHIF as an analytic scaffold to explore how structural conditions, intersecting identities, and cognitive-behavioral processes jointly shape the lived experiences of ageing hidden workers.

Analytic Approach

Interviews will be transcribed verbatim and analyzed thematically following the 6-phase process—familiarization, coding, theme development, review, definition, and reporting [34] —using NVivo 12 software. Coding and interpretation will be guided by the IHHIF domains, while remaining open to emergent, inductive insights.

1. Structural determinants (Commission on Social Determinants of Health layer): Codes will first identify macro- and mesolevel conditions influencing participants' employment trajectories, such as labor-market policies, welfare and pension rules, employer practices, digital access, and regional or industry-specific constraints. Attention will be given to how these structural factors interact with participants' material circumstances (housing, income, transport, and health service access) to enable or constrain participation.

2. Intersecting identities: Next, analytic focus will shift to how social positions—age, gender, class, ethnicity, cultural background, health, and caregiving—combine to produce unique configurations of advantage or exclusion. The analysis will examine how participants describe the simultaneous effects of these identities (eg, being an aging migrant woman caring for grandchildren) and how these combinations influence perceptions of employability, discrimination, and well-being.

3. Cognitive–behavioral mediators (Social Cognitive Career Theory layer): Themes will then explore individual-level mechanisms, such as self-efficacy, outcome expectations, attitudes toward aging and work, intentions to re-enter employment, and enacted behaviors (job search, learning, and adaptation). Narrative coding will examine how experiences of rejection, support, or discrimination shape these internal processes over time.

4. Health and employment outcomes: Analyses will integrate descriptions of participants' health trajectories (physical, mental, and emotional) and employment status to map how cumulative disadvantage manifests in outcomes. Links will be traced between structural barriers, identity intersections, and cognitive mediators to illustrate the pathways through which inequities develop.

5. Assets and feedback loops: Finally, data will be reviewed for evidence of resilience and enabling resources—such as community belonging, informal work, volunteering, retraining, or supportive employers—and for feedback mechanisms where improved health or social capital facilitates re-engagement.

Interpretive Synthesis

Using a matrix-coding approach, themes will be compared across subgroups (eg, gender, Culturally and Linguistically Diverse status, and caregiving role) to identify recurring intersectional patterns. A conceptual map will then be produced linking thematic domains to the IHHIF components (Structural Determinants → Identities → Cognitive Mediators→Outcomes→Assets), providing an integrated

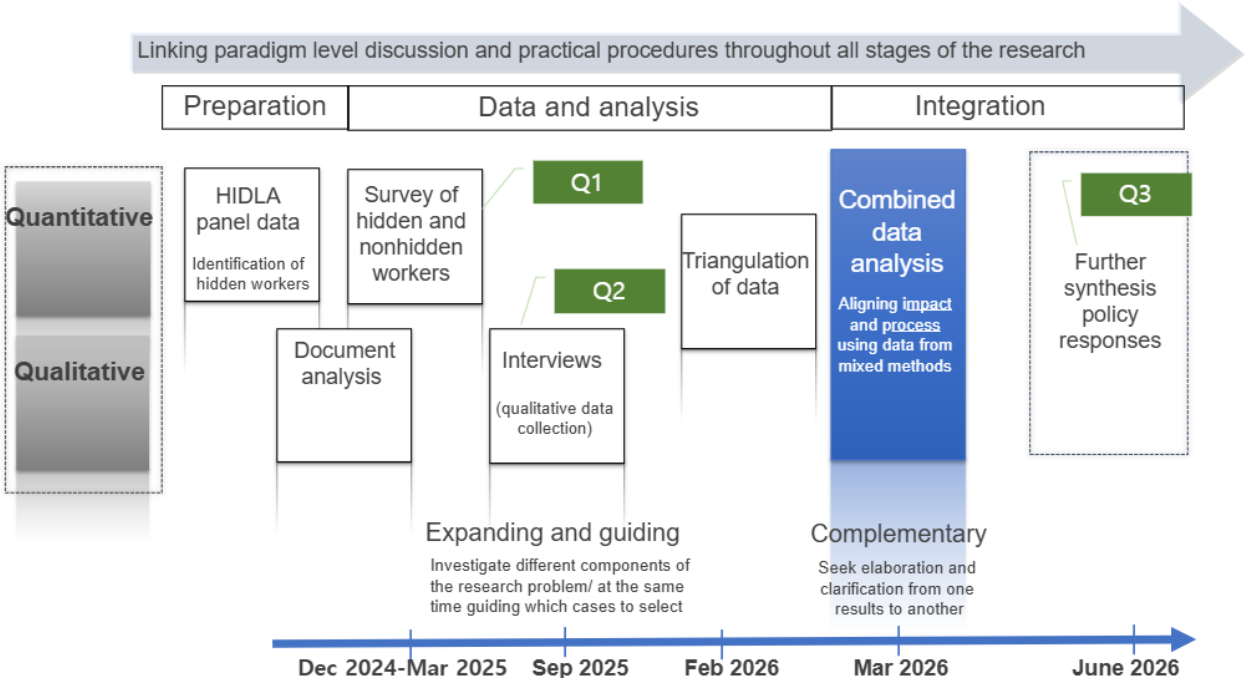
qualitative representation of how multilevel forces shape hidden workers' health and employment experiences.

To enhance rigor, 2 researchers will independently code a subset of transcripts, and discrepancies will be resolved through reflexive discussion. Memos will document analytic decisions and reflexivity regarding researchers' positionalities. The final synthesis will inform integration with quantitative findings in phase 3, ensuring the qualitative insights directly illuminate the mechanisms hypothesized by the IHHIF.

Phase 3: Integration of Quantitative and Qualitative Findings

As shown in Figure 2, this phase will integrate outputs from phase 1 (survey) and phase 2 (interviews) to provide a comprehensive synthesis (from February to June 2026).

Figure 2. Mixed methods research schematic.



Triangulation is defined as the act of seeking convergence of results of the same research question from different methods to increase the validity of results. A main advantage of triangulation is its attempts to validate, or enhance the accuracy of, research findings by comparing different sorts of data on the same topic, with qualitative findings substantiating quantitative findings. Moreover, if convergence is not achieved, quantitative and qualitative data can be put into dialogue with each other through the use of participant review groups, who can offer improved interpretations on both sets of findings [47].

Complementarity, in contrast, allows scholars to elaborate and enhance results from one method with results from another method, with attention to multiple facets of the same question. For instance, combining qualitative data with quantitative results contextualizes hidden female workers' experiences by highlighting how labor market practices create a caustic environment to be kept hidden. A complementary intersectional mixed methods research approach is useful for research on multiply marginalized hidden workers, specifically because it uses an intersectional framework to both identify patterns relevant to hidden workers and explain why these patterns may exist in a single study.

Implementing these strategies within a single study could provide a comprehensive understanding of the desired needs and services for this client group while also providing clear direction to the center for addressing gaps. To date, the scholarship on intersectionality theory and the literature on mixed methods research have largely developed in silos, with limited interdisciplinary conversation about the benefits of their integration. Intersectionality scholars have elucidated some advantages of combining statistical approaches with in-depth narratives [32-34]; however, in practice, few studies have fully realized what is possible in intersectional mixed methods research, especially regarding tackling complex questions concerning multiply marginalized hidden workers.

Integration will be conducted collaboratively by both qualitative and quantitative researchers to ensure balanced interpretation. The final outcome of this phase will be a synthesis report, policy recommendations, and community briefs co-developed with the Project Advisory Group and stakeholders. Thus, this study aimed to highlight how intersectional mixed methods research could be used for several purposes to advance research on hidden workers.

Disseminations

Communications will be achieved through the participants' preferred method of communication. We will tailor to our key audiences, which emphasize practical solutions and implementation. The dissemination plan will be determined with our Project Advisory Group and through our cocreation meetings, with an indicative timeline to ensure early, interim, and final updates are shared in sequence. Findings will be

disseminated through peer-reviewed publications, national, and international conferences.

Overall synthesis will provide an executive overview for easy assimilation by policymakers and practitioners. This will indicate where changes to health and social care policy and practice are likely to be most effective, with targeted briefings and roundtable discussions to maximize uptake. An overview of findings and ideas for outputs will be presented to participating communities more widely via collaborator platforms to give them the opportunity to reflect upon and interrogate researchers' interpretations and analysis of the data, and their feedback will be incorporated where appropriate.

Findings and ideas for outputs will also be distributed through trusted community channels, such as places of worship, trusted religious leaders, and community champions. This will enable broader community input into the final project outputs. All findings will be publicly available via our website in accessible forms for lay consumption. Confidentiality will be maintained throughout, with any potentially identifying information removed before dissemination.

Ethical Considerations

Ethical Approval

Ethics approval was granted by the La Trobe University Human Research Ethics Committee (HEC 23459). All participants provide informed consent prior to participation. Survey data are anonymous, interview data are deidentified, and all files are stored on encrypted, access-controlled university servers. All procedures complied with the ethical standards of the institutional and national research committees and with the principles outlined in the Declaration of Helsinki.

Informed Consent All participants were provided with a detailed plain language statement outlining the study purpose, procedures, voluntary participation, and their right to withdraw at any time without penalty. Informed consent was obtained from all participants prior to data collection. For online surveys, consent was documented through an electronic consent form embedded at the start of the questionnaire (participants could not proceed without agreeing).

Privacy and Confidentiality Data were collected and stored in accordance with institutional policies and applicable privacy regulations. Identifiable information was not collected unless explicitly required for follow-up procedures and was stored separately from survey/interview responses. All data were deidentified prior to analysis. Only authorized members of the research team had access to the encrypted, password-protected data repository. No identifiable information will appear in publications or presentations.

Compensation Participants did/did not receive compensation for their involvement in the survey, but interview participants were compensated with an AUD $25 (US $16.55) Coles voucher.

Results

Funding for this study was awarded by La Trobe University in June 2024 (HEC23459). The online survey (phase 1) was launched in December 2024 and completed in March 2025, achieving a total sample of 1166 participants aged 45 years and older across all Australian states and territories. Recruitment for the qualitative interview phase (phase 2) commenced in September 2025 and is ongoing. Data cleaning for the survey responses and preliminary coding has been completed. Integration of survey and interview findings (phase 3) will occur between September and February 2026. Papers reporting the quantitative and qualitative findings are expected to be submitted to peer-reviewed journals in 2026.

Discussion

Anticipated Findings and Potential Impact

In undertaking this study, we will fill a gap in the evidence about the hidden workers in aging Australia. We expect to contribute considerable new knowledge through our mixed methods approach, aligned with national priorities on workforce participation and skills, including the current Australian workforce and aging strategies [49]. Drawing on the survey data, we will quantify issues, such as those relating to access to labor market resources, social networks of support, and discrimination and marginalization. However, we are particularly interested in the strengths and assets that have improved our participants' capacity to cope with their unemployment or underemployment to identify scalable supports and pathways that can be piloted and, if effective, implemented nationally with employer and community partners. We will track uptake through policy citations, stakeholder workshops, and media mentions within 12 months post publication as indicators of impact.

We believe this is important, as many health and well-being challenges, such as those faced by minority ethnic groups at the intersection with chronic conditions or impairments and insecure citizenship status, can be mitigated by adjustments to health and social care services, policy, and delivery; formal networks such as community health services; and informal networks such as family and friends. We expect to provide recommendations for these adjustments and for potential interventions through this mixed methods analysis, translated into policy briefs, practitioner guidance, and community toolkits that can support rapid adoption by government, providers, and employers. We may also design some simple interventions ourselves, including low-cost, co-designed pilots targeting identified barriers, such as digital skills gaps, flexible work design, or navigation support. To attempt to tease out the impact of the aging hidden workers, we will (1) model relationships between mediating variables (including social network features) and health and social outcomes (and consider indicative economic and workforce implications of reduced early exit and improved re-entry) and (2) explore participants' current and recent experiences and labor market access.

It is anticipated that the research will provide new information on the interventions, support, and individual factors that assist

the aging hidden workers, with relevance to other aging economies facing similar hidden workforce challenges. The academic research will not only help inform how the Australian government can improve its interventions but also will provide new information on how to prevent people from having to leave work and extend working lives. This research will inform current and future welfare-to-work and job retention initiatives and improve their effectiveness in helping aging people extend their healthy working lives.

Building on Prior Research

This study builds directly on emerging work examining the visibility and experiences of hidden workers [8,36,50]. Foundational Australian research has shown the long-term impacts of unemployment and care-related labor interruptions on financial security, labor force attachment, and health [19,20]. International scholarship has also emphasized the need to address structural conditions shaping the opportunities of older, disadvantaged workers [37]. By integrating intersectional mixed methods data, this study will extend existing research by providing deeper, multidimensional evidence on how overlapping disadvantages shape employment trajectories among those aged 45 years and older.

Strengths and Limitations

We will provide rich quantitative and qualitative data, with an adequate sample size for qualitative interviews, providing in-depth information through quota sampling. Our research approach will be key to cocreating our outputs with relevant stakeholders. This will include members of the populations we hope will benefit, hidden workers, industry, communities, and the government. This will ensure outputs that have real credibility, real-world relevance, and value can be implemented and are sustainable.

Nonetheless, the study has its limitations. First, the survey, being primarily digital, will exclude people with poor access to the digital world, although we do offer alternatives, such as phone-based interviews. Second, providing participant information forms in the English language only may result in the exclusion of individuals with limited English proficiency. Potential self-selection and recall bias may occur, and social desirability effects could lead to underreporting of discrimination. Triangulation with qualitative data will help mitigate these.

Finally, although the ideal study design would have a longitudinal survey, we cannot undertake repeated surveys due to various limitations. However, rigorous synthesis of the multiple types of data we produce and a reflexive approach to biases should help to contextualize findings within these limitations.

Conclusions

Current understandings of hidden workers in the aging workforce are limited with regard to the intersections of various minoritized population subgroups. Existing inequities may have worsened, and public and policy awareness of this exacerbation provides an opportunity for change. This study, using an intersectional assets-based approach and drawing on participatory and mixed methods, aims to fill a gap in the evidence to help inform changes that reduce the health inequities of hidden workers in an aging context.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to ethics requirements but are available from the corresponding author under ethics-approved conditions.

Authors' Contributions

Conceptualization: SL
Formal analysis: WK
Funding acquisition: SL
Investigation: SL
Methodology: SL
Project administration: SL, WK
Supervision: SL
Writing–original draft: SL
Writing–review & editing: SL, LY, MB, WK

Conflicts of Interest

None declared

Multimedia Appendix 1
The Hidden Workers in Ageing Australia Survey.
[DOCX File , 73 KB - resprot_v14i1e83401_app1.docx]

References

1. Policy Statement: Mature Age Employment. COTA Australia. 2023 Jun 27. URL: https://cota.org.au/wp-content/uploads/2024/07/Policy-Statement-Mature-Age-Employment.pdf [accessed 2025-07-01]
2. Australian Institute of Health and Welfare. Older Australians. 2024 Jul 02. URL: https://www.aihw.gov.au/reports/older-people/older-australians/contents/summary [accessed 2025-12-05]
3. Maestas N, Li X. Discouraged workers? Job search outcomes of older workers. SSRN Journal 2006:1-48. [doi: 10.2139/ssrn.1095278]
4. Labour Force, Australia. Australian Bureau of Statistics. 2025. URL: https://www.abs.gov.au/statistics/labour/employment-and-unemployment/labour-force-australia/latest-release [accessed 2025-12-02]
5. OECD. Ageing and employment policies: Australia. Paris, France: OECD Publishing; 2023.
6. Fuller JB, Raman M, Sage-Gavin E, Hines K. Hidden Workers: Untapped Talent. 2021. URL: https://www.hbs.edu/managing-the-future-of-work/Documents/research/hiddenworkers09032021.pdf [accessed 2025-12-05]
7. Potential workers statistics. Australian Bureau of Statistics. 2023. URL: https://www.abs.gov.au/statistics/labour/employment-and-unemployment/potential-workers/latest-release [accessed 2025-12-02]
8. Lee S, Kang W. Research Landscape on Hidden Workers in Aging Populations: Bibliometric Review. Social Sciences 2024 Jun 27;13(7):342. [doi: 10.3390/socsci13070342]
9. Closing the gap in a generation: health equity through action on the social determinants of health - Final report of the commission on social determinants of health. World Health Organization. 2008. URL: https://www.who.int/publications/i/item/WHO-IER-CSDH-08.1 [accessed 2022-02-10]
10. Employing and retaining older workers. Australian Human Rights Commission. 2021. URL: https://humanrights.gov.au/resource-hub/by-resource-type/publications/employing-and-retaining-older-workers-2021 [accessed 2025-03-01]
11. Pennington A, Stanford J. Gender inequality in Australia's labour market: a factbook. The Australia Institute's Centre for Future Work. 2020. URL: https://futurework.org.au/wp-content/uploads/sites/2/2022/11/Gender_Inequality_in_Australias_Labour_Market_Formatted.pdf [accessed 2025-12-05]
12. An ageing Australia: preparing for the future. Productivity Commission. 2013. URL: https://www.pc.gov.au/inquiries-and-research/ageing-australia/ [accessed 2025-12-05]
13. Key Figures on Europe. European Commission. 2010. URL: https://ec.europa.eu/eurostat/documents/3217494/11432756/KS-EI-20-001-EN-N.pdf [accessed 2025-12-05]
14. Fact or Fiction? Stereotypes of older Australians. Australian Human Rights Commission. 2013. URL: https://humanrights.gov.au/resource-hub/by-resource-type/projects-and-reports-folder/fact-or-fiction-stereotypes-older-australians [accessed 2025-12-02]
15. Borland J. Scarring effects: a review of Australian and international evidence. Aust J Labour Econ 2020;23(2):173-188 [FREE Full text]
16. Guo Y, Shen M, Zhang X, Xiao Y, Zhao S, Yin M, et al. Unemployment and health-related quality of life in melanoma patients during the COVID-19 pandemic. Front Public Health 2021;9:630620-630612 [FREE Full text] [doi: 10.3389/fpubh.2021.630620] [Medline: 33692982]
17. Dinh H, Strazdins L, Doan T, Do T, Yazidjoglou A, Banwell C. Workforce participation, health and wealth inequality among older Australians between 2001 and 2015. Arch Public Health 2022;80(1):104 [FREE Full text] [doi: 10.1186/s13690-022-00852-z] [Medline: 35361261]
18. Bowman D, McGann M, Kimberley H, Biggs S. 'Rusty, invisible and threatening': ageing, capital and employability. Work Employ Soc 2016;31(3):465-482. [doi: 10.1177/0950017016645732]
19. McGann M, Kimberley H, Bowman D, Biggs S. The Netherworld between work and retirement. Soc Pol Soc 2016 Jun 03;15(4):625-636. [doi: 10.1017/S147474641600021X]
20. Duncan C. Assessing anti-ageism routes to older worker re-engagement. Work Employ Soc 2003;17(1):101-120. [doi: 10.1177/0950017003017001265]
21. Tempest S, Coupland C. Lost in time and space: temporal and spatial challenges facing older workers in a global economy from a career capital perspective. Int J Hum Resour Manag 2016 Jan 20;28(15):2159-2183. [doi: 10.1080/09585192.2015.1128455]
22. Kelly EL, Moen P, Oakes JM, Fan W, Okechukwu C, Davis KD, et al. Changing work and work-family conflict: evidence from the work, family, and health network*. Am Sociol Rev 2014;79(3):485-516 [FREE Full text] [doi: 10.1177/0003122414531435] [Medline: 25349460]

23. Heslin PA, Bell MP, Fletcher PO. The devil without and within: A conceptual model of social cognitive processes whereby discrimination leads stigmatized minorities to become discouraged workers. J Organ Behavior 2012 May 07;33(6):840-862. [doi: 10.1002/job.1795]
24. Haynes H. Social media in employment decisions. SSRN Journal 2015 Mar 17:1-36 [FREE Full text] [doi: 10.2139/ssrn.2579948]
25. Desmette D, Gaillard M. When a "worker" becomes an "older worker": the effects of age-related social identity on attitudes towards retirement and work. Career Dev Int 2008;13(2):168-185. [doi: 10.1108/13620430810860567]
26. Crenshaw KW, Oristelle B. Mapping the margins: intersectionality, identity politics, and violence against women of color. Cahiers du Genre 2005;39(2):51-82. [doi: 10.3917/cdge.039.0051]
27. Hankivsky O. Intersectionality 101. Vancouver: The Institute for Intersectionality Research & Policy, SFU; 2014.
28. Lewis JA. Intersectionality theory and microaggressions: implications for research, teaching, and practice. In: Torino GC, Rivera DP, Capodilupo CM, Nadal KL, Sue DW, editors. Microaggression Theory: Influence and Implications. Hoboken, NJ: Wiley; 2018.
29. Lee S, Kang W. What contributes to the gender gap? A Blinder–Oaxaca decomposition analysis of hidden workers in Australia. Soc Sci 2024 Dec 30;14(1):9-79. [doi: 10.3390/socsci14010009]
30. Kavas S, de Jong J. Exploring the mechanisms through which social ties affect fertility decisions in Turkey. J Marriage Fam 2020 Mar 04;82(4):1250-1269. [doi: 10.1111/jomf.12668]
31. Lu L. Attitudes towards aging and older people's intentions to continue working: a Taiwanese study. Career Dev Int 2012;17(1):83-98. [doi: 10.1108/13620431211201346]
32. Gonzalez R, Fuentes A, Muñoz E. On social capital and health: the moderating role of income inequality in comparative perspective. Int J Sociol 2020 Jan 06;50(1):68-85. [doi: 10.1080/00207659.2019.1709138]
33. Thematic analysis of interview data: 6 ways NVivo can help. Lumivero. URL: https://lumivero.com/resources/blog/thematic-analysis-of-interview-data-nvivo/ [accessed 2025-03-01]
34. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2008;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
35. A conceptual framework for social determinants of health. World Health Organization. 2010. URL: https://www.who.int/publications/i/item/9789241500852 [accessed 2025-12-05]
36. Lee S. Officially, the unemployment rate is 4.2%. But that doesn't count all the hidden workers in Australia. Conversation. 2025 Aug 24. URL: https://theconversation.com/officially-the-unemployment-rate-is-4-2-but-that-doesnt-count-all-the-hidden-workers-in-australia-262870 [accessed 2025-08-24]
37. Grenier A, Phillipson C, Settersten Jr RA. Precarity and ageing: new perspectives for social gerontology. In: Precarity and Ageing: Understanding Insecurity and Risk in Later Life. Bristol: Bristol University Press; 2020:1-16.
38. Clark VLP. Meaningful integration within mixed methods studies: identifying why, what, when, and how. Contemp Educ Psychol 2019 Apr;57:106-111. [doi: 10.1016/j.cedpsych.2019.01.007]
39. How to create a survey? QuestionPro. URL: https://www.questionpro.com/help/create-survey.html [accessed 2025-03-01]
40. Bastos JL, Celeste RK, Faerstein E, Barros AD. Racial discrimination and health: a systematic review of scales with a focus on their psychometric properties. Soc Sci Med 2010 Apr;70(7):1091-1099. [doi: 10.1016/j.socscimed.2009.12.020] [Medline: 20122772]
41. Lewis TT, Cogburn C, Williams D. Self-reported experiences of discrimination and health: scientific advances, ongoing controversies, and emerging issues. Annu Rev Clin Psychol 2015;11:407-440 [FREE Full text] [doi: 10.1146/annurev-clinpsy-032814-112728] [Medline: 25581238]
42. Scheim A, Bauer G. The Intersectional Discrimination Index: development and validation of measures of self-reported enacted and anticipated discrimination for intercategorical analysis. Soc Sci Med 2019 Apr;226:225-235 [FREE Full text] [doi: 10.1016/j.socscimed.2018.12.016] [Medline: 30674436]
43. Marchiondo LA, Gonzales E, Ran S. The workplace age discrimination scale (WADS). J Appl Psychol 2016;101:928. [doi: 10.1037/t59268-000]
44. Harpham T, Grant E, Thomas E. Measuring social capital within health surveys: key issues. Health Policy Plan 2002;17(1):106-111. [doi: 10.1093/heapol/17.1.106] [Medline: 11861592]
45. Narayan D, Cassidy M. A dimensional approach to measuring social capital: Development and validation of a social capital inventory. Curr Sociol 2001 Mar 01;49(2):59-102. [doi: 10.1177/0011392101049002006]
46. Szreter S, Woolcock M. Health by association? Social capital, social theory, and the political economy of public health. Int J Epidemiol 2004 Aug;33(4):650-667. [doi: 10.1093/ije/dyh013] [Medline: 15282219]
47. Fielding NG. Triangulation and mixed methods designs: data integration with new research technologies. J Mixed Methods Res 2012;6(2):124-136. [doi: 10.1177/1558689812437101]
48. StataCorp LLC. Stata. 2023. URL: https://www.stata.com/company/ [accessed 2025-12-02]
49. Future directions for an ageing Australia. Australian Law Reform Commission. 2019. URL: https://www.alrc.gov.au/ [accessed 2025-12-02]

50. Lee S, Kang W, Oakman J. Unveiling the hidden workers in Australia: who are the hidden workers and what makes them hidden? Soc Sci 2025 Jul 21;14(7):446-433. [doi: 10.3390/socsci14070446]

Abbreviations

ABS: Australian Bureau of Statistics
DEWR: Department of Employment and Workplace Relations
IHHIF: Intersectionality-based Hidden Workers Health Inequality Framework
ILO: International Labour Organization
OECD: Organisation for Economic Co-operation and Development
WADS: Workplace Age Discrimination Scale
WSC: Workplace Social Capital

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Protocol

Effects of Oliceridine Versus Sufentanil on Postoperative Recovery Quality During Hysteroscopy Under Laryngeal Mask Airway Anesthesia: Protocol for a Single-Blind and Randomized Controlled Trial

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Abstract

Background: Hysteroscopy, the gold standard for diagnosing and treating intrauterine pathologies, has shown substantial increase in its adoption in clinical practice. Nevertheless, early postoperative pain and opioid-related adverse effects remain critical determinants of recovery quality. Oliceridine—a novel G protein-biased μ-opioid receptor agonist—demonstrates an improved therapeutic range over conventional opioids in preliminary studies.

Objective: This study aims to evaluate whether oliceridine enhances recovery quality while reducing opioid-related complications compared to sufentanil in patients undergoing hysteroscopy under general anesthesia.

Methods: This single-center randomized controlled trial will enroll 120 patients undergoing hysteroscopy under general anesthesia with 1:1 randomization to sufentanil- or oliceridine-based analgesia. The primary outcome is early recovery quality assessed by the 15-item Quality of Recovery scale at 24 hours after the surgery, while secondary outcomes include hemodynamic fluctuations during induction, total intraoperative opioid consumption and supplemental bolus frequency, proportion requiring vasoactive agents, incidence of respiratory depression in postanesthesia care unit, postoperative extubation time, opioid-related adverse events within 24 hours, and Visual Analog Scale pain scores at 30 minutes, 4 hours, 8 hours, and 24 hours postextubation.

Results: This study received approval from the Medical Ethics Committee of Deyang People's Hospital, Deyang, China, on April 16, 2025 (approval 2025-03-009-K01). Participant recruitment is anticipated to be completed by December 2025. Data analysis, manuscript preparation, and submission for publication are expected to be completed by February 2026.

Conclusions: The successful completion of this trial will generate evidence regarding whether oliceridine enhances recovery quality while reducing opioid-related complications compared to sufentanil in patients undergoing hysteroscopy under general anesthesia.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2500104024; https://www.chictr.org.cn/showproj.html?proj=275501

International Registered Report Identifier (IRRID): DERR1-10.2196/84521

(JMIR Res Protoc 2026;15:e84521) doi:10.2196/84521

KEYWORDS

oliceridine; hysteroscopy; quality of recovery; opioid-related adverse events; sufentanil; general anesthesia

Introduction

Hysteroscopy is currently recognized as the gold standard for diagnosing and treating intrauterine pathologies, having revolutionized gynecological diagnostics and operative interventions. This modality enables both diagnostic evaluations and surgical treatments through a minimally invasive approach, characterized by rapid postoperative recovery. Advancements in hysteroscopic technologies and instrumentation have substantially increased its adoption across diverse patient populations [1,2]. Pain remains a leading cause of procedural failure during hysteroscopy. To optimize surgical conditions and enhance satisfaction for both patients and surgeons, hysteroscopic procedures in China are predominantly performed under general anesthesia. A nationwide survey revealed that 63.8% of the hysteroscopic surgeries used anesthesia in 2021, underscoring its critical role in contemporary practice [3]. European data corroborate this pattern, with a retrospective analysis confirming that a proportion of hysteroscopic procedures also necessitate general anesthesia for successful completion [4].

To date, no robust evidence exists to define optimal anesthesia protocols for pain management in hysteroscopy, and standardized approaches remain underexplored. For hysteroscopic procedures anticipated to be lengthy or involving significant tissue trauma, the 2020 Chinese Expert Consensus on Anesthesia Management recommends general anesthesia with laryngeal mask airway (LMA) to ensure procedural tolerance [5]. Current clinical practice predominantly uses conventional opioids such as sufentanil for intraoperative analgesia. However, sufentanil administration is associated with multiple opioid-related adverse effects, including nausea, vomiting, excessive sedation, respiratory depression, drug dependence, and opioid-induced hyperalgesia, which collectively compromise early postoperative recovery [6].

Oliceridine is a novel G protein-biased μ-opioid receptor agonist that selectively activates G protein signaling while minimizing β-arrestin recruitment. This pharmacological profile confers a mechanistic advantage: selectively engaging intracellular analgesic pathways while avoiding those mediating adverse effects [7,8]. As such, oliceridine has garnered emerging clinical interest for hysteroscopic analgesia.

The 15-item Quality of Recovery scale (QoR-15) is a multidimensional construct evaluating patient-centered recovery, encompassing physical, physiological, psychological, social, and functional domains [9,10]. The QoR-15—validated for reliability and clinical utility—quantifies recovery across 5 dimensions: physical comfort, emotional status, psychological support, independence, and pain experience. Postoperative pain intensity, nausea/vomiting incidence, and opioid consumption profiles constitute key determinants of patient recovery quality [11,12].

Therefore, this study uses QoR-15 as the primary endpoint to evaluate oliceridine's efficacy within LMA-based general anesthesia for hysteroscopy. We aim to determine whether oliceridine enhances recovery quality while reducing opioid-related complications compared to sufentanil in patients undergoing hysteroscopy under general anesthesia.

Methods

Study Design

This prospective, single-center, single-blind, randomized controlled study will be conducted at Deyang People's Hospital, Deyang, China. The protocol received ethical approval from the institutional ethics committee (2025-03-K01) and was registered at the Chinese Clinical Trial Registry on June 10, 2025. Written informed consent will be obtained from all participants or their legal guardians. Eligible patients will be randomly allocated to either the sufentanil (S) group or oliceridine (O) group. The participant recruitment timeline is shown in Figure 1. A time schedule for the enrollment, interventions, and assessments is detailed in Table 1.

Figure 1. Flowchart for this study.

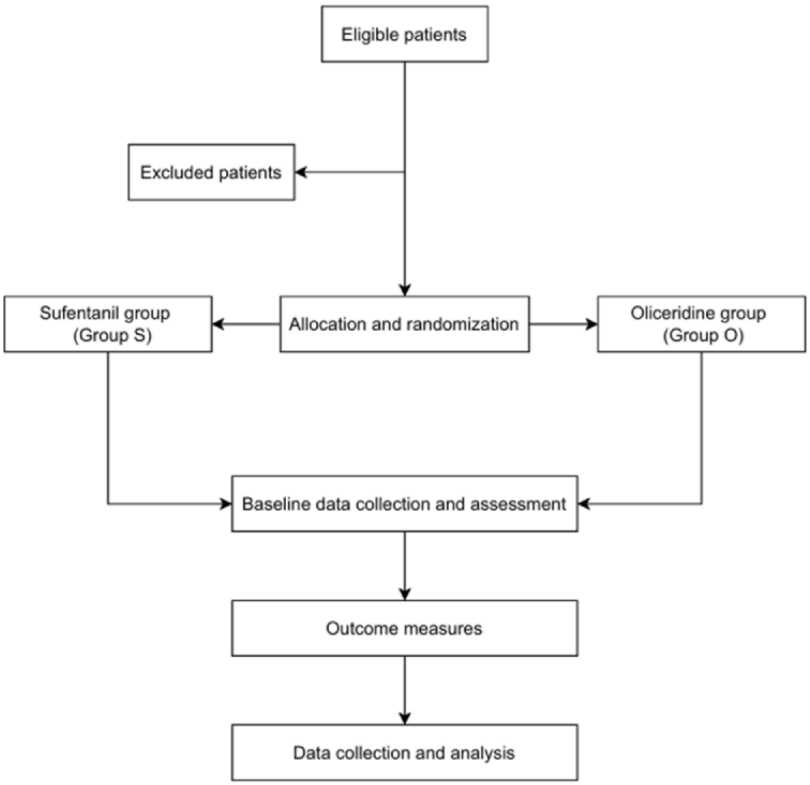

Table 1. The study schedule of the enrollment, interventions, and assessments.

Timepoint	Enrollment phase (day 1)	Allocation (before surgery)	Surgery (during anesthesia)	Follow-up (within 24 h after surgery)
Enrollment				
Eligibility screening	✓			
Informed consent	✓			
Allocation		✓		
Interventions				
Sufentanil			✓	
Oliceridine			✓	
Assessments				
Baseline data	✓			
Primary outcome				✓
Secondary outcome			✓	✓

Eligibility Criteria

Inclusion criteria are as follows: (1) patients scheduled for hysteroscopic surgery under LMA general anesthesia who were assessed by physicians as unable to tolerate the pain stimuli associated with surgical manipulation, (2) patients aged 18 to 65 years, (3) patients with American Society of Anesthesiologists physical status I-III, and (4) patients who voluntarily sign informed consent.

Exclusion criteria are as follows: (1) patients with American Society of Anesthesiologists physical status IV or higher (indicating severe systemic disease, functional incapacity, including but not limited to New York Heart Association class III or higher heart failure, myocardial ischemia, severe reduction in cardiac ejection fraction, third-degree atrioventricular block, stage 3 hypertension, respiratory failure, severe chronic obstructive pulmonary disease, severe pulmonary dysfunction, or decompensated hepatic or renal insufficiency); (2) patients with known allergy to any component of the investigational drugs or contraindications to their use; (3) patients unable to cooperate (eg, psychiatric disorders, anticipated difficulty with neuropsychological assessment, or communication barriers due to pronunciation or dialect); (4) patients with a history of alcohol

or substance abuse; (5) patients with concurrent participation or participation in another clinical trial within 12 weeks prior to this trial; (6) patients with BMI>30 kg/m²; (7) patients unable to comprehend the study procedures or refusal to participate; and (8) patients with any condition deemed by the investigator to pose an unacceptable risk or to contraindicate participation, such as anticipated difficult airway management.

Randomization and Blinding

Block randomization with block sizes of 4 or 6 will be performed using a computer-generated sequence. An independent researcher not involved in the trial will prepare sequentially numbered, opaque, sealed envelopes containing group assignments. Participants will be allocated in a 1:1 ratio to either the experimental or control group by opening these envelopes in a sequential order at the time of enrollment. Allocation cards will be sealed inside opaque envelopes to ensure concealment. The study medications (oliceridine or sufentanil) will be prepared by a dedicated research nurse as visually identical clear solutions in 10-mL syringes. These prepared syringes will then be provided to the anesthesiologist, who will remain unaware of the treatment allocation. Blinding will be maintained for the participants, the anesthesiologist, and the outcome assessors throughout the trial to minimize assessment bias. The blinding will be broken only in the event of severe adverse events. Study participants, their legally authorized representatives, the anesthesiologist, and outcome assessors will be blinded to group allocation throughout the trial. Unblinding the allocation is generally not required per protocol. Emergency unblinding will be performed exclusively to determine rescue medications for critical adverse events or during other medical emergencies

Interventions

Explanation for the Choice of Comparators

This study evaluates the impact of oliceridine (group O) on early postoperative recovery quality in patients undergoing hysteroscopic surgery under general anesthesia. The sufentanil-based regimen (group S) serves as the comparator because of its status as the conventional analgesic approach for such procedures in current clinical practice.

Both groups will receive identical anesthesia induction and maintenance protocols but with divergent analgesic regimens. Group O will be administered oliceridine at a dose of 60 µg/kg (diluted to 10 mL with normal saline) as a slow intravenous bolus for induction. Supplemental doses of 30 µg/kg will be provided if intraoperative analgesia is deemed inadequate, defined as mean arterial pressure and/or heart rate exceeding 20% above baseline values. Group S will receive sufentanil at a dose of 0.3 µg/kg (similarly diluted to 10 mL) as an induction bolus, with supplemental doses of 0.15 µg/kg administered under the same hemodynamic criteria.

Anesthesia Protocol

Upon arrival in the operating room, standard monitoring, including pulse oximetry, invasive radial arterial blood pressure, and electrocardiography will be initiated. Thirty minutes prior to induction, the attending anesthesiologist will administer intravenous penehyclidine hydrochloride (0.01 mg/kg) and ondansetron (4 mg). Anesthesia induction will begin with a slow intravenous bolus of either sufentanil or oliceridine according to group assignment. One minute later, propofol (2 mg/kg) and cisatracurium (0.15 mg/kg) will be administered. After satisfactory neuromuscular blockade is achieved, an LMA will be inserted. Mechanical ventilation will be initiated with a tidal volume of 6-8 mL/kg predicted body weight and positive end-expiratory pressure of 5 cmH_2O. Anesthesia will be maintained using a continuous infusion of propofol (4-12 mg/kg/h), with supplemental opioids administered based on hemodynamic criteria (mean arterial pressure or heart rate >20% above baseline). The propofol infusion rate will be titrated to maintain a bispectral index value between 40 and 60. Neuromuscular blockade will be maintained with intermittent boluses of cisatracurium (one-third of the induction dose). If reversal is required, neostigmine (0.02 mg/kg) and atropine (0.01 mg/kg) will be administered. After surgery, all patients will be transferred to the postanesthesia care unit.

Criteria for Discontinuing or Modifying Allocated Interventions

The criteria for discontinuing are as follows: (1) severe anesthesia/surgical complications (eg, anaphylaxis, shock, cardiac arrest, malignant arrhythmias, aspiration requiring intervention, malignant hyperthermia), (2) protocol deviation in anesthesia/surgical technique, (3) withdrawal of consent, (4) anticipated difficult airway, and (5) failed LMA placement.

Strategies to Improve Adherence to Interventions

The principal investigator will conduct preoperative evaluations against inclusion/exclusion criteria one day prior to surgery. During informed consent, the investigator will detail the study procedures to participants and legally authorized representatives, outlining participant responsibilities.

Relevant Concomitant Care Permitted or Prohibited During the Trial

The provision of additional care during the trial followed institutional protocols.

Outcomes

The primary outcome is defined as the quality of postoperative recovery at 24 hours after surgery and will be assessed using QoR-15 (score range: 0-150; higher scores indicate better recovery). Secondary efficacy endpoints are (1) hemodynamic changes during induction (mean arterial pressure/heart rate at T0 [pre-drug], T1 [pre-LMA], T2 [post-LMA immediate], T3 [5-min post-LMA]); (2) total intraoperative opioid consumption and supplemental bolus frequency; (3) proportion requiring vasoactive agents; (4) incidence of postanesthesia care unit respiratory depression (defined as respiratory rate <6 bpm, end-tidal carbon dioxide amplitude change >50 mm Hg or <30 mm Hg, or waveform loss >20 s); (5) time to extubation; (6) opioid-related adverse events within 24 hours; and (7) Visual Analog Scale pain scores at 30 minutes, 4 hours, 8 hours, and 24 hours postextubation.

Data Collection and Management

Baseline data will include demographic characteristics (age, sex, BMI), the preoperative QoR-15 score, and comorbidities with diagnostic verification. Intraoperative records will include vital signs, anesthetic agents/dosages, surgical duration, and proportion requiring vasopressor administration. In the postanesthesia care unit, time to extubation, early postoperative Visual Analog Scale pain scores, and incidence of respiratory depression will be documented. Postoperative recovery quality will be assessed at 24 hours by using QoR-15, with 24-hour adverse events systematically recorded. Predefined subgroup analyses stratified by age will be conducted for primary and secondary outcomes, applying identical statistical approaches as specified for the main analyses.

Source data will be documented using standardized case report forms. To minimize data entry errors, independent dual-entry verification will be performed. Physical records will be stored securely in locked cabinets with restricted access within the Department of Anesthesiology. Electronic data will be hosted on encrypted, cloud-based platforms.

Data Reporting Guidelines

The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines will be used for this paper (Multimedia Appendix 1).

Sample Size

An initial retrospective review of 10 patients who underwent hysteroscopy under sufentanil-based general anesthesia resulted in a mean QoR-15 score of 129.8 (SD 4.92). Based on published literature, the minimal clinically important difference for QoR-15 is 6 [13]. We hypothesize that oliceridine will improve the postoperative QoR-15 score by this minimal clinically important difference (6 points). Sample size was calculated using PASS 15 software with the following parameters: a standard deviation of 11.5 [13], a 2-sided α of 0.05, and 90% power. The calculation indicated that 48 patients are required per group. To account for an estimated 20% attrition rate, the total sample size was set at 120 patients (60 per group).

Recruitment Plan

Based on institutional surgical volume projections, patient recruitment is scheduled to commence in July 2025 and is anticipated to be completed within a 5-month period to enroll the target cohort of 120 participants. Eligible patients will be identified primarily through active screening of institutional surgical schedules for planned hysteroscopies. Preoperative screening for eligible candidates will be conducted by the investigators. Written informed consent will be obtained from all participants or their legally authorized representatives either before or on the day of surgery. The consent process, approved by the institutional review board, ensures comprehensive disclosure of the potential benefits, risks, and alternative treatments. Documentation will confirm that all participants have fully understood the information before providing their signature.

Statistical Analysis

The primary analysis will be conducted on a modified intention-to-treat population, defined as all randomized participants who receive the study drug (oliceridine or sufentanil) at anesthesia induction. The per-protocol population will consist of modified intention-to-treat participants who complete the 24-hour follow-up assessment without major protocol deviations, serving as the population for supportive analyses. All participants who receive the study drug will be included in the safety analysis set.

Primary/secondary outcomes will be analyzed using SPSS software (version 27.0; IBM Corp), with continuous variables first assessed for normality via Kolmogorov-Smirnov testing; normally distributed data will be expressed as mean (SD), nonnormal data as median (IQR), and categorical variables as counts (%). Quantitative between-group comparisons will employ independent-samples *t* tests or Mann-Whitney *U* tests, while qualitative comparisons will use chi-square, continuity-corrected chi-square, or Fisher exact tests, with all tests being 2-tailed (statistical significance threshold: $P<.05$).

Methods to Handle Protocol Nonadherence and Any Statistical Methods to Handle Missing Data

Prior to enrollment, comprehensive study details will be disclosed to potential participants, with written informed consent obtained from patients and their legally authorized representatives. Investigators may discontinue participation for substantial protocol deviations (eg, nonattendance at scheduled visits), initiating replacement recruitment according to the randomization sequence.

Plans to Promote Participant Retention and Complete Follow-Up

Investigators will maintain ongoing communication with the participants throughout the trial to address concerns while ensuring protocol adherence. Participant involvement may be discontinued by investigators in cases of nonadherence to scheduled visits or substantial protocol deviations, with all collected data excluded from the final analysis per intention-to-treat principles.

Ethical Considerations

This study received approval from the institutional ethics committee of Deyang People's Hospital (approval 2025-03-009-K01). All procedures strictly adhered to legislative and institutional requirements, with no involvement of vulnerable populations. Eligible patients will undergo preoperative screening. Written informed consent will be obtained from all participants or their legal guardians prior to or on the day of surgery. We ensure comprehensive disclosure of potential benefits and risks, with full participant comprehension verified before consent signing. Participants will be informed that participation is voluntary and that they may withdraw at any time without penalty. Each participant will receive ¥100 (US $14.12) as compensation. All investigators adhere strictly to confidentiality protocols and ethical standards throughout the trial. Personally identifiable data will be maintained with maximized confidentiality.

Confidential information undergoes secure processing/storage protocols, with exclusively anonymized datasets shared for analysis.

Dissemination Plans

Study findings will be submitted for publication in peer-reviewed anesthesiology journals. Access to trial data and protocols is exclusively restricted to the trial leader. No personnel may access participant data without documented prior approval from the principal investigator.

Results

The first patient was enrolled on July 11, 2025. As of September 2025, a total of 55 participants has been enrolled. Data analysis, manuscript preparation, and submission for publication are expected to take place throughout the first quarter of 2026.

Discussion

Anticipated Findings

Hysteroscopy serves as a minimally invasive modality for diagnosing and treating intrauterine pathologies, with indispensable roles in managing endometrial polyps, abnormal uterine bleeding, intrauterine adhesions, uterine septa, endometrial hyperplasia, and early-stage endometrial cancer [14-16]. Procedures requiring prolonged operative time or large instrumentation necessitate anesthesia in operating room settings [17]. In China, LMA-based general anesthesia is currently a prevalent approach for hysteroscopic surgery [18]. Conventional analgesic protocols predominantly use traditional opioids such as sufentanil. However, these agents frequently induce respiratory/circulatory depression, nausea/vomiting, excessive sedation, immunosuppression, opioid-induced hyperalgesia, constipation, and abdominal distension [19-22]. Although effective for anesthesia, these complications prolong hospitalization, increase perioperative management complexity, and compromise postoperative recovery quality. Consequently, reducing opioid-related adverse events is crucial for enhancing recovery.

Oliceridine is a synthetic μ-opioid receptor agonist distinguished from conventional opioids by its G protein-biased selectivity, which mediates potent analgesia while substantially reducing β-arrestin recruitment—a signaling pathway strongly associated with opioid-related adverse events. In contrast, traditional opioids (eg, morphine, fentanyl) nonselectively activate both G protein and β-arrestin pathways upon μ-receptor binding [23,24]. Clinical trial evidence confirms that oliceridine significantly reduces nausea, vomiting, and respiratory complications compared to morphine [25-28]. Therefore, we postulate that this mechanistic advantage of oliceridine may similarly confer clinical benefits when compared with sufentanil.

QoR-15 was selected to assess postoperative recovery quality as a validated patient-reported outcome measure evaluating 5 key recovery dimensions following anesthesia and surgery. Its established reliability and practical clinical utility underpin widespread adoption [11]. The Chinese version has been formally validated, demonstrating robust reliability, validity, and user-friendliness [29]. These properties support its extensive application in clinical trials for postoperative recovery assessment.

Limitations

No prior studies have established whether oliceridine's mechanistic advantages translate to enhanced recovery quality in hysteroscopic surgery under general anesthesia. However, there are a number of potential limitations in the study design: (1) single-center design—though protocol standardization ensures internal validity, generalizability may be limited; (2) exclusive focus on 24-hour recovery without long-term follow-up; and (3) exclusion of high-risk populations (BMI>30 kg/m²), who exhibit heightened susceptibility to opioid-related complications and may theoretically derive the greatest benefit from oliceridine.

Acknowledgments

We are grateful to all the patients and families who participated in this study. We also thank all the anesthesiologists and surgeons who contributed to this study.

Data Availability

Deidentified participant data generated in this study will be made accessible upon reasonable request to the corresponding author following paper publication.

Authors' Contributions

JH and YHS conceptualized and designed the trial and drafted the initial protocol. YHS prepared the preliminary manuscript. JH and XJZ finalized the manuscript. JSL and WHZ were responsible for participant recruitment and allocation. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

SPIRIT checklist.
[DOCX File , 29 KB - resprot_v15i1e84521_app1.docx]

References

1. Vitale SG, Giannini A, Carugno J, van Herendael B, Riemma G, Pacheco LA, et al. Hysteroscopy: where did we start, and where are we now? The compelling story of what many considered the "Cinderella" of gynecological endoscopy. Arch Gynecol Obstet 2024 Oct;310(4):1877-1888. [doi: 10.1007/s00404-024-07677-x] [Medline: 39150502]
2. Buzzaccarini G, Alonso Pacheco L, Vitagliano A, Haimovich S, Chiantera V, Török P, et al. Pain management during office hysteroscopy: an evidence-based approach. Medicina (Kaunas) 2022 Aug 20;58(8):1132 [FREE Full text] [doi: 10.3390/medicina58081132] [Medline: 36013599]
3. Huang L, Yu Q, Zhu Z, Huang P, Ding X, Ma X, et al. The current situation of anaesthesia for hysteroscopy in mainland China: a national survey. J Pers Med 2023 Sep 26;13(10):1436 [FREE Full text] [doi: 10.3390/jpm13101436] [Medline: 37888047]
4. Biela M, Doniec J, Szafarowska M, Sobocinski K, Kwiatkowski A, Kamiński P. Is every patient eligible to have an office hysteroscopy? A retrospective analysis of 1301 procedures. Wideochir Inne Tech Maloinwazyjne 2020 Jun;15(2):337-345 [FREE Full text] [doi: 10.5114/wiitm.2019.89609] [Medline: 32489495]
5. No authors listed. Anesthesia. Anesthesiology 1969;30(1):11. [doi: 10.1097/00000542-196901000-00006]
6. Adams TJ, Aljohani DM, Forget P. Perioperative opioids: a narrative review contextualising new avenues to improve prescribing. Br J Anaesth 2023 Jun;130(6):709-718 [FREE Full text] [doi: 10.1016/j.bja.2023.02.037] [Medline: 37059626]
7. Liu Y, Zhu Y, Fu H. Tolerability of different doses of oliceridine versus traditional opioids in acute pain management: a systematic review and meta-analysis. Sci Rep 2025 Apr 03;15(1):11470 [FREE Full text] [doi: 10.1038/s41598-025-95978-9] [Medline: 40181183]
8. Viscusi ER. A critical review of oliceridine injection as an IV opioid analgesic for the management of severe acute pain. Expert Rev Neurother 2022 Jun;22(6):419-426 [FREE Full text] [doi: 10.1080/14737175.2022.2072731] [Medline: 35502668]
9. Wessels E, Perrie H, Scribante J, Jooma Z. Quality of recovery in the perioperative setting: a narrative review. J Clin Anesth 2022 Jun;78:110685. [doi: 10.1016/j.jclinane.2022.110685] [Medline: 35190342]
10. Markos Z, Amsalu H, Mekuanint A, Yirga S, Simegn AE, Kassegn A. Assessment of intermediate phase post anesthesia quality of recovery and its affecting factors. BMC Anesthesiol 2024 Sep 28;24(1):342 [FREE Full text] [doi: 10.1186/s12871-024-02696-2] [Medline: 39342095]
11. Kleif J, Waage J, Christensen K, Gögenur I. Systematic review of the QoR-15 score, a patient- reported outcome measure measuring quality of recovery after surgery and anaesthesia. Br J Anaesth 2018 Jan;120(1):28-36 [FREE Full text] [doi: 10.1016/j.bja.2017.11.013] [Medline: 29397134]
12. Stark P, Myles P. Burke JA: Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15. Anesthesiology 2013 2013 Jun 23;118(6):1332-1340. [doi: 10.1097/aln.0b013e318289b84b] [Medline: 23411725]
13. Myles P. Myles DB: an updated minimal clinically important difference for the QoR-15 scale. Anesthesiology 2021 Nov 12;135(5):1. [doi: 10.1097/aln.0000000000003977] [Medline: 34543410]
14. No authors listed. The use of hysteroscopy for the diagnosis and treatment of intrauterine pathology: ACOG committee opinion summary, number 800. Obstet Gynecol 2020 Mar;135(3):754-756. [doi: 10.1097/AOG.0000000000003713] [Medline: 32080048]
15. No authors listed. ACOG technology assessment no. 13 summary: hysteroscopy. Obstet Gynecol 2018 May;131(5):1. [doi: 10.1097/AOG.0000000000002629] [Medline: 29683907]
16. Yen C, Chou H, Wu H, Lee C, Chang T. Effectiveness and appropriateness in the application of office hysteroscopy. J Formos Med Assoc 2019 Nov;118(11):1480-1487 [FREE Full text] [doi: 10.1016/j.jfma.2018.12.012] [Medline: 30611636]
17. De Silva PM, Smith PP, Cooper NAM, Clark TJ, Royal College of ObstetriciansGynaecologists. Outpatient hysteroscopy: (green-top guideline no. 59). BJOG 2024 Dec;131(13):e86-e110. [doi: 10.1111/1471-0528.17907] [Medline: 39160077]
18. ji M, Zhang YZ, Wu Y. Deng X-F: Clinical trial of cis-atracurium in the treatment of patients with hysteroscopic surgery. The Chinese Journal of Clinical Pharmacology 2024;40(18):2640-2644. [doi: 10.13699/j.cnki.1001-6821.2024.18.007]
19. Mauermann E, Clamer D, Ruppen W, Bandschapp O. Association between intra-operative fentanyl dosing and postoperative nausea/vomiting and pain: a prospective cohort study. Eur J Anaesthesiol 2019 Nov;36(11):871-880. [doi: 10.1097/EJA.0000000000001081] [Medline: 31567573]
20. Hoshijima H, Takeuchi R, Kuratani N, Nishizawa S, Denawa Y, Shiga T, et al. Incidence of postoperative shivering comparing remifentanil with other opioids: a meta-analysis. J Clin Anesth 2016 Aug;32:300-312. [doi: 10.1016/j.jclinane.2015.08.017] [Medline: 26432635]
21. de Boer HD, Detriche O, Forget P. Opioid-related side effects: postoperative ileus, urinary retention, nausea and vomiting, and shivering. A review of the literature. Best Pract Res Clin Anaesthesiol 2017 Dec;31(4):499-504. [doi: 10.1016/j.bpa.2017.07.002] [Medline: 29739538]
22. Forget P. Opioid-free anaesthesia. Why and how? A contextual analysis. Anaesth Crit Care Pain Med 2019 Apr;38(2):169-172. [doi: 10.1016/j.accpm.2018.05.002] [Medline: 29775728]

23. Bergese SD, Brzezinski M, Hammer GB, Beard TL, Pan PH, Mace SE, et al. ATHENA: a phase 3, open-label study of the safety and effectiveness of oliceridine (TRV130), a G-protein selective agonist at the μ-opioid receptor, in patients with moderate to severe acute pain requiring parenteral opioid therapy. JPR 2019 Nov;12:3113-3126. [doi: 10.2147/jpr.s217563]
24. Gan T, Wase L. Oliceridine, a G protein-selective ligand at the μ-opioid receptor, for the management of moderate to severe acute pain. Drugs Today (Barc) 2020 Apr;56(4):269-286. [doi: 10.1358/dot.2020.56.4.3107707] [Medline: 32309822]
25. Soergel D, Subach R, Burnham N, Lark M, James I, Sadler B, et al. Biased agonism of the μ-opioid receptor by TRV130 increases analgesia and reduces on-target adverse effects versus morphine: a randomized, double-blind, placebo-controlled, crossover study in healthy volunteers. Pain 2014 Sep;155(9):1829-1835. [doi: 10.1016/j.pain.2014.06.011] [Medline: 24954166]
26. Viscusi E, Webster L, Kuss M, Daniels S, Bolognese J, Zuckerman S, et al. A randomized, phase 2 study investigating TRV130, a biased ligand of the μ-opioid receptor, for the intravenous treatment of acute pain. Pain 2016 Jan;157(1):264-272. [doi: 10.1097/j.pain.0000000000000363] [Medline: 26683109]
27. Singla N, Minkowitz H, Soergel D, Burt D, Subach RA, Salamea M, et al. JPR 2017 Oct;10:2413-2424. [doi: 10.2147/jpr.s137952]
28. Singla NK, Skobieranda F, Soergel DG, Salamea M, Burt DA, Demitrack MA, et al. APOLLO‐2: A Randomized, Placebo and Active‐Controlled Phase Study Investigating Oliceridine (130), a G Protein–Biased Ligand at the μ‐Opioid Receptor, for Management of Moderate to Severe Acute Pain Following Abdominoplasty. Pain Practice 2019 Jun 24;19(7):715-731. [doi: 10.1111/papr.12801]
29. Bu X, Zhang J, Zuo Y. Validation of the Chinese version of the Quality of Recovery-15 score and its comparison with the Post-Operative Quality Recovery Scale. Patient 2016 Jun;9(3):251-259. [doi: 10.1007/s40271-015-0148-6] [Medline: 26518201]

Abbreviations

LMA: laryngeal mask airway
QoR-15: 15-item Quality of Recovery scale
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

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Protocol

Women's Occupational Tobacco Dust Exposure in Indonesia (T-CHARM): Protocol for a Prospective Cohort Study

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Abstract

Background: The consumption of tobacco is regarded as a contributing factor to several diseases. However, the impact of tobacco dust exposure (TDE) on tobacco workers has not been extensively investigated.

Objective: This protocol introduces the design and implementation of the Tobacco Dust Cohort for Health Assessment and Risk Monitoring (T-CHARM) study, a prospective cohort study aimed at evaluating the health impacts of TDE.

Methods: This prospective cohort study will recruit women working in tobacco processing who are nonsmokers and women who do not work for the tobacco industry and are nonsmokers living in a nearby area (unexposed group), with a total of 400 expected participants. The impact of TDE on health, including metabolic syndrome parameters; complete blood count; and cardiovascular, liver, renal, and lung function, will be evaluated in relation to urine cotinine levels. Air quality and chemical substances in the air and leaves will also be analyzed. The data will be subsequently analyzed using appropriate statistical tools.

Results: A total of 120 respondents have participated as of August 2025. Another 80 respondents will be recruited, laboratory analysis is ongoing, and baseline results are expected by the end of 2025.

Conclusions: The strength of the T-CHARM study's approach is its detailed occupational and environmental factors and longitudinal health data from the corporate clinic or the district health center, as well as links to cancer and mortality registries and self-reported health. The current phase of the study focuses on baseline data collection for long-term follow-up. The cohort will be monitored for up to 20 years, depending on sustained funding. T-CHARM offers a robust framework for understanding the chronic health effects of occupational TDE.

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KEYWORDS

tobacco dust; women health; preventive medicine; occupational disease; industrial hazard

Introduction

The tobacco industry is one of the biggest industries and provides millions of jobs [1]. In Indonesia, Jember Regency has long been recognized as "Tobacco City," reflecting its deep-rooted economic and cultural ties to tobacco cultivation and processing [2]. While most research on tobaccosis (chronic tobacco poisoning) has focused on people who smoke, there is a gap in studies examining occupational exposure, particularly among workers in tobacco processing environments who do not smoke [3]. The health effects of tobacco dust exposure (TDE), especially from nicotine-laden particulates, remain poorly understood despite growing concern [4]. This lack of data is critical, as workers may experience chronic exposure without direct tobacco use. Addressing these issues is complex, as the tobacco industry intersects with economic welfare, government policy, and political influence, making regulatory and public health interventions particularly challenging [5,6].

A study was conducted to investigate the concentration of tobacco dust in a tobacco factory in Thessaloniki, Greece. The findings revealed a markedly elevated level of total suspended dust in the workplace, with concentrations ranging from 45.3 to 54.4 $\mu g/m^{-3}$ [7]. Nicotine has been demonstrated to elevate both blood pressure and heart rate, and to induce atherogenesis in coronary artery endothelial cells [8]. This is attributed to its sympathomimetic effects, which result in an increased heart rate, myocardial contractility, elevated coronary vascular resistance, and decreased insulin sensitivity. Consequently, there is an increased risk of developing cardiovascular diseases, including coronary heart disease and atherosclerosis [9].

This research builds on a 2015 study that yielded notable insights into the impact of TDE on worker well-being [4]. The issue of workers' health is frequently overlooked due to a lack of knowledge and the absence of the requisite infrastructure, with the health of workers in the tobacco industry being of particular concern. Further evaluation is required to ascertain the effects of chronic TDE, which will be conducted using a prospective cohort study design. We will use an observational design with a cross-sectional method as a preliminary baseline for a prospective cohort study. A future cohort study is anticipated to ascertain the definitive effects of TDE, circumventing the inherent biases of cross-sectional research [10]. The nature of TDE exposure shares similarities with thirdhand smoke, the residual tobacco pollutants that linger on surfaces and in dust, posing risks even in the absence of active smoking. Therefore, the findings from this study are expected to benefit not only tobacco workers but also individuals exposed to thirdhand smoke in residential and occupational settings.

Methods

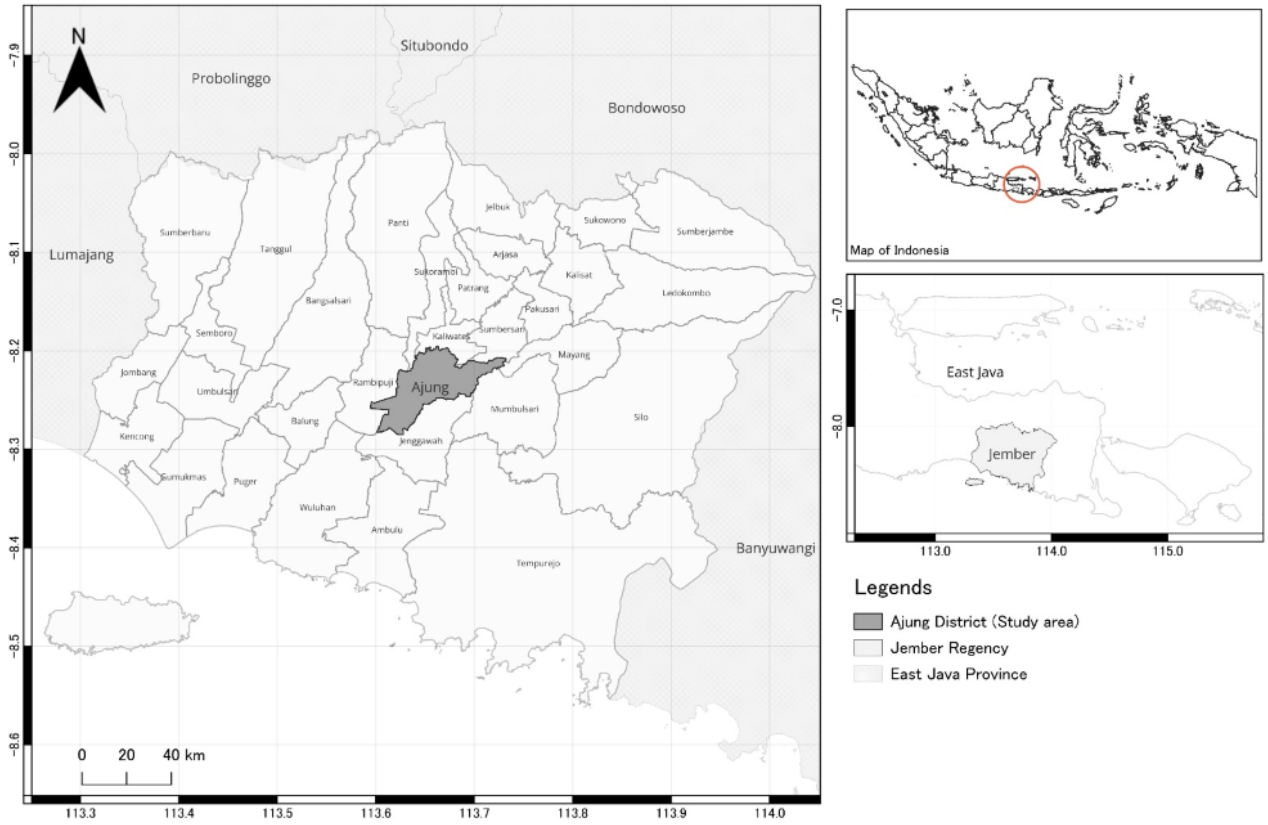
Study Design

The Tobacco Dust Cohort for Health Assessment and Risk Monitoring (T-CHARM) study examines how occupation and the environment of an agricultural area (especially tobacco) can cause diseases and affect people's well-being over time.

Starting in 2024, the T-CHARM cohort is based on a tobacco factory and its surrounding areas under the jurisdiction of the Ajung Health Center in Jember, Indonesia (Figure 1). The study is led by local research teams from a regional university in collaboration with international partners from Kagoshima University (Japan), the University of Occupational and Environmental Health (Japan), and the National Research and Innovation Agency (Indonesia).

The project is supported by a range of funding sources, including Directorate of Research and Community Service (Direktorat Penelitian dan Pengabdian kepada Masyarakat), Indonesia; Japan's Ministry of Education, Culture, Sports, Science and Technology; and institutional grants and travel programs from participating universities in both Indonesia and Japan.

Figure 1. Geographic location of study groups in the Tobacco Dust Cohort for Health Assessment and Risk Monitoring (T-CHARM) cohort. This map illustrates the research location of the T-CHARM study in Ajung District, Jember Regency, East Java, Indonesia. The gray-shaded area represents Ajung District, where both the exposed group (nonsmoking women tobacco processing workers) and the unexposed group (nonsmoking women workers from nontobacco occupations) were recruited.



Study Population and Eligibility Criteria

The T-CHARM study recruited participants from one of the largest tobacco processing industries in Jember, Indonesia, which employs approximately 2333 women in its processing section and is certified by international occupational and safety standards.

Exposed Group

Participants in the exposed group are women who work in tobacco processing who are nonsmokers. These individuals are regularly exposed to tobacco dust and related particulates through their occupational activities.

Unexposed Group

The comparison group consisted of women who are nonsmokers and employed in occupations unrelated to tobacco within the same district as the tobacco factory. This geographic proximity helps to control for environmental factors unrelated to occupational exposure.

Inclusion Criteria

Participants were eligible if they met the following criteria:

- Woman aged 18-55 years
- Nonsmoker (confirmed by self-report and urine cotinine screening)
- Actively employed as laborers for ≥8 hours per day, 6 days per week
- Healthy at the time of recruitment
- Provided written informed consent after screening for eligibility

Exclusion Criteria

Participants were excluded for the following reasons:

- Presented with fever or diarrhea, as determined by body temperature screening
- Had any condition that could confound biomarker or health assessments

Data Collection Method

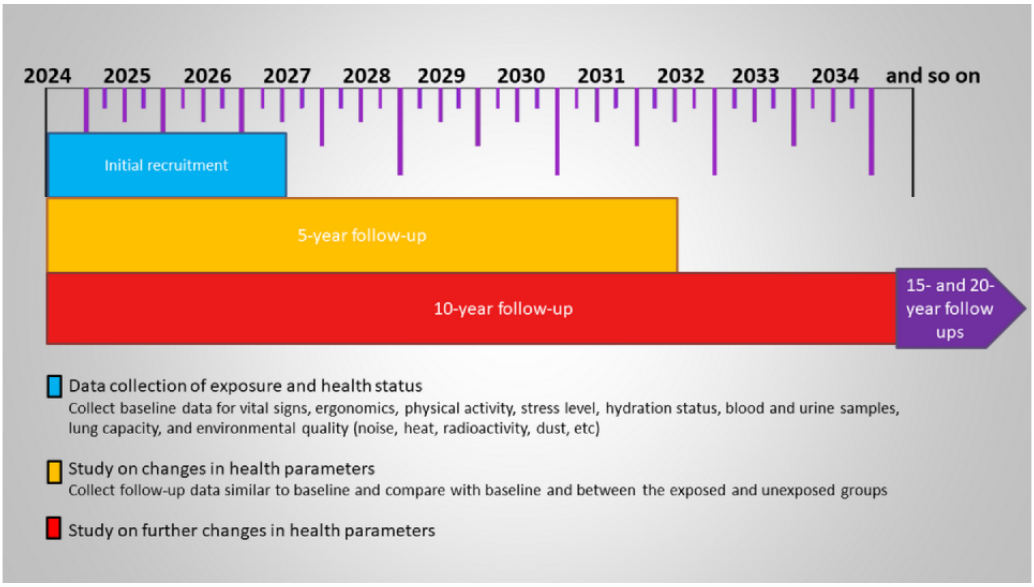
Overview

Baseline data for the T-CHARM study were collected through direct, face-to-face interviews conducted by researchers, with support from physicians and trained surveyors. Data collection took place at the tobacco factory and associated workplaces. A structured questionnaire was administered, comprising closed-ended questions across multiple domains, including sociodemographic information, duration of employment, medical history, smoking status, menstrual history [11], hydration status, ergonomic concerns [12], physical activity levels [13], sleep quality [14], anxiety potential [15], and tobacco exposure assessment.

In addition to the questionnaire, a series of clinical and physiological examinations were performed to evaluate the general health status of participants. These included vital signs assessment [16], BMI calculation, ergonomic observation [17],

pulmonary function testing using a portable spirometer (Contec SP10, Contec Medical System Co, Qinhuangdao, Hebei, China) [18], and venous blood sampling (3 mL) for serum analysis, including complete blood count, blood glucose, lipid profile, liver function, and renal function tests. Furthermore, a random urine sample was collected in a sterile container to analyze urine profile and cotinine levels, adjusted for creatinine concentration, using an enzyme-linked immunosorbent assay. To monitor longitudinal changes in health parameters, the same data collection protocol will be repeated every 5 years over 20 years (Figure 2).

Figure 2. Assessment and data collection schedule.



Blood Examination Procedures

An automatic hematology analyzer is used to examine the complete blood count [19,20]. A small aliquot of a well-mixed blood is placed into the hematology analyzer sample holder. The analyzer uses optical and electrical methods (eg, Coulter principle) to count and characterize blood cells, including red blood cells, white blood cells, hemoglobin, hematocrit, and platelets. The reaction happens inside chambers where cells are lysed or stained as needed for measurement. The analyzer then calculates and displays complete blood count parameters such as red blood cell count, white blood cell count, hemoglobin concentration, hematocrit, platelet count, and red blood cell indices (mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration).

An enzymatic UV test is conducted using hexokinase to examine fasting blood glucose [21]. Glucose is phosphorylated by hexokinase in the presence of adenosine triphosphate to form glucose-6-phosphate, which is then converted in the presence of NAD^+ by glucose-6-phosphate dehydrogenase to gluconate-6-phosphate and $NADH+H^+$. The increase in absorbance of $NADH+H^+$ is determined spectrophotometrically at a wavelength of 340 nm as the end point measurement. Lipid parameters are assessed using standardized enzymatic methods:

- High-density lipoprotein cholesterol and total cholesterol: measured via direct enzymatic homogeneous assays in accordance with International Federation of Clinical Chemistry and Laboratory Medicine guidelines
- Low-density lipoprotein cholesterol: calculated using the Friedewald formula [22]
- Triglycerides: determined by a colorimetric enzymatic test using glycerol-3-phosphate oxidase

Urine Examination Procedures

Urine specimens are stored at –20 °C until analysis. Before testing, frozen samples are thawed to room temperature and thoroughly mixed to ensure homogeneity. The cotinine kit is procured from Calbiotech, El Cajon, California, and is a solid-phase competitive enzyme-linked immunosorbent assay. In this method, the sample and cotinine enzyme conjugate are added to the wells coated with anticotinine antibody. Cotinine in the samples competes with a cotinine enzyme (horseradish peroxidase) conjugate for binding sites [23]. The unbound cotinine and cotinine enzyme conjugate are removed by washing. Upon the addition of the substrate, the intensity of the color is inversely proportional to the concentration of cotinine in the sample. The cutoff level of urinary cotinine is considered to be 10 ng/mL.

Environment Examination Procedures

Air Quality Monitoring

Air quality parameters—including humidity, temperature, and other site-specific conditions—are measured inside the tobacco company to ensure compliance with standards set by the World Health Organization and the Indonesian Ministry of Health [24].

Inhalation Exposure Assessment

Inhalation exposure measurements involve radon, thoron, and thoron progeny. Radon (^{222}Rn) and thoron (^{220}Rn) concentrations are measured with a RADUET monitor (Radosys Ltd, Budapest, Hungary). The RADUET has solid-state track detectors and a thoron monitor. Radon, thoron, and thoron progeny measurements are carried out with indoor and outdoor ambient

dose rate measurements. The CR-39 is chemically etched for 24 hours in 6 M NaOH solution at 60 °C to count the tracks, and the radon and thoron concentrations are calculated. The thoron progeny is measured with a stainless steel plate, CR-39, and an aluminized film. Diurnal exposure variation will also be measured with an active detector. A type ^{222}Rn monitor (RAD 7, Durridge Co, Billerica, Massachusetts) measures the samples and detects alpha activity for three 24-hour periods for a short-term measurement [25].

Particulate Matter Sampling and Analysis

Particulate matter (PM) is collected and analyzed to determine concentration and chemical composition:

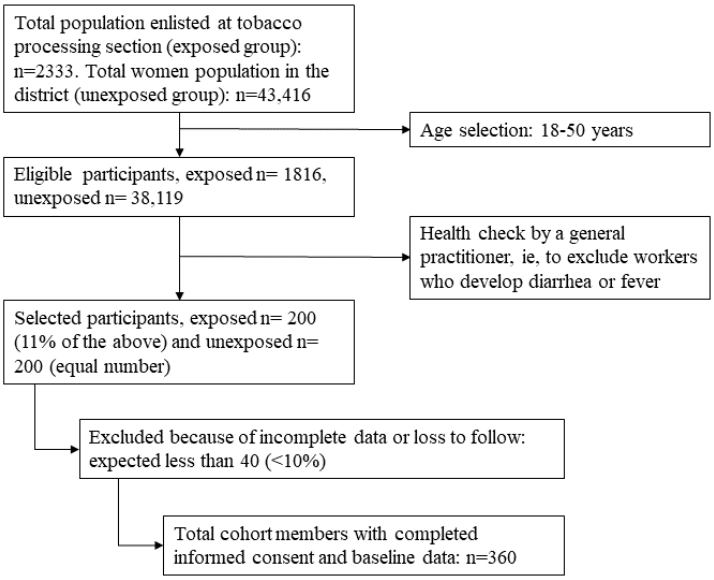
- Sampling method: The 4-stage impactor is used to collect samples over 48 hours; PM fractions include total suspended particulates, PM_1, $PM_{2.5}$, and PM_{10}.
- Analytical techniques: Inorganic constituents will be analyzed using Inductively Coupled Plasma Mass Spectrometry (ICP-MS/MS; Perkinelmer, Shelton, Connecticut), and cation and anion speciation is performed via ion chromatography (Thermo, Germany) [26].

Bioindicator Sampling

Tobacco leaves are also collected to study the accumulation of airborne pollutants, particularly radionuclides and heavy metals, as bioindicators of environmental exposure.

Figure 3 illustrates the recruitment process for the T-CHARM study. The exposed group consisted of a total population of 2333 women who work in tobacco processing, of whom 1816 met the eligibility criteria following screening. From this eligible pool, a target sample of 200 participants was estimated and recruited. To ensure comparability, the unexposed group—women who were nonsmokers and residents of nearby communities—was also designed to include 200 participants, matched by key demographic and environmental factors. The total cohort size for follow-up is projected to reach 400 participants, with data collection encompassing baseline and longitudinal health metrics. All collected data are subjected to analysis using appropriate statistical tools, as outlined in the study's analysis plan.

Figure 3. Flowchart of recruitment and participation.



Ethical Considerations

The T-CHARM study received ethical approval from the Institutional Ethical Board in Jember, Indonesia, in July 2024 (2883/UN25.1.10.2/KE/2024) and from the Institutional Ethical Board in Kagoshima, Japan, in September 2024 (240076). Both approvals adhere to the Guideline for Ethical Clearance of Human Research and ensure compliance with national and international standards for research involving human participants. Subsequent continuation of the study was approved by the Faculty of Medicine Ethics Committee under approval number 1578/UN25.1.10.2/KE/2025.

All participants were fully informed of the study's purpose, procedures, potential risks, and their right to withdraw at any time without consequence; screened according to predefined inclusion and exclusion criteria; and provided written informed consent before enrollment. These procedures ensure that participant autonomy, safety, and confidentiality are upheld throughout the study.

Data Analysis Plan

All analyses for the T-CHARM study will be conducted using the latest version of Stata (StataCorp). Data entry and cleaning will be performed by trained personnel using a double-entry verification system to ensure data integrity.

Missing Data Handling

For missing outcome data at follow-ups, the last observation carried forward method will be applied. Sensitivity analyses will be conducted to evaluate the robustness of findings under alternative missing data assumptions, including complete case analysis and multiple imputations if appropriate.

Outlier Management

Outliers in biomarker measurements will be identified using the IQR method. Outliers will be retained unless a confirmed analytic error or sample contamination is identified. Results will be assessed with and without outliers to determine their influence on statistical outcomes.

Group Comparisons

Comparative analyses between the exposed and unexposed groups will be performed for respondent characteristics, health examination results, medical history, lung function, and blood and urine parameters. Statistical tests will include Student *t* test for continuous (ratio) variables and Pearson χ^2 test or Fisher exact test for categorical variables, and *P* values <.05 will be considered statistically significant.

Exploratory Subgroup Analyses

To minimize bias and explore potential effect modifiers, subgroup analyses may be stratified by BMI, age, and length of employment. These stratified analyses will help identify differential health impacts and refine risk estimates across population subgroups.

Results

The T-CHARM study was officially funded in the year 2024, with data collection commencing in July 2024. As of August 2025, the study has successfully enrolled 60 participants in each group—women who are nonsmokers and work in tobacco processing (exposed group) and women who are nonsmokers and community members (unexposed group). Recruitment for an additional 80 participants is currently underway, alongside laboratory analyses for the second phase of baseline data collection. These analyses include biomarker profiling, clinical assessments, socioeconomic status, and environmental exposure measurements. The cohort baseline results are expected to be published by the end of 2025, marking a key milestone in the study's longitudinal design and setting the foundation for future follow-up waves.

In general, among the 60 women recruited for the exposed group, most of them were obese (n=28, 46.7%) and overweight (n=11, 18.3%), 76.7% (n=46) were of Madurese ethnicity, 53.3% (n=32) had education in elementary school, and 45.0% (n=27) were educated until middle and high school. Their mean age was 40 (range 21-52) years. Compared to the other work in that area, tobacco workers are paid well, with 76.7% (n=46) having an income as high as 875,000 IDR (US $52.50). Another key finding is that all the study participants are nonsmokers but exposed to tobacco dust occupationally, and 57.1% (n=60) reported being passive smokers. Health questionnaire answers showed that 60 people complained of eye problems, 28 had dermatological issues, 5 had respiratory diseases, 11 had cardiovascular disease, 60 had neurological problems, and 37 had reproductive issues.

Discussion

Study Implications

Most studies related to tobaccosis use active smokers as participants [27,28]. In Indonesia, there has been no research collecting data on tobacco-related diseases, including in the workplace, so the effects of exposure to nicotine-containing tobacco dust on workers' health are unknown and have not been studied [4]. Problems in this industry are also not easy to solve because they are often related to public welfare, government policy, and sometimes political influence [29]. Previous studies have found significant effects of tobacco dust on tobacco industry workers [4]. Further evaluation is needed to determine the effects of chronic exposure to tobacco dust. This study serves as a baseline for a future cohort study. Further evaluations are expected to determine the effects of tobacco dust, avoiding the biases in cross-sectional studies. This exposure is similar to thirdhand smoking conditions, so the results of this study will benefit those exposed to tobacco at work and through thirdhand smoke in the wider community.

Tobacco leaf sorters play a critical role in determining the appropriate use of tobacco leaves, whether as wrappers or binders, based on their quality. Leaf inspection involves both internal assessments (eg, human sensory evaluation, smoking tests, and chemical analysis) and external examinations (primarily visual inspection) [30]. Workers sort tobacco leaves by evaluating attributes such as quality, size, color, and dryness, requiring sustained attention to fine details over extended periods. This meticulous and repetitive visual task places workers at elevated risk for eye fatigue or asthenopia, particularly in the absence of proper environmental controls and scheduled rest periods [31].

Itching is a common health complaint among new tobacco leaf sorters, often presented as a mild form of contact dermatitis resulting from exposure to nicotine and other chemical residues on the leaves [32,33]. Preventive measures such as the use of personal protective equipment and maintaining proper skin hygiene can significantly reduce the risk of dermatitis [34,35]. However, implementing personal protective equipment—particularly gloves—poses a practical challenge. Sensory assessment of tobacco leaves, which relies heavily on tactile feedback, often requires workers to sort without gloves, limiting the feasibility of full protection.

Tobacco leaf sorters are at risk of developing neurological symptoms such as paresthesia, headaches, and dizziness, which are commonly linked to green tobacco sickness, a form of acute nicotine poisoning caused by transdermal absorption of nicotine from wet tobacco leaves [36,37]. The likelihood of absorption increases significantly when leaves are damp due to dew, rain, or sweat, particularly during early morning or humid working conditions.

Even when individuals are not employed during pregnancy, nausea experienced during pregnancy may be associated with residual effects of prior green tobacco sickness exposure, suggesting potential long-term or latent impacts. To mitigate these risks, it is essential to implement comprehensive

preventive strategies aimed at minimizing direct skin contact with tobacco leaves. This includes the use of protective clothing and gloves, although such measures present practical challenges. Gloves, for instance, may interfere with the sensitivity required for leaf sorting, necessitating a careful balance between occupational safety and task performance [38].

Strengths and Limitations

The goal is to understand how TDE affects health over a person's lifetime. At enrollment, the T-CHARM study collects demographic and occupational data (eg, current address, job role); lifestyle factors (eg, smoking status, dietary habits); biomarkers of exposure, including urine cotinine and other relevant indicators; and general health assessments, covering cardiovascular, respiratory, hepatic, renal, and metabolic parameters. Follow-up assessments will update exposure metrics and health status periodically, enabling dynamic tracking of disease progression and risk factors [39].

T-CHARM's major asset is its multisource medical data integration, which includes clinical records from corporate clinics and district health centers; national health insurance data, offering continuity and completeness; and direct input from general practitioners affiliated with the research team, allowing for nuanced clinical insights beyond standard registry linkages. This approach mitigates common limitations in cohort studies, such as recall bias and loss to follow-up from self-reported questionnaires.

While traditional epidemiological studies focus on cancer, respiratory, and cardiovascular diseases, T-CHARM broadens the scope to include neurological disorders, degenerative diseases, and chronic morbidity patterns linked to environmental and occupational exposures. The longitudinal nature of general practitioner data enables detailed tracking of disease onset, progression, and comorbidities—offering a more comprehensive understanding of health trajectories in exposed populations.

Existing biases or weaknesses have been minimized, but as a cohort study, there are some limitations. The limitations include changes in characteristics of participants over time, loss to follow-up, and confounding variables that complicate data analysis due to a lack of randomization. Potential respondents are also sometimes difficult to recruit due to the invasive nature of blood collection. Additionally, biases can arise from knowledge of exposure status, participant dropout, changes in behavior due to participation, and data quality issues in retrospective studies.

Conclusion

The T-CHARM study is currently in the baseline data collection phase, with plans for long-term follow-up over the next 20 years, contingent on future funding availability. To promote scientific collaboration and maximize the utility of the cohort, external researchers are invited to submit proposals for noncommercial research using the available T-CHARM data. Researchers may also request additional data collection contingent on appropriate funding support. All proposals will be reviewed by the T-CHARM Management Committee to ensure alignment with the study's objectives and ethical standards. Requests should be directed to the corresponding author, and a data management fee will apply to cover administrative and technical costs associated with data preparation and transfer.

Acknowledgments

This study was conducted with the invaluable assistance of colleagues from the authors' institutions, in collaboration with representatives from the tobacco industry and the Ajung Health Center in the Jember region. Data collection was made possible through the dedicated support of medical students. We also extend our sincere thanks to Yoshifumi Hidaka, Inria Astari Zahra, Shiroh Tanoue, and Chihaya Koriyama, colleagues from Kagoshima University, Kagoshima, Japan, for their pivotal role in supporting the initiation of this project.

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Data Availability

The datasets generated or analyzed during this study will be made available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: ACNM, AN
Methodology: ACNM, ENS, AN
Investigation, ACNM, DAR, JF, ERMP
Resources: SS, HH
Writing – original draft preparation: ACNM, AN
Writing – review and editing: DAR, SS, HH, EDN

Visualization: JF
Supervision: EDN
Project administration: ERMP
Funding acquisition: ACNM, AN
All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Peer-review reports.
[PDF File (Adobe PDF File), 485 KB - resprot_v14i1e84231_app1.pdf]

References

1. Jiang D, Ning L, Liu T, Zhang Y, Liu Q. Job demands-resources, job crafting and work engagement of tobacco retailers. Front Public Health 2022;10:925668 [FREE Full text] [doi: 10.3389/fpubh.2022.925668] [Medline: 36072378]
2. Amaliah K, Prihandono T, Sudarti S. Tobacco drying mechanism study of temperature and heat physics. Jurnal Pendidikan Fisika Dan Teknologi 2022;8(1):82-89. [doi: 10.29303/jpft.v8i1.3591]
3. Damarawati AT, Rachmawati DA, Hairrudin H. Effect of cigarette smoke exposure status on pregnant women as passive smokers with birth weight in Arjasa Health Center, Jember Regency [Article in Indonesian]. J Agromedicine Med Sci 2020 May 20;6(2):103-109. [doi: 10.19184/ams.v6i2.9650]
4. Marchianti ACN, Christanti FD, Riyanti R. Industrial tobacco dusts' exposure chronic impacts on workers' health. Eur J Public Health 2016 Nov;26(suppl_1):ckw174.149. [doi: 10.1093/eurpub/ckw174.149]
5. Sabila S, Marchianti A, Fatmawati H. Determinants of musculoskeletal disorders in tobacco farmers in Antirogo Village, Jember Regency [Article in Indonesian]. Community Med Public Health Indonesia J 2023 Oct 1;3(3):10.37148/comphijournal.v3i3.119. [doi: 10.37148/comphijournal.v3i3.119]
6. Yunanto R, Susanto T, Hairrudin H, Indriana T, Rahmawati I, Nistiandani A. A community-based program for promoting a healthy lifestyle among farmers in Indonesia: a randomized controlled trial. Health Education Health Promotion 2023;11(3):447-454. [doi: 10.58209/hehp.11.3.447]
7. Mohammadyan M, Baharfar Y. Evaluation of tobacco dust and designing of local exhaust ventilation (LEV) systems in a tobacco processing industry. Int J Occup Hyg 2015;4(1):47-52 [FREE Full text]
8. Wang X, Qin L, Arafa A, Eshak ES, Hu Y, Dong JY. Smoking cessation, weight gain, cardiovascular risk, and all-cause mortality: a meta-analysis. Nicotine Tob Res 2021 Nov 05;23(12):1987-1994. [doi: 10.1093/ntr/ntab076] [Medline: 33876246]
9. Price LR, Martinez J. Cardiovascular, carcinogenic and reproductive effects of nicotine exposure: a narrative review of the scientific literature. F1000Res. Preprint posted online on September 4, 2019 2025. [doi: 10.12688/f1000research.20062.2]
10. Zellers S, Maes H, Latvala A, Kaprio J. Cohort effects on tobacco consumption and its genetic and environmental variance among Finnish adults born between 1880 and 1957. Nicotine Tob Res 2024 Nov 22;26(12):1607-1615. [doi: 10.1093/ntr/ntae091] [Medline: 38630445]
11. Cassioli E, Rossi E, Melani G, Faldi M, Rellini AH, Wyatt RB, et al. The Menstrual Distress Questionnaire (MEDI-Q): reliability and validity of the English version. Gynecol Endocrinol 2023 Jun 19;39(1):2227275 [FREE Full text] [doi: 10.1080/09513590.2023.2227275] [Medline: 37356456]
12. Thamrin Y, Pasinringi S, Darwis AM, Putra IS. Musculoskeletal disorders problems and its relation to age, working periods, and smoking habit among fishermen. Gac Sanit 2021;35 Suppl 2:S417-S420 [FREE Full text] [doi: 10.1016/j.gaceta.2021.10.065] [Medline: 34929865]
13. Guidelines for data processing and analysis of the International Physical Activity Questionnaire (IPAQ) – short and long forms. Share.Google. 2005 Nov. URL: https://share.google/q0UI0qRL751cgLnoX [accessed 2025-12-15]
14. Yarlas A, White MK, St Pierre DG, Bjorner JB. The development and validation of a revised version of the Medical Outcomes Study Sleep Scale (MOS Sleep-R). J Patient Rep Outcomes 2021 May 19;5(1):40. [doi: 10.1186/s41687-021-00311-3] [Medline: 34009504]
15. Toussaint A, Hüsing P, Gumz A, Wingenfeld K, Härter M, Schramm E, et al. Sensitivity to change and minimal clinically important difference of the 7-item Generalized Anxiety Disorder Questionnaire (GAD-7). J Affect Disord 2020 Mar 15;265:395-401. [doi: 10.1016/j.jad.2020.01.032] [Medline: 32090765]
16. Brekke IJ, Puntervoll LH, Pedersen PB, Kellett J, Brabrand M. The value of vital sign trends in predicting and monitoring clinical deterioration: a systematic review. PLoS One 2019;14(1):e0210875 [FREE Full text] [doi: 10.1371/journal.pone.0210875] [Medline: 30645637]

17. Gada H, Parvez S, Ahmad B. Statistical and video graphic posture analysis of work-related musculoskeletal disorders among carpet weavers in Kashmir, India. J Bodyw Mov Ther 2024 Oct;40:117-126. [doi: 10.1016/j.jbmt.2024.04.014] [Medline: 39593430]
18. Xiao S, Wu F, Wang Z, Chen J, Yang H, Zheng Y, et al. Validity of a portable spirometer in the communities of China. BMC Pulm Med 2022 Mar 05;22(1):80 [FREE Full text] [doi: 10.1186/s12890-022-01872-9] [Medline: 35248001]
19. Zhu H, Huang Z, Huang H, Wang C, Wu L, Lin R, et al. Evaluation of a point-of-care testing analyzer for measuring peripheral blood leukocytes. J Vis Exp 2022 Mar 22:181. [doi: 10.3791/63364] [Medline: 35404351]
20. Hwang DH, Dorfman DM, Hwang DG, Senna P, Pozdnyakova O. Automated nucleated RBC measurement using the Sysmex XE-5000 hematology analyzer: frequency and clinical significance of the nucleated rbcs. Am J Clin Pathol 2016 Mar;145(3):379-384. [doi: 10.1093/ajcp/aqv084] [Medline: 26834126]
21. George K, Joy S, Kaladi Palliyalil H, Shaji SM, Ajayakumar Sunanda V, Sreedevi A. Benchmarking point-of-care glucometers: a comparative study using the hexokinase test and International Organization for Standardization (ISO) standards. Cureus 2024 Oct;16(10):e70981. [doi: 10.7759/cureus.70981] [Medline: 39507142]
22. Khan SH, Niazi NK, Sobia F, Fazal N, Manzoor SM, Nadeem A. Friedewald's equation for calculating LDL-cholesterol: is it the time to say "Goodbye" and adopt direct LDL cholesterol methods? Pak J Med Sci 2019;35(2):388-393 [FREE Full text] [doi: 10.12669/pjms.35.2.679] [Medline: 31086520]
23. Matsumoto A, Ino T, Ohta M, Otani T, Hanada S, Sakuraoka A, et al. Enzyme-linked immunosorbent assay of nicotine metabolites. Environ Health Prev Med 2010 Jul;15(4):211-216 [FREE Full text] [doi: 10.1007/s12199-009-0129-2] [Medline: 21432547]
24. Zhao L, Zhou Y, Qian Y, Yang P, Zhou L. A novel assessment framework for improving air quality monitoring network layout. J Air Waste Manag Assoc 2022 Apr;72(4):346-360. [doi: 10.1080/10962247.2022.2027295] [Medline: 35037589]
25. Pradana R, Nugraha ED, Omori Y, Shilfa SN, Winarni ID, Wahyudi W, et al. Public exposure from inhalation of radon and thoron around the tin mine and smelter areas in Bangka, Indonesia. Sci Rep 2024 Dec 28;14(1):30731. [doi: 10.1038/s41598-024-80443-w] [Medline: 39730506]
26. Dos Santos Souza EJ, Zapata Mora C, Aristizábal Zuluaga BH, Britto do Amaral CD, Grassi MT. Multi-elemental analysis of particulate matter PM and PM by ICP OES. Talanta 2021 Jan 01;221:121457. [doi: 10.1016/j.talanta.2020.121457] [Medline: 33076079]
27. Jacob L, Freyn M, Kalder M, Dinas K, Kostev K. Impact of tobacco smoking on the risk of developing 25 different cancers in the UK: a retrospective study of 422,010 patients followed for up to 30 years. Oncotarget 2018 Apr 03;9(25):17420-17429 [FREE Full text] [doi: 10.18632/oncotarget.24724] [Medline: 29707117]
28. Lin C, Li C, Liu C, Lin C, Yang S, Li T. Relationship between tobacco smoking and metabolic syndrome: a Mendelian randomization analysis. BMC Endocr Disord 2025 Mar 28;25(1):87 [FREE Full text] [doi: 10.1186/s12902-025-01910-7] [Medline: 40155847]
29. Przewozniak K, Cedzynska M, Przepiórka I, Koczkodaj P. Tobacco, war and politics: a look at historical facts, political science and public health. Tobacco Prev Cessation 2022;8(Supplement):A60. [doi: 10.18332/tpc/151009]
30. Zhang F, Zhang X. Classification and quality evaluation of tobacco leaves based on image processing and fuzzy comprehensive evaluation. Sensors (Basel) 2011;11(3):2369-2384 [FREE Full text] [doi: 10.3390/s110302369] [Medline: 22163744]
31. Wali BS, Patil VN, Raut PD. Occupational health profile and problems among female workers processing dried tobacco leaves in tobacco industries. J Ecophysiology Occup Health 2014;14(1 & 2):12-16. [doi: 10.15512/joeoh/2014/v14i1-2/50719]
32. Bonamonte D, Vestita M, Filoni A, Mastrolonardo M, Angelini G, Foti C. Tobacco-induced contact dermatitis. Eur J Dermatol 2016 Jun 01;26(3):223-231. [doi: 10.1684/ejd.2016.2771] [Medline: 27020490]
33. Le Coz CJ, Foti C, Bonamonte D, Angelini G, Romita P. Cigarette and cigar makers and tobacco workers. In: John SW, Johansen JD, Rustemeyer T, Elsner P, Maibach HI, editors. Kanerva's Occupational Dermatology. Cham: Springer; 2020:1855-1860.
34. Silvestre Salvador JF, Heras Mendaza F, Hervella Garcés M, Palacios-Martínez D, Sánchez Camacho R, Senan Sanz R, et al. Guidelines for the diagnosis, treatment, and prevention of hand eczema. Actas Dermosifiliogr (Engl Ed) 2020 Jan 02;111(1):26-40. [doi: 10.1016/j.ad.2019.04.005] [Medline: 32197684]
35. Houle M, Holness DL, DeKoven J. Occupational contact dermatitis: an individualized approach to the worker with dermatitis. Curr Dermatol Rep 2021;10(4):182-191 [FREE Full text] [doi: 10.1007/s13671-021-00339-0] [Medline: 34540358]
36. Fotedar S, Fotedar V. Green tobacco sickness: a brief review. Indian J Occup Environ Med 2017;21(3):101-104 [FREE Full text] [doi: 10.4103/ijoem.IJOEM_160_17] [Medline: 29618907]
37. Campos É, Costa VID, Alves SR, Rosa ACS, Geraldino BR, Meira BDC, et al. Occurrence of green tobacco sickness and associated factors in farmers residing in Dom Feliciano Municipality, Rio Grande do Sul State, Southern Region of Brazil. Cad Saude Publica 2020;36(8):e00122719 [FREE Full text] [doi: 10.1590/0102-311x00122719] [Medline: 32813792]
38. Wang Y, Zhang C, Wu M, Luo R, Lu L, Chen Z, et al. A method for detecting the rate of tobacco leaf loosening in tobacco leaf sorting scenarios. Front Plant Sci 2025;16:1578317. [doi: 10.3389/fpls.2025.1578317] [Medline: 40538881]

39. Choudhry NK, Priyadarshini S, Swamy J, Mehta M. Use of machine learning to predict individual postprandial glycemic responses to food among individuals with type 2 diabetes in India: protocol for a prospective cohort study. JMIR Res Protoc 2025 Jan 23;14:e59308 [FREE Full text] [doi: 10.2196/59308] [Medline: 39847416]

Abbreviations

220Rn: thoron
222Rn: radon
ICP-MS/MS: Inductively Coupled Plasma Mass Spectrometry
PM: particulate matter
T-CHARM: Tobacco Dust Cohort for Health Assessment and Risk Monitoring
TDE: tobacco dust exposure

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Self-Management Combined With Digital Health Interventions to Improve Dietary Behavior, Exercise Behavior, Stress Management Behavior, and Blood Pressure Among Thais With Uncontrolled Hypertension: Protocol for an Explanatory Sequential Study

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Abstract

Background: Uncontrolled hypertension causes substantial morbidity and mortality as well as rising health care costs. Adherence to self-management is critical for minimizing the risk of hypertensive complications. Traditional self-management is hindered by delayed management and insufficient support. Digital health interventions offer a feasible solution for closing these gaps and enhancing hypertension self-management. Little is known about patients' perspectives and experiences concerning how digital health interventions influence their self-management.

Objective: This study aims to determine the effectiveness of a self-management intervention combined with digital health interventions on dietary behavior, exercise behavior, stress management behavior, and blood pressure among Thais with uncontrolled hypertension. The study explored and compared experiences and perceptions among participants with varying levels of blood pressure control.

Methods: This study uses an explanatory sequential design performed in 2 phases comprising (1) a quasi-experimental design with 2 groups using repeated measures to determine the effects of self-management combined with digital health intervention and (2) an in-depth interview approach to explore the perceptions and experiences of 24 participants regarding the combination of self-management and digital health interventions after the intervention. In phase 1, participants were allocated by lottery to either the intervention group, which underwent an 8-week self-management intervention combined with digital health interventions, or the control group. The Dietary Approaches to Stop Hypertension Questionnaire, the Exercise Behavior Questionnaire, the Brief COPE inventory (Thai Version), and an automatic blood pressure measurement were used for data collection at baseline and the 4th and 8th weeks. In phase 2, semistructured interviews were used to conduct in-depth interviews. The analysis will take into account the effects of the interventions on dietary, exercise, and stress management behaviors, as well as blood pressure, using generalized estimating equations and linear mixed-effects modeling. We will perform the method by Colaizzi for the qualitative portion of the analysis.

Results: Funded in December 2024, this study recruited 86 patients with uncontrolled hypertension at the Siriraj Primary Care Unit, Thailand. This study received ethical approval on May 31, 2025, and participant recruitment began in August 2025. In phase 1, this study began recruiting participants in August 2025, with data collection occurring from August through the first half of November 2025. Phase 2 was completed at the end of November 2025. The data analysis is expected to be completed by December 2025. The expected date for the results to be submitted for publication is March 2026.

Conclusions: This study has the potential to address the gap between traditional self-management and digital health interventions for improving self-management behaviors and reducing blood pressure. The findings may offer practical guidance for nurses and other health care providers for managing uncontrolled hypertension in Thailand and contribute valuable insights for shaping future health care policies.

Trial Registration: Thai Clinical Trials Registry (TCTR), via the WHO International Clinical Trials Registry Platform (ICTRP), TCTR20250722001; https://www.thaiclinicaltrials.org/show/TCTR20250722001

International Registered Report Identifier (IRRID): PRR1-10.2196/81148

(JMIR Res Protoc 2026;15:e81148) doi:10.2196/81148

KEYWORDS

uncontrolled hypertension; self-management; digital health intervention; web-based application; dietary behavior; exercise behavior; stress management behavior; blood pressure; explanatory sequential design

Introduction

Uncontrolled hypertension (blood pressure [BP]≥140/90 mm Hg) is a substantial health problem that presents a challenge for the global health system, including in Thailand. Approximately 26% of patients with hypertension worldwide have uncontrolled hypertension [1]. Thailand follows this trend, with 24.6% of the population with hypertension having uncontrolled hypertension, often linked to lifestyle-related factors [1,2]. In Thailand, 15% of Thais with uncontrolled hypertension experience complications such as cardiovascular disease, stroke, or chronic kidney disease [3]. Moreover, hypertension is associated with an average cost of 964 (US $30.96) per visit, resulting in a total expenditure of 1.4367 billion (US $46,135,167) [4]. In Thailand, like most other countries, uncontrolled hypertension is associated with poor self-management, such as an unhealthy diet, a lack of exercise, and inappropriate stress management [5-7]. A study by Sodkhomkham [8] found that self-management, including dietary behavior, exercise behavior, stress management, and medication adherence, could predict BP control with an accuracy of 82%. Thus, focusing on self-management is indispensable for addressing uncontrolled hypertension.

Self-management is widely recognized as a pivotal aspect of improving self-management behaviors and clinical outcomes in hypertensive care [9]. Successful hypertension self-management requires interactive group education on hypertension and its management, which can be linked to the condition, monitoring with feedback, the provision of equipment, and lifestyle advice with support related to diet and exercise, weight reduction, stress management, and medication adherence [9]. Nurses play a crucial role in supporting patients with uncontrolled hypertension by providing health education, counseling, coaching, and facilitation of support [10-12]. However, a study by Liang et al [13] illustrated that traditional hypertension self-management is less effective due to the barriers to communication between health care providers and patients, a lack of timely and detailed management, and a lack of instrumental support. Likewise, time constraints and heavy workloads hinder nurses' ability to prioritize hypertension management while providing patient care [14]. To overcome these limitations, digital health interventions (DHIs) serve as a complementary method to support self-management [15].

DHIs have emerged as effective, beneficial, and widely accessible strategies for supporting hypertension self-management [16,17] and promoting health equity for patients with uncontrolled hypertension [17]. The World Health Organization (WHO) [18] emphasized the importance of patient-centered DHIs, including interactive voice response systems, phone calls, web-based telecare platforms, smartphone apps, SMS, and multimedia messaging services. Nurses play a pivotal role in promoting self-management to prevent and control hypertension. They empower individuals to adopt and maintain healthy behaviors through comprehensive education, personalized goal setting, and ongoing support [19]. Nurses meticulously assess risk factors, provide tailored counseling, and leverage digital health tools to help patients effectively monitor their conditions [20]. By consistently following up with patients and coordinating care, nurses enhance patient engagement, adherence, and, ultimately, long-term health outcomes [20]. An updated systematic review by Sukpattanasrikul et al [21] highlighted that the most effective DHIs for patients with uncontrolled hypertension target multiple health behaviors, incorporating key components such as health education, reminders, self-monitoring, feedback, and instrumental support.

Investigation into previous self-management combined with DHIs used for patients with uncontrolled hypertension between 2014 and 2024 revealed that most previous studies conducted research in an effort to control hypertension through self-management education, including health education related to the disease and self-care management [22-24]; self-management skill development through goal setting, decision-making, action plans, self-monitoring, and self-evaluation [23,25,26]; and providing instrumental support such as automatic BP measurement [27], salt meters [28], and graphics displaying BP over time [29]. Concurrently, DHIs being used to support self-management include health education [22,30], medication reminders [22,30-33], and BP monitoring reminders [27,31,33,34], as well as consultation through social media platforms such as WeChat [35] and Line applications [32].

This study identified a gap in knowledge among Thai patients with uncontrolled hypertension concerning self-management combined with DHIs by reviewing the literature over 1 decade (2014 - 2024). Traditional self-management approaches within service units have limitations due to their group-based nature. They may not adequately address the specific challenges and requirements of patients with uncontrolled hypertension. Additionally, providing consultation through the Line application increases the workload for health care personnel, who must manually review information from patients with hypertension and respond [19]. Integrating automated response programs (chatbots) into consultations can help patients with uncontrolled hypertension seek advice or consultations tailored specifically to their needs and receive it more quickly [19].

Literature reviews have also shown that providing health education through applications alone increases patients' knowledge of hypertension [36] but fails to control BP levels within the recommended range (BP<140/90 mm Hg) [37]. Meanwhile, the perceptions and experiences of patients regarding the use of DHIs to support self-management processes remain unclear. Thus, this study addresses the knowledge gap by implementing multiple interventions that integrate

self-management with DHIs for patients with uncontrolled hypertension, emphasizing a hybrid reinforcement model. This approach has the potential to offer nurses and other health care providers practical guidance on how to care for patients with uncontrolled hypertension, thereby improving their hypertensive outcomes. This study could also provide important information leading to the further development of health care policies in Thailand.

The objectives of this study are (1) to determine the dietary, exercise, and stress management behaviors, as well as BP, among Thais with uncontrolled hypertension after receiving a self-management intervention combined with DHIs and (2) to explore their experiences and perceptions after receiving the interventions. More specifically, this study aims to (1) evaluate the effectiveness of self-management combined with DHIs for improving dietary, exercise, and stress management behaviors, as well as BP, among Thais with uncontrolled hypertension and (2) explore the perceptions and experiences of study participants regarding the combined self-management and DHIs after the intervention and to compare these perceptions and experiences with varying levels of BP control.

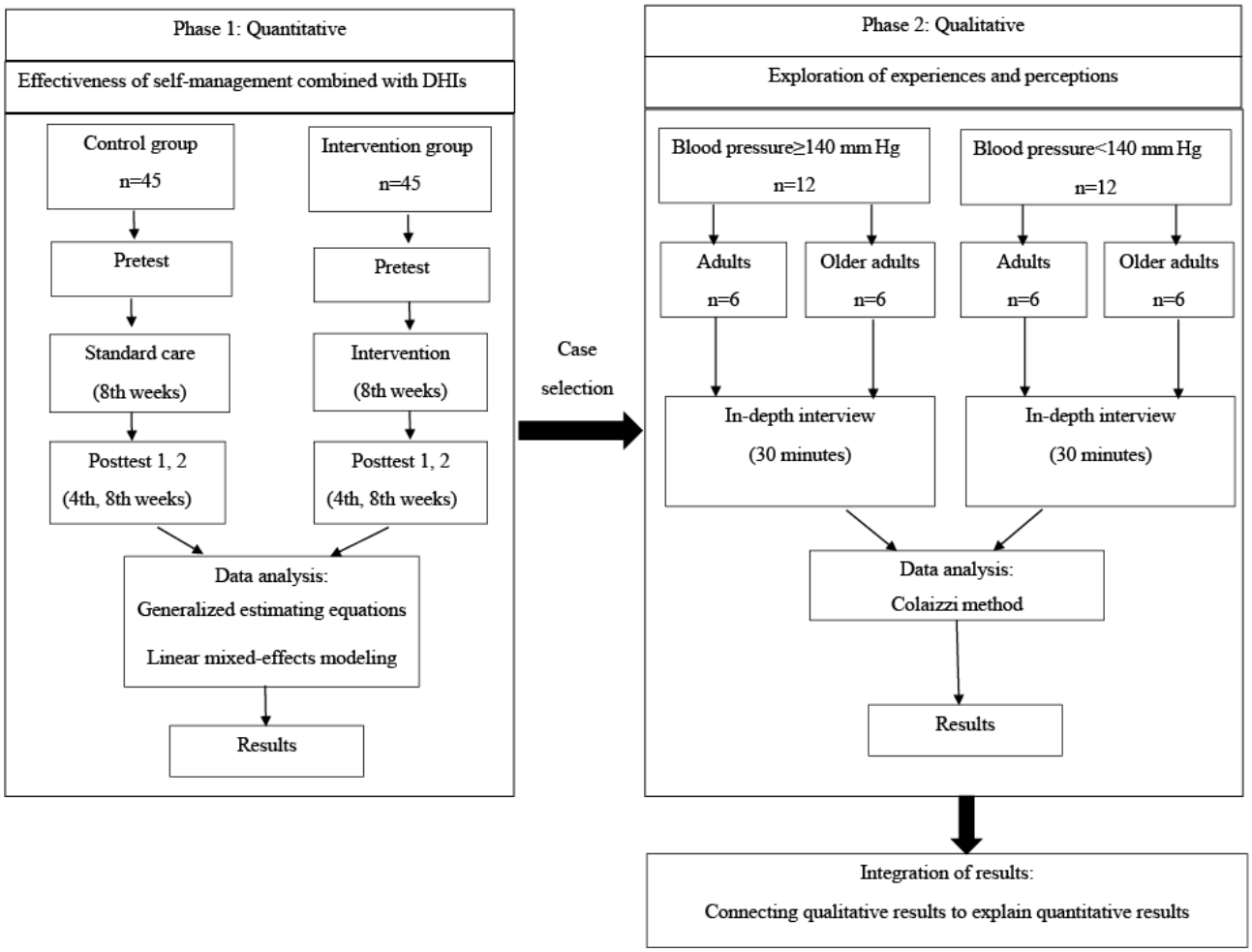
Methods

Overview

The study uses an explanatory sequential design to determine the effectiveness of self-management combined with DHIs among patients with uncontrolled hypertension, exploring the experiences and perceptions after receiving the intervention among patients with uncontrolled hypertension who received treatment at Siriraj Primary Care Unit. The study achieves its objectives in 2 phases: phase 1, a quasi-experimental design with 2 groups and repeated measures, and phase 2, an in-depth interview approach.

The integration of the 2 phases aligns with an explanatory sequential design. First, the connecting integration was applied to the sampling design. The researcher determined the participants in phase 2 by purposively selecting them based on phase 1 results (eg, BP≥140/90 mm Hg or BP<140/90 mm Hg) and age group, to ensure we capture a range of perceptions and experiences. Second, after both phases are completed, the integration of results will take place. As to the purpose of this protocol, the qualitative themes are used to explain dietary, exercise, and stress management behaviors, as well as BP, among Thais with uncontrolled hypertension. Joint displays and narratives will integrate quantitative and qualitative information, integrating outcome patterns with significant themes to draw conclusions on how self-management and DHIs impact outcomes (Figure 1).

Figure 1. Explanatory sequential design. DHI: digital health intervention.



Phase 1: Quantitative Method to Evaluate the Effectiveness of Self-Management Combined With DHIs

This study involves a quasi-experimental design comparing 2 groups with repeated measures to determine the effectiveness of an 8-week self-management program combined with DHIs on dietary behavior, exercise behavior, stress management behavior, and BP.

Recruitment

Participant recruitment included poster advertisements at the Siriraj Primary Care Unit, plus an announcement of the invitation at the Siriraj Primary Care Unit. Patients with uncontrolled hypertension who were interested in participating in the project could express their interest to the nurse at the Siriraj Primary Care Unit or the researchers. The researchers then screened patients with hypertension according to the inclusion and exclusion criteria. The study approached those who passed all inclusion criteria individually to sign an informed consent document. Participants who met the inclusion and exclusion criteria were allocated to either the control or experimental group. The recruitment protocol enphasized that participants could opt out at any time before, during, or after participation, without consequences from the Siriraj Primary Care Unit. In addition, participants who attended fewer than 75% of the activities (less than 6 weeks out of 8 weeks) were withdrawn from this study without consequences from the Siriraj Primary Care Unit.

Participants

The study selected participants by proportional stratified random sampling, followed by purposive sampling adhering to the inclusion criteria. The inclusion criteria were ages 45 years to 79 years old, previous history of a diagnosis of mild to moderate hypertension for at least 1 year and recorded in the database at the Siriraj Primary Care Unit, a determination of uncontrolled hypertension according to the BP criteria (BP 140/90 mm Hg to 179/100 mm Hg) for 2 consecutive measurements among patients with hypertension who received pharmacological and nonpharmacological treatments at the Siriraj Primary Care Unit, had an intention to change self-management behaviors, could be accessed by smartphone, and ability to communicate in Thai. The study excluded those with any severe complications such as cardiovascular, cerebrovascular, and end-stage renal disease; inadequate digital health literacy; cognitive impairment; moderate to total dependency for undertaking basic activities of daily living; an inability to use a telephone or manage their medications; and similar characteristics but were previously exposed to education programs. Additionally, the study excluded participants who experienced abnormal symptoms during the activity, such as dizziness or fainting, and who did not improve after receiving first aid. The study withdrew participants who attended the activities for fewer than 75% of the time (less than

6 weeks out of 8 weeks). Regarding participant allocation, this study used the lottery method to determine the days to assign research participants to either the intervention or control group. The study designated the first and second lottery draws as the control group (Monday and Thursday), with the third and fourth lottery draws designated as the intervention group (Tuesday and Wednesday).

This study requires a total of 90 patients with uncontrolled hypertension to achieve a representative sample for phase 1, and we used the G*power program version 3.1.9.7 [38] to determine the estimated sample size based on repeated-measures ANOVA. An effect size (*f*) of 0.25 was set [39], with a significance level of .05, power of .80, the number of groups set at 2, the number of measurements set at 3, and the correlation among repeated measures set at 0.5. Therefore, the determined total sample size was 86 participants, with 43 participants per group. A previous study showed that patients with uncontrolled hypertension dropped out of the self-management program at a rate of 5% [39]. Finally, the total sample size was determined to be 90. Next, the proportional stratification was calculated using the following formula: sample size = (sample size/population size) × stratum size. Thus, in this study, 18 adults with uncontrolled hypertension and 72 older adults with uncontrolled hypertension were selected as the sample.

Research Measurements

The study used research instruments consisting of (1) screening measurements, (2) experimental measurements, and (3) outcome measurements. The details are presented in the following sections.

Screening Measurements

Cardiovascular Prevention Stage of Change Questionnaire

The study used the cardiovascular prevention stage of change questionnaire to screen the readiness of patients with uncontrolled hypertension to change their behavior, with permission from the developers. Singha-Dong et al [40] developed this measurement. It consists of 13 items, with response options reflecting the stages of behavior change, ranging from 0 points (not considering change) to 5 points (maintaining the behavior for more than 6 months). The total score ranges from 0 to 65. Regarding its psychometric properties, the test-retest reliability is 0.91.

Thai Version of the Mini-Cog

The study used the Thai version of Mini-Cog for screening for cognitive impairment of Thais with uncontrolled hypertension, with permission from the developers and translators. Borson et al [41] developed this measurement, and Trongsakul et al [42] subsequently translated it into the Thai version. It consists of 2 sections, including a memory test (3-item word recall) and a clock-drawing test. The memory test is assigned a score of 1 point per item, giving it a total of 3 possible points. The clock-drawing test is assigned a score of 2 points, giving it a total of 2 possible points. The scores are calculated from these 2 sections. Therefore, the total possible score for the Thai version of the Mini-Cog is 5 points. Possible scores range from 0 to 5, with a cutoff point of ≥3 indicating cognitive intactness. Regarding its psychometric properties, the Mini-Cog has shown high sensitivity (99%) and specificity (96%) [41].

eHealth Literacy Scale (eHEALS)

The study used the eHealth Literacy Scale (eHEALS) to screen the digital health literacy of patients with uncontrolled hypertension, with permission from the developers. Norman and Skinner [43] developed this measurement, and the Office of the Department of Health [44] subsequently translated it into the Thai version. It consists of 8 items rated on a Likert scale from 1 (strongly disagree) to 5 (strongly agree). Possible scores range from 8 to 40, with a cutoff point of ≥26 indicating adequate digital health literacy [45]. Regarding its psychometric properties, the test-retest reliability is 0.85 [46].

Participants must score 26 or higher on the eHEALS to demonstrate their intention to utilize digital tools throughout the screening process. This threshold ensures that participants can safely and effectively engage with the digital intervention. In practice, this threshold is used to maximize participation and minimize dropout rates during the intervention phase. This is crucial for the initial assessment of the intervention's effectiveness.

Thai Version of the Barthel Index

The study used the Barthel index-Thai version to screen activities of daily living of participants who are aged 60 years through 79 years, with permission from the developers and translators. Mahoney and Barthel [47] developed this instrument, and Jitapankul and colleagues [48] subsequently translated it into the Thai version. It consists of 10 items, including feeding, grooming, transfer, toilet use, mobility, dressing, stairs, bathing, bowels, and bladder. The minimum score for the Barthel index is 0, and the maximum score is 20. The Barthel index categorizes dependency as totally dependent (0 to 4 points), severely dependent (5 to 8 points), moderately dependent (9 to 11 points), mildly dependent (12 points or more), and independent (20 points). Regarding psychometric property, the Kappa coefficients for the interrater reliability test were 0.79 and 0.68, respectively [48].

Lawton-Instrumental Activities of Daily Living Scale-Thai Version

The study used the Lawton-Instrumental Activities of Daily Living Scale-Thai version to screen independent living skills for patients who were aged 60 years to 79 years, with permission from the developers and translator. Lawton and Brody [49] developed this instrument, and Phanasathit [50] subsequently translated it into the Thai version. It consists of 8 items: using a telephone, shopping, food preparation, housekeeping, laundry, transportation, responsibility for own medications, and handling finances. The summary score ranges from 0 (low function, dependent) to 8 (high function, independent). Regarding the psychometric property, the Kappa coefficient of interrater reliability test was 0.85, with a Cronbach α reliability of 0.32 (95% CI –0.12 to 0.66), and the test-retest reliability according to the Spearman rank correlation coefficient was 0.46 [50].

Experimental Measurements

The study established a self-management intervention combined with DHIs, including a web-based application, chatbot, salt meter, and smartwatch. The study developed self-management skills combined with DHIs according to the Integrated Theory of Health Behavior Change [51]. The feasibility of this program for objective congruence was examined by 3 experts, including a nurse instructor specializing in self-management, a nurse instructor specialist experienced in hypertensive care, and an instructor specializing in digital health. The index of congruence was 1.00. A team of software developers developed the web-based application and chatbot. Table 1 shows the details of the self-management intervention combined with the activities in the DHIs.

Table . Details of self-management combined with the digital health intervention activities.

Week	Activities
Week 1	Group activity, 5 - 6 participants, 60 min • Assessing the knowledge and health beliefs and then providing accurate information (15 min) • Self-management skills development (20 min) • Accessibility and utilizing support instruments, including a salt meter, a smartwatch, web-based application, and chatbot (25 min)
Weeks 2 - 3	The chatbot follow-ups encourage self-care twice a week (Wednesday and Friday at 8 AM), offering personalized feedback and allowing participants to request one-on-one consultations with the researcher.
Week 4	Group activity, 5 - 6 participants, 60 min • Follow-up and review of self-management skills (20 min) • Training about reading nutrition labels (20 min) • Reviewing the web-based application and its functions, followed by a question-and-answer session (20 min)
Weeks 5, 6, and 7	The chatbot follow-ups encourage self-care twice a week (Wednesday and Friday, 8 AM), offering personalized feedback and allowing participants to request one-on-one consultations with the researcher.
Week 8	Group activity, 5 - 6 participants, 60 min • Knowledge sharing and self-management evaluation with goal comparison, followed by a question-and-answer session (30 min) • Reviewing self-management skills (20 min) • Encouragement to practice self-care at home (10 min)

Outcome Measurements

Overview

At each time point in phase 1, the study collected outcome measurements including (1) the demographic data form (baseline), (2) Dietary Approaches to Stop Hypertension Questionnaire (DASHQ; baseline and 4th and 8th weeks), (3) Exercise Behavior Questionnaire (EBQ; baseline and 4th and 8th weeks), (4) the Brief COPE inventory (Thai version; baseline and 4th and 8th weeks), and (5) an automatic BP measurement (baseline and 4th and 8th weeks).

Demographic Data Form

The researchers developed the demographic data form to collect the participants' demographic data. This semistructured interview form includes questions regarding gender, age, marital status, education, religion, occupation, income, sources of income, adequacy of income, living arrangement, duration of hypertension, received medicines, and underlying diseases.

Dietary Approaches to Stop Hypertension Questionnaire

The study used the DASHQ to examine the dietary behaviors of the participants, with permission from the developers, Siriboonyarit et al [52]. This measurement consists of 13 items: 8 items for the positive approach and 5 for the negative approach. This measurement utilizes a Likert scale with 5 categories, from 1 to 5 (1="not at all" and 5="always"), for items related to the positive approach. The response choices for all items are standardized on a scale from 13 to 65, with a score from 13 to 30.33 reflecting low dietary behavior, a score from 30.34 to 47.67 reflecting moderate dietary behavior, and a score from 47.68 to 65 reflecting high dietary behavior. The content validity was 0.91, with a reliability Cronbach α coefficient of 0.80. This study examined the reliability of the measurement using 30 patients with uncontrolled hypertension and determined it using the Cronbach α coefficient before collecting the data.

Exercise Behavior Questionnaire

The study used the EBQ to examine the exercise behaviors of the participants, with permission from the developers, Pieasakran et al [53]. The EBQ consists of 10 items. The measurement utilizes a Likert scale of 5 categories, from 0 to 4 (0="not at all" and 4="always") for items related to the positive approach. The response choices for all items are standardized on a scale from 0 to 40, with higher scores indicating better exercise behavior. The content validity is 0.80, with a Cronbach α coefficient reliability at 0.87. This study examined the measurement reliability using 30 patients with uncontrolled hypertension and determined it using the Cronbach α coefficient before collecting the data.

Brief COPE inventory (Thai Version)

The study used the Brief COPE inventory (Thai version) to document the stress management behaviors of the participants, with permission from the developers, Numsang and Tantrarungroj [54]. This measurement consists of 28 items, including active coping, planning, positive reframing, acceptance, humor, religion, using emotional support, using instrumental support, self-distraction, denial, venting, substance use, behavioral disengagement, and self-blame. This measurement uses a Likert scale of 4 categories, from 1 to 4 (1="not at all" and 4="always"). The response choices for all items are standardized on a scale from 28 to 112, with higher scores indicating better stress management behavior. Regarding the psychometric properties, the test-retest reliability was 0.70. This study examined the reliability of the measurement using 30 patients with uncontrolled hypertension and determined it using the Cronbach α coefficient before collecting data.

Automatic BP Measurement

This study took an automatic BP measurement using an HEM-9200T (Omron Healthcare Inc), along with the standard method for measuring BP based on the guidelines from the Thai Hypertension Society [55]. The standard calibrator lab at the clinical instrument testing center calibrated the automatic BP measurement for accuracy at the start of the intervention and during the study.

Preparation of the Research Assistant

The research assistant was a nurse who was trained in data collection. Initially, the researcher explained the objectives and methods of the study, including human rights protection of the sample. Second, the research assistant received a questionnaire and instructions for collecting the data. Third, the research assistant was, if not already, trained in BP measurement following the Thai Hypertension Society guidance [55]. After training, the research assistant carried out data collection under real situations to demonstrate an understanding of the instructions.

Data Collection

In phase 1, we used a quasi-experimental design comparing 2 groups with repeated measures to determine the effects of self-management combined with DHIs on dietary, exercise, and stress management behaviors and BP.

First, we asked 45 participants in the control group to complete their demographic data, dietary behavior, exercise behavior, stress-management behavior, and BP measurement as a pretest. They then received standard medical treatments in accordance with the standards of the Siriraj Primary Care Unit. After completion of the intervention (4th week) and a follow-up period (8th week), they completed post-test I and post-test II. The research assistant collected the data.

The study asked the 45 participants in the intervention group to provide their demographic data, as well as dietary behavior, exercise behavior, stress-management behavior, and BP measurement as a pretest. They then received 8 weeks of self-management combined with DHIs. After completion of the intervention (4th week) and a follow-up period (8th week), they completed posttest I and posttest II. The research assistant collected the data.

Data Analysis

In phase 1, the analysis will include both the complete case and intention-to-treat analyses. A statistical software program will be used to analyze the data from this phase. The study uses descriptive statistics (eg, frequency, percentage, mean, and SD) to describe the demographic data and characteristics of the sample. The study will use the χ^2 test or independent *t* test to compare differences in the demographic data and outcome variables between the control and intervention groups at baseline. If differences are identified in the demographic data, the study will set different variables as covariates to control for the confounding factors. This study will use generalized estimating equations to test the effects of self-management combined with DHIs on dietary, exercise, and stress management behaviors, as well as BP, compared between the control and intervention groups. This study will use linear mixed-effects modeling to test the effects of self-management combined with DHIs on dietary, exercise, and stress management behaviors, as well as BP, within the intervention group at baseline, after completion of the intervention, and after completion of a follow-up period.

Phase 2: Qualitative Method to Explore Experiences and Perceptions After Receiving the Interventions

This study conducted in-depth interviews to collect the participants' perceptions and experiences after completing all self-management activities combined with DHIs.

Recruitment

In Phase 2, the research assistant screened potential participants for eligibility based on the inclusion criteria and informed them of the results by telephone. If the potential participants were deemed eligible and willing to participate in the study, the researcher scheduled a meeting. The researcher then screened the qualifications of patients with hypertension according to the inclusion criteria. The study approached those who passed all inclusion criteria individually to sign the informed consent document.

Participants

The study recruited participants through purposive sampling using the inclusion criteria. The inclusion criteria for this phase included individuals aged 45 years through 79 years old who had a BP lower than 140/90 mm Hg after participating in self-management combined with DHIs or individuals aged 45 years through 79 years old who had a BP higher than 140/90 mm Hg after participating in self-management combined with DHIs. The study withdrew participants who experienced abnormal symptoms during the activity, such as dizziness or fainting, that did not resolve after receiving first aid.

Additionally, the study determined the sample size for phase 2 in accordance with the data collection procedure. The minimum sample size for an in-depth interview approach is 12 participants, which aligns with the qualitative research principle that emphasizes data saturation [56]. However, the objective in phase 2 is to explore participants' perceptions and experiences after

receiving self-management combined with DHIs, stratified by age group and BP status. The researcher used a stratified approach, interviewing 6 adults and 6 older adults with uncontrolled hypertension, as well as 6 adults and 6 older adults with controlled BP. Finally, a total number of 24 participants were included in an in-depth interview.

Research Measurements

In phase 2, the researcher used a background information form, semistructured interviews, and an interview guide for data collection. The interview guide was comprised of a set of open-ended questions, including (1) How does hypertension affect your daily life? (2) After participating in the self-management activities combined with the web-based application, how do you feel your self-management behaviors have changed? (3) What are the factors that reinforce or hinder your self-care? (4) How has the web-based application helped you adjust your self-care behaviors? (5) What is the level of your satisfaction with the web-based application? (6) Which function(s) do you use most frequently? And why? and (7) What are the prominent features or any elements of the web-based application that you feel need improvement? The content validity was examined by 3 experts, including a nurse instructor specializing in self-management, a nurse instructor specializing in hypertensive care, and an instructor specializing in digital health. The content validity was 1.00.

Data Collection

In this phase, the study used in-depth and semistructured interviews and an interview guide to collect participants' perceptions and experiences after completing all self-management activities combined with DHIs. The researcher conducted all interviews at a convenient time for the participants at the Siriraj Primary Care Unit for 30 minutes each in Thai, and each interview was audiorecorded.

Data Analysis

We will analyze the in-depth interviews in phase 2 using the method by Colaizzi [57]. The researcher will read the transcribed interviews multiple times to truly understand the feelings of the informants. After that, the researcher will thoroughly review each statement on every page to discern the narrative's significance, understand the content's significance and meaning, and define the meaning of the key phrases. The study will gather and thoroughly explain or describe the results obtained from the phenomenon under study. The study will clarify any ambiguous phenomena as much as possible and return the findings to the informants for verification.

Ethical Considerations

The study was approved by the Human Research Ethics Committee of the Faculty of Nursing and the Human Research Ethics Committee of Siriraj Hospital Faculty of Medicine, which jointly considered and approved the research project in the form of a Memorandum of Understanding (MU-MOU COA number IRB-NS2025/948.3105). The study protocol was registered under a Universal Trial Number (U1111-1324-0264), and approved by the Thai Clinical Trials Registry (TCTR20250722001).

Additionally, we informed all participants about the study's objectives, procedures, risks, and benefits. Participation was voluntary, and participants could withdraw at any time. Further, we required the participants to complete and sign consent forms before participation. Moreover, participants were able to stop attending the intervention at any time, before or after deciding to take part in this study, without any effects on their care at the Siriraj Primary Care Unit. In addition, the participants in the control group had access to the intervention upon request within 1 week after the intervention completion because this approach allowed us to minimize contamination and preserve the internal validity of the study while also ensuring that the participants in the control group could benefit from the intervention afterwards.

Further, the study keeps all collected data confidential following standard data protection laws (eg, participant anonymity was assured as the study would only disclose their participant numbers and initials) [58]. When study results are disseminated, only aggregated findings will be presented, ensuring that no individual participant can be identified. The researcher has stored the collected data in password-protected files on a personal computer, and documents related to the research participants have been kept in a locked cabinet accessible only to the researcher. Data stored on the cloud and audio recording files can only be accessed by the researcher with a password. After the research project is completed, the researcher will immediately destroy the data.

Moreover, the researcher covered each participant's travel expenses, totaling 160 (US $5.14) per trip. The researcher also covered the cost of a flat-rate internet service for each participant in the experimental group, at 300 (US $9.63) per month for 2 months, to support group activities and self-care practices at home. Each participant in the experimental group received compensation in 2 installments of 300 each, paid directly in weeks 1 and 4. In phase 2, the researcher paid each participant's travel expenses for attending 1 in-depth interview, with a fee of 160 per interview. No additional compensation was provided for the interview.

Results

This study received a grant in December 2024 and ethical approval on May 31, 2025. We recruited 86 individuals, including 18 adults and 68 older adults, with uncontrolled hypertension from the Siriraj Primary Care Unit in Thailand. In phase 1, this study began recruiting participants in August 2025. Data were collected between August 2025 and the first half of November 2025. In-depth interviews were conducted in phase 2 and continued through the end of November 2025. The data analysis should be completed by December 2025. The expected date for the results to be submitted for publication is March 2026.

Regarding the results presentation, the quantitative results from phase 1, including eating behavior, exercise behavior, stress management behavior, and BP, will be descriptively summarized by gender and age group. Age group and gender will be included as factors in the analyses, considering the limited sample size of the adult group. In phase 2, this study will use purposive sampling across age groups and BP status, and phase 2 will be

conducted after completion of phase 1 to compare themes between groups and help explain how self-management combined with DHIs influences outcomes. Subsequent academic publications will highlight age-specific findings, including any identified digital challenges.

Discussion

Overview

This protocol describes the rationale and design of an explanatory sequential mixed methods study to evaluate the effectiveness of self-management combined with DHIs while also exploring participants' experiences and perceptions after the intervention among patients with uncontrolled hypertension in Thailand. Uncontrolled hypertension is a significant public health issue in Thailand, leading to elevated morbidity, death, and increasing health care expenses. Previous evidence indicates that DHIs can support self-management and improve BP control [16,17], and their integration with nurses and other health care providers can further enhance adherence to self-management behaviors and BP control [21]. The researchers hypothesize that combining these self-management strategies with DHIs will improve dietary, exercise, and stress management behaviors and lower BP compared with standard care.

Existing research illustrated that DHIs have potential for improving both behavioral and clinical outcomes among patients with uncontrolled hypertension [16,17,22,30]. However, previous interventions in Thailand have emphasized single behaviors rather than adopting a comprehensive, multibehavior change approach [23,32,33]. The systematic review conducted by our team identified that the most effective DHIs for self-management among patients with uncontrolled hypertension address multiple health behaviors [21]. Our protocol addresses this gap by incorporating diet, exercise, and stress management strategies as core components that are often overlooked in interventions. In addition, several DHIs for patients with uncontrolled hypertension have been designed and focus on health education [22,30], medication reminders [22,30-33], and home BP monitoring [27,31,33,34] delivered through mobile apps, text messages, or web platforms. A key innovation of this study is a hybrid self-management model combined with DHIs targeting multiple behaviors.

The use of DHIs, such as web-based applications, chatbots, smartwatches, and salt meters, is not a one-size-fits-all solution. Several factors—including age group, digital health literacy, living area, and infrastructure—influence acceptance and uptake [59]. In this study, adults who are good with technology may find the web-based application and chatbot easy to use, whereas older adults who are digitally challenged may feel anxious or struggle with this technology, making it harder for them to use. To mitigate this, the researchers will incorporate a user-friendly interface with large text and initial in-person training sessions [60]. In addition, participants living in households with good infrastructure (good internet connectivity and affordability) may face fewer barriers than those living in households with poor infrastructure. To address this issue, the researchers will allocate a budget for internet connectivity and ease of internet access [61]. Recognizing these potential differences is important for correctly interpreting the study results.

An explanatory sequential design is used to address variations in users' perceptions and experiences. The quantitative phase will estimate changes in dietary, exercise, and stress management behaviors, as well as BP, associated with the self-management combined with DHIs. The qualitative phase will provide a deeper understanding of why the intervention succeeds or fails in primary care units in Thailand. Researchers planned to purposefully sample both adults and older adults with either controlled or uncontrolled BP for in-depth interviews. This qualitative inquiry will uncover specific barriers to implementation, allowing the researchers to distinguish between intervention success or failure and identify barriers.

This protocol has two main strengths. First, this protocol is a theory-informed, multicomponent design that combines self-management approaches with DHIs to address multiple behaviors for uncontrolled hypertension. These interventions provide evidence-based information, develop self-management skills, and offer instrumental support, as outlined by the Individual and Family Self-Management Theory [51]. Finally, the use of an explanatory, sequential, mixed methods design allows us to examine both behavioral and clinical outcomes in depth, as well as the subtleties of user engagement. Nonetheless, limitations are anticipated. The requirement for participants to use their own smartphone devices, to have adequate digital health literacy, and to have data plans may create a selection bias, thereby omitting the most economically disadvantaged persons. Also, data synchronization may be interrupted in remote regions where the internet is not always available. Another limitation is that it is a single-center study conducted in a primary care unit in Thailand; therefore, generalizability may be limited. Because of ethical limits on collecting data from people who did not provide consent, the researchers could not compare participants with those who were excluded or chose not to take part. This means the findings may not generalize to people who are less comfortable with technology, underscoring how difficult it can be to close the digital divide in eHealth.

Implications and Future Directions

The results of this study will have important effects on how Thailand deals with uncontrolled hypertension. If this combined self-management and DHI approach works, it could serve as a model for primary care units and noncommunicable disease clinics across the country. The explanatory sequence design is essential because it provides more than just data on effectiveness. It also helps us understand how factors like age, ability to use digital technology, and different experiences with health technologies influence outcomes.

Future research will focus on mitigating the gap of DHIs, including web-based applications and chatbots highlighted in this study. Insights from the qualitative phase on the digital divide and user acceptance will be critical for future DHI iterations. We aim to use these findings to develop more personalized, age-friendly interfaces or voice-activated features to further reduce barriers for patients with uncontrolled hypertension who are digitally challenged in Thailand. Furthermore, subsequent studies should evaluate the

cost-effectiveness of this intervention to support policy decisions regarding its integration into the national health security system.

Conclusion

Uncontrolled hypertension remains a critical public health challenge in Thailand, requiring innovative solutions that align with standard care. This protocol describes an innovative approach to addressing the knowledge gap between traditional self-management and DHIs, focusing on enhancing dietary, exercise, and stress management behaviors and reducing BP. This study aims to determine the effectiveness of self-management combined with DHIs and to explore participants' experiences and perceptions after receiving the intervention. The results from this study will be used to determine the effectiveness of self-management combined with DHI solutions in primary care units in Thailand. Moreover, the results will have the potential to offer practical guidance on how to care for patients with uncontrolled hypertension, thereby improving their hypertensive outcomes. These results could also provide important information that will lead to the further development of health care policies in Thailand.

Acknowledgments

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The authors declare the use of generative AI (GAI) in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: idea generation, proofreading, and editing.

The GAI tools used were ChatGPT-5.2Pro, Gemini-3Pro, and Grammarly AI.

Responsibility for the final manuscript lies entirely with the authors.

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Data Availability

This paper is a study protocol. As such, datasets have not yet been generated nor analyzed. The authors are willing to share a complete, cleaned, and de-identified copy of the data after completing the study. The study team may make this study available upon approval of a written request, which must include an analytic plan, after publication of the primary and secondary aims in a peer-reviewed journal.

Authors' Contributions

Conceptualization: SS, NS, YS
Methodology: SS, NS, YS
Writing – original draft: SS, NS, YS
Writing – review & editing: SS, NS, YS

Conflicts of Interest

None declared.

Checklist 1
SPIRIT Checklist.
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References

1. Global report on hypertension: the race against a silent killer. World Health Organization. 2023. URL: https://www.who.int/publications/i/item/9789240081062 [accessed 2024-07-01]
2. Sakboonyarat B, Rangsin R, Kantiwong A, Mungthin M. Prevalence and associated factors of uncontrolled hypertension among hypertensive patients: a nation-wide survey in Thailand. BMC Res Notes 2019 Jul 4;12(1):380. [doi: 10.1186/s13104-019-4417-7] [Medline: 31272496]

3. Teza H, Boonmanunt S, Unwanatham N, et al. Evaluation of transitions from early hypertension to hypertensive chronic kidney disease, coronary artery disease, stroke and mortality: a Thai real-world data cohort. Front Cardiovasc Med 2023;10:1170010. [doi: 10.3389/fcvm.2023.1170010] [Medline: 37206104]
4. Khiaocharoen O, Prasertworakul CP, Khattiyod T, et al. Outpatient cost by disease: outputs from the first phase cost per disease project. HISPA Compendium 2023;1(7):100-112. [doi: 10.14456/hispa.2023.7]
5. Aytenew TM, Kassaw A, Simegn A, et al. Uncontrolled hypertension among hypertensive patients in Sub-Saharan Africa: a systematic review and meta-analysis. PLoS ONE 2024;19(6):e0301547. [doi: 10.1371/journal.pone.0301547] [Medline: 38870163]
6. Dewi TP, Ahmad A. The most common predictors of uncontrolled blood pressure among hypertensive elders: a systematic review. International Journal of Advanced Health Science and Technology 2023;3(1):437-443. [doi: 10.35882/ijahst.v3i1.210]
7. Jariyasakulwong P, Wattanakitkrileart D, Pongthavornkamol K, Piaseu N, Roubsanthisuk W. Factors influencing self-care practices and blood pressure among individuals with uncontrolled hypertension: a cross-sectional study. Patient Prefer Adherence 2025;19:1-17. [doi: 10.2147/PPA.S497555] [Medline: 39764477]
8. Sodkhomkham N. Factors affecting blood pressure control among patients with primary hypertension, Samut Songkhram Province. J Res Health Improv Qual Life 2022;2(2):25-36 [FREE Full text]
9. Shahaj O, Denneny D, Schwappach A, et al. Supporting self-management for people with hypertension: a meta-review of quantitative and qualitative systematic reviews. J Hypertens 2019 Feb;37(2):264-279. [doi: 10.1097/HJH.0000000000001867] [Medline: 30020240]
10. Coates V. Role of nurses in supporting patients to self-manage chronic conditions. Nurs Stand 2017 May 17;31(38):42-46. [doi: 10.7748/ns.2017.e10742] [Medline: 28513400]
11. Hussien M, Muhye A, Abebe F, Ambaw F. The role of health care quality in hypertension self-management: a qualitative study of the experience of patients in a public hospital, North-West Ethiopia. Integr Blood Press Control 2021;14:55-68. [doi: 10.2147/IBPC.S303100] [Medline: 33948092]
12. Tharani A, Van Hecke A, Ali TS, Duprez V. Factors influencing nurses' provision of self-management support for patients with chronic illnesses: a systematic mixed studies review. Int J Nurs Stud 2021 Aug;120:103983. [doi: 10.1016/j.ijnurstu.2021.103983] [Medline: 34147728]
13. Liang J, He X, Jia Y, Zhu W, Lei J. Chinese mobile health apps for hypertension management: a systematic evaluation of usefulness. J Healthc Eng 2018;2018:7328274. [doi: 10.1155/2018/7328274] [Medline: 29744027]
14. Thongtaeng P, Seesawang J. Barriers and facilitators to successful hypertension management in older adults from the perspectives of community health nurses: a qualitative study. Nurs Sci J Thail 2022;40(1):35-49 [FREE Full text]
15. Fujiwara T, Tucker KL, McManus RJ. Future of hypertension management through mobile applications. Hypertens Res 2024 Apr;47(4):1087-1089. [doi: 10.1038/s41440-023-01568-5] [Medline: 38242947]
16. Boima V, Doku A, Agyekum F, Tuglo LS, Agyemang C. Effectiveness of digital health interventions on blood pressure control, lifestyle behaviours and adherence to medication in patients with hypertension in low-income and middle-income countries: a systematic review and meta-analysis of randomised controlled trials. EClinicalMedicine 2024 Mar;69:102432. [doi: 10.1016/j.eclinm.2024.102432] [Medline: 38333367]
17. Katz ME, Mszar R, Grimshaw AA, et al. Digital health interventions for hypertension management in US populations experiencing health disparities: a systematic review and meta-analysis. JAMA Netw Open 2024 Feb 5;7(2):e2356070. [doi: 10.1001/jamanetworkopen.2023.56070] [Medline: 38353950]
18. Classification of digital health interventions v1.0. World Health Organization. 2018. URL: https://www.who.int/publications/i/item/WHO-RHR-18.06 [accessed 2024-05-03]
19. Enhancing nursing and midwifery capacity to contribute to the prevention, treatment and management of noncommunicable diseases. World Health Organization. 2012. URL: https://www.who.int/publications/m/item/9789241504157 [accessed 2025-12-10]
20. Sharma A, Singh RK. The role of general nurses in non-communicable disease prevention: community-based interventions in action and their impact on public health outcomes in low resource settings. J Innov Ment Health Psychiatr Nurs 2025;1(2):54-62 [FREE Full text]
21. Sukpattanasrikul S, Singha-Dong N, Sitthimongkol Y, Anonjarn K. Efficacy and cost-effectiveness of digital health interventions in improving hypertensive outcomes among patients with uncontrolled hypertension: a systematic review. Int J Nurs Sci 2025 May;12(3):225-232. [doi: 10.1016/j.ijnss.2025.04.001] [Medline: 40529464]
22. Gong K, Yan YL, Li Y, et al. Mobile health applications for the management of primary hypertension: a multicenter, randomized, controlled trial. Medicine (Baltimore) 2020 Apr;99(16):e19715. [doi: 10.1097/MD.0000000000019715] [Medline: 32311957]
23. Rethanu T, Nuysri M, Jantacumma N. Effects of behavioral modification program on medication adherence among uncontrolled hypertension patients in Nawa District, Nakhon Phanom Province. J Public Health Nurs 2021;35(2):90-107 [FREE Full text]
24. Penpoompaung IJ, Inkoom J, Jaisangad S. Effects of a perceived self-efficacy, disease knowledge, and social support enhancement program on knowledge, self-care behaviors, and blood pressure among the older adults with uncontrolled hypertension. J Med Health Sci 2023;30(3):118-134 [FREE Full text]

25. Yookong K, Kitreerawutiwong N. Effectiveness of a telehealth self-management support program on self-management behavior and blood pressure among essential hypertension patients in Sawankhalok District, Sukhothai Province. Nurs J Minist Public Health 2023;33(3):25-38 [FREE Full text]
26. Sukpattanasrikul S, Monkong S, Leelacharas S, Krairit O, Viwatwongkasem C. Comparison of hypertensive outcomes after the implementation of self-management program for older adults with uncontrolled hypertension in Krabi, Thailand: a quasi-experimental study. JHR 2022 Jul 4;36(4):641-651. [doi: 10.1108/JHR-12-2020-0626]
27. Kario K, Nomura A, Kato A, et al. Digital therapeutics for essential hypertension using a smartphone application: a randomized, open-label, multicenter pilot study. J Clin Hypertens (Greenwich) 2021 May;23(5):923-934. [doi: 10.1111/jch.14191] [Medline: 33484628]
28. Wiriyatanakorn S, Mukdadilok A, Kantachuvesiri S, Mekhora C, Yingchoncharoen T. Impact of self-monitoring of salt intake by salt meter in hypertensive patients: a randomized controlled trial (SMAL-SALT). J Clin Hypertens (Greenwich) 2021 Oct;23(10):1852-1861. [doi: 10.1111/jch.14344] [Medline: 34510703]
29. Leupold F, Karimzadeh A, Breitkreuz T, et al. Digital redesign of hypertension management with practice and patient apps for blood pressure control (PIA study): a cluster-randomised controlled trial in general practices. EClinicalMedicine 2023 Jan;55:101712. [doi: 10.1016/j.eclinm.2022.101712] [Medline: 36386033]
30. Yilmaz E, Uzuner A, Bajgora M, et al. Effect of eTansiyon smartphone application on hypertension control. Prim Health Care Res Dev 2022 Oct 19;23:e64. [doi: 10.1017/S146342362100058X] [Medline: 36259143]
31. Still CH, Margevicius S, Harwell C, et al. A community and technology-based approach for hypertension self-management (COACHMAN) to improve blood pressure control in African Americans: results from a pilot study. Patient Prefer Adherence 2020;14:2301-2313. [doi: 10.2147/PPA.S283086] [Medline: 33262580]
32. Charoenwongsa K, Wirojratana V, Wattanakitkrileart D. The effect of a medication adherence promotion program through the Line application on older persons with essential hypertension. Nurs J CMU 2022;49(2):313-325 [FREE Full text]
33. Promrat S, Kapol P, Kapol N. Effects of a program to promote medication adherence using telepharmacy in patients with hypertension. Thai Bull Pharm Sci 2022;17(1):31-41 [FREE Full text] [doi: 10.69598/tbps.17.1.31-41]
34. McManus RJ, Little P, Stuart B, et al. HOME and Online Management and Evaluation of Blood Pressure (HOME BP) using a digital intervention in poorly controlled hypertension: randomised controlled trial. BMJ 2021 Jan 19;372:m4858. [doi: 10.1136/bmj.m4858] [Medline: 33468518]
35. Li X, Li T, Chen J, et al. A WeChat-based self-management intervention for community middle-aged and elderly adults with hypertension in Guangzhou, China: a cluster-randomized controlled trial. Int J Environ Res Public Health 2019 Oct 23;16(21):4058. [doi: 10.3390/ijerph16214058] [Medline: 31652688]
36. Thajang S, Panyathorn K, Loonprom N, et al. Effects of using media applications on the prevention of complications for knowledge of patients with hypertension. UDRU Sci Tech J 2020;8(2):89-104 [FREE Full text]
37. Samranbua A, Thamcharoentrakul B. The effects of relieving hypertension diet application on health beliefs among patients with hypertension. Thai J Cardio-Thorac Nurs 2021;32(1):228-242 [FREE Full text]
38. Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. Behav Res Methods 2009 Nov;41(4):1149-1160. [doi: 10.3758/BRM.41.4.1149] [Medline: 19897823]
39. Sukpattanasrikul S, Wirojratana V, Hiransaroj B, et al. The report of health literacy development for patients with uncontrolled hypertension in the communities. 2023 Unpublished report.
40. Singha-Dong N, Pongpoottipatchara R, Anonjarn K, Prawatwong W. Comprehensive integrated program for the prevention and control of non-communicable diseases. 2024 Unpublished report.
41. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The Mini-COG: a cognitive “vital signs” measure for dementia screening in multi-lingual elderly. Int J Geriatr Psychiatry 2000 Nov;15(11):1021-1027. [doi: 10.1002/1099-1166(200011)15:11<1021::aid-gps234>3.0.co;2-6] [Medline: 11113982]
42. Trongsakul S, Lambert R, Clark A, Wongpakaran N, Cross J. Development of the Thai version of Mini-Cog, a brief cognitive screening test. Geriatr Gerontol Int 2015 May;15(5):594-600. [doi: 10.1111/ggi.12318] [Medline: 25155468]
43. Norman CD, Skinner HA. eHEALS: the eHealth Literacy Scale. J Med Internet Res 2006 Nov 14;8(4):e27. [doi: 10.2196/jmir.8.4.e27] [Medline: 17213046]
44. Department of Health. Thai version of the eHealth Literacy Questionnaire.: Department of Health, Ministry of Public Health; 2021. URL: https://multimedia.anamai.moph.go.th/infographics/ehealth-literacy-questionnaire/ [accessed 2024-07-20]
45. Richtering SS, Hyun K, Neubeck L, et al. eHealth literacy: predictors in a population with moderate-to-high cardiovascular risk. JMIR Hum Factors 2017 Jan 27;4(1):e4. [doi: 10.2196/humanfactors.6217] [Medline: 28130203]
46. Plagatong W, Chanapai W, Srisomnuek A, Katchamart W. Reliability and feasibility of the eHEALS in Thai patients with rheumatic and autoimmune diseases. Thai J Rheumatol 2024;1(3):1-16 [FREE Full text]
47. Mahoney FI, Barthel DW. Functional evaluation: the Barthel index. Md State Med J 1965 Feb;14:61-65. [Medline: 14258950]
48. Jitapunkul S, Kamolratanakul P, Chandraprasert S, Bunnag S. Disability among Thai elderly living in Klong Toey slum. J Med Assoc Thai 1994 May;77(5):231-238. [Medline: 7869003]
49. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. Gerontologist 1969;9(3):179-186. [Medline: 5349366]

50. Phanasathit M. Validity and reliability of lawton instrumental activities of daily living scale (l-IADL) and older people's quality of life questionnaire (OPQOL-brief): Thai version. ResearchGate. 2017. URL: https://www.researchgate.net/publication/342096615_karsuksakhwamtrnglaeakhwamtheiyngkhxngbaebsxbtham_The_Lawton_Instrumental_Activities_of_Daily_Living_IADL_Scale_chbabphasathiy [accessed 2025-12-24]
51. Ryan P. Integrated Theory of Health Behavior Change: background and intervention development. Clin Nurse Spec 2009;23(3):161-170. [doi: 10.1097/NUR.0b013e3181a42373] [Medline: 19395894]
52. Siriboonyarit N, Wattanakitkrileart D, Phligbua W. Effects of nutrition education program through LINE application on dietary behaviors in patients with primary hypertension. Royal Thai Navy Med J 2023;50(2):328-345 [FREE Full text]
53. Pieasakran T, Jiewpattanakul Y, Rerkluenrit J. Effects of a health literacy exercise program on the exercise behaviors and health literacy of older adults with hypertension in the communities, Bangkok Metropolis. Nurs Sci J Thail 2023;41(4):44-55 [FREE Full text]
54. Numsang T, Tantrarungroj T. Validity and reliability of the Brief COPE Inventory: Thai version. J Psychiatr Assoc Thailand 2018;63(2):189-198 [FREE Full text]
55. Thai hypertension guideline on the treatment of hypertension. Thai Hypertension Society. 2024. URL: https://thaihypertension.org/2024-guideline/ [accessed 2025-12-24]
56. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. Field Methods 2006;18(1):59-82. [doi: 10.1177/1525822X05279903]
57. Application of Colaizzi's method of data analysis in phenomenological research. MLU 2021;21(2):914-918 [FREE Full text] [doi: 10.37506/mlu.v21i2.2800]
58. Personal Data Protection Act, BE 2562. Royal Thai Government Gazette. 2019 May 27. URL: https://ratchakitcha.soc.go.th/documents/17088936.pdf [accessed 2025-12-01]
59. Hu S, Song D, Wan S, et al. Digital health: current applications, challenges, and future directions for enhancing healthcare quality and safety. Front Public Health 2025;13:1646802. [doi: 10.3389/fpubh.2025.1646802] [Medline: 41089861]
60. Jiang Q, Deng L, Zhang J, Pengbo Y. User-centered design strategies for age-friendly mobile news apps. SAGE Open 2024 Oct;14(4):21582440241285393. [doi: 10.1177/21582440241285393]
61. Chamwong S, Chomtohsuwan T, Charoenphandhu N. Analysis of inequality in household internet utilization and policy implications. Journal of Demography 2024;40(1):27-48. [doi: 10.56808/2730-3934.1369]

Abbreviations

BP: blood pressure
DASHQ: Dietary Approaches to Stop Hypertension Questionnaire
DHIs: digital health interventions
EBQ : Exercise Behavior Questionnaire
eHEALS: eHealth Literacy Scale
WHO: World Health Organization

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Bedside Clinical Ultrasound Performed by Family Physicians in Adult Patients With Abdominal Pain in a Hospital Emergency Department: Protocol for a Pilot Quasi-Experimental Study

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Abstract

Background: Point-of-care ultrasound is a valuable bedside tool that, with adequate training, can reduce diagnostic uncertainty and improve clinical accuracy. Abdominal pain is a frequent complaint in emergency departments and often requires imaging for appropriate management.

Objective: This study aims to assess the impact of bedside clinical ultrasound performed by family physicians on length of stay, number of basic radiological tests, and need for further diagnostic evaluations in adult patients with abdominal pain.

Methods: This is a pilot quasi-experimental study assessing feasibility and viability, with a nonrandomized control group, to be conducted in the Emergency Department of Hospital Comarcal de Riotinto. Adult patients (≥18 y) presenting with abdominal pain will be included. Both groups will receive standard care. In the intervention group, bedside ultrasound will be performed by trained family physicians; in the control group, ultrasound will be performed by radiologists only if deemed necessary. The primary outcome is the improvement in quality of care, assessed through a reduction in emergency department length of stay, fewer basic radiology tests requested, and diagnostic concordance. Secondary outcomes include the need for additional diagnostic studies and the appropriateness of referrals, evaluated through 1-month follow-up and reconsultation.

Results: The first phase of the project began in 2023 with the validation of the data collection form. Subsequently, the patient satisfaction questionnaire was validated, and the results were published in the journal *Care Primary*. The study has received external funding, and patient recruitment is currently ongoing and expected to be completed in December 2025.

Conclusions: This study aims to demonstrate the clinical and organizational benefits of implementing bedside ultrasound by family physicians in emergency care.

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KEYWORDS

abdominal pain; emergency; personal satisfaction; quality of health care; ultrasonography

Introduction

Ultrasound is a diagnostic technique based on the emission and reception of high-frequency waves, so-called ultrasound. It is a patient-friendly technique but requires an interpretation of possible artifacts, as well as progression through a learning curve. Ultrasound in the clinical setting complements physical examination in the same medical procedure, as it is accessible and fast and can be reproduced [1].

The use of ultrasound in emergencies began between 1991 and 1992 by surgeons in the United States, and later in 1996, the acronym FAST (Focused Abdominal Sonography for Trauma)

was adopted [2]. From then on, the term POCUS (point-of-care ultrasound) also became commonly used [3].

A review in 2019 showed that POCUS was used for a variety of conditions, although most focused on abdominal and obstetric indications with a good level of diagnostic accuracy [4]. Therefore, it seems appropriate to focus this study on abdominal pain, a common pathology encountered in the emergency department. In fact, a 2010 review indicated that the percentage of nonspecific pain was 24% - 44%, followed by acute appendicitis (15.9% - 28.1%), acute biliary disease (2.9% - 9.7%), and bowel obstruction or diverticulitis in older adults [5].

The pathology related to abdominal pain is highly varied, and training in clinical ultrasound requires a minimal learning curve. Consequently, a number of studies have assessed the training and education of professionals in the detection of biliary tract−related diseases. In this study [6], an acceptable level of agreement was found in the detection of hepatobiliary pathology among junior emergency medicine trainee doctors and radiologists after a short training program. In fact, ultrasound performed by emergency department clinicians affects the diagnostic certainty of abdominal pain in the right hypochondrium, particularly when requesting additional diagnostic studies or in patients with uncertain pathology [7]. The ability of emergency department physicians to diagnose cholelithiasis with bedside ultrasound has also been evaluated [8] and more recently also to rule out cholecystitis [9]. Furthermore, a recent review supports the use of POCUS for gallbladder examination by emergency physicians [10], and another review also suggests that this scan may help in arranging outpatient follow-ups if symptoms have disappeared [11].

In the diagnosis of nephrourological pathology such as renal colic, clinical ultrasound is a good diagnostic tool with a high level of accuracy in detecting urinary tract dilation [12]. These patients may also benefit from an improved level of risk stratification [13]. An observational study has already validated an algorithm for patients with flank pain in the examination and detection of urolithiasis [14]. The use of computed tomography for this pathology has increased, so a review was carried out to compare ultrasound as an alternative and safe test for the patient, which concluded that there is sufficient evidence to determine a more rational algorithm for the management of renal colic [15]. The use of POCUS was also found to be associated with a shorter emergency department stay compared to computed tomography [16].

In the emergency department, the length of stay is determined by many factors, such as the patient's age, the need for laboratory tests, or referral for consultation, but another factor to be taken into account is the need for ultrasound in abdominal pain [17]. In view of the limited time in the emergency department, ultrasound examination by family doctors is regarded as helping to improve the overall diagnosis and treatment of patients [18]. A recent study from October 2022 also analyzed the effect of POCUS in the initial assessment of patients with acute abdominal pain by evaluating the diagnosis and the decrease in patient waiting time without significant changes in the cost of the service [19].

Many of these patients presenting with abdominal pain at the emergency department require the performance of various complementary tests such as simple radiography. However, the diagnostic efficiency of abdominal radiography in urgent pathologies is not related to the high number of examinations performed as reported in this publication [20]. It is sometimes performed as a routine test despite recommendations to reduce radiation doses to patients and to select pathologies requiring radiography more carefully. This review has already indicated that the use of plain radiography in abdominal pain should be limited to very specific indications [21]. The overuse of these complementary tests leads to unnecessary exposure and increased waiting times in the emergency department. This has been supported by another systematic review [22] where 38 original studies were collected, and the conclusion was that, in most cases, their indiscriminate routine use is not indicated.

Finally, the assessment of the quality of health care is complex and highly subjective as it depends on both the care itself and the patient's expectations. This analysis of the patient's experience was carried out using a patient questionnaire, in which the patient's experience of receiving ultrasound scanning at the point of care was rated positively [23]. However, among the multidimensional models for the assessment of the quality of services provided are the SERVQUAL and SERVPERV questionnaires. The SERVPERF model has been used to assess the perception of quality of care in an emergency department [24], outpatient departments [25], hospital units [26], primary care [27], and even reassessment during the COVID-19 pandemic [28]. The score is calculated by the sum of the scores, and the quality of service is deemed to be as high as the total of the sum of the scores [29]. The SERVPERF model allows the level of quality to be measured by patient assessment.

Accordingly, considering that POCUS can assist professionals in the emergency department to exclude serious causes of abdominal pain−related pathologies, as well as to detect other pathologies that could be followed up at home, this study is proposed to assess the impact of its implementation in a hospital emergency department. Furthermore, the implementation of clinical ultrasound is intended to improve the quality of care and analyze the degree of patient satisfaction.

Methods

Study Design and Setting

A quasi-experimental pilot study of feasibility and viability with a control group will be carried out at Hospital Riotinto's Emergency Department. This center is located in the north of Huelva (Spain) and serves a population of almost 70,000 inhabitants with a high geographical distribution, as some localities are more than 80 km away from the hospital.

This study does not require registration in ClinicalTrials.gov as it does not meet the criteria for a clinical trial according to the International Committee of Medical Journal Editors and US Food and Drug Administration definitions. The project is a quasi-experimental feasibility and implementation study conducted in a real-world clinical setting, with no randomization, no experimental interventions, and no

administration of investigational drugs or devices. The study aims to evaluate the impact and utility of point-of-care ultrasound performed by family physicians in emergency departments as part of standard clinical practice. Therefore, it is considered a health services research study rather than a clinical trial, and formal registration is not applicable.

The implementation of bedside clinical ultrasound performed by family physicians in the emergency department is hypothesized to reduce patient length of stay as well as the need for additional diagnostic tests, such as plain radiography or specialist-performed ultrasound, thereby improving the overall quality of patient care. The primary objective is to analyze the impact of this intervention on length of stay, the number of simple radiology tests requested, and the necessity for further examinations by radiodiagnostic specialists.

Specific objectives include determining the length of stay for patients receiving clinical ultrasound by family physicians compared to usual care, quantifying and comparing the number of radiographs and ultrasounds performed, and analyzing patients' diagnostic and clinical progression over at least 1 month of follow-up. In cases where the process is not resolved, the patient can be monitored for the next 6 months. Additionally, the study aims to evaluate the number and outcomes of specialist-requested ultrasounds in relation to those performed by family physicians, identify factors influencing care quality related to patient health and sociodemographic characteristics, perform diagnostic concordance analyses, and assess patient satisfaction with the service provided.

The sample will consist of patients over the age of 18 years presenting with abdominal pain in the emergency department, who will be assigned to the experimental group (POCUS is performed) or the control group (no clinical ultrasound is performed) consecutively. Patients readmitted for the same pathology will be ruled out. Patients will be invited by the investigators to participate freely, and the recruitment will end when the minimum sample size is reached in each cohort.

The inclusion and exclusion criteria are presented in Textbox 1.

Textbox 1. The inclusion and exclusion criteria.

Inclusion criteria

- Patients treated at the Emergency Department of Riotinto Hospital during the study and follow-up period
- Patients presenting with acute de novo abdominal pain, defined as a clinical condition causing pain localized by the patient between the thorax and the pelvis. Additionally, patients must not have been admitted for the same condition in the previous 3 months.
- Age ≥18 years
- Patients with sufficient capacity to provide written informed consent
- Experimental group: Patients will be attended by physicians from the Emergency Department of Riotinto Hospital and by professionals with demonstrated training in clinical ultrasound
- Control group: Patients will be attended by physicians from the Emergency Department of Riotinto Hospital and by professionals without demonstrated training in clinical ultrasound

Exclusion criteria

- Patients with readmission due to abdominal pain
- Patients who leave the emergency department before completing care
- Patients followed in other regional health systems or private health care
- Pregnant women
- Patients with morbid obesity
- Patients with severe mental illness
- Patients whose clinical severity prevents obtaining informed consent
- Intercurrent illness that makes participation impossible

The reasons for study discontinuation are as follows: (1) patient withdrawal, (2) withdrawal of informed consent, (3) death, (4) protocol violation, and (5) intercurrent illness preventing continued participation.

Informed consent will be obtained by the attending physician at the time of patient evaluation, prior to any study-related procedures.

For the sample size calculation, emergency department length of stay was used as the primary variable, as it is the only parameter that has been studied to date (19). A 25% reduction in the mean length of stay is expected in the intervention group compared with the control group. According to the multicenter trial [30], the mean length of stay for patients with nontraumatic abdominal pain in the emergency department was 5.2 (SD 3) hours. Assuming a 25% reduction (1.3 h) in the intervention group, with a 2-sided significance level of 0.05 and a power of 80%, and applying a Student *t*-test for independent samples, a minimum of 84 patients per group is required. Considering an

anticipated 15% attrition rate, the total number of participants to be recruited will be 194 patients (97 per group).

There will be no randomization of the sample, as the 2 groups will receive the same care as normal for their pathology; however, in the experimental group, the intervention (clinical ultrasound) will also be carried out to test its effectiveness and assess whether it improves the quality of care. It is important to consider that clinical ultrasound is not a regulated ultrasound, but rather a response to a clinical question; therefore, it is not a complex intervention, and with the usual pressure of the service, it can be performed at any time of the year.

To achieve the target sample size, recruitment will be conducted consecutively among eligible patients presenting with abdominal pain at the Emergency Department. All family physicians participating in the study have been informed and trained to identify and invite potential participants. The collaboration of the entire emergency care team will be essential to ensure continuous enrollment during the study period. Regular follow-up meetings will be held to monitor recruitment progress and address potential barriers.

Prior to this, training will be provided to professionals, and a common understanding will be reached on the possible main findings. This is intended to reduce clinical variability and improve the external validity of the study.

Given the limited sample size, short duration, and minimal risk involved in this pilot quasi-experimental study, a formal independent data monitoring committee has not been established. The principal investigator and the co-investigators will be responsible for monitoring trial conduct, data accuracy, and participant safety. As no data monitoring committee is planned, further details regarding its charter are not applicable.

No interim analyses are planned for this study due to its exploratory nature and short timeframe. Consequently, no predefined stopping rules have been established. The final decision to complete or terminate the study will rest with the principal investigator, based on recruitment feasibility, protocol adherence, or unforeseen safety concerns.

To ensure data integrity, a quality control procedure has been designed, including predefined field validation rules within the case report form. Participating clinicians were trained during project initiation to minimize data entry errors. Data entry will follow the case report form sequence, and filters will prompt the confirmation of extreme or illogical values. The principal investigator will perform monthly audits, and a second investigator will periodically review the database or a sample of its records. Questionnaire variables will be coded numerically, and preliminary analyses will be performed to detect inconsistencies or missing data. All efforts will focus on minimizing missing data and correcting errors promptly to reduce potential biases and ensure the reliability of the findings.

All individual participant data will be deidentified and securely stored in the REDCap platform hosted by semFYC. Access to the data dictionary, statistical analysis code, and related materials will be available upon reasonable request to the corresponding author, in accordance with ethical and data protection regulations. These materials will be used exclusively for academic or research purposes.

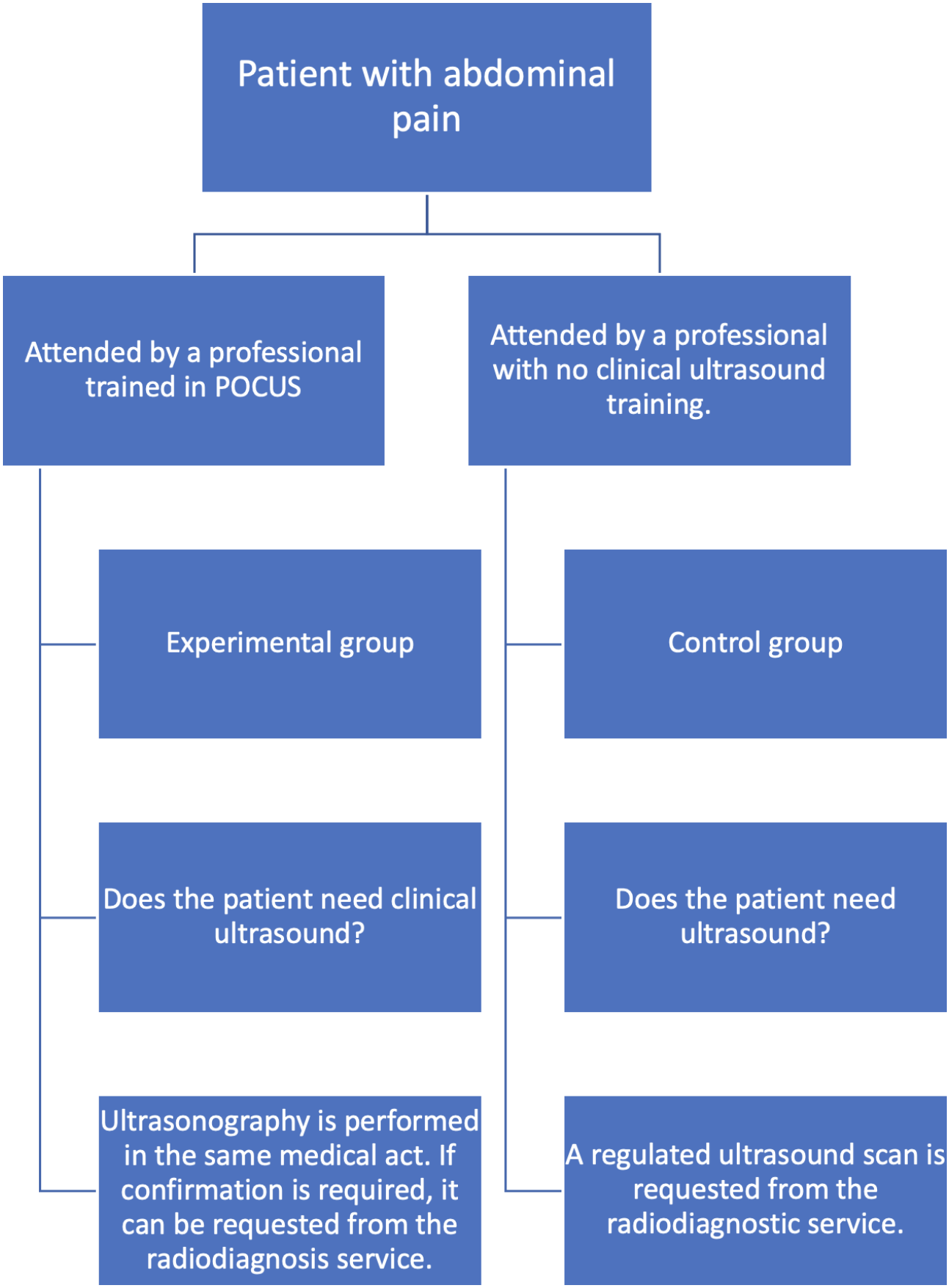
Table 1 shows the summary with the most frequent coded findings in clinical ultrasound.

Table . Summary with the most frequent coded findings in clinical ultrasounds.

	Encoding	Image
Renal ultrasound		
Kidney cyst	E1	
Renal pelvis dilatation	E2	
Bladder polyp	E3	
Kidney stones	E4	
Other (specify)	E5	
Hepatobiliary ultrasound		
Cholelithiasis	H1	
Biliary sludge	H2	
Cholecystitis	H3	
Liver angioma	H4	
Metastasis	H5	
Liver cyst	H6	
Other (specify)	H7	
Abdominal trauma		
Abdominal free liquid	T1	
Other (specify)	T2	

The study protocol is represented in Figure 1.

Figure 1. Flowchart depicting study protocol. POCUS: point-of-care ultrasound.



Subjects will be observed for a period of 1 month to determine whether they have returned for a repeat consultation for the same reason, and if so, to check the degree of alignment of the final diagnosis with the initial care. Only in cases where the process is not resolved can the patient be monitored for the next 6 months.

Statistical Analysis

A descriptive analysis will be carried out including proportions, measures of central tendency, and measures of dispersion, according to the nature of the variables (quantitative variables expressed as mean and SD and qualitative variables as a percentage). The analysis will include description and statistical analysis to identify any significant differences between men and women.

Comparison of the variables of interest and the stratification and potentially confounding variables at the start of the study will be carried out in both groups. The baseline values of the study variables will be tested for their homogeneity between the two groups (Student *t*-tests and chi-square tests, depending on the nature of the variables). There will also be a normality check for variables such as length of stay and those that require it.

The emergency department length of stay will be compared using a Student *t* test for independent samples, and a multiple linear regression model will be applied to adjust for potential confounding factors. The number of plain radiographs and complementary imaging studies in the Radiology Department will be analyzed using Poisson or logistic regression models, as appropriate. To account for multiple hypothesis testing, a Holm-Bonferroni correction will be applied.

The possible existence of potential confounding factors or the interaction of other variables in the relationship between the proposed intervention and the outcome variables will be assessed using logistic regression models. For continuous variables, it will be assessed by multiple linear regression.

In all cases, a statistical significance of 5% ($P<.05$) is required. The data will be processed and analyzed with SPSS (version 25.0; IBM Corp).

Variables

The main outcome variables aligned with the study objectives include the length of stay in the emergency department (measured in minutes), the number and type of radiological tests requested, the performance of bedside ultrasound (POCUS), diagnostic concordance, and the patient's satisfaction with the care received. Sociodemographic variables such as age, sex, and distance from home, as well as clinical and procedural variables, will also be collected.

A complete list of all study variables, including their measurement units or response categories, is provided in Table 2, grouped into thematic blocks: sociodemographic, clinical, diagnostic, and outcome variables.

Table . Study protocol variables.

Block and variable		Unit or format	Notes or response options
Sociodemographic			
	Identification code	Alphanumeric	Unique ID per patient
	Gender	Categorical	Male or female or other
	Date of birth	Date (dd/mm/yyyy)	Age will be calculated
	Distance to home	Kilometers	Estimated by postal code
Clinical			
	Health problems	Free text or ICD-10[a]	Comorbidities
	Current medications	Free text	List of active treatments
	Vital signs	Numeric (per parameter)	BP[b] (mm Hg), HR[c] (bpm), EVA[d], temperature (°C), $SatO_2$ (%)
	Reason for consultation	Free text	Chief complaint
Care process			
	Attending doctor	Code or initials	Family physician ID
	Date or time of arrival	Time stamp	Format: dd/mm/yyyy hh:mm
	Date or time of discharge	Time stamp	Format: dd/mm/yyyy hh:mm
	Origin	Categorical	Self-referred or primary care or ambulance or other
	POCUS[e] performed	Binary	Yes or no
	POCUS findings	Free text	Based on clinical protocol
	Other tests requested	Categorical or multiple	Blood tests or ECG[f] or other
	Radiology test performed	Categorical	X-ray or formal ultrasound or CT[g] or none
	Interconsultation	Binary	Yes or no; specialty if applicable
Outcome			
	Diagnosis	Free text or ICD-10	Final ED[h] diagnosis
	Discharge referral	Categorical	Home or hospitalization or specialist or follow-up
	Length of stay	Minutes	Calculated from entry and discharge times
	Satisfaction questionnaire	Likert scale or categorical	1 - 5 scale or qualitative responses
	Diagnostic concordance	Binary	Yes or no (based on follow-up or second opinion)

[a] *ICD-10: International Classification of Disease, Tenth Revision.*

[b]BP: blood pressure.

[c]HR: heart rate.

[d]EVA: Escala Visual Analógica (VAS: visual analog scale).

[e]POCUS: point-of-care ultrasound.

[f]ECG: electrocardiogram.

[g]CT: computed tomography.

[h]ED: emergency department.

Table 3 shows the results of the satisfaction questionnaire based on the SERVPERF model.

Table . Satisfaction questionnaire based on the SERVPERF model[a].

Dimensions and questions		Score range (strongly disagree to strongly agree)
Tangible elements		
1.	The facilities are suitable for patient care	1-7
1.	Technological equipment is adequate	1-7
1.	The emergency department has sufficient capacity to attend to the population	1-7
Responsiveness dimension		
1.	If you have any questions, you will receive a response within a reasonable time	1-7
1.	The attention of the staff provides a fast and high-quality service	1-7
1.	You have been dealt with quickly and promptly	1-7
Reliability dimension		
1.	When staff commit to doing something within a certain time frame, it is fulfilled	1-7
1.	If you have a problem, the staff show an interest in solving it	1-7
1.	Staff perform the service well the first time	1-7
1.	Professionals are ready to help when they are needed	1-7
Security dimension		
1.	Staff behavior imparts confidence	1-7
1.	There is a capacity to resolve doubts accurately	1-7
1.	Staff are knowledgeable when responding to queries	1-7
Empathy dimension		
1.	Care is offered that responds to the needs of the users	1-7
1.	Staff care about your interests and needs	1-7
1.	The emergency service provides a solution to the health needs of users	1-7
Access dimension		
1.	The waiting time for service was adequate	1-7
1.	Waiting time for tests and results was adequate	1-7
1.	The overall waiting time was adequate	1-7

[a]Likert scale (1-7) from least to most satisfaction.

Table 4 shows the work schedule for the study protocol.

Potential harms will be defined as any adverse event or unintended consequence resulting from the use of bedside ultrasound by nonradiologist physicians. Harms will be assessed systematically, using a structured reporting form completed by the attending physician and monitored through follow-up at 1 month. Any serious adverse events will be documented and reviewed by the principal investigator and the ethics committee if needed.

Table . Timeline of the study.

		Year 1												Year 2											
	Phase 0	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Ultrasound training	✓																								
Literature review update		✓																							
Presentation of the research project in the emergency department			✓																						
Protocol development				✓	✓																				
Design of the data collection form					✓	✓																			
Training and consensus on key pathologies							✓	✓																	

	Year 1						Year 2											
Data collection							✓	✓	✓	✓	✓	✓						
Data cleaning, analysis, and results generation													✓	✓	✓	✓	✓	
Results dissemination and manuscript preparation																		✓ ✓ ✓ ✓ ✓ ✓

Ethical Considerations

This study has been approved by the Huelva Provincial Independent Ethics Committee (reference code PEIBA 1923-N-21). Any significant modifications to the protocol will be submitted for approval to the same ethics committee and promptly communicated to all relevant stakeholders, including participating investigators and, where necessary, trial registries.

Informed consent will be obtained by the attending family physicians or authorized research team members prior to the inclusion of any participant. Participants will receive both oral and written information about the study objectives, procedures, risks, and benefits and will be given the opportunity to ask questions before providing written consent. No biological specimens will be collected, and no ancillary studies requiring additional consent are planned. Participants will not receive any financial compensation or incentives for their participation in the study.

Personal data will be collected and stored using anonymized codes to ensure confidentiality. Access to identifiable information will be restricted to the research team and stored securely in password-protected systems in accordance with national data protection regulations. Data will be treated with strict confidentiality before, during, and after the trial, and only aggregated, deidentified data will be reported in publications or presentations.

Given the minimal-risk nature of this study, no specific post-trial care provisions are foreseen. However, if any harm were to occur as a result of participation, appropriate medical care and any necessary support will be provided by the institution in accordance with applicable regulations and institutional policies. The application procedures and the study were approved by the Huelva Provincial Ethics Committee (Comité de Ética de Investigación de Huelva) (Code PEIBA 1923-M1-21).

Results

The first phase of the project began in 2023 with the validation of the data collection form. Subsequently, the patient satisfaction questionnaire was validated, and the results were published in the journal Care Primary. The study has received external funding, and patient recruitment is currently ongoing and expected to be completed in December 2025.

The project was initiated in 2023. Between March and July 2023, an initial validation phase of the data collection form was conducted. Preliminary findings were presented as a clinical communication at the 44th semFYC National Congress, held in Barcelona, 14 - 16 November 2024. A total of 65 patients were included in this first sample, with a mean age of 56.6 (SD 20.0) years, of whom 53.8% (n=35) were women and 46.2% (n=30) were men. The validation of the data collection form showed that 76.9% (n=50) of the ultrasound examinations were performed as point-of-care clinical ultrasounds (POCUS), whereas only 6.2% (n=4) were formal imaging studies referred to the Radiology Department.

Based on this pilot experience, the study protocol was further developed. Funding was subsequently obtained through the 2024 Call of the Fundación Progreso y Salud (Andalusian Public Health System) under the Research and Innovation Projects

category in Primary Care, Regional Hospitals, and High-Resolution Healthcare Centers (grant ID: AP-0561 - 2024-C5-F2).

Further work focused on refining the study protocol and validating the patient satisfaction questionnaire was published in [31].

Patient recruitment is currently ongoing and is expected to be completed by December 2025. We anticipate that the implementation of POCUS in patients presenting with abdominal pain in emergency settings will lead to a reduction in length of stay and a decrease in the use of additional diagnostic tests, such as plain radiography or formal radiology−performed ultrasound.

Discussion

Principal Findings

POCUS has emerged as a valuable tool in emergency medicine, particularly for its potential to reduce diagnostic uncertainty and enhance clinical accuracy in decision-making. Despite these recognized advantages, there is limited evidence regarding its overall impact on the quality of care, and even less from the patient's perspective. This study protocol is based on the hypothesis that the implementation of clinical ultrasound performed by family physicians in emergency departments can reduce length of stay and decrease the need for complementary diagnostic tests, such as plain radiography or radiology-performed ultrasound. Collectively, these improvements may lead to a measurable enhancement in both perceived and actual quality of care.

The geographic context of this study adds a relevant dimension to the analysis. The target population resides in an area characterized by wide territorial dispersion and significant population aging, factors that place additional demands on emergency services. In such settings, clinical practice often prioritizes the resolution of health problems in a single visit to avoid repeated travel—especially for patients with reduced mobility or limited access to transportation. POCUS performed by emergency physicians may therefore not only optimize diagnostic workflows but also align more closely with the health care needs of the community.

One of the main methodological challenges in this study is interoperator variability in the interpretation of ultrasound findings. To minimize this, a reference image repository has been developed, alongside simplified visual guides to standardize the use of clinical ultrasound in patients presenting with abdominal pain. In addition, prestudy training sessions were conducted in collaboration with the radiology department to promote consistency in image acquisition and interpretation among participating physicians.

Beyond evaluating diagnostic efficiency, the study also aims to identify the key factors contributing to improved quality of care from the health care professional's perspective. This approach will provide both qualitative and quantitative insights into the clinical, organizational, and human elements that influence better health outcomes.

Finally, this research initiative may pave the way for broader applications of clinical ultrasound beyond hospital-based emergency settings, including prehospital care and primary health care services. If the results are favorable, they could support the development and implementation of standardized protocols for the use of POCUS by family physicians, with potential implications for health care system efficiency and patient-centered outcomes.

Conclusion

This study aims to assess whether the implementation of POCUS performed by family doctors in the emergency department reduces the length of stay in the department, as well as other diagnostic tests such as simple radiology or regulated ultrasound, improving the quality of patient care.

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Data Availability

Data collection for this study is currently ongoing. Preliminary datasets have already been generated and stored securely in compliance with institutional and ethical regulations. Upon the completion of data collection and analysis, all deidentified datasets supporting the findings of this study will be made available without access restrictions.

The datasets will be available from the corresponding author upon reasonable request and will also be deposited in a publicly accessible data repository once the final analyses are completed.

The deidentified dataset and statistical code will be made available under a CC BY-NC 4.0 license.

All data used in the research will be available without access restrictions.

We are committed to disseminating the trial results to all relevant stakeholders, including study participants, health care professionals, the general public, and other interested parties. Dissemination will be conducted through multiple channels such as updating the trial registry with results, providing a plain language summary accessible to nonspecialist audiences, and publishing findings in peer-reviewed scientific journals.

The datasets generated or analyzed during the current study are available from the corresponding author on reasonable request. The datasets will be available from the corresponding author upon reasonable request and will also be deposited in a publicly accessible data repository once the final analyses are completed.

Authors' Contributions

Conceptualization: LCM.
Data curation: LCM.
Formal analysis: LCM, MBW.
Funding acquisition: LCM.
Investigation: IPM, LCM, LMBR, MBW, NHHMARG.
Methodology: IPM, LCM, LMBR, MBW.
Project administration: LCM.
Resources: IPM, LCM, LMBR, MBW.
Supervision: IPM, MBW.
Validation: IPM, LMBR, MBW.
Visualization: MBW.
Writing – original draft: LCM.
Writing – review & editing: IPM, LCM, LMBR, MBW.

Conflicts of Interest

None declared.

Checklist 1
SPIRIT checklist.
[DOCX File, 23 KB - resprot_v15i1e82393_app1.docx]

Peer Review Report 1
Peer review report by the 2024 Call for R&I Projects in Primary Care, Regional Hospitals, and CHARES Review Committee, Fundación Andaluza Beturia para la Investigación en Salud (FABIS; Beturia Andalusian Foundation for Health Research, Spain.
[PDF File, 13 KB - resprot_v15i1e82393_app2.pdf]

References

1. Kameda T, Taniguchi N. Overview of point-of-care abdominal ultrasound in emergency and critical care. J Intensive Care 2016;4:53. [doi: 10.1186/s40560-016-0175-y] [Medline: 27529029]

2. De Cabo Francés FM. Utilidad de la ecografía en la emergencia. Prehosp Emerg Care 2008 Jul;1(3):295-300 [FREE Full text]
3. Choi W, Cho YS, Ha YR, et al. Role of point-of-care ultrasound in critical care and emergency medicine: update and future perspective. Clin Exp Emerg Med 2023 Dec;10(4):363-381. [doi: 10.15441/ceem.23.101] [Medline: 38225778]
4. Andersen CA, Holden S, Vela J, Rathleff MS, Jensen MB. Point-of-care ultrasound in general practice: a systematic review. Ann Fam Med 2019 Jan;17(1):61-69. [doi: 10.1370/afm.2330] [Medline: 30670398]
5. Grundmann RT, Petersen M, Lippert H, Meyer F. Das akute (chirurgische) Abdomen – Epidemiologie, Diagnostik und allgemeine Prinzipien des Managements. Z Gastroenterol 2010 Jun;48(6):696-706. [doi: 10.1055/s-0029-1245303]
6. Seyedhosseini J, Nasrelari A, Mohammadrezaei N, Karimialavijeh E. Inter-rater agreement between trained emergency medicine residents and radiologists in the examination of gallbladder and common bile duct by ultrasonography. Emerg Radiol 2017 Apr;24(2):171-176. [doi: 10.1007/s10140-016-1468-0] [Medline: 27878404]
7. Bektas F, Eken C, Soyuncu S, Kusoglu L, Cete Y. Contribution of goal-directed ultrasonography to clinical decision-making for emergency physicians. Emerg Med J 2009 Mar;26(3):169-172. [doi: 10.1136/emj.2008.059220] [Medline: 19234003]
8. Cox C, MacDonald S, Henneberry R, Atkinson PR. My patient has abdominal and flank pain: identifying renal causes. Ultrasound 2015 Nov;23(4):242-250. [doi: 10.1177/1742271X15601617] [Medline: 27433264]
9. Sharif S, Vlahaki D, Skitch S, et al. Evaluating the diagnostic accuracy of point-of-care ultrasound for cholelithiasis and cholecystitis in a Canadian emergency department. CJEM 2021 Sep;23(5):626-630. [doi: 10.1007/s43678-020-00068-6] [Medline: 34491557]
10. Dupriez F, Geukens P, Penaloza A, Vanpee D, Bekkering G, Bobbia X. Agreement of emergency physician-performed ultrasound versus RADiology-performed UltraSound for cholelithiasis or cholecystitis: a systematic review. Eur J Emerg Med 2021 Oct 1;28(5):344-351. [doi: 10.1097/MEJ.0000000000000815] [Medline: 33758146]
11. Ross M, Brown M, McLaughlin K, et al. Emergency physician-performed ultrasound to diagnose cholelithiasis: a systematic review. Acad Emerg Med 2011 Mar;18(3):227-235. [doi: 10.1111/j.1553-2712.2011.01012.x] [Medline: 21401784]
12. Bourcier JE, Gallard E, Redonnet JP, et al. Ultrasound at the patient's bedside for the diagnosis and prognostication of a renal colic. Ultrasound J 2021 Nov 22;13(1):45. [doi: 10.1186/s13089-021-00246-2] [Medline: 34807330]
13. Lee WF, Goh SJ, Lee B, Juan SJ, Asinas-Tan M, Lim BL. Renal point-of-care ultrasound performed by ED staff with limited training and 30-day outcomes in patients with renal colic. Can J Emerg Med 2024 Mar;26(3):198-203. [doi: 10.1007/s43678-023-00645-5] [Medline: 38219263]
14. Kartal M, Eray O, Erdogru T, Yilmaz S. Prospective validation of a current algorithm including bedside US performed by emergency physicians for patients with acute flank pain suspected for renal colic. Emerg Med J 2006 May;23(5):341-344. [doi: 10.1136/emj.2005.028589] [Medline: 16627832]
15. Dalziel PJ, Noble VE. Bedside ultrasound and the assessment of renal colic: a review. Emerg Med J 2013 Jan;30(1):3-8. [doi: 10.1136/emermed-2012-201375] [Medline: 22685250]
16. Orosco E, Terai H, Lotterman S, et al. Point-of-care ultrasound associated with shorter length of stay than computed tomography for renal colic. Am J Emerg Med 2024 May;79:167-171. [doi: 10.1016/j.ajem.2024.02.024] [Medline: 38452429]
17. Dadeh AA, Phunyanantakorn P. Factors affecting length of stay in the emergency department in patients who presented with abdominal pain. Emerg Med Int 2020;2020:5406516. [doi: 10.1155/2020/5406516] [Medline: 32566303]
18. Abdolrazaghnejad A, Rajabpour-Sanati A, Rastegari-Najafabadi H, Ziaei M, Pakniyat A. The role of ultrasonography in patients referring to the emergency department with acute abdominal pain. Adv J Emerg Med 2019;3(4):e43. [doi: 10.22114/ajem.v0i0.152] [Medline: 31633098]
19. Durgun Y, Yurumez Y, Guner NG, Aslan N, Durmus E, Kahraman Y. Abdominal pain management and point-of-care ultrasound in the emergency department: a randomised, prospective, controlled study. J Coll Physicians Surg Pak 2022 Oct;32(10):1260-1265. [doi: 10.29271/jcpsp.2022.10.1260] [Medline: 36205268]
20. Martín JMA, de Gracia MM, Torres CR, Martínez DM, Herranz PP. Radiografía del abdomen en Urgencias. ¿Una exploración para el recuerdo? Radiología 2015 Sep;57(5):380-390. [doi: 10.1016/j.rx.2015.06.002]
21. Wolfe C, Halsey-Nichols M, Ritter K, McCoin N. Abdominal pain in the emergency department: how to select the correct imaging for diagnosis. Open Access Emerg Med 2022;14:335-345. [doi: 10.2147/OAEM.S342724] [Medline: 35899220]
22. Smith JE, Hall EJ. The use of plain abdominal x rays in the emergency department. Emerg Med J 2009 Mar;26(3):160-163. [doi: 10.1136/emj.2008.059113] [Medline: 19234001]
23. Andersen CA, Brodersen J, Rudbæk TR, Jensen MB. Patients' experiences of the use of point-of-care ultrasound in general practice - a cross-sectional study. BMC Fam Pract 2021 Jun 18;22(1):116. [doi: 10.1186/s12875-021-01459-z] [Medline: 34144701]
24. Torres Navarro C, Jélvez Caamaño A, Vega Pinto F. Evaluación de la calidad de un servicio de urgencia utilizando el modelo servperf. Universidad, Ciencia y Tecnología 2014;18:38-49 [FREE Full text]
25. Campoverde RE, Baldeón M, González V, Montero M. Calidad de servicios médicos ambulatorios: un análisis confirmatorio del modelo SERVPERF. Agosto 2020;41(31):33-45 [FREE Full text]
26. Duc Thanh N, Quynh Anh P, Thi Huyen Chang P, Minh Nguyet HT. Cross-cultural adaption and validation of SERVPERF tool for measuring healthcare quality in an oncology public hospital, Vietnam. Inquiry 2023;60:469580221146826. [doi: 10.1177/00469580221146826] [Medline: 36680357]

27. Gómez-Besteiro MI, Somoza-Digón J, Einöder-Moreno M, Jiménez-Fraga MN, Castiñeira-Pereira S, Feijoo-Fuentes ML. Calidad de atención en salud percibida por los pacientes en un centro de salud urbano de A Coruña. Enferm Clín 2012 Jul;22(4):182-190. [doi: 10.1016/j.enfcli.2012.04.004]
28. Babroudi NEP, Sabri-Laghaie K, Ghoushchi NG. Re-evaluation of the healthcare service quality criteria for the Covid-19 pandemic: Z-number fuzzy cognitive map. Appl Soft Comput 2021 Nov;112:107775. [doi: 10.1016/j.asoc.2021.107775] [Medline: 34377110]
29. Ibarra Morales LE, Casas Medina EV. Aplicación del modelo Servperf en los centros de atención Telcel, Hermosillo: una medición de la calidad en el servicio. Contad Adm 2015;60:229-260 [FREE Full text]
30. Slagman A, Schenk L, Huscher D, et al. Management of non-traumatic abdominal pain in the emergency department: a multicentre, stepped-wedge, cluster-randomised trial. Lancet Reg Health Eur 2025 Aug;55:101362. [doi: 10.1016/j.lanepe.2025.101362] [Medline: 40678036]
31. Carbajo Martín L, Párraga-Martínez I, Rosado Cabral JJ, Beltrán Romero LM, Bernabeu Wittel M, Grupo de Investigación AGS Norte de Huelva. Hospital de Riotinto. Validation of the SERVPERF tool for quality analysis in emergency care with clinical ultrasound. Aten Primaria 2025 Jun;57(6):103204. [doi: 10.1016/j.aprim.2024.103204] [Medline: 39731851]

Abbreviations

POCUS: point-of-care ultrasound

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Protocol

Neighborhood Differences in Omnipresent Policing and Sleep Health in New York City: Protocol for a Multimethod Quantitative Study

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Abstract

Background: Poor or insufficient sleep is associated with numerous adverse, potentially serious physical and mental health outcomes. Equally concerning are the substantial racial, gender, and socioeconomic disparities, with minorities and those experiencing poverty disproportionately affected by poor sleep quality and sleep disorders. Both theory and research suggest that sleep health is negatively impacted by concentrated poverty at the neighborhood level due to the deterioration of the built and social environments, thereby creating conditions that disrupt sleep.

Objective: This research considers an under-studied factor related to these conditions and sleep health—policing and police surveillance. Specifically, the study compares 4 neighborhoods within New York City at different levels of residential segregation.

Methods: The study design consists of a baseline survey, with 40 residents recruited in each neighborhood, and a 1-week diary phase with a subsample of residents. Neighborhood conditions are also assessed in each of the neighborhoods using a neighborhood audit tool.

Results: The study received funding in July 2024. Data collection commenced in September 2024. As of August 2025, we have enrolled more than 100 participants in the baseline survey. Planned analyses will begin once data collection has concluded.

Conclusions: This information will help establish the extent to which surveillance and policing differentially impact the lives of New Yorkers as a function of where they live. Specifically, the results should be relevant and important for understanding the impact of novel policing strategies on underprivileged neighborhoods. This exploratory research will be useful for identifying populations and residential settings that may be most at risk for poor sleep health.

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KEYWORDS

protocol; sleep health; omnipresent policing; surveillance; neighborhood segregation

Introduction

Background and Rationale

Poor sleep health is considered a public health threat in the United States [1]. Among US adults, the prevalence of self-reported sleeping problems is 56%, whereas that of insomnia is estimated to be 27% [1,2]. Moreover, the prevalence of moderate to extreme insomnia symptoms suggests that this sleep disorder is underdiagnosed [3]. A 2020 poll [4] found that approximately half of Americans felt sleepy anywhere from 3 to 7 days a week, and for many, this sleepiness impeded their daily activities. Poor or insufficient sleep is associated with numerous adverse, potentially serious, physical and mental health outcomes [5-7]. Equally concerning are the substantial racial, gender, and socioeconomic disparities in sleep health

[8-11]. Theory and research suggest that sleep disparities are partially driven by residential segregation or spatial and neighborhood separation along racial, ethnic, and socioeconomic lines [12]. This segregation shapes the physical (eg, crowding and walkability), social (eg, disorder and safety), and ambient (eg, light and noise pollution) environments, thereby contributing to poor sleep [13-15]. This study considers an under-studied factor related to sleep health, policing—specifically, police surveillance.

In the United States, communities of color are burdened by overpolicing and police brutality [16,17], which contribute to stress [18], adverse mental health outcomes [19,20], and poor sleep [21]. In recent decades, police departments in the United States have shifted toward omnipresent policing, which includes traditional ground presence as well as covert surveillance and deterrence strategies [22]. Examples include the placement of floodlights and surveillance towers in high-crime areas, increased undercover police presence, reliance on closed-circuit television, the use of drone footage and facial recognition software, and the interception of cellphone data. The New York City (NYC) Police Department recently vowed to expand its use of police surveillance [23]. Data indicate that surveillance is more common in communities of color [22], and footage obtained from thousands of drivers demonstrates that the NYC Police Department deployed more police to patrol low-income areas with higher Black and Latino populations [24]. It appears that omnipresent policing varies as a function of residential segregation, much like traditional policing, but little research has systematically examined cross-neighborhood differences or the impact of these strategies on sleep health.

These strategies are thought to influence sleep through physical, social, and ambient environments. Specifically, increased police presence contributes to noise and light pollution (eg, sirens and police lighting). For example, floodlights placed in areas identified as high crime [25] may contribute to light pollution and, in turn, worsen sleep health outcomes [26,27]. The principal investigators in this study previously conducted a small-scale survey on omnipresent policing in the Bronx borough of NYC and found that police surveillance evokes complex feelings of both safety and unease, which are emotional responses known to impact sleep quality [28-30]. Our pilot data similarly found that residents of the Bronx who are more worried about neighborhood crime safety, especially those identifying as Hispanic or Latino, reported more insomnia symptoms [31]. In contrast, feelings of unease related to being surveyed may lead to stress and negative emotions, thereby having a negative impact on sleep [12]. The complex interplay of these factors may also influence residents' propensity to spend time outdoors and engage in social and physical activities, which have a known impact on sleep health [14]. For example, O'Connor and Jahan [32] found that Muslims who were targets of post-9/11 surveillance reacted more with anxiety than anger and modified their behaviors to avoid situations that might lead to further monitoring.

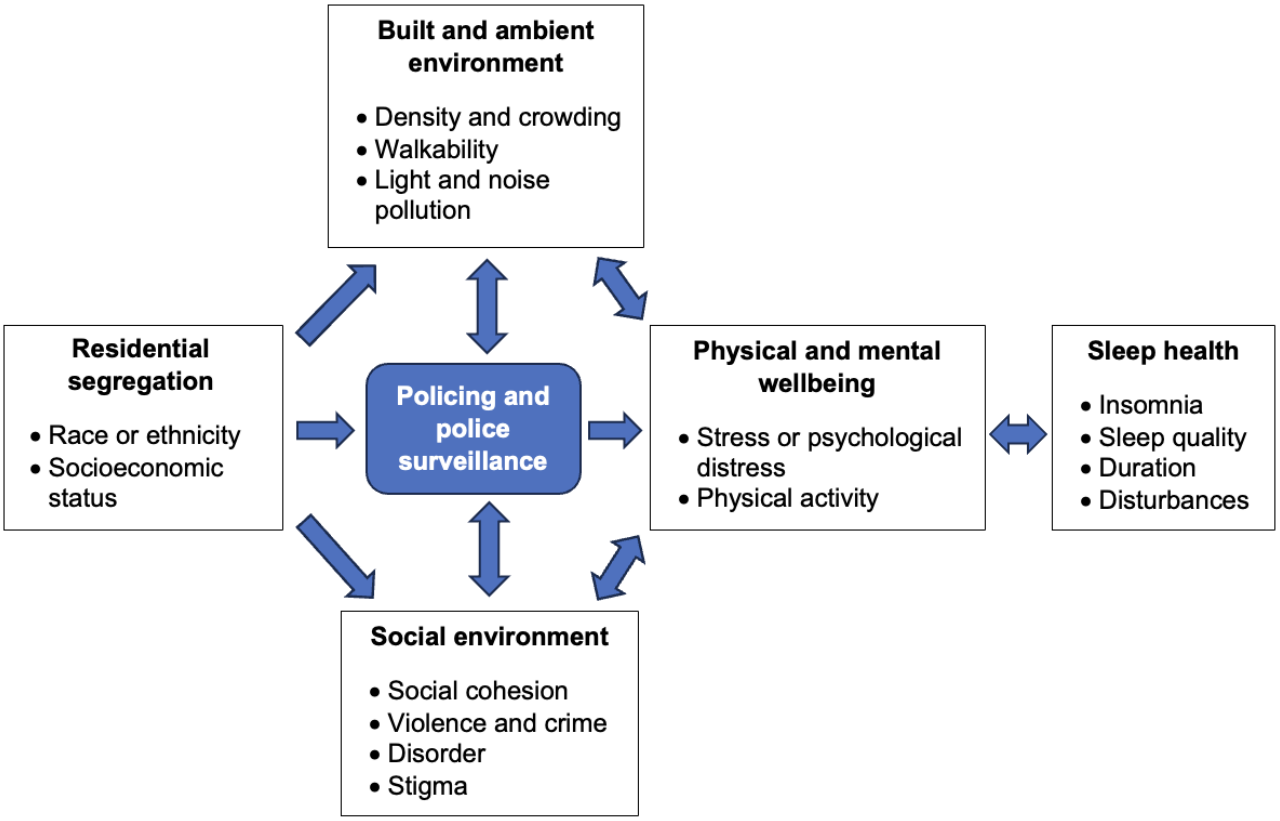
Previous theoretical models and research suggest that the neighborhood context is associated with sleep health [12,14]. However, these studies have not accounted for policing and specifically, surveillance, as a symptom of segregation. Studies on policing have largely relied on national samples, making it difficult to control for city- or county-level differences in crime levels and law enforcement policies. Finally, previous models [12] have relied on socioeconomic features to measure neighborhood disadvantage, not accounting for the confluence of race and socioeconomic status (SES) in shaping urban neighborhoods [33,34]. This study aims to address these gaps by surveying residents of, and comparing, 4 neighborhoods within NYC, at low, medium, and high levels of residential segregation, as measured by the Index of Concentration at the Extremes (ICE). The ICE race-income subset is a segregation measure that simultaneously accounts for race and SES [35]. The study also includes a 7-day diary period in which a subset of participants, equally represented across the neighborhoods, are asked to report on police interactions (both covert and overt) throughout the day as well as their sleep quality the same night.

Diary data are important since there is very little data on how often police interactions occur daily and their immediate impact on sleep and psychological health. Additionally, this design will help disentangle the extent to which residents of particular neighborhoods share similarities among themselves while being distinct from residents of neighborhoods with different levels of segregation, in terms of their police experiences and sleep health. This information can establish the extent to which surveillance and policing differentially impact the lives of New Yorkers as a function of where they live. Additionally, the study considers whether individual-level variables, such as household SES, psychological, and physical characteristics, exacerbate or mitigate neighborhood-level forces, with the hopes of informing future interventions. Importantly, this study also serves as a methodological pilot to determine the feasibility of eventually including a wider breadth of NYC neighborhoods for a more holistic understanding of sleep health and policing in the city.

Conceptual Framework

This formative study applies a modified conceptual framework [12] positing that neighborhood segregation is associated with sleep health through the built and physical, social, and ambient environments, with a unique emphasis on policing (Figure 1). We are comparing 4 neighborhoods within a single city (ie, NYC), allowing us to control for variations in city-level policies that dictate law enforcement decisions. Not only are between-neighborhood differences relevant to understanding sleep health, but research is equally needed to address within-neighborhood variations (eg, why some residents may be more or less affected by the symptoms of neighborhood segregation). To test this framework, we are using a multilevel approach to examine between- and within-neighborhood differences in policing in relation to sleep health data.

Figure 1. Modified conceptual framework.



Study Goals

Goal 1

This study aims to investigate between-neighborhood differences in self-reported sleep health, including perceived sleep quality and insomnia, as a function of policing, both overt and covert. The following hypotheses are proposed:

1. The neighborhoods with higher levels of residential segregation (across racial-SES lines) will also have poorer overall sleep health and higher levels of policing compared with their less segregated counterparts.
2. Consistent with Figure 1, the association between policing and sleep health will be mediated by related neighborhood characteristics, including features of the built, social, and ambient environments.

Goal 2

This study aims to investigate individual (person-level) differences in sleep health, as a function of neighborhood and individual-level factors, to test two hypotheses:

1. Using baseline, cross-sectional data, it is hypothesized that individuals with more negative interactions and sentiments related to omnipresent policing will report lower levels of self-reported sleep health.
2. It is expected that individual-level factors (eg, household income, gender, race, ethnicity, education, and mental and physical health) will moderate the association identified in the previous hypothesis. Using intensive longitudinal data (the 1-week diary study), it is predicted that negative policing interactions on any given day will be associated with poorer self-reported sleep health on the same night.

Methods

Study Design

This study consists of a cross-sectional, baseline survey (phase 1; n=160) and a daily diary (phase 2; n=72). Given the preliminary nature of this research, eligible participants must be aged at least 18 years, fluent in English, and own a smartphone. Although these exclusions limit the generalizability of the results to the larger NYC population, they are deemed necessary given the budget and time constraints of this study.

Neighborhood Tabulation Areas

We generated a list of all 197 neighborhood tabulation areas (NTAs) in NYC. These catchment areas are approximations of NYC neighborhoods created for the purpose of reporting decennial census and American community survey data. Then, we calculated measures of income and racial segregation for each NTA using the ICE for race-income [35]. ICE captures the degree to which residents are concentrated into areas with extreme deprivation or privilege and has a possible range of values from –1 (100% of the population consists of the deprived group) to +1 (100% of the population consists of the privileged group) [35]. ICE (income) is computed as follows: $ICE_{income} = (A_i - P_i)/T_i$. A_i is the number of persons in the top 80th percentile for income or higher (>$150K), P_i is the number of people in the bottom 20th percentile (<$25,000), and is the total NTA population. ICE (race) is computed by subtracting the number of non-White residents from the number of White residents and

then dividing by the population size [35]. We selected a random sample of 4 NTAs: one in the lowest quartile (Highbridge), 2 in the middle quartiles (Morningside Heights and Bensonhurst), and one in the highest quartile (Midtown South, Flatiron, and Union Square) on both ICEs. These NTAs represent 3 of the 5 NYC boroughs.

Participant Flow: Recruitment, Baseline Survey (Phase 1), and Daily Diary (Phase 2)

We are conducting a street-intercept baseline survey (phase 1) with 40 residents from each of the 4 randomly selected NTAs (total baseline survey sample size=160). A street-intercept approach generates robust response rates when capturing specific health behaviors [36,37]. Moreover, this methodology is effective in obtaining crucial public health information about hard-to-reach communities. The survey, hosted on Qualtrics, is completed on the spot on a tablet and takes approximately 15 minutes to complete. The principal investigators for this project previously conducted street-intercept surveys with approximately 200 Bronx residents during 1- to 2-hour recruitment shifts across 23 nonconsecutive days over 1 year [31].

Recruitment takes place outdoors at high-volume locations, such as public parks, sidewalk intersections, and parking lots. Interested individuals are briefly screened, including verifying that they live in the target NTA. This is done by having participants identify where they live in the target NTA on a digital map [38] and tracking each participant's census block. Eligible individuals provide informed consent before completing the survey using a study tablet. We will end recruitment in each NTA once the target goal of 40 participants, including 18 randomly selected for the daily diary, is reached.

Street-intercept recruitment efforts can be affected by weather conditions. On days with cooler temperatures, study team members screen potential participants during street-intercept recruitment and collect an email address for eligible persons willing to complete the survey. The lead investigators follow up with a same-day email that includes a link to the baseline survey, the recipient's census block (as determined during screening) to enter in the survey, and information about how the US $15 compensation is provided.

Daily Diary Procedures (Phase 2)

Following completion of the baseline survey, a subsample of 72 participants (n=18 from each NTA) is randomly selected for a 1-week daily diary consisting of 2 short daily surveys (morning and evening) hosted on Qualtrics. Enrolled participants begin their diary period approximately 24 to 96 hours after the baseline survey. The daily diary consists of 14 short (about 5 min) surveys (2 per d, for 7 d). Nightly surveys are completed between 7 PM and 3 AM, and interactions with the police and other daily stressors are assessed. Morning surveys are completed at any time between 5 AM and noon and assess sleep quality the night before. Every evening at 7 PM and morning at 5 AM, participants receive a text message to their personal smartphone with a link to that survey, hosted on an online survey platform (Qualtrics). Eligible participants must have their own smartphone that can connect to the internet. Although this may limit generalizability, recent Pew Research Center data suggest that 91% of US adults have a smartphone [39].

Ethical Considerations

The study received approval (2024-0453-Lehman) from the institutional review board affiliated with the City University of New York. Individuals who screen eligible for the baseline survey provide informed consent on a study tablet before completing the survey. Following completion of the baseline survey, anyone who is randomly selected for the 1-week daily diary and agrees to participate is asked to provide informed consent on a study tablet. The internet-based consent forms for the baseline survey and daily diary state the voluntary nature of this study, indicate that the risks of participating are minimal, and specify that the participant does not have to answer any question that they do not want to answer. Diary participants provide their mobile phone number and a name to receive daily text messages with links to the surveys. For the purpose of participant validation, they are asked to re-enter this information on each daily survey. To maintain privacy and confidentiality, any participant contact information will be separated from the survey files and deleted at the conclusion of the study. Participants receive US $15 as compensation for their time for completing the baseline survey. For the diary phase, participants receive US $2.50 for completing their daily surveys (US $1.25 each) plus a US $7.50 bonus for completing the 7 days for a potential total of US $25. Completed surveys are automatically recorded and stored securely by the survey host.

Study Measures

For the baseline survey, we are using validated instruments to measure sleep health (primary outcome), stress, neighborhood walkability, and social cohesion (Table 1). As the primary outcome for this study, sleep health will be captured using a composite score based on 4 indicators from the baseline survey, as shown in Table 1. The baseline survey also includes measures of noise, neighborhood reputation, perceived police surveillance, and over- and underpolicing, as well as perceptions of violent and property crime. We added a measure of police surveillance strategies (eg, awareness of and emotional reactions to) developed for a previous study of Bronx residents. The daily diary surveys include measures of sleep health, psychological distress, discrimination, stressful events, somatic symptoms, and police interactions (Table 1). We also added several items from the National Sleep Foundation diary (eg, sleep and wake times, nap taking, and exercise) [40].

Table 1. Study measures using validated instruments and measures adapted for this study.

Domain and measure	Study phase	
	Baseline	Diary
Sleep health		
Subjective sleep quality [41]	✓	✓
Insomnia severity [42]	✓	
Sleep hygiene [43]		✓
Daytime dysfunction [41]	✓	
Use of pharmacological sleep aids [41]	✓	
Stress and physical activity		
Psychological distress [44]	✓	✓
Perceived stress [45]	✓	
Everyday discrimination [46]	✓	✓
Daily stressful events [47]		✓
Daily somatic symptoms[a] [48]		✓
Recreational activities [49]	✓	
Neighborhood environment and policing		
Walkability, lighting, and crime safety [50]	✓	
Noise	✓	
Social cohesion [51]	✓	
Neighborhood reputation or spatial stigma [52]	✓	
Perceived police surveillance (adapted) [53]	✓	
Awareness of, and emotional reactions to police surveillance (Budescu M, unpublished data, June 2025)	✓	
Over- and underpolicing [54]	✓	
Perceptions of violent and property crime [55]	✓	
Police interactions [56]		✓
Covariates		
Crime victimization	✓	
Substance use [57,58]	✓	
Sex at birth	✓	
Gender identity	✓	
Sexual orientation	✓	
Ethnicity	✓	
Race	✓	
Employment status	✓	
Household income	✓	
Education	✓	
Cohabiting with a romantic partner	✓	
Children under the age of 18 or dependents	✓	
Born in the United States (or Puerto Rico, Guam, United States Virgin Islands, and other US territories)	✓	

[a]We assessed the presence of several daily somatic symptoms, including abdominal pain or gastrointestinal issues, tingling or numbness, dizziness or fainting, and headache [48]. Our list also included changes in appetite and whole-body aches.

Neighborhood Audit

Studies of neighborhood environment quality (eg, physical incivilities, defensible space, natural elements, and surveillance) have relied, at least in part, on the use of a neighborhood audit tool. Examples include the Residential Environment Assessment Tool 2.0 [59], the Built Environment Assessment Tool [60], the Microscale Audit of Pedestrian Streetscapes [61], and the Block Environmental Inventory [62]. These tools measure the physical environment of urban residential areas via on-the-ground observations by trained raters who look for and document evidence of block-level cues, social (eg, presence of people outside) and physical (eg, presence of abandoned cars, sidewalks, and crime watch signs) environment, as well as information about residential and nonresidential properties. The study investigators, along with trained research assistants, make assessments of neighborhood conditions using a modified version of the Revised Block Environmental Inventory [63].

We modified the Revised Block Environmental Inventory in several ways: fewer person entries (maximum 5), revised age categories for person entries (ie, child, adolescent, adult, or older adult [>60 years]), no sex categories for person entries, fewer nonresidential land use entries (maximum 3), and fewer residential property entries (maximum 3). We added several block items [64,65], such as grooves or bumps in the curb, path obstructions (eg, trees and poles), garbage cans, benches, water fountains, bicycle parking and lanes, public spaces (eg, playground or garden), pedestrian crossing signs or activated signals, transit stops (eg, bus stop), outdoor public dining areas, as well as the number of sidewalk cracks (defined as substantially hazardous for walking), speed bumps in the street, accessibility options (eg, ramp), and pits containing trees. For the modified version, raters assessed the block for aesthetics (ie, attractive for walking and cycling) and feelings of safety (for walking and cycling) [64]. For nonresidential land use properties, we assessed evidence of vandalism in addition to the original graffiti item. Finally, we added several police surveillance items to the audit, including floodlights, towers (to monitor and record ground movements), vans, cameras, ShotSpotters (ie, sound sensors), and in-person police presence.

First, we identified all census blocks within each of the 4 NTAs [66] and generated a random set of 2 census block codes for each (n=8 blocks). We included one additional census block in each NTA (a total of 3 blocks per NTA) that was not randomly selected but rather based on the study team's familiarity with the neighborhood as part of our street-intercept recruitment (described earlier). The study team conducted several training sessions, which led to many of the modifications noted above. Using best practices [60,61], we are conducting observations (during team shifts) of the social (eg, presence of people outside) and physical (eg, presence of abandoned cars, sidewalks, and crime watch signs) environment, including gathering information about residential and nonresidential properties (eg, broken windows, litter, gardens), as well as looking out for known signs of police surveillance (eg, sound sensors, floodlights, towers, police presence). Auditors also measure census block noise levels using a sound level meter app installed on study tablets. This is done 3 times during each block audit. The sound level meter app was developed by the National Institute for Occupational Safety and Health to measure noise in the workplace and can be used anywhere for accurate noise measurement [67,68].

Data Analysis

For goal 1, we will test 3 serial mediation models to estimate the direct and indirect pathways between neighborhood segregation and sleep health. Each model will consist of 2 serial mediators between these 2 variables: (1) policing and (2) a variable capturing either the built and physical, social, or ambient environment. Sleep health will be the primary outcome for these analyses and will be captured using a composite score based on 4 indicators from the baseline survey as shown in Table 1, which includes subjective sleep quality, insomnia severity, daytime dysfunction, and use of sleeping medication. A Monte Carlo power analysis for indirect effects for a model with 2 serial mediators [69] should have adequate power (0.78-0.82) for a sample size of 160 participants, assuming a moderate correlation between the predictor and mediators.

For goal 2, the diary data will be analyzed using multilevel modeling in which the 14 observations (7 nights and mornings) are nested within the individual respondents [70]. This approach will allow us to test within- and between-subject effects simultaneously. Within-subject analyses will address whether participants report worse or better sleep health than on previous days, depending on experiences they had that day, as well as potential lagged effects. The between-subject analyses will address whether certain baseline characteristics predict individual variability in daily reactivity. For the multilevel modeling, it is not possible to calculate expected power without making assumptions about the covariance matrix, because work on police surveillance and sleep of this kind is still exploratory. However, within-subjects models tend to be more robust in their assumptions and require a smaller sample, compared with between-subject analyses. For example, assuming a repeated measures analysis of variance with 14 measurements per person, a diary sample size of 72 participants is sufficiently powered (0.85) to detect a small effect size (f=0.1).

Results

The study received funding in July 2024. Data collection commenced in September 2024. Data collection is underway, and the results are forthcoming. As of August 2025, we have enrolled more than 100 participants in the baseline survey; approximately 35 randomly selected participants have also consented to the diary study.

Discussion

Principal Findings

The study is important in that it is one of the few to consider the role of overt and covert policing on sleep health within a single city (where all neighborhoods share the same law enforcement policies), and how these factors vary among neighborhoods based on their socioeconomic and racial or ethnic makeup. Moreover, this study will help elucidate the pathways by which residential disadvantage is associated with sleep health. Furthermore, using a 1-week diary study should help us to better

understand the real-time impact of policing and crime on mental health and sleep health across different neighborhood contexts.

Dissemination Plan

Findings will be disseminated broadly at professional conferences and in peer-reviewed publications. Given that we are at a primarily undergraduate institution (PUI) that is also a commuter campus, this study presents a unique opportunity to train future scholars in the areas of sleep health, health disparities, and health psychology. Thus, some of our dissemination efforts will include our student research assistants and will target student-oriented conferences, presentation opportunities, and peer-reviewed journals (eg, *Psi Chi Journal of Psychological Research*). We also plan to share a summary of the findings with the NYC community boards serving the NTAs where the data are collected.

Limitations

Funding and time constraints restricted our ability to make the study materials available in other languages. We recognize that the exclusion of non-English–speaking NYC residents, particularly those who speak Spanish, will potentially limit generalizability. Previous research has identified budget constraints, as well as interpretation and translation services, among others, as barriers to the inclusion of participants who speak a language other than English [71]. To mitigate these concerns and capture perspectives of non-English–speaking persons in future studies, it is recommended that researchers plan for interpretation and translation of study materials in grant proposal budgets and seek institutional guidance for accessing these critical services [71]. We further acknowledge that Spanish-speaking or bilingual residents might be concerned about participating due to their immigration status; thus, we do not require anyone to disclose their immigration status.

Although eligible participants must own a smartphone to complete the daily diary, potentially reducing generalizability, recent estimates by the Pew Research Center suggest that 91% of US adults own a smartphone [39]. Additionally, our use of self-report measures for sleep and policing experiences is subject to recall bias. However, this risk is mitigated by using daily diary data. Recruitment efforts that are entirely based on street-intercept can be hindered by external factors, such as poor weather conditions (eg, too cold, too hot and humid, rain, or snow), lack of traffic or slow foot traffic, as well as few or limited public spaces within particular NTAs that are conducive to resident traffic (eg, fewer green spaces). Lack of traffic or slow foot traffic may also be related to the timing of our recruitment shifts. For example, late morning shifts in one NTA may be better for recruitment than late morning shifts in another NTA. Finally, our street-intercept recruitment approach does not document the number of persons approached during a shift. We made the decision not to document this because our eligibility criteria are relatively strict (ie, live in the designated NTA; comfortably fluent in English) and there are numerous instances where “no” responses are not necessarily a lack of study interest, but merely reflect ineligibility prior to official screening. Meaning, our population of interest is never fully represented by those who are available during any given recruitment shift. For example, public parks in NYC are inviting to, and often frequented by, individuals who may not live in the surrounding area (ie, the NTA).

Conclusions

The study is expected to be useful for identifying populations and residential settings that are most at risk for poor sleep health and should inform future interventions. Despite the potential recruitment limitations, data collection is ongoing, demonstrating the feasibility of this study’s protocol.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to the ongoing nature of the study but may be available from the corresponding author at the conclusion of the study on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Funding proposal reviewer comments.
[PDF File (Adobe PDF File), 113 KB - resprot_v14i1e82605_app1.pdf]

References

1. Léger D, Poursain B, Neubauer D, Uchiyama M. An international survey of sleeping problems in the general population. Curr Med Res Opin 2008 Jan;24(1):307-317. [doi: 10.1185/030079907x253771] [Medline: 18070379]
2. Leger D, Poursain B. An international survey of insomnia: under-recognition and under-treatment of a polysymptomatic condition. Curr Med Res Opin 2005 Nov;21(11):1785-1792. [doi: 10.1185/030079905X65637] [Medline: 16307699]
3. Ram S, Seirawan H, Kumar SK, Clark GT. Prevalence and impact of sleep disorders and sleep habits in the United States. Sleep Breath 2010 Feb;14(1):63-70. [doi: 10.1007/s11325-009-0281-3] [Medline: 19629554]
4. Americans feel sleepy 3 days a week, with impacts on activities, mood and acuity. National Sleep Foundation. 2020. URL: https://www.thensf.org/wp-content/uploads/2020/03/SIA-2020-Report.pdf [accessed 2025-12-12]
5. Buysse DJ. Sleep health: can we define it? Does it matter? Sleep 2014 Jan 01;37(1):9-17 [FREE Full text] [doi: 10.5665/sleep.3298] [Medline: 24470692]
6. Irwin MR. Why sleep is important for health: a psychoneuroimmunology perspective. Annu Rev Psychol 2015 Jan 03;66:143-172 [FREE Full text] [doi: 10.1146/annurev-psych-010213-115205] [Medline: 25061767]
7. Redline S, Redline B, James P. Sleep epidemiology: an introduction. In: Duncan DT, Kawachi I, Redline S, editors. The Social Epidemiology of Sleep. New York, NY: Oxford University Press; 2019.
8. Robbins R, Seixas A, Williams N, Kim B, Blanc J, Nunes J, et al. Race as a social determinant of sleep health. In: Duncan DT, Kawachi I, Redline S, editors. The Social Epidemiology of Sleep. New York, NY: Oxford University Press; 2019:167-186.
9. Billings ME, Cohen RT, Baldwin CM, Johnson DA, Palen BN, Parthasarathy S, et al. Disparities in sleep health and potential intervention models: a focused review. Chest 2021 Mar;159(3):1232-1240 [FREE Full text] [doi: 10.1016/j.chest.2020.09.249] [Medline: 33007324]
10. Grandner MA. Socioeconomic status and sleep. In: Duncan DT, Kawachi I, Redline S, editors. The Social Epidemiology of Sleep. New York, NY: Oxford University Press; 2019:235-256.
11. Trinh MH, Agénor M, Austin SB, Jackson CL. Health and healthcare disparities among U.S. women and men at the intersection of sexual orientation and race/ethnicity: a nationally representative cross-sectional study. BMC Public Health 2017 Dec 19;17(1):964 [FREE Full text] [doi: 10.1186/s12889-017-4937-9] [Medline: 29258470]
12. Billings ME, Hale L, Johnson DA. Physical and social environment relationship with sleep health and disorders. Chest 2020 May;157(5):1304-1312 [FREE Full text] [doi: 10.1016/j.chest.2019.12.002] [Medline: 31870910]
13. Hunter JC, Hayden KM. The association of sleep with neighborhood physical and social environment. Public Health 2018 Sep;162:126-134 [FREE Full text] [doi: 10.1016/j.puhe.2018.05.003] [Medline: 30036811]
14. Johnson DA, Al-Ajlouni YA, Duncan DT. Connecting neighborhoods and sleep health. In: Duncan DT, Kawachi I, Redline S, editors. The Social Epidemiology of Sleep. New York, NY: Oxford University Press; 2019:409-430.
15. Kim B, Branas CC, Rudolph KE, Morrison CN, Chaix B, Troxel WM, et al. Neighborhoods and sleep health among adults: a systematic review. Sleep Health 2022 Jun;8(3):322-333. [doi: 10.1016/j.sleh.2022.03.005] [Medline: 35504838]
16. Alang S, McAlpine D, McCreedy E, Hardeman R. Police brutality and black health: setting the agenda for public health scholars. Am J Public Health 2017 May;107(5):662-665 [FREE Full text] [doi: 10.2105/AJPH.2017.303691] [Medline: 28323470]
17. Bor J, Venkataramani AS, Williams DR, Tsai AC. Police killings and their spillover effects on the mental health of Black Americans: a population-based, quasi-experimental study. Lancet 2018 Jul 28;392(10144):302-310 [FREE Full text] [doi: 10.1016/S0140-6736(18)31130-9] [Medline: 29937193]
18. Smith Lee JR, Robinson MA. "That's my number one fear in life. It's the police": examining young black men's exposures to trauma and loss resulting from police violence and police killings. J Black Psychol 2019 Jul 30;45(3):143-184 [FREE Full text] [doi: 10.1177/0095798419865152]
19. McLeod MN, Heller D, Manze MG, Echeverria SE. Police interactions and the mental health of Black Americans: a systematic review. J Racial Ethn Health Disparities 2020 Feb;7(1):10-27. [doi: 10.1007/s40615-019-00629-1] [Medline: 31482464]
20. Smith JR, Patton DU. Posttraumatic stress symptoms in context: examining trauma responses to violent exposures and homicide death among Black males in urban neighborhoods. Am J Orthopsychiatry 2016 Mar;86(2):212-223. [doi: 10.1037/ort0000101] [Medline: 26963344]
21. Lo Martire V, Caruso D, Palagini L, Zoccoli G, Bastianini S. Stress and sleep: a relationship lasting a lifetime. Neurosci Biobehav Rev 2020 Oct;117:65-77. [doi: 10.1016/j.neubiorev.2019.08.024] [Medline: 31491473]
22. Oliver M, Kugler MB. Surveying surveillance: a national study of police department surveillance technologies. Arizona State Law J 2021;54:103 [FREE Full text] [doi: 10.2139/ssrn.3911442]
23. Goldenberg S, Anuta J. Adams eyes expansion of highly controversial police surveillance technology. Politico. 2022 Aug 2. URL: https://www.politico.com/news/2022/02/08/adams-police-surveillance-technology-00006230 [accessed 2025-12-12]
24. Mehta N. The NYPD doesn't report where it deploys police. So scientists used AI, dashcams to find out. Gothamist. 2023 Jul 12. URL: https://gothamist.com/news/nypd-does-not-report-where-it-deploys-police-scientists-used-ai-dashcams-to-find-out [accessed 2025-12-12]
25. Linnemann T, Turner J. Three-dimensional policeman: security, sovereignty and volumetric police power. Theor Criminol 2020 Dec 18;26(1):23-39. [doi: 10.1177/1362480620981103]

26. Cho Y, Ryu SH, Lee BR, Kim KH, Lee E, Choi J. Effects of artificial light at night on human health: a literature review of observational and experimental studies applied to exposure assessment. Chronobiol Int 2015;32(9):1294-1310. [doi: 10.3109/07420528.2015.1073158] [Medline: 26375320]
27. Obayashi K, Saeki K, Iwamoto J, Okamoto N, Tomioka K, Nezu S, et al. Effect of exposure to evening light on sleep initiation in the elderly: a longitudinal analysis for repeated measurements in home settings. Chronobiol Int 2014 May;31(4):461-467. [doi: 10.3109/07420528.2013.840647] [Medline: 24147658]
28. Desantis AS, Diez Roux AV, Moore K, Baron KG, Mujahid MS, Nieto FJ. Associations of neighborhood characteristics with sleep timing and quality: the Multi-Ethnic Study Of Atherosclerosis. Sleep 2013 Oct 01;36(10):1543-1551 [FREE Full text] [doi: 10.5665/sleep.3054] [Medline: 24082314]
29. Simonelli G, Dudley KA, Weng J, Gallo LC, Perreira K, Shah NA, et al. Neighborhood factors as predictors of poor sleep in the Sueño ancillary study of the Hispanic Community Health Study/Study of Latinos. Sleep 2017 Jan 01;40(1):zsw025 [FREE Full text] [doi: 10.1093/sleep/zsw025] [Medline: 28364454]
30. Troxel WM, DeSantis A, Richardson AS, Beckman R, Ghosh-Dastidar B, Nugroho A, et al. Neighborhood disadvantage is associated with actigraphy-assessed sleep continuity and short sleep duration. Sleep 2018 Oct 01;41(10):zsy140 [FREE Full text] [doi: 10.1093/sleep/zsy140] [Medline: 30016507]
31. Downing JMJ, Budescu M, Gonzalez T, Gregory K, Ortega D, Vitiello S, et al. Sleep health, stress, and neighborhood perceptions of crime, safety, and walkability in the Bronx. In: Proceedings of the APA 2023 Convention. 2023 Presented at: APA 2023 Convention; August 3-5, 2023; Washington, DC. [doi: 10.1037/e501982025-001]
32. O'Connor AJ, Jahan F. Under surveillance and overwrought: American Muslims' emotional and behavioral responses to government surveillance. J Muslim Ment Health 2014;8(1) [FREE Full text] [doi: 10.3998/jmmh.10381607.0008.106]
33. Larrabee Sonderlund A, Charifson M, Schoenthaler A, Carson T, Williams NJ. Racialized economic segregation and health outcomes: a systematic review of studies that use the Index of Concentration at the Extremes for race, income, and their interaction. PLoS One 2022 Jan 28;17(1):e0262962 [FREE Full text] [doi: 10.1371/journal.pone.0262962] [Medline: 35089963]
34. Massey DS. Still the linchpin: segregation and stratification in the USA. Race Soc Probl 2020 Jan 07;12:1-12. [doi: 10.1007/s12552-019-09280-1]
35. Krieger N, Waterman PD, Spasojevic J, Li W, Maduro G, Van Wye G. Public health monitoring of privilege and deprivation with the Index of Concentration at the Extremes. Am J Public Health 2016 Feb;106(2):256-263. [doi: 10.2105/AJPH.2015.302955] [Medline: 26691119]
36. Chatterjee N, Hosain GM, Williams S. Condom use with steady and casual partners in inner city African-American communities. Sex Transm Infect 2006 Jun;82(3):238-242 [FREE Full text] [doi: 10.1136/sti.2005.018259] [Medline: 16731677]
37. Graham K, Bernards S, Clapp JD, Dumas TM, Kelley-Baker T, Miller PG, et al. Street intercept method: an innovative approach to recruiting young adult high-risk drinkers. Drug Alcohol Rev 2014 Jul;33(4):449-455. [doi: 10.1111/dar.12160] [Medline: 24890452]
38. NYC Population FactFinder homepage. NYC Population FactFinder. URL: https://popfactfinder.planning.nyc.gov [accessed 2025-12-13]
39. Mobile fact sheet. Pew Research Center. 2025 Nov 20. URL: https://www.pewresearch.org/internet/fact-sheet/mobile/ [accessed 2025-12-13]
40. NSF sleep diary. National Sleep Foundation. 2021 Feb 25. URL: https://www.thensf.org/nsf-sleep-diary/ [accessed 2025-12-13]
41. Buysse DJ, Reynolds CF3, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res 1989 May;28(2):193-213. [doi: 10.1016/0165-1781(89)90047-4] [Medline: 2748771]
42. Bastien CH, Vallières A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med 2001 Jul;2(4):297-307. [doi: 10.1016/s1389-9457(00)00065-4] [Medline: 11438246]
43. Mastin DF, Bryson J, Corwyn R. Assessment of sleep hygiene using the Sleep Hygiene Index. J Behav Med 2006 Jun;29(3):223-227. [doi: 10.1007/s10865-006-9047-6] [Medline: 16557353]
44. Kessler RC, Andrews G, Colpe LJ, Hiripi E, Mroczek DK, Normand SL, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol Med 2002 Aug;32(6):959-976. [doi: 10.1017/s0033291702006074] [Medline: 12214795]
45. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983 Dec;24(4):385-396. [Medline: 6668417]
46. Sternthal MJ, Slopen N, Williams DR. Racial disparities in health: how much does stress really matter? Du Bois Rev 2011;8(1):95-113 [FREE Full text] [doi: 10.1017/S1742058X11000087] [Medline: 29887911]
47. Almeida DM, Wethington E, Kessler RC. The daily inventory of stressful events: an interview-based approach for measuring daily stressors. Assessment 2002 Mar;9(1):41-55. [doi: 10.1177/1073191102091006] [Medline: 11911234]
48. Pedersen T. All about somatic anxiety. PsychCentral. 2022 Jul 8. URL: https://psychcentral.com/anxiety/somatic-anxiety [accessed 2025-12-13]

49. NHANES 2019-2020 questionnaire instruments. Centers for Disease Control and Prevention. 2019. URL: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/questionnaires.aspx?BeginYear=2019 [accessed 2025-12-13]
50. Cerin E, Saelens BE, Sallis JF, Frank LD. Neighborhood Environment Walkability Scale: validity and development of a short form. Med Sci Sports Exerc 2006 Sep;38(9):1682-1691. [doi: 10.1249/01.mss.0000227639.83607.4d] [Medline: 16960531]
51. Smith J, Fisher G, Ryan L, Clarke P, House J, Weir D. Psychosocial and lifestyle questionnaire 2006 - 2010. University of Michigan. 2013. URL: https://hrsonline.isr.umich.edu/sitedocs/userg/HRS2006-2010SAQdoc.pdf [accessed 2025-12-13]
52. Duncan DT, Ruff RR, Chaix B, Regan SD, Williams JH, Ravenell J, et al. Perceived spatial stigma, body mass index and blood pressure: a global positioning system study among low-income housing residents in New York City. Geospat Health 2016 May 31;11(2):399 [FREE Full text] [doi: 10.4081/gh.2016.399] [Medline: 27245795]
53. Martin AJ, Wellen JM, Grimmer MR. An eye on your work: how empowerment affects the relationship between electronic surveillance and counterproductive work behaviours. Int J Hum Resour Manag 2016 Sep 27;27(21):2635-2651. [doi: 10.1080/09585192.2016.1225313]
54. Boehme HM, Cann D, Isom DA. Citizens' perceptions of over- and under-policing: a look at race, ethnicity, and community characteristics. Crime Delinq 2020 Dec 03;68(1):123-154. [doi: 10.1177/0011128720974309]
55. Ratcliffe JH, Groff ER, Sorg ET, Haberman CP. Citizens' reactions to hot spots policing: impacts on perceptions of crime, disorder, safety and police. J Exp Criminol 2015 Apr 19;11:393-417. [doi: 10.1007/s11292-015-9230-2]
56. DeVylder JE, Oh HY, Nam B, Sharpe TL, Lehmann M, Link BG. Prevalence, demographic variation and psychological correlates of exposure to police victimisation in four US cities. Epidemiol Psychiatr Sci 2017 Oct;26(5):466-477 [FREE Full text] [doi: 10.1017/S2045796016000810] [Medline: 27834166]
57. Higgins-Biddle JC, Babor TF. A review of the Alcohol Use Disorders Identification Test (AUDIT), AUDIT-C, and USAUDIT for screening in the United States: past issues and future directions. Am J Drug Alcohol Abuse 2018 May 03;44(6):578-586 [FREE Full text] [doi: 10.1080/00952990.2018.1456545] [Medline: 29723083]
58. McNeely J, Cleland CM, Strauss SM, Palamar JJ, Rotrosen J, Saitz R. Validation of self-administered single-item screening questions (SISQs) for unhealthy alcohol and drug use in primary care patients. J Gen Intern Med 2015 Dec;30(12):1757-1764 [FREE Full text] [doi: 10.1007/s11606-015-3391-6] [Medline: 25986138]
59. Poortinga W, Calve T, Jones N, Lannon S, Rees T, Rodgers SE, et al. Neighborhood quality and attachment: validation of the revised residential environment assessment tool. Environ Behav 2017 Apr 27;49(3):255-282. [doi: 10.1177/0013916516634403] [Medline: 28260806]
60. The built environment: an assessment tool and manual. Centers for Disease Control and Prevention. 2015 Jul 12. URL: https://www.cdc.gov/nccdphp/dnpao/state-local-programs/built-environment-assessment/pdfs/BuiltEnvironment-v3.pdf [accessed 2025-12-13]
61. Cain K, Millstein R, Geremia C. Microscale Audit of Pedestrian Streetscapes (MAPS). 2012. URL: https://www.drjimsallis.com/maps
62. Perkins DD, Meeks JW, Taylor RB. The physical environment of street blocks and resident perceptions of crime and disorder: implications for theory and measurement. J Environ Psychol 1992 Mar;12(1):21-34. [doi: 10.1016/s0272-4944(05)80294-4]
63. Perkins DD, Larsen C, Brown BB. Mapping urban revitalization: using GIS spatial analysis to evaluate a new housing policy. J Prev Interv Community 2009;37(1):48-65. [doi: 10.1080/10852350802498698] [Medline: 19197674]
64. Clifton KJ, Livi Smith AD, Rodriguez D. The development and testing of an audit for the pedestrian environment. Landsc Urban Plann 2007 Mar;80(1-2):95-110. [doi: 10.1016/j.landurbplan.2006.06.008]
65. Cunningham GO, Michael YL, Farquhar SA, Lapidus J. Developing a reliable senior walking environmental assessment tool. Am J Prev Med 2005 Oct;29(3):215-217. [doi: 10.1016/j.amepre.2005.05.002] [Medline: 16168871]
66. Population. NYC Planning. URL: https://www.nyc.gov/content/planning/pages/planning/population [accessed 2025-12-13]
67. NIOSH sound level meter app. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/niosh/noise/about/app.html [accessed 2025-12-13]
68. Noisy Planet Free Sound Level Meter App. Puro Sound Labs. 2019. URL: https://purosound.com/blogs/news/noisy-planet [accessed 2025-12-13]
69. Schoemann AM, Boulton AJ, Short SD. Determining power and sample size for simple and complex mediation models. Soc Psychol Pers Sci 2017 Jun 15;8(4):379-386 [FREE Full text] [doi: 10.1177/1948550617715068]
70. Bolger N, Laurenceau JP. Intensive Longitudinal Methods: An Introduction to Diary and Experience Sampling Research. New York, NY: Guilford Press; 2013.
71. Hoffman H, Doan TT, Migliori O, Khan A, Sidani J, Liu S, et al. Researcher perceptions of inclusion of study participants who use languages other than English. JAMA Netw Open 2025 Mar 03;8(3):e252380 [FREE Full text] [doi: 10.1001/jamanetworkopen.2025.2380] [Medline: 40152859]

Abbreviations

ICE: Index of Concentration at the Extremes

NTA: neighborhood tabulation area
NYC: New York City
PUI: primarily undergraduate institution
SES: socioeconomic status

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Protocol

Clinical Effectiveness and Cost-Effectiveness of Collaborative Treatment With Korean and Western Medicine for Primary Headache Disorders: Protocol for a Multicenter Prospective Observational Study

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Abstract

Background: Primary headache disorders, including migraine and tension-type headache, are among the most prevalent neurological conditions worldwide, significantly contributing to disability and socioeconomic burden. While Western medicine (WM) predominantly focuses on pharmacological symptom management, Korean medicine (KM) emphasizes a holistic, individualized approach using modalities such as acupuncture and herbal medicine. Collaborative treatment, which combines these approaches, has been proposed as an alternative approach; however, robust evidence on its clinical effectiveness and cost-effectiveness remains limited.

Objective: This study aims to evaluate the clinical effectiveness and economic value of collaborative treatment compared with usual care (UC) in patients with primary headache disorders in real-world clinical settings.

Methods: This prospective, 2-arm, multicenter observational study will assess and compare the clinical effectiveness and economic value of collaborative treatment versus UC alone for patients with primary headache disorders. Adults aged ≥19 years with a primary diagnosis of primary headache disorders visiting participating hospitals under South Korea's national collaborative treatment pilot project will be enrolled. Participants will receive either collaborative treatment (integrating WM pharmacotherapy with KM therapies such as acupuncture, pharmacopuncture, and herbal medicine) or UC (monodisciplinary care with WM or KM alone) based on informed choice. Clinical and cost-related outcomes will be assessed at baseline and 6 and 12 weeks. Clinical outcomes include monthly headache days, the numeric rating scale, the Headache Impact Test, the EQ-5D-5L, and the EuroQol visual analogue scale. The cost-effectiveness evaluation includes the cost per quality-adjusted life year, the incremental cost-effectiveness ratio, and the cost-effectiveness acceptability curve. Both intention-to-treat and per-protocol analyses will be performed.

Results: The study protocol was approved by the institutional review boards in July 2025. The study is funded by the Ministry of Health and Welfare, Republic of Korea (grant 202500900001). Participant recruitment commenced in August 2025, aiming to enroll 312 patients across multiple centers. Data collection is currently ongoing and is projected to be completed by December 2027, with results expected to be published in 2028.

Conclusions: This study is designed to generate real-world evidence on whether collaborative treatment yields superior clinical outcomes and greater cost-effectiveness compared to UC for primary headache disorders. The findings are expected to address

existing evidence gaps by integrating multidimensional clinical and economic measures, supporting informed decision-making for health policy, and contributing to the advancement of collaborative treatment models for headache management within South Korea's medical system and beyond.

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KEYWORDS

primary headache disorders; collaborative treatment; cost-effectiveness; quality-adjusted life year; QALY

Introduction

Headache disorders are among the most prevalent neurological conditions worldwide, affecting over 52% of the global population and contributing substantially to disability and health care costs [1,2]. According to the Global Burden of Disease 2019 study, headache disorders rank as the leading cause of years lived with disability worldwide [1,3]. In South Korea, National Health Insurance Service (NHIS) data from 2023 indicate that 580,292 patients were treated for migraine and 543,750 were treated for other headache disorders, such as tension-type headache (TTH), with total health care expenditures exceeding KRW 255.82 billion (US $172.6 million) [4]. Additionally, chronic headaches can lead to reduced productivity, depression, and insomnia [5,6].

Headache disorders are classified into primary and secondary types; primary headache disorders, encompassing migraine and TTH, are estimated to account for approximately 90% of all headache cases [7]. Primary headache disorders are typically managed with pharmacological interventions, whereas the priority for secondary headache disorders lies in identifying and treating the underlying cause [8]. Pharmacological treatments for primary headache disorders—such as nonsteroidal anti-inflammatory drugs and tricyclic antidepressants—often demonstrate limited long-term efficacy and may cause adverse effects [9-11]. Chronic headache in particular is frequently resistant to pharmacotherapy, and overuse of analgesics can exacerbate headache symptoms [9,12].

These substantial impacts underscore the urgent need for structured, multidisciplinary national strategies and alternative approaches for the management and treatment of primary headache disorders [5,13].

Korean medicine (KM) uses a whole person–centered approach, identifying health conditions not merely as localized pathologies but as "patterns" that reflect the systemic active response of the patient. Unlike a disorder diagnosis, which focuses on the pathological process itself, pattern differentiation in KM incorporates systemic findings, innate or acquired constitutional traits, and the balance of yin and yang to capture the individual characteristics of the patient [14,15]. Specifically, electroacupuncture has proven effective in mitigating chronic headache severity, offering a viable option when pharmacological treatments yield limited results [16]. Collaborative treatment aims to integrate these holistic, restorative benefits of KM with the rapid symptom relief provided by Western medicine (WM) [17-20]. There is emerging evidence suggesting that collaborative care can reduce headache frequency and intensity more effectively than monotherapy alone [19,21]. However, robust clinical data comparing the effectiveness and cost-efficiency of collaborative treatment for various health conditions, including primary headache disorders, remain limited [22-24]. Since 1951, South Korea has maintained a dual medical system that legally recognizes both WM and KM [25]. While this structure preserves patient choice and cultural tradition, it can also result in overlapping resources and practice-related disputes [26]. To address these challenges, pilot programs were introduced to support WM-KM collaboration [27]. Despite these initiatives, barriers persist. Treatments from both disciplines provided on the same day for the same condition are typically not jointly reimbursed under the NHIS, resulting in higher out-of-pocket costs for patients [28]. Additionally, limited information exchange and the absence of standardized protocols hinder effective interdisciplinary coordination. To overcome these obstacles, the Korean government launched pilot programs that expanded insurance coverage for collaborative treatment, resulting in improved satisfaction among patients and medical professionals and reduced treatment duration [29,30].

Since its launch in 2016, South Korea's pilot program for collaborative treatment has progressed through 4 stages and is now preparing for its fifth phase [28,30]. The program has gradually evolved from parallel practice to protocol-based models for specific conditions, along with a unified reimbursement system and strengthened institutional support for collaborative treatment [24,30,31]. Notable advancements include the introduction of interinstitutional electronic medical record sharing systems and joint training programs for WM and KM practitioners. Nonetheless, persistent challenges—such as fragmented delivery systems, insufficient clinical experience with interdisciplinary practice, and the lack of unified clinical guidelines—continue to limit the wider adoption of collaborative care models. To address these gaps and validate the feasibility of a structured collaborative model before a large-scale trial, preliminary data are required. Before designing this multicenter trial, we conducted an internal pilot study (KCT0010198) involving 59 patients with primary headache disorders to assess feasibility and preliminary efficacy.

The primary objective of this multicenter study is to investigate whether collaborative treatment provides greater clinical effectiveness and cost-efficiency for patients with primary headache disorders compared to usual care (UC) alone. We hypothesize that patients receiving collaborative treatment will exhibit significantly greater improvements in headache intensity (numeric rating scale; NRS) and frequency (monthly headache days; MHDs) compared to those receiving UC and that

collaborative treatment will prove to be a cost-effective strategy from a societal perspective. To achieve this, we will conduct a prospective, multicenter observational study using validated patient-centered instruments focusing on headache-related disability, quality of life, and self-rated health status alongside an economic evaluation based on health care costs and utility measures.

Methods

Study Design

This is a prospective, 2-arm, multicenter observational study of patients with primary headache disorders at medical institutions participating in the fifth phase of the national pilot project for collaborative treatment [28]. The study protocol was developed following the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines (Multimedia Appendix 1) and registered with the Clinical Research Information Service of South Korea (registration KCT0010812; July 28, 2025) [32]. The study will be conducted as part of the Registry for Korean Medicine and Western Medicine Collaborative Treatment study, with participant recruitment scheduled from the date of institutional review board approval to December 12, 2025. The detailed study schedule, as outlined in the SPIRIT guidelines, is illustrated in Table 1. Additionally, a schematic diagram displaying the study flow and timing of assessments is presented in Figure 1.

Table 1. Schedule of enrollment and assessments according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines.

	Study stage			
	Enrollment	Baseline and allocation	Treatment and follow-up	
			6 weeks	12 weeks
Enrollment				
Informed consent	✓			
Inclusion and exclusion criteria	✓			
Sociodemographic information and medical history		✓		
Assessments				
MHDs[a]		✓	✓	✓
NRS[b]		✓	✓	✓
HIT-6[c]		✓	✓	✓
EQ-5D-5L		✓	✓	✓
EQ-VAS[d]		✓	✓	✓
Cost information			✓	✓
Hospital medical records and administrative data				✓

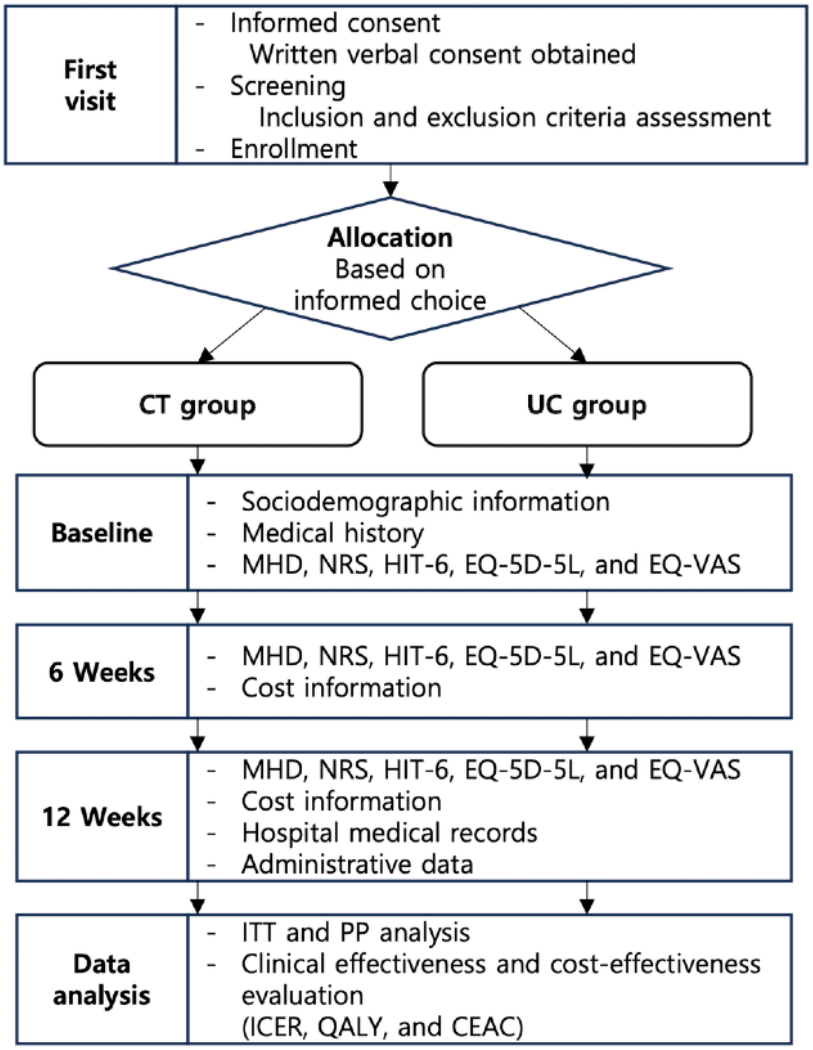
[a]MHD: monthly headache day.

[b]NRS: numeric rating scale.

[c]HIT-6: Headache Impact Test.

[d]EQ-VAS: EuroQol visual analogue scale.

Figure 1. Schematic figure displaying the study flow and timing of assessments. CEAC: cost-effectiveness acceptability curve; CT: collaborative treatment; EQ-VAS: EuroQol visual analogue scale; HIT-6: Headache Impact Test; ICER: incremental cost-effectiveness ratio; ITT: intention to treat; MHD: monthly headache day; NRS: numerical rating scale; PP: per protocol; QALY: quality-adjusted life year; UC: usual care.



Participants and Treatments

The study participants comprise patients diagnosed with primary headache disorders who visit hospitals participating in the fifth phase of the collaborative treatment pilot project and receive either collaborative treatment or UC alone [28]. Patients receiving UC are those treated exclusively with either KM or WM, whereas collaborative treatment refers to treatment involving both KM and WM. To minimize treatment heterogeneity and ensure clinical rigor, the therapeutic procedures for both WM and KM are conducted in strict accordance with the standard clinical practice guidelines (CPGs) for headaches in South Korea [10,33,34]. Specifically, following these standard CPGs, WM interventions typically involve acute abortive medications (eg, nonsteroidal anti-inflammatory drugs and triptans) and prophylactic agents (eg, β-blockers, anticonvulsants, and antidepressants) tailored to the specific headache disorder. Similarly, KM interventions are standardized to include acupuncture, electroacupuncture, pharmacopuncture (herbal injection), chuna manual therapy, and herbal prescriptions as outlined in the corresponding CPGs. In the collaborative treatment group, these standardized modalities are integrated to maximize therapeutic synergy; for instance, a patient may receive WM pharmacotherapy for rapid pain relief concurrently with KM acupuncture or chuna therapy to relieve muscle tension and address functional imbalances. Conversely, the UC group receives monodisciplinary care consisting exclusively of either WM or KM modalities. To ensure consistency across multiple centers, all participating practitioners will undergo standardized training on the study protocol and clinical guidelines before study initiation. Furthermore, adherence to these treatment standards will be periodically monitored by the Monitoring Center for Korean Medicine and Western Medicine Collaboration (MCMC) throughout the study period.

A nonrandomized observational design was adopted to reflect real-world clinical settings where patient preference acts as a crucial determinant of treatment adherence and outcomes. Consequently, participants will exercise informed choice regarding their treatment modality. During the consultation, practitioners will provide comprehensive information on the expected benefits, potential side effects, and cost implications of both collaborative treatment and UC. On the basis of this shared decision-making process, patients will select their preferred treatment group, ensuring that the study findings

mirror actual health care use patterns in South Korea. If a participant opts for collaborative treatment, one practitioner will initiate a collaborative treatment request to the other practitioner. Treatment choices can be adjusted at any time through consultation with practitioners, and all treatments will be recorded and monitored. Patients who agree to participate will be given detailed information about the study and all safety-related aspects before they provide informed consent. After obtaining written consent, a medical doctor or a KM doctor will assess the participant's eligibility. Those who meet the inclusion criteria will be enrolled in the study and assigned an enrollment number to preserve anonymity. To ensure fair and open participation, announcements about the study will be made publicly available at the participating institutions.

Inclusion Criteria

Inclusion criteria are as follows: (1) adults aged ≥19 years; (2) individuals with a primary diagnosis of primary headache disorders who are first-time outpatients at one of the participating institutions as systematically defined by the *International Classification of Diseases, 10th Revision* (*ICD-10*; G43 [migraine], G44.0 [cluster headaches and other trigeminal autonomic cephalgias], G44.2 [TTH], and G44.8 [other specified headache syndromes]); and (3) individuals who voluntarily agree to participate in the study or whose legal representatives provide both written and verbal informed consent.

Exclusion Criteria

Exclusion criteria are as follows: (1) individuals covered by automobile insurance (ineligible for treatment under the collaborative treatment pilot project) [28], (2) individuals with difficulty understanding the research questionnaire, (3) individuals with difficulty adhering to the study schedule and follow-up assessments, (4) individuals deemed unsuitable for participation at the discretion of the investigator, and (5) individuals participating in the national pilot project for herbal medicine coverage under the NHIS [28].

Sample Size Estimation

To determine the appropriate sample size, we referenced data from our preceding pilot study, which was a multicenter prospective observational study conducted across 5 medical institutions during the fourth phase of the national collaborative treatment pilot project (December 2023-December 2024). This pilot study aimed to assess the feasibility and preliminary clinical effectiveness of collaborative treatment versus UC in patients with migraine (*ICD-10* code G43) and other headache syndromes (*ICD-10* code G44; Clinical Research Information Service registration KCT0010198). On the basis of the analysis of 59 participants from this pilot study, the NRS values were derived (group 1: mean 1.85, SD 1.66; group 2: mean 2.48, SD 2.13). Using the G*Power program with a 2-sided significance level of .05 and power of 80% (α=.05) and adjusting for a 10% discontinuation rate, the total required sample size for the study was determined to be 312 participants.

Data Collection and Management

Data for the study will be collected through participant surveys using a standardized case report form (CRF). The CRF is designed to capture participants' baseline characteristics, hospital medical records, and administrative data from each participating institution. This includes sociodemographic information, medical history, clinical indicators, and cost-related details. Administrative and medical data will be used to assess treatment costs associated with primary headache disorders, types and frequencies of treatment, medical expenses, duration of health care use, and types of services used. Trained and experienced researchers at each institution will be responsible for collecting both baseline and follow-up data. Face-to-face or telephone interviews will be conducted. All data will be entered and managed using the Internet-Based Clinical Research and Trial Management System developed by the Korea National Institute of Health. To protect participant confidentiality, all collected documents will use identification codes instead of personal names and will be stored as encrypted files, with access limited to authorized researchers. The MCMC will independently oversee data handling, storage, and validation throughout the study. This center, established under the Ministry of Health and Welfare as part of the fifth phase of the national pilot project, will serve as the study's executive data management body. The monitoring center personnel will ensure compliance with the observational study protocol, authorize any modifications to the registry protocol, oversee the accuracy and appropriateness of data collection, and verify that informed consent has been properly obtained from all participants.

Ethical Considerations

The study adheres to the principles outlined in the Declaration of Helsinki and follows good research practices as recommended by the Professional Society for Health Economics and Outcomes Research [35]. This study protocol was reviewed and approved by the institutional review boards of Wonkwang University Gwangju Oriental Medicine Hospital (approval WKIRB-2025-10) and Dongshin University Mokpo Oriental Medicine Hospital (approval DSMOH25-4). Written informed consent will be obtained from all participants or their legal representatives before enrollment. Participants will be fully informed about the study's purpose, procedures, and potential risks and their right to withdraw at any time without penalty. To ensure privacy and confidentiality, all participant data will be deidentified and assigned a unique study identification code. Personal information will be stored separately from clinical data in encrypted files accessible only to authorized research personnel. No financial compensation is provided for participation.

Measures

Baseline Characteristics

The participants' baseline information will be collected on the first hospital visit. This includes age, gender, monthly household income (in KRW), history of treatment for primary headache disorders and other medical conditions, medication use, occupation and employment status, insurance status, and onset duration (duration from headache onset to first hospital visit).

Clinical Effectiveness

The clinical effectiveness of the treatment will be evaluated using MHDs [36], the NRS [37], the Headache Impact Test (HIT-6) [38,39], the EQ-5D-5L [40], and the EuroQol visual

analogue scale (EQ-VAS) [41], with assessments conducted at each study time point: baseline and 6 and 12 weeks. Evidence indicates that increases in MHDs are linked to lower health-related quality of life (HRQOL) and that a reduction in MHDs by ≤4 contributes to improved patient health outcomes [36,42]. Thus, assessing MHDs in this study is crucial for evaluating treatment efficacy. The NRS measures overall pain intensity and discomfort associated with headache, with patients rating their pain on a scale from 0 (no pain) to 10 (worst pain imaginable) [37,43].

The HIT-6 is a widely used validated tool designed to measure the impact of headaches on a patient's ability to function normally in daily life, comprising 6 items, each with 5 graded response options [38,39]. Each response is assigned a score ranging from 6 to 13 points per item, resulting in total scores that range from 36 to 78, with higher scores indicating greater impact or burden of headaches [44]. The patients' HRQOL will be evaluated using the Korean version of the EQ-5D-5L [45]. The EQ-5D-5L assesses HRQOL across 5 dimensions: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression [40,46]. The EQ-VAS will be used to measure the patients' self-perceived health status on a scale from 0 to 100 [41,47]. Higher scores on the EQ-5D-5L and EQ-VAS indicate better HRQOL and overall health, respectively.

Cost-Effectiveness

Cost use for both treatments will be comprehensively assessed, including direct medical costs, direct nonmedical costs, and indirect costs such as productivity losses, derived from CRFs and hospital administrative data. The cost-effectiveness of the treatments will be evaluated using several measures: cost per quality-adjusted life year (QALY) [48,49], the incremental cost-effectiveness ratio (ICER) [50], and the cost-effectiveness acceptability curve (CEAC) [51]. The cost per QALY will be estimated using the area under the curve method [48,52] based on utility scores captured through the EQ-5D-5L and EQ-VAS. The ICER, representing the economic value of collaborative treatment compared with UC, is determined by dividing the incremental cost by the incremental QALYs gained [50,53]. The CEAC illustrates the probability that a treatment is cost-effective across a range of willingness-to-pay thresholds per QALY, with the horizontal axis denoting willingness-to-pay values and the vertical axis representing the corresponding probabilities [51,54].

Safety

This study establishes standardized guidelines for reporting adverse events during the study period. All abnormal symptoms, adverse effects, or illnesses occurring in participants—regardless of their relation to the treatment received—will be documented. Recorded data will include a description of the event, time of onset, severity assessment by the practitioner, and relationship to the treatment. The research team will assess participant eligibility and determine the need for withdrawal. Additional visits may be scheduled for further evaluation. For participants who withdraw, the reasons will be documented, assessed, and followed up on accordingly.

Statistical Analyses

Baseline data will be summarized using descriptive statistics such as percentages, frequencies, and means and SDs for both the UC and collaborative treatment groups. The UC group refers to participants receiving treatment exclusively with either KM or WM, whereas the collaborative treatment group includes those receiving both KM and WM. Data normality will be evaluated using the Shapiro-Wilk test and *Q-Q* plots. Between-group differences will be assessed using chi-square tests (Fisher exact test) for categorical data and the 2-tailed Student *t* test or ANOVA for continuous data. When normality or equal variance assumptions are violated, the Mann-Whitney *U* test and Kruskal-Wallis test will be performed.

Per-protocol and intention-to-treat (ITT) analyses will be conducted to assess clinical effectiveness and cost-effectiveness. To establish the ITT dataset, the proportion and mechanism of missing data will be evaluated using the Little test. If the data are identified as missing completely at random or missing at random, as defined by Rubin [55], multiple imputation will be performed [55,56]. Mean changes in clinical outcomes over time will be compared between groups as part of the effectiveness analysis. Furthermore, a generalized linear mixed model will be used to assess between-group effects at each time point. To rigorously control for heterogeneity and potential confounders, the model will adjust for fixed effects, including age, sex, headache history (onset duration), specific diagnosis, and comorbidities. While specific treatment modalities vary, reflecting real-world practice, the analysis adheres to the ITT principle to evaluate the effectiveness of the collaborative treatment strategy compared to UC rather than the efficacy of individual modalities. Subgroup analyses will be performed according to headache type (migraine, TTH, or other) and headache severity (episodic or chronic).

Utility values from the EQ-5D-5L and EQ-VAS will be used to estimate QALYs using the area under the curve method [48]. Deterministic analyses for the ICER will be performed using both ITT and per-protocol data from a limited societal perspective and a societal perspective. A probabilistic sensitivity analysis will also be carried out using parameter distributions and estimates. To account for sampling uncertainty in the ICER point estimates, 95% CIs will be calculated using the bootstrapping method or a seemingly unrelated regression model. All statistical analyses will be conducted using Stata/MP (version 14.0; StataCorp) and SAS (version 9.4; SAS Institute), with the significance level set at a P value of <.05.

Results

The study was funded in June 2025. This trial protocol was approved by the institutional review boards in July 2025. Participant recruitment commenced in August 2025, with a target enrollment of 312 patients across multiple clinical centers. As of December 2025, participant recruitment is ongoing. Baseline data collection includes sociodemographic characteristics, clinical history, and treatment preferences. Clinical outcomes (MHDs, NRS, and HIT-6), HRQOL (EQ-5D-5L and EQ-VAS), and economic measures (QALYs, ICER, and CEAC) are being systematically collected during

the study period. Data collection is expected to be completed by December 2027, and results are expected to be published in summer 2028.

Discussion

Anticipated Findings and Comparison to Prior Work

We hypothesize that collaborative treatment will provide greater reduction in headache frequency and intensity compared to UC while demonstrating its cost-effectiveness from a societal perspective. By incorporating real-world data from multiple medical institutions participating in the fifth phase of the national collaborative treatment pilot project, the study integrates multidimensional patient-centered measures to provide evidence supporting effective and sustainable collaborative treatment integration in headache treatment.

Previous studies on KM, WM, or collaborative treatment for headaches have shown potential benefits, including pain reduction and improved quality of life [10,18,19,22,57]. However, the evidence remains limited and inconsistent, often relying on single-center designs and short follow-up periods and lacking cost-effectiveness analyses, thereby reducing both generalizability and methodological rigor [17,18,58].

Unlike prior research, this study intends to address these gaps by using a multicenter prospective design with a comprehensive cost-effectiveness analysis, thereby aiming to provide more generalizable evidence on the clinical and economic value of integrating pharmacological and nonpharmacological interventions. Furthermore, this study follows the research framework previously applied in a study for facial palsy [24], supporting the feasibility of our approach.

Strengths and Limitations

The strength of this study lies in its real-world, multicenter design within South Korea's national health care framework, enhancing the generalizability of the findings. To our knowledge, this is the first study to comprehensively evaluate both the clinical effectiveness and cost-effectiveness of collaborative treatment for primary headache disorders. In interpreting the findings, certain methodological considerations inherent to this observational design should be noted. While the nonrandomized design and patient-driven treatment choices introduce potential selection bias, these features are inherent to observational studies reflecting actual clinical practice. To rigorously mitigate these factors, we will use generalized linear mixed models to control for baseline differences and injury mechanisms. Additionally, although the exclusion of patients covered by automobile insurance may limit generalizability to specific posttraumatic cases, this criterion aligns with the current operational guidelines of the national collaborative treatment pilot project. Regarding potential heterogeneity across institutions, standardized treatment protocols based on CPGs have been implemented across all centers to ensure consistency. Finally, cost data derived from patient self-reports will be cross-verified where possible to minimize recall bias. Finally, as this study is embedded within South Korea's dual health care system, the findings may have specific relevance to similar integrative models but require careful adaptation for countries with different health care structures.

Dissemination

The findings of this study will be disseminated through academic conferences and seminars and published in peer-reviewed journals. In addition, the results will inform the development of CPGs for the use of collaborative treatment for primary headache disorders. Progress updates will be reported annually, and ongoing information and additional resources will be made available through the MCMC's dedicated website.

Future Directions and Conclusions

If our hypotheses are confirmed, this study will generate robust, actionable evidence on the clinical effectiveness and cost-effectiveness of collaborative treatment for primary headache disorders. Beyond confirming efficacy, the findings will provide critical data to standardize collaborative treatment protocols and optimize insurance reimbursement models. This contributes to the growing body of evidence supporting collaborative approaches in chronic disease management, including primary headache disorders, and may help inform policy development for collaborative treatment–based health care delivery in South Korea and beyond.

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Data Availability

Data sharing is not applicable to this paper as no datasets were generated or analyzed during this study.

Authors' Contributions

JK and JY conducted the literature review and wrote the original draft. LK contributed to study design, conducted the literature review, developed the manuscript structure, and performed critical clinical review. SRA contributed to study design, performed data analysis, provided statistical review, and wrote the statistical sections of the manuscript. CH performed critical clinical review, contributed ethical perspectives to support institutional review board approval, and revised the manuscript for intellectual

and clinical content. NK supervised the overall study and serves as the corresponding author. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
SPIRIT 2025 checklist.
[PDF File (Adobe PDF File), 127 KB - resprot_v14i1e82819_app1.pdf]

References

1. Stovner LJ, Hagen K, Linde M, Steiner TJ. The global prevalence of headache: an update, with analysis of the influences of methodological factors on prevalence estimates. J Headache Pain 2022 Apr 12;23(1):34 [FREE Full text] [doi: 10.1186/s10194-022-01402-2] [Medline: 35410119]
2. Peng KP, Wang SJ. Epidemiology of headache disorders in the Asia-Pacific region. Headache 2014 Apr 25;54(4):610-618. [doi: 10.1111/head.12328] [Medline: 24666014]
3. GBD 2019 Diseases and Injuries Collaborators. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet 2020 Oct 17;396(10258):1204-1222 [FREE Full text] [doi: 10.1016/S0140-6736(20)30925-9] [Medline: 33069326]
4. Health insurance statistics. Korean Statistical Information Service. 2023. URL: https://kosis.kr/statHtml/statHtml.do?orgId=350&tblId=DT_35001_A075111&conn_path=I2 [accessed 2025-12-22]
5. Kim KM, Cho SJ, Shin HJ, Yang KI, Kim D, Yun CH, et al. Prevalence, disability, and management patterns of migraine in Korea: nationwide survey data from 2009 and 2018. J Clin Neurol 2021 Jan;17(1):77-85 [FREE Full text] [doi: 10.3988/jcn.2021.17.1.77] [Medline: 33480202]
6. Kim BK, Chu MK, Lee TG, Kim JM, Chung CS, Lee KS. Prevalence and impact of migraine and tension-type headache in Korea. J Clin Neurol 2012 Sep;8(3):204-211 [FREE Full text] [doi: 10.3988/jcn.2012.8.3.204] [Medline: 23091530]
7. Rizzoli P, Mullally WJ. Headache. Am J Med 2018 Jan;131(1):17-24. [doi: 10.1016/j.amjmed.2017.09.005] [Medline: 28939471]
8. Gama-Reyes EG, de Caceres-García AN, Castillo-Vaca MF, Hernandez-Ramirez J, Jimenez-Romo AE, Fuentes-Mendoza JM, et al. Migraine-like headaches: a systematic review of secondary etiologies, clinical features and therapeutic patterns (1977-2024). J Headache Pain 2025 Oct 28;26(1):232 [FREE Full text] [doi: 10.1186/s10194-025-02151-8] [Medline: 41152703]
9. Ferrari A, Baraldi C, Sternieri E. Medication overuse and chronic migraine: a critical review according to clinical pharmacology. Expert Opin Drug Metab Toxicol 2015 Jul 31;11(7):1127-1144 [FREE Full text] [doi: 10.1517/17425255.2015.1043265] [Medline: 26027878]
10. Kim BS, Chung PW, Chung JM, Park KY, Moon HS, Park HK, The Clinical Practice Guideline Committee of the Korean Headache Society. Evidence-based recommendations on pharmacologic treatment for migraine prevention: a clinical practice guideline from the Korean Headache Society. Headache Pain Res 2025 Feb;26(1):5-20. [doi: 10.62087/hpr.2024.0019]
11. Katsarava Z, Schneeweiss S, Kurth T, Kroener U, Fritsche G, Eikermann A, et al. Incidence and predictors for chronicity of headache in patients with episodic migraine. Neurology 2004 Mar 09;62(5):788-790. [doi: 10.1212/01.wnl.0000113747.18760.d2] [Medline: 15007133]
12. Bendtsen L, Evers S, Linde M, Mitsikostas DD, Sandrini G, Schoenen J, EFNS. EFNS guideline on the treatment of tension-type headache - report of an EFNS task force. Eur J Neurol 2010 Nov;17(11):1318-1325 [FREE Full text] [doi: 10.1111/j.1468-1331.2010.03070.x] [Medline: 20482606]
13. Kim BK, Chu MK, Yu SJ, Dell'Agnello G, Han JH, Cho SJ. Burden of migraine and unmet needs from the patients' perspective: a survey across 11 specialized headache clinics in Korea. J Headache Pain 2021 May 24;22(1):45 [FREE Full text] [doi: 10.1186/s10194-021-01250-6] [Medline: 34030630]
14. Yin CS, Ko SG. Introduction to the history and current status of evidence-based Korean medicine: a unique integrated system of allopathic and holistic medicine. Evid Based Complement Alternat Med 2014;2014:740515 [FREE Full text] [doi: 10.1155/2014/740515] [Medline: 24834097]
15. Hao X, Liang F, Wang L, Greenwood KM, Xue CC, Zheng Z, et al. Identifying Chinese medicine patterns of tension-type headache and understanding its subgroups. Evid Based Complement Alternat Med 2021 Sep 23;2021:5544571 [FREE Full text] [doi: 10.1155/2021/5544571] [Medline: 34603470]
16. Gao N, Wu L, Liu X, Lin Z, Liu Z, Liang J, et al. Effects of electroacupuncture on treatment-resistant chronic migraine with medication overuse headache: a 12-month follow-up case report. Heliyon 2024 Apr 28;10(9):e30417 [FREE Full text] [doi: 10.1016/j.heliyon.2024.e30417] [Medline: 38720738]

17. Mohandes B, Bayoumi FE, AllahDiwaya AA, Falah MS, Alhamd LH, Alsawadi RA, et al. Cupping therapy for the treatment of migraine headache: a systematic review and meta-analysis of clinical trials. J Pharmacopuncture 2024 Sep 30;27(3):177-189. [doi: 10.3831/kpi.2024.27.3.177] [Medline: 39350928]
18. Hwang DR, Lee JH, Hong SH, Choi HM, Park HA. A review of acupuncture treatment for primary headache disorders in Korea. J Acupunct Res 2019 Nov;36(4):187-196. [doi: 10.13045/JAR.2019.00185]
19. Ou MQ, Fan WH, Sun FR, Jie WX, Lin MJ, Cai YJ, et al. A systematic review and meta-analysis of the therapeutic effect of acupuncture on migraine. Front Neurol 2020 Jun 30;11:596 [FREE Full text] [doi: 10.3389/fneur.2020.00596] [Medline: 32714268]
20. Son JY, Goo K, Kim NY, Yang SG, Lee DH, Im YR, et al. Effectiveness and safety of pharmacopuncture on inpatients with tension headache caused by traffic accidents: a pragmatic randomized controlled trial. J Clin Med 2024 Jul 30;13(15):4457 [FREE Full text] [doi: 10.3390/jcm13154457] [Medline: 39124723]
21. Ni X, Dong L, Tian T, Liu L, Li X, Li F, et al. Acupuncture versus various control treatments in the treatment of migraine: a review of randomized controlled trials from the past 10 years. J Pain Res 2020 Aug 12;13:2033-2064 [FREE Full text] [doi: 10.2147/JPR.S259390] [Medline: 32884332]
22. Millstine D, Chen CY, Bauer B. Complementary and integrative medicine in the management of headache. BMJ 2017 May 16;357:j1805. [doi: 10.1136/bmj.j1805] [Medline: 28512119]
23. Lee HG, Kwon S, Goto H, Fujimoto M, Kainuma M, Cho KH. Successful treatment of chronic migraine unresponsive to triptans with herbal medicines containing Cinnamomi Cortex: a case report. Explore (NY) 2025 Mar;21(2):103115. [doi: 10.1016/j.explore.2025.103115] [Medline: 39848118]
24. Acharya SR, Kim L, Kim N. Clinical outcomes and cost-effectiveness of collaborative treatment with Korean and Western medicine in patients with facial palsy: a multicenter prospective observational study. BMC Complement Med Ther 2025 May 15;25(1):178 [FREE Full text] [doi: 10.1186/s12906-025-04910-1] [Medline: 40375250]
25. Wang F. A study on collaborative medical care system of Korean medicine and Western medicine. Chung-Ang J Leg Stud 2021;45(2):207-242. [doi: 10.22853/caujls.2021.45.2.207]
26. Park J, Oh K, Kwon S, Chu H, Kim J. A study on the precedents changing related to using medical devices of Korean medicine doctors. J Int Korean Med 2021 Dec;42(6):1303-1318. [doi: 10.22246/jikm.2021.42.6.1303]
27. Lee KJ, Lee GR, Song YK. A report on the status of cooperation through the Korean medicine and western medicine collaboration process. J Korean Med Rehabil 2019 Jul 31;29(3):129-139. [doi: 10.18325/jkmr.2019.29.3.129]
28. Guidelines for the pilot project in the fifth stage of Western medicine and Korean medicine collaborative treatment. Health Insurance Review and Assessment Service, Ministry of Health and Welfare. URL: https://www.mohw.go.kr/board.es?mid=a10503010100&bid=0027&act=view&list_no=1486295&tag=&nPage=1 [accessed 2025-06-17]
29. Lee SY. Policy directions to promote integrated services of the Western and the Oriental medicines. Health Welf Policy Forum 2004 Nov;97:66-70. [doi: 10.23062/2004.11.6]
30. Park S, Lee Y, Kim L, Acharya SR, Kim N. Assessing patient satisfaction and the need for collaborative treatment with Korean and Western medicine. Healthcare (Basel) 2024 Sep 23;12(18):1901 [FREE Full text] [doi: 10.3390/healthcare12181901] [Medline: 39337242]
31. Lee HY, Cho MK, Kim N, Lee SY, Gong NG, Hyun EH. Comparative effectiveness of collaborative treatment with Korean and Western medicine for low back pain: a prospective cohort study. Evid Based Complement Alternat Med 2021 Jul 28;2021:5535857 [FREE Full text] [doi: 10.1155/2021/5535857] [Medline: 34367301]
32. Clinical Research Information Service. Korea Disease Control and Prevention Agency. URL: https://cris.nih.go.kr [accessed 2025-12-23]
33. Lee SK. Clinical practice guideline of korean medicine for migraine. National Institute for Korean Medicine Development. URL: https://nikom.or.kr/nckm/module/practiceGuide/view.do?guide_idx=171&menu_idx=14 [accessed 2025-05-29]
34. Yook TH. Clinical practice guideline of Korean medicine for headache. National Institute for Korean Medicine Development. URL: https://nikom.or.kr/engnckm/module/practiceGuide/view.do?guide_idx=236&menu_idx=4 [accessed 2025-04-25]
35. Berger ML, Dreyer N, Anderson F, Towse A, Sedrakyan A, Normand SL. Prospective observational studies to assess comparative effectiveness: the ISPOR good research practices task force report. Value Health 2012 Mar;15(2):217-230 [FREE Full text] [doi: 10.1016/j.jval.2011.12.010] [Medline: 22433752]
36. Kaniecki RG, Friedman DI, Asher D, Hirman J, Cady R. Improving to four or fewer monthly headache days per month provides a clinically meaningful therapeutic target for patients with chronic migraine. Pain Ther 2023 Oct 28;12(5):1179-1194 [FREE Full text] [doi: 10.1007/s40122-023-00525-x] [Medline: 37378754]
37. Young IA, Dunning J, Butts R, Cleland JA, Fernández-de-Las-Peñas C. Psychometric properties of the Numeric Pain Rating Scale and Neck Disability Index in patients with cervicogenic headache. Cephalalgia 2019 Jan 19;39(1):44-51. [doi: 10.1177/0333102418772584] [Medline: 29673262]
38. Joo MK, Lim HJ, Joo YS, Kim JY, Kim YJ, Yoo KH, et al. Validity and reliability assessment of Korean Headache Impact Test-6 (HIT-6). J Korean Neurol Assoc 2009;27(1):1-6 [FREE Full text]
39. Houts CR, McGinley JS, Wirth RJ, Cady R, Lipton RB. Reliability and validity of the 6-item headache impact test in chronic migraine from the PROMISE-2 study. Qual Life Res 2021 Mar 20;30(3):931-943 [FREE Full text] [doi: 10.1007/s11136-020-02668-2] [Medline: 33079313]

40. Domitrz I, Golicki D. Health-related quality of life in migraine: EQ-5D-5L-based study in routine clinical practice. J Clin Med 2022 Nov 24;11(23):6925 [FREE Full text] [doi: 10.3390/jcm11236925] [Medline: 36498500]
41. Cheng LJ, Tan RL, Luo N. Measurement properties of the EQ VAS around the globe: a systematic review and meta-regression analysis. Value Health 2021 Aug;24(8):1223-1233 [FREE Full text] [doi: 10.1016/j.jval.2021.02.003] [Medline: 34372988]
42. Lipton RB, Pozo-Rosich P, Orr SL, Reed ML, Fanning KM, Dabruzzo B, et al. Impact of monthly headache days on migraine-related quality of life: results from the Chronic Migraine Epidemiology and Outcomes (CaMEO) study. Headache 2023;63(10):1448-1457 [FREE Full text] [doi: 10.1111/head.14629] [Medline: 37795746]
43. Loder E, Burch R. Measuring pain intensity in headache trials: which scale to use? Cephalalgia 2012 Feb 27;32(3):179-182. [doi: 10.1177/0333102411434812] [Medline: 22287565]
44. Kosinski M, Bayliss MS, Bjorner JB, Ware JE, Garber WH, Batenhorst A, et al. A six-item short-form survey for measuring headache impact: the HIT-6. Qual Life Res 2003 Dec;12(8):963-974. [doi: 10.1023/a:1026119331193] [Medline: 14651415]
45. Kim SH, Ahn J, Ock M, Shin S, Park J, Luo N, et al. The EQ-5D-5L valuation study in Korea. Qual Life Res 2016 Jul 10;25(7):1845-1852. [doi: 10.1007/s11136-015-1205-2] [Medline: 26961008]
46. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011 Dec;20(10):1727-1736 [FREE Full text] [doi: 10.1007/s11136-011-9903-x] [Medline: 21479777]
47. Seong SS, Choi CB, Seong YG, Park YW, Lee HS, Eom WS, et al. Health-related quality of life using EQ-5D in Koreans. J Rheum Dis 2004;11(3):254-262 [FREE Full text]
48. Brazier J, Ratcliffe J, Saloman J, Tsuchiya A. Measuring and Valuing Health Benefits for Economic Evaluation. 2nd edition. Oxford, UK: Oxford University Press; 2016.
49. Polsky D, Baiocchi M. Observational studies in economic evaluation. In: Culyer AJ, editor. Encyclopedia of Health Economics. New York, NY: Elsevier; 2014:399-408.
50. Gafni A, Birch S. Incremental cost-effectiveness ratios (ICERs): the silence of the lambda. Soc Sci Med 2006 May;62(9):2091-2100 [FREE Full text] [doi: 10.1016/j.socscimed.2005.10.023] [Medline: 16325975]
51. Löthgren M, Zethraeus N. Definition, interpretation and calculation of cost-effectiveness acceptability curves. Health Econ 2000 Oct;9(7):623-630. [doi: 10.1002/1099-1050(200010)9:7<623::aid-hec539>3.0.co;2-v] [Medline: 11103928]
52. Richardson G, Manca A. Calculation of quality adjusted life years in the published literature: a review of methodology and transparency. Health Econ 2004 Dec;13(12):1203-1210 [FREE Full text] [doi: 10.1002/hec.901] [Medline: 15386669]
53. Ramsey SD, Willke RJ, Glick H, Reed SD, Augustovski F, Jonsson B, et al. Cost-effectiveness analysis alongside clinical trials II-an ISPOR good research practices task force report. Value Health 2015 Mar;18(2):161-172 [FREE Full text] [doi: 10.1016/j.jval.2015.02.001] [Medline: 25773551]
54. Fenwick E, O'Brien BJ, Briggs A. Cost-effectiveness acceptability curves--facts, fallacies and frequently asked questions. Health Econ 2004 May 29;13(5):405-415 [FREE Full text] [doi: 10.1002/hec.903] [Medline: 15127421]
55. Rubin DB. Inference and missing data. Biometrika 1976 Dec;63(3):581-592. [doi: 10.2307/2335739]
56. Drechsler J. Multiple imputation for nonresponse. In: Drechsler J, editor. Synthetic Datasets for Statistical Disclosure Control: Theory and Implementation. New York, NY: Springer New York; 2011:27-37.
57. Laube JG, Salles Araujo T, Taw LB. Integrative east-west medicine intervention for chronic daily headache: a case report and care perspective. Glob Adv Health Med 2020 Feb 13;9:2164956120905817 [FREE Full text] [doi: 10.1177/2164956120905817] [Medline: 32110474]
58. Herman PM, Craig BM, Caspi O. Is complementary and alternative medicine (CAM) cost-effective? A systematic review. BMC Complement Altern Med 2005 Jun 02;5:11 [FREE Full text] [doi: 10.1186/1472-6882-5-11] [Medline: 15932647]

Abbreviations

CEAC: cost-effectiveness acceptability curve
CPG: clinical practice guideline
CRF: case report form
EQ-VAS: EuroQol visual analogue scale
HIT-6: Headache Impact Test
HRQOL: health-related quality of life
ICD-10: International Classification of Diseases, 10th Revision
ICER: incremental cost-effectiveness ratio
ITT: intention to treat
KM: Korean medicine
MCMC: Monitoring Center for Korean Medicine and Western Medicine Collaboration
MHD: monthly headache day
NHIS: National Health Insurance Service
NRS: numeric rating scale
QALY: quality-adjusted life year

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
TTH: tension-type headache
UC: usual care
WM: Western medicine

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Protocol

Intimate Partner Violence and HIV Prevention Among Transgender and Nonbinary Persons: Protocol for a Prospective Mixed Methods Cohort Study

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Abstract

Background: Transgender and nonbinary (TNB) individuals experience intimate partner violence (IPV) at twice the rates of cisgender populations. Although prior research has linked IPV to elevated HIV risk and vulnerability among TNB persons, there is limited understanding of how IPV influences key HIV prevention behaviors, such as HIV and sexually transmitted infection (STI) testing, and initiation and use of pre-exposure prophylaxis (PrEP). IPV experiences among TNB individuals are complex and diverse, varying by type, frequency, severity, and power and relationship dynamics, and often intersect with systemic forms of marginalization. Additional research is needed to investigate the mechanisms linking IPV and HIV outcomes to inform effective, tailored prevention strategies.

Objective: This prospective mixed methods cohort study seeks to advance understanding of the risk and protective pathways between IPV (both perpetration and victimization) and HIV-related outcomes, including engaging in condomless sex, STI acquisition, PrEP uptake, adherence, and persistence among TNB individuals experiencing IPV.

Methods: This study includes two sequential phases. Phase 1 consisted of formative qualitative interviews with 32 TNB individuals with recent IPV experience and 10 key informants (eg, service providers and advocates) in the United States. These interviews informed the design of a national, web-based cohort study. Phase 2 will enroll 600 HIV-negative, currently partnered TNB participants living in the United States. Participants will be followed for 24 months, with surveys and at-home biospecimen collection (HIV and STI testing and PrEP adherence) at baseline, 6, 12, 18, and 24 months. Brief surveys assessing changes in key variables will also be completed at 3, 9, 15, and 21 months.

Results: Phase 1 was initiated in October 2023, with interviews conducted through October 2024 until thematic saturation was reached. Rapid qualitative analysis was completed between November 2024 and January 2025 to inform measurement selection for the phase 2 surveys. Enrollment for phase 2 began in February 2025 and is expected to continue through December 2025.

Conclusions: This study will provide essential insights into how IPV impacts HIV risk and prevention practices among TNB individuals. Results will guide the development or refinement of gender-affirming, trauma-responsive, and culturally grounded IPV and HIV prevention interventions tailored to the needs of TNB communities.

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KEYWORDS

intimate partner violence; IPV; transgender; health equity; HIV prevention; pre-exposure prophylaxis; PrEP

Introduction

Transgender and nonbinary (TNB) individuals experience intimate partner violence (IPV) at rates twice that of their cisgender peers [1-3]. Over half (54%) of TNB persons in the United States report having experienced some type of IPV, including acts involving coercive control or physical harm [4]. IPV is associated with condomless sex, sexually transmitted infection (STI), and HIV among TNB individuals [5-8]. A review of 88 studies found a high burden of HIV among transgender populations, with laboratory-confirmed prevalence estimates of 14.1% among transgender women and 3.2% among transgender men [9]. HIV prevalence was highest among Black transgender individuals (44.2%) [9]. The study also revealed significant prevention gaps, with 27% reporting no prior HIV testing and fewer than half aware of HIV pre-exposure prophylaxis (PrEP) [9]. Nonbinary individuals have been largely excluded from these estimates and continue to be underrepresented in epidemiological and intervention research.

The disproportionately high HIV risk among TNB individuals is largely shaped by structural factors—including stigma, discrimination, and systemic exclusion from health, legal, and economic institutions [9-13]. Barriers such as limited access to gender-affirming care, economic marginalization, and medical mistrust reduce engagement in prevention and treatment [14-17]. Many TNB individuals face compounding mental health challenges, and some may engage in survival economies, including sex work, which further increases their vulnerability to HIV [14,18,19]. These intersecting factors also contribute to heightened vulnerability to IPV [2,20,21], which itself may disrupt engagement in the HIV prevention continuum (HPC)—including HIV and STI testing, PrEP initiation, adherence, and persistence—by inducing fear, controlling behavior, and limiting autonomy in health decision-making [22,23].

Despite growing recognition of these disparities, the current evidence base on IPV among TNB populations remains limited in scope, quality, and specificity. For example, the impact of IPV on HPC outcomes may vary among TNB subgroups (ie, transmasculine, transfeminine, and nonbinary persons) and be influenced by other contextual factors such as gender expression, stage of transition, partner dynamics, and relationship type. Methodological limitations have constrained the state of knowledge regarding IPV among TNB subgroups. The limited prior work has been cross-sectional with diverse recall periods, greatly limiting causal and temporal inferences about the mechanisms underlying the associations found between IPV and HPC outcomes [2,20]. Combining TNB individuals with other populations, such as cisgender sexual minority men, has obscured the study of subgroup-specific dynamics and experiences of violence (ie, TNB-specific, psychological, emotional, sexual, and physical), frequency, escalation, and directionality of IPV within the relationships of TNB persons [2]. Additionally, most prior studies used measures of IPV that were developed for cisgender heterosexual populations and may fail to capture forms of abuse specific to TNB individuals, such as partner interference with gender affirmation or threats to disclose gender identity without consent [6-8,24]. The field also lacks data on key structural and interpersonal drivers of IPV among TNB individuals (eg, early life trauma, housing instability, social and community isolation, partner characteristics, and gender role ideologies) and how these shape HPC outcomes [6-8,24]. These gaps in our current understanding of IPV in TNB communities highlight the need for more rigorous research approaches to better explain these relationships.

Importantly, while IPV victimization has received some attention in the literature, IPV perpetration among TNB individuals remains understudied [2]. Very few studies have examined bidirectional IPV, or how violence manifests and is experienced across different relationship types, partner genders, or sexual orientations [2]. There has also been little differentiation between acts of self-defense and intentional perpetration, or between the genders of the individuals involved (ie, transmasculine, transfeminine, and nonbinary persons and cisgender male or female partners) [1]. IPV-like behaviors, such as physical altercations, have not been analyzed with appropriate nuance to distinguish intent, context, self-defense, or power dynamics. Additionally, although studies have identified an association between IPV and HIV seroconversion risk among TNB individuals [5,6,25-27], the mechanisms underlying this relationship are not well understood, and few studies have examined how IPV influences HPC engagement specifically [14,15,22,23,28,29].

Emerging evidence suggests that IPV and general experiences of violence may act as significant barriers to PrEP uptake and persistence among TNB persons [14,22,30]. One recent study found that general violence victimization was negatively associated with PrEP use in TNB populations [31]. Our prior research similarly found that gender-based violence was associated with both failure to initiate PrEP and early discontinuation among TNB participants in a PrEP demonstration project [22]. Concerns about potential IPV triggered by conversations about HIV prevention have also been identified as barriers to PrEP adherence and disclosure in intimate relationships [28,31]. Yet the field lacks a

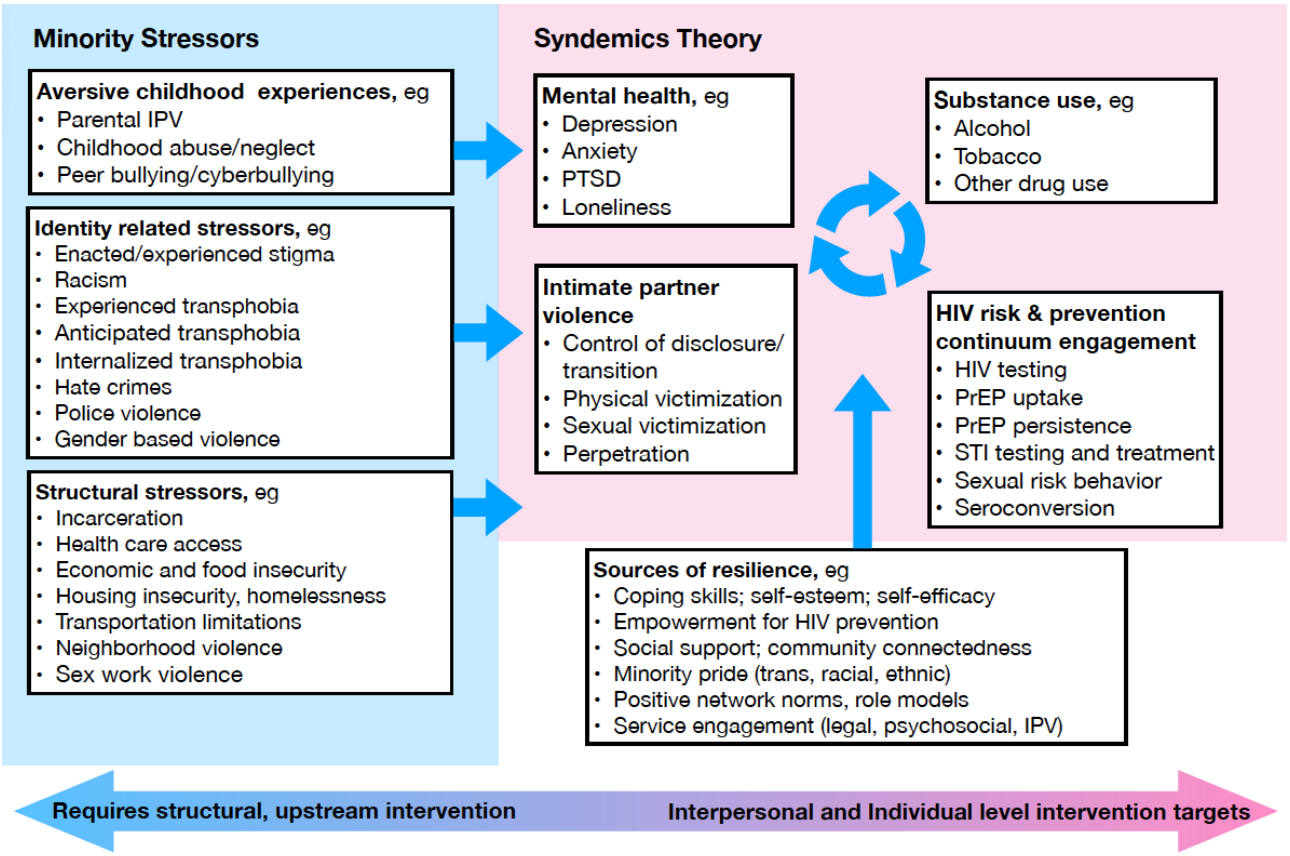
comprehensive, longitudinal understanding of how IPV interacts with relational, social, and structural factors to influence trajectories of engagement in HIV prevention. Specific antecedents—such as undisclosed gender identity, gender affirmation dynamics, partner control, HIV serodiscordance, or threats to partner self-concept—may uniquely impact how IPV is experienced and how it impacts HPC engagement among TNB individuals.

To address these significant knowledge gaps, Project RADIANT (Relationships And Dynamics—Improving Advocacy for Nonbinary and Trans) was designed to examine how IPV influences HIV and STI risk and protective behaviors among TNB individuals and how it contributes to disparities in engagement across the HPC. This project will focus on three specific points of engagement in the HPC—(1) HIV and STI testing (awareness), (2) PrEP initiation (uptake), and (3) PrEP persistence (adherence and retention) [32]—and will examine how HPC engagement varies by TNB subgroup. The project also aims to advance the field methodologically by using a validated, TNB-specific IPV scale developed by Peitzmeier and colleagues [3,33,34], which captures TNB-specific experiences of both victimization and perpetration, such as partner interference with gender affirmation or threats of outing. These items will be combined with additional constructs derived from phase 1 qualitative interviews to offer a multidimensional understanding of the relationship between IPV and HPC engagement. The study will also consider possible confounding, mediating, and moderating variables—including resilience factors and community support—that may shape these outcomes over time.

This mixed methods, observational cohort study is guided by both syndemics theory [8,35-37] and the gender minority stress and resilience framework [38-44], which together provide a lens for understanding how IPV may influence engagement in the HPC among TNB individuals. Syndemics theory emphasizes how co-occurring psychosocial and health conditions, such as depression, substance use, trauma, and IPV, interact synergistically to worsen health outcomes like HIV, especially when shaped by shared social contexts [35,45,46]. These conditions do not arise in isolation, but are driven by upstream structural factors such as transphobia, racism, economic marginalization, and discriminatory legislation, which increase vulnerability to multiple, mutually reinforcing health challenges [35,45,46]. While these structural drivers (eg, legislation, stigma, racism, social exclusion, homelessness, poverty, and criminalization) are not themselves syndemic conditions, they create the environments in which syndemic conditions emerge and intensify risks among TNB persons [8,36,37,47,48]. The gender minority stress and resilience framework builds on this by focusing on the unique stressors experienced by TNB individuals due to their minoritized gender identity (eg, anticipated rejection, internalized stigma, and identity concealment) contribute to greater stress and poorer overall health while also recognizing the protective role of resilience factors like social support and community connectedness [36,49-51]. Both frameworks have been frequently applied to explore the underlying drivers of HIV inequities among TNB individuals, particularly in relation to the ways health disparities interact and amplify one another [8,36,37,47,48]. Together, these theories offer us guiding frameworks (Figure 1) for analyzing the broader consequences of IPV, extending beyond physical harm, to illuminate how IPV may directly and indirectly influence engagement in the HPC among TNB individuals, while also identifying possible points for intervention.

Anchored in these frameworks, this study seeks to address three major gaps in the literature: (1) the lack of longitudinal data linking IPV to HPC engagement among TNB individuals; (2) the widespread use of IPV measures developed for cisgender populations, which fail to capture TNB-specific experiences of abuse; and (3) the limited understanding of how subgroup differences (eg, transfeminine, transmasculine, and nonbinary) and relationship dynamics (eg, partner gender, power imbalances, and disclosure status) shape these associations. To fill these gaps, Project RADIANT will use a rigorous longitudinal cohort design, a validated TNB-specific IPV scale, along with additional items informed by phase 1 qualitative data, to assess a broad range of IPV experiences, including perpetration, directionality, coercive control, and interference with gender affirmation. By integrating these novel measurement tools into a longitudinal, community-informed study design, Project RADIANT aims to illuminate the pathways through which IPV affects HPC engagement and ultimately inform the development of effective, trauma-informed, and culturally responsive IPV and HIV prevention interventions to improve health outcomes for TNB communities.

Figure 1. Conceptual model for IPV and HPC engagement among transgender and nonbinary persons. HPC: HIV prevention continuum; IPV: intimate partner violence; PrEP: pre-exposure prophylaxis; PTSD: posttraumatic stress disorder; STI: sexually transmitted infection.



Methods

Study Design

RADIANT is a prospective mixed methods cohort study. The study team comprises researchers and staff at San Diego State University, Drexel University, Yale University, the University of Washington, and RAND, with the RAND Survey Research Group programming and administering the survey components of the study. The study is being carried out in two phases. Phase 1 involved semistructured interviews with TNB persons with experiences of IPV and key informants, such as TNB-focused health care and social service providers working with TNB persons who have experienced IPV. The main purpose of phase 1 was to inform the selection of survey measures and activities for phase 2. Phase 2 is currently ongoing and involves the recruitment and retention of a prospective cohort of 600 TNB persons from across the United States who will complete online surveys and HIV and STI at-home test kits to assess subgroup differences in IPV and HPC engagement over 24 months.

Community Advisory Board

The RADIANT study established a community advisory board (CAB) composed of TNB leaders and advocates to ensure community-centered research practices throughout the study. Initially, the project team consulted with subject matter experts, including members of existing TNB-specific CABs. Following these preliminary meetings, recruitment for the ongoing RADIANT CAB was conducted nationally through word-of-mouth and online advertisements via Instagram and Facebook. From these recruitment efforts, 224 individuals completed the interest screener, and 15 were selected to form the RADIANT CAB. Members were chosen to ensure representation across geography, age, gender identity, and racial or ethnic background, reflecting the diverse communities most affected by both IPV and HIV disparities within TNB populations.

The first CAB meeting took place in August 2024, and 8 additional meetings have been held to date. These ongoing virtual meetings ensure consistent engagement with the CAB and provide continual opportunities to incorporate their guidance on study design decisions (eg, study measurements and recruitment methods), methodological approaches, and interpretation of preliminary findings. Specifically, the CAB has provided critical input into the development of the study name, logo, and recruitment materials and methods, and has offered essential feedback on phase 1 interview questions, phase 2 survey development, and a conference presentation of phase 1 preliminary findings. CAB members are compensated for each meeting they attend and for their time spent providing in-depth feedback. This equitable, collaborative structure ensures that the research remains grounded in community knowledge and priorities, in service of TNB communities' well-being [52]. CAB members have also opted to serve as coauthors on papers currently in development and to provide essential oversight to maintain the study's cultural responsiveness, trauma-informed practices, and overall relevance to TNB communities.

Phase 1 Qualitative Data Collection

Formative qualitative interviews were conducted in phase 1 with a racially, ethnically, and gender-diverse sample of TNB persons who reported prior experiences of IPV (victimization or perpetration) within the past 12 months (n=32), as well as with key informants who provide services to TNB individuals experiencing IPV (n=10). This qualitative data collection aimed to explore relationship characteristics and dynamics, IPV experiences, IPV service usage, and HIV and STI risk and HPC engagement, with the purpose of informing the development of phase 2 online survey measures and recruitment strategies. In-depth, semistructured, one-on-one interviews were conducted by trained members of the research team who also identified as members of the TNB community. Participants were purposively sampled across gender identities and racial and ethnic groups to ensure that diverse perspectives were represented. Interview participants experiencing IPV were recruited through a combination of online responses to a flyer advertising a TNB health and relationships study—posted on social media and dating sites frequently used by TNB individuals—and through referrals from TNB community health care settings. Potential participants completed a brief screener that included self-reports of recent IPV experiences (victimization or perpetration). Key informants were recruited through network referrals from community-based IPV service settings.

Interviews were conducted using secure online videoconferencing software. After orienting participants to the purpose of the interviews, answering their questions, and obtaining informed consent, the interviewer followed a semistructured protocol to guide inquiries about participants' lived experiences of romantic relationships, experiences of different forms of violence in intimate relationships, including any forms of violence that may be specific to TNB persons, and the ways in which these experiences may directly or indirectly impact HPC engagement. For key informants, interview questions focused on their professional roles and experiences providing services to TNB individuals who had experienced IPV (victimization or perpetration), as well as on their perspectives regarding the possible impacts of IPV on HPC engagement. Interviews lasted approximately 60 minutes, and all participants were remunerated US $100 for their time.

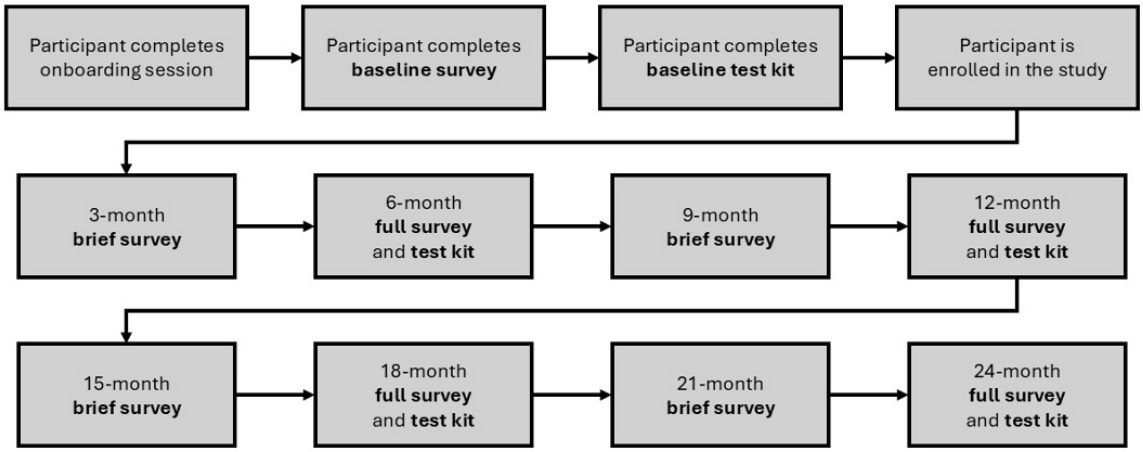
Phase 2 Longitudinal Cohort Data Collection

For phase 2, we plan to enroll 600 TNB individuals, 300 assigned male at birth (AMAB) and 300 assigned female at birth (AFAB), who identify as either transgender (75%) or nonbinary (25%) and report recent (past 6 months) sexual behavior with at least one person with a penis, given the study's focus on HIV risk and HPC engagement [9]. Details on inclusion criteria and the recruitment process for phase 2 are listed below in the Recruitment section. Upon enrollment into the open prospective cohort, 600 TNB participants will be followed for 24 months. We anticipate up to 20% attrition, resulting in a final sample of ~480 TNB (240 AFAB and 240 AMAB) participants at the final 24-month assessment. This sample size was informed by Monte Carlo simulation data from Wolf et al [53], indicating that a sample of 180 provides 83% power to detect a moderate mediated indirect effect (0.4) with minimal bias; thus, enrolling 600 participants will ensure adequate power for the planned longitudinal structural equation and mediation models, allowing for robust model estimation across multiple time points, covariates, and subgroup comparisons (eg, by gender identity and AMAB or AFAB status).

Full study assessments, which include completing a full-length survey and biospecimen test-kit collection, are administered at baseline and at 6-, 12-, 18-, and 24-month assessment points. At each time point, participants receive a link to an online survey that asks about their HIV and STI testing behavior, HIV status, STI infection and treatment history, and PrEP use during the past 6 months. Participants are also asked to complete a battery of demographic, psychosocial, relational, IPV, and structural measures. To maintain engagement and retention, brief interim surveys focusing on key study outcomes (eg, changes in relationship status, mental health, and HPC engagement) are administered at 3-, 9-, 15-, and 21-month intervals. The flow of the study assessment schedule is depicted in Figure 2.

All surveys and test kits are self-administered. Participants are instructed that they may contact study staff via email, SMS text message, or phone call should any questions or concerns arise. Study staff notify participants of any preliminary reactive HIV or STI test results and facilitate linkage to care within 48 hours of a reactive result. Participants receive up to 6 weekly reminders to complete their survey or return a test-kit, based on their preferred method of contact, either SMS text message or email.

Figure 2. Flow diagram of the study assessment schedule in phase 2.



Phase 2 Recruitment

Because the primary goal of RADIANT is to understand HIV risk and HIV prevention behaviors in the context of relationship dynamics and IPV, eligibility is focused on TNB individuals who report recent sex with persons AMAB. Individuals who recently left relationships are not included in baseline eligibility, as enrolling participants in ongoing relationships is essential to prospectively capture dyadic processes and IPV-related changes in HIV prevention behaviors over the 24-month study period. As such, TNB individuals are eligible if they (1) are 18-45 years old, (2) currently identify as transgender or nonbinary, (3) report sex with a person with a penis in the past 6 months (given elevated HIV risk and the study's focus on HIV outcomes [9]), (4) report being in a relationship for the past 3 months, and (5) have an HIV-negative or unknown status (verified at baseline via dried blood spot [DBS] assay). A detailed list of inclusion and exclusion criteria is provided in Textbox 1. We plan to stratify enrollment, as needed, to ensure that 75% of participants identify with one or more racial or ethnic minority groups, 50% are AMAB, 50% are AFAB, and at least 25% identify as nonbinary. We will also stratify to ensure that a minimum of 60% of participants report a history of IPV at baseline. This recruitment strategy will allow us to examine and compare differences in IPV experiences and their associations with HPC engagement across TNB subgroups. Based on prior work with this population, we anticipate that an additional 15% of participants who report no past-year IPV at baseline will report IPV exposure during the study, yielding a final sample of at least 400 (66.6% of study participants) with IPV exposure.

Textbox 1. Phase 2 study eligibility criteria.

Inclusion criteria

- Currently identify as transgender, nonbinary, or another gender identity that differs from the sex they were assigned at birth
- 18-45 years of age
- Report currently being in a relationship; relationship is defined as "Do you have a primary partner, that is, someone you feel emotionally, romantically committed to above others?"
- Reside in the United States
- Have a physical (non-PO Box) address where they can receive an HIV, STI, and PrEP test kit by the US Postal Service priority mail
- Able to provide at least 2 means of contact for follow-up
- Not currently enrolled in an HIV prevention intervention study
- Have a self-reported HIV-negative serostatus at baseline (status confirmed via home-test kit mailed to laboratory)
- We may stratify eligibility as needed to ensure that at least 60% report past year IPV at baseline
- We will stratify as needed to ensure at least 35% of the sample identifies as Black or African American, and at least 35% identifies as Hispanic or Latinx
- We will stratify to ensure at least 50% were AMAB and 50% were AFAB
- We will stratify to ensure 75% identify as transgender and 25% identify as nonbinary

Exclusion criteria

- Under 18 years old, or older than 45 at enrollment
- Partnered for less than 3 months, or currently unpartnered
- Lives outside of the United States
- Self-reports HIV positive status or is laboratory-determined to be HIV positive at baseline
- Individual expresses unwillingness to complete regular surveys during informed consent
- Unwillingness to provide biospecimens with home testing kits during informed consent
- Unwillingness to provide partner contact information (to allow us to screen for dyads)
- Individual's romantic partner is already enrolled in the study (we will not enroll dyads)

To ensure the participation of TNB individuals from diverse backgrounds, it has been essential to work closely with organizations and individuals within the TNB community who are connected to relevant venues and services. We continue to collaborate with members of our CAB to assess the suitability of websites, social media platforms (eg, Facebook and Instagram), and dating apps (eg, Grindr and Taimi) for online advertising of our study recruitment materials. In addition to online recruitment, we have implemented targeted strategies to reach racially and ethnically minoritized TNB individuals by partnering with community organizations to promote the study within their networks, at TNB-specific events [54], and in virtual community spaces.

Individuals interested in participating are directed from an online or offline advertisement (as shown in Figure 3) to an online study screener that asks about TNB identity and experiences of conflict and violence in intimate relationships. Drawing from methods used previously to recruit sexual and gender minorities experiencing IPV [55], we will not refer directly to IPV in recruitment efforts. Eligible participants are contacted by study staff to schedule a 20-minute virtual onboarding session to verify their identity, obtain informed consent, and provide an orientation to the study. During the consent process, participants will choose whether to receive study reminders via email or SMS text and are informed of potential privacy risks if partners access their devices. Messages will be sent from a neutral sender name and will not include any information about the study topic. Consistent with the World Health Organization ethical guidelines for IPV research [56], only one partner from any relationship will be enrolled to protect participant safety. During this onboarding session, participants are guided through the informed consent form, study assessment schedule, and biospecimen collection procedures (ie, oral and anal swabs, urine collection, and DBS collection) via written and video instructions. Once the live onboarding session has concluded, consented participants who agree to participate are sent a unique link to the baseline survey that takes approximately 1 hour to complete. Participants who complete the baseline survey are then mailed a biospecimen collection kit to test for HIV, gonorrhea, and chlamydia. For participants who reported PrEP use in their baseline survey, the kit will also include testing to assess PrEP adherence.

Figure 3. Sample phase 2 study advertisements.

Baseline Survey

During each participant's onboarding session, the study staff complete an online enrollment form, which includes items on the participant's name, gender identity, race and ethnicity, phone number, email, and mailing address. This information is then matched with a unique ID number (assigned consecutively by enrollment date) and a random personal identification number and securely stored in a record management system. Upon completion of the enrollment form and receipt of an electronically signed informed consent form from the participant, an automated email with a unique link to the baseline survey is sent to the participant.

The baseline survey was developed based on the findings from phase 1 interviews, past literature on IPV and HIV risk among TNB populations, and our team's prior experience administering surveys focused on IPV and HIV prevention [55]. The baseline survey includes items centered on the following domains: experiences of IPV victimization and perpetration, including items on TNB-specific, psychological, sexual, emotional, and physical experiences of violence; HIV and STI risk and prevention, including HIV testing, PrEP uptake, adherence, and persistence; physical and mental health status and health care usage; sociodemographic and relationship characteristics; experiences of racial and transphobic stigma and discrimination; sexual behavior, particularly condomless sex; substance use; and structural and protective factors. A detailed list of proposed measures for the baseline survey is presented in Textbox 2. Some non-TNB-specific measures were modified to include TNB-inclusive language. Forsta, a survey software, was used to program the baseline survey.

Participants receive up to 3 weekly automated reminders from RAND Survey Research Group and 3 additional weekly reminders from study staff sent by participants' preferred method of communication (SMS text or email). Participants who do not complete the baseline survey or test kit are withdrawn from the study.

Textbox 2. Key measures included in the baseline survey and the planned 6-month follow-up survey.

Intimate partner violence (IPV)

- IPV-Transgender and Gender Diverse Populations scale (modified to be 34 items assessing IPV among transgender and gender diverse populations, including transgender and nonbinary (TNB)–specific IPV, psychological, sexual, emotional, and physical IPV) [3,33,34,57] and adapted financial control items [58], whether they consider relationship abusive, whether IPV occurred in the context of self-defense for both victimization and perpetration
- Disclosure of IPV, help-seeking behaviors, and receipt of IPV services [55,59-61]
- IPV victimization stigma and shame [62], IPV perpetration stigma and shame [63]

HIV and STI prevention behaviors

- HIV testing [64] (self-report and medical record confirmation)
- Sexually transmitted infection testing, diagnosis, and treatment [64] (self-report and biomarker)
- Pre-exposure prophylaxis (PrEP) uptake and PrEP persistence [64] (self-report and biomarker)
- Perceived PrEP adherence [64] (self-report)
- Reasons for not using PrEP or stopping PrEP [59-61] (self-report)
- PrEP modality acceptability [65] (self-report)
- Long-acting injectable PrEP use and acceptability [55]
- PrEP stigma [66] (self-report)
- Doxy-PEP (post-exposure prophylaxis) awareness, use, and willingness [64]
- Sexual behaviors and condomless sex (self-reported) [55,64]

Demographics

- Age, race, and ethnicity [67,68]
- Gender identity, sex assigned at birth, gender expression, age at which started living in true gender, intersex diagnosis or characteristics [69], sexual orientation [69]
- Educational attainment [70], employment status [70], employment precarity [71]
- Household and individual income, financial well-being [72], food insecurity [73]

Health status and health care

- Self-rated health [74], physical health care use [75], insurance coverage [76], bowel health [77]
- Behavioral health care use and perceived unmet need, for mental health care and substance use treatment [78]

Partner and relationship characteristics (reported by index participant)

- Current relationship status, marital status, cohabitation, partner demographics [55,67-69]
- Relationship characteristics (type, duration, and history of separations)
- Relationship role models, globally and specifically within TNB and the nonbinary community (regardless of relationship status)
- Relationship satisfaction [79], intimacy with partner [80], overall relationship quality and well-being [81], perceived commitment to relationship [82,83], communication patterns [84]
- Partner PrEP use or HIV treatment status or viral suppression [55,64]
- Partner knowledge of, attitudes toward, and support for taking PrEP [59-61], PrEP conversations [59-61], sexual agreements (type and adherence) [55]
- Relationship power balance and decision-making [85], financial dependence
- Social support from partner [86]

Early life and childhood experiences

- Adverse childhood violence and abuse, general items and items specific to sexual and gender minorities [87,88] (planned for 6-month survey), witnessed parental IPV
- Mistreatment by adults in childhood [87,89], discrimination and other minority stress experiences based on one's gender identity or expression in childhood [51]

Social and structural factors

- Recent exchange or transactional sex [55,64]
- Justice system involvement (lifetime and recent) [64], experience with stop and frisk [64]
- Experienced discrimination due to race, ethnicity, or color (and frequency of these events) [90]
- Housing status and housing instability [91], recent homelessness, ever been homeless [92], perceived neighborhood safety [93]

Mental health

- Depressive symptoms [94], posttraumatic stress disorder symptoms [95], anxiety symptoms [96]
- Loneliness [97], social isolation symptoms [98] (planned for 6-month survey)
- DSM-5 (*Diagnostic and Statistical Manual of Mental Disorders* [Fifth Edition]) cross-cutting symptoms [99] (planned for 6-month survey)
- Sleep quality [100] (planned for 6-month survey)
- Emotional regulation ability [101] (planned for 6-month survey)

Substance use and abuse

- Alcohol use [102], illicit and licit substance use [103], substance use consequences [103]

Psychosocial and resilience factors

- Internalized societal gender roles [104], comfort with gender identity [105]
- Discrimination and other minority stress experiences due to gender identity or expression in adulthood, past year [51], anticipated stigma (global demographics) [106]
- Discrimination due to sexual orientation, frequency [107] (planned for 6-month survey)
- Connectedness to TNB and nonbinary community [108]
- Perceived social support (global) (eg, emotional and instrumental) [86]
- Coping self-efficacy [109], global resiliency traits [110,111], global self-esteem [112] (planned for 6-month survey)

Biospecimen Sample Collection Procedures

Upon completion of the baseline survey, participants are mailed a biospecimen collection kit by the study's designated lab partner, using the address provided during onboarding. Kits are shipped via the US Postal Service in plain, discreet packaging and include a prepaid return label. Each kit contains DBS cards, a urine collection cup, oral and anal swabs, collection tubes, lancets, and detailed self-collection instructions. Participants begin receiving automated weekly reminders via SMS text or email 1 week after the kit is mailed, up to 6 reminders in total. Participants who do not return their kit after 6 reminders and wish to remain in the study will be encouraged to complete a new kit. Those who do not return a kit or test positive for HIV at baseline will have their baseline survey data retained but will be withdrawn from the cohort and excluded from further study activities.

Biospecimen kits are also mailed at baseline, 6-, 12-, 18-, and 24-month follow-ups, with contents tailored based on the study time point and the participant's PrEP use. DBS samples are collected to measure PrEP adherence (when use is self-reported) at baseline, 6, 12, 18, and 24 months. HIV is measured at baseline (to determine eligibility) and again at 24 months. For STI testing (chlamydia and gonorrhea), participants self-collect urine (30-50 mL from the initial stream), as well as rectal and pharyngeal swabs at baseline, 6, 12, 18, and 24 months. Urine samples are tested via nucleic acid probe, and swabs are analyzed using nucleic acid amplification. Table 1 presents the full schedule of survey assessments and biospecimen collection activities.

Table 1. Schedule of survey assessment and biospecimen collection by time point[a].

Outcome	Study time point				
	Baseline	6-month	12-month	18-month	24-month
Primary					
HIV testing behavior	Survey	Survey	Survey	Survey	Survey
PrEP[b] uptake	Survey + DBS[c]	Survey + DBS	Survey + DBS	Survey + DBS	Survey + DBS
PrEP persistence	Survey + DBS	Survey + DBS	Survey + DBS	Survey + DBS	Survey + DBS
STI[d] (CT[e] and GC[f])	Survey + culture	Survey	Survey + culture	Survey	Survey + culture
Secondary					
Sexual risk behavior	Survey	Survey	Survey	Survey	Survey
HIV seroconversion	Survey + DBS	Survey	Survey	Survey	Survey + DBS

[a]Brief assessments of relationship changes, experiences of intimate partner violence, and self-reported HIV prevention continuum and STI outcomes will be administered at 3, 9, 15, and 21 months (not shown).

[b]PrEP: preexposure prophylaxis.

[c]DBS: dried blood spot.

[d]STI: sexually transmitted infection.

[e]CT: chlamydia.

[f]GC: gonorrhea.

Laboratory Testing and Follow-Up

Biospecimen testing is conducted by our external lab partner. If a sample is determined to be insufficient, participants are contacted via their preferred communication method (email or SMS text) to request a second collection. A replacement kit is mailed by the lab, and participants are asked to recollect and return the sample by mail. Test results are shared with study staff through the lab's secure online portal. If a result is reactive, study staff contact the participant by phone to deliver the result verbally, confirm their identity, and explain that the testing was conducted for research purposes only. Participants will be encouraged to seek confirmatory testing from a medical provider and offered referrals to local resources. Upon request, study staff will provide an electronic copy of the test results, which will be password-protected to ensure secure transmission of protected health information.

Study Communication and Participant Retention

The study uses multiple methods of communication to maintain participant database, program and send automated study task reminders, and contact participants to follow up on unfinished study activities and reactive test results. Participant information, survey response data, test results, and other administrative data are stored and maintained separately, each in securely encrypted online databases. Most contacts with the participants will be made via SMS text messages and emails, in the forms of automated messages or prewritten templates sent by the study staff. These messages will use conversational tones and an accessible reading level. Videoconferencing will be used for the initial onboarding sessions, with follow-up sessions made available on request regarding test kit completion.

Compensation

Participants receive US $20 for completing each full-length survey at baseline, 6-, 12-, 18-, and 24-month follow-ups, and US $40 for returning each corresponding test kit with sufficient biospecimen for analysis. They will also receive US $10 for each brief survey completed at 3, 9, 15, and 21 months, which assess relationship status changes, HPC engagement, and STI diagnoses and treatment. Participants who complete all 5 full-length surveys and return all 5 corresponding test kits will receive a US $50 bonus. In total, participants may earn up to US $390 for full study participation. All compensation is provided as electronic gift cards.

Data Analysis Plan

Overview

This study uses both gender-inclusive and gender-specific approaches to analyze experiences of IPV and HPC engagement across all phases of the research. This analytic framing is aligned with current guidance for research involving TNB populations [113] and is supported by evidence that transfeminine, transmasculine, and nonbinary individuals often report distinct experiences of violence [108,109], as well as differing barriers and facilitators to HPC engagement [23]. Using both gender-inclusive and gender-specific approaches is necessary to identify shared as well as unique patterns across groups.

In phase 1, qualitative data are being examined both across all participants and separately within transfeminine, transmasculine, and nonbinary groups to explore common themes and preserve distinct narratives and lived experiences. In phase 2, quantitative analyses will include longitudinal modeling to assess changes in IPV and HIV prevention outcomes over time, using both full-sample and subgroup-specific models. This combined approach will allow the study to generate evidence that supports both broadly applicable recommendations for all TNB participants and targeted insights that address the specific needs of transfeminine, transmasculine, and nonbinary individuals. These findings will contribute to the development of more

effective and culturally responsive interventions to address IPV and support HIV prevention.

The following section outlines the analytic approaches for data collected in phases 1 and 2 of the study. While the central focus will remain on examining IPV experiences and their associations with HPC engagement and STI outcomes, specific analytic methods may be refined based on the characteristics of the data (eg, distributional properties), emerging research questions, and input from the study statistician. Additional analyses will also be conducted to explore secondary outcomes of interest as appropriate.

Phase 1 Qualitative Data Analyses

To analyze the qualitative interview data from phase 1, grounded theory was used to allow themes to emerge from the data [114]. Interviews were audio-recorded and transcribed verbatim and reviewed independently by investigators to identify analytic thematic categories that emerged in response to the interview topics. The transcripts were reviewed periodically to determine whether thematic saturation had occurred, using a saturation grid [115]. Additional interviews were conducted until saturation was achieved. Investigators independently developed an initial list of themes and then developed a codebook listing each theme accompanied by a detailed description, inclusion and exclusion criteria, and typical examples. Dedoose (version 7; Sociocultural Research Consultants, LLC) was used for coding. Two coders marked areas of text pertaining to each theme. They practiced with a sample of 20% of transcript selections, coding independently and reviewing together. If coder disagreement reveals ambiguity in the codebook, code definitions, examples, or criteria are revised as needed. Training continues until coders consistently identify themes.

Next, both coders work on each passage independently, after which the research team measures coder consistency, evidenced by a weighted kappa of ≥0.7, a more rigorous approach than simple percent agreement [116]. Best practices for validity are used, including triangulation and an audit trail [117]. Distribution of themes within and across age, gender, racial and ethnic identity, IPV type, frequency, severity, and community member versus provider status are examined to determine whether there are differences in perceptions of associations of various forms of IPV and HIV risk and HPC engagement.

Interview findings were used to help refine measures to be used in phase 2 in the cohort study by building upon the research team's preliminary work with community partners and experts on IPV among TNB persons. The themes that emerged from phase 1 interviews helped to contextualize the knowledge on TNB-specific forms of IPV provided by participants and key informants and consequently informed survey development in phase 2, like selecting relevant measures and developing relevant items. Qualitative and quantitative data will be brought together again at the end of the quantitative analysis phase to assess complementarity [118]. An overall summary of study findings that includes the most salient aspects of IPV in relation to HIV risk and HPC engagement gleaned from the quantitative analyses with complementary qualitative data will be developed.

Phase 2 Quantitative Data Analyses

In phase 2, we will examine the robustness of our measures and our sample, with particular attention to participant attrition and patterns of missing data. First, we will assess the psychometric properties of all measures. Second, we will perform Wilcoxon and chi-square tests to compare baseline and follow-up characteristics between participants who completed the study and those who did not. Statistical methods will be applied to adjust for potential bias due to attrition [119]. To address missing data, we may use standard multiple imputation approaches [120], including the use of sequential Bayesian additive regression trees (R package "sbart"), a nonparametric method that does not rely on assumptions about covariate relationships [121]. Before building more elaborate latent curve models (LCMs), we will conduct preliminary analyses—such as bivariate correlations, regression models, and basic structural equation modeling (SEM) and LCMs—to examine associations among key study variables.

To evaluate the proposed study aims with 5 waves of full data collection (baseline, 6, 12, 18, and 24 months), we will apply SEM and specifically LCMs to examine the trajectories of one or more outcome variables over time. LCM is a flexible technique for modeling systematic within- and between-individual differences in longitudinal change and offers several well-documented advantages over other methods [122,123]. LCM will be used to model multiple parallel developmental trajectories of change and the relations between them (eg, between the predictor IPV measures and the outcome HPC measures). Another advantage of LCM is that one can incorporate multiple indicators to form a "measurement model" that teases out the measurement error from observed behaviors [124]. LCM allows for testing complex relationships between the predictor and outcomes with time-invariant and time-varying covariates. We will also use longitudinal latent class analysis [125,126] to identify phenotypes that may extend beyond groups of gender identity, for example, family history, substance use, incarceration, IPV subtypes, and geographic differences, therefore enabling us to understand relationships between IPV and HIV outcomes and identify groups that may benefit from tailored interventions.

One of the aims of the study is to examine gender-based differences in the longitudinal associations of IPV with HPC engagement, STI diagnosis, condomless sex, and HIV seroconversion among a racially, ethnically, and gender diverse cohort of TNB persons. To address this aim, we will model multiple developmental trajectories of 5 full survey (baseline, 6, 12, 18, and 24 months) waves of data using LCM for transgender women, transgender men, and nonbinary subgroups. There are three developmental trajectories we will examine for each group: (1) the predictor: IPV; (2) the primary outcomes: HPC engagement and STI diagnoses; and (3) the secondary outcomes: condomless sex and seroconversion. The predictor trajectory is defined by repeated measures of IPV. Because LCM enables the simultaneous estimation of multiple developmental pathways, we will model parallel trajectories of HPC engagement across subgroups. Key outcomes will be derived from repeated measures of 3 binary indicators: HIV testing, PrEP initiation, and PrEP continuation. These indicators

will be used to define a single latent HPC factor (*f*). With the 5 full survey waves of data, the repeated measures of the same latent variable are represented by *f*1 to *f*5 in the LCM. The developmental trajectory of HPC engagement will then be based on the latent variables *f*1 to *f*5. Similarly, we will examine parallel developmental trends in outcomes such as STI diagnoses, condomless sex, and HIV seroconversion. To assess the shape of these trajectories, we will evaluate whether growth is best represented as linear or nonlinear, incorporating quadratic terms or piecewise models if needed. Further, we will have multiple parallel developmental processes (eg, IPV, HPC, and STIs) in the growth model.

The study also aims to determine the individual-, interpersonal-, network-, and structural-level risk and resilience factors that mediate (or moderate) the associations between IPV and HIV risk and protective behaviors for each group. It is hypothesized that resilience factors, such as coping skills, greater social support, and positive role models, will act as a mediator or a moderator in the relationships that IPV will have with HIV risk and HPC outcomes. We also hypothesize mediating effects of potential risk factors (eg, substance use, poorer mental health, engagement in transactional sex, incarceration, and partner- and relationship-level factors). Such potential mediating effects will be incorporated into SEM.

Because of the complexity of the LCM approach with multiple developmental trajectories, we anticipate challenges in adding moderators directly into the growth model. One way to address this is by using multiple group analyses as a strategy for evaluating moderation effects across subgroups. By comparing relationships between the predictor trajectory and the outcome trajectories across different groups (transfeminine, transmasculine, and nonbinary individuals or by groups identified in the LCA), the multiple group analyses will allow us to test different assumptions about group equality [127] and build appropriate models for different, heterogeneous subpopulations. In addition, by incorporating measures of resilience, this study supports the design of strength-based interventions, building on evidence that resilience can serve a protective, buffering role [128].

We will incorporate both time-varying and time-invariant covariates into the LCMs to examine the influence of individual characteristics of TNB participants, their partners, and relationship dynamics. Analyses will be conducted using Mplus Version 7 (Muthén & Muthén). We will examine a range of moderation and mediation effects to assess how various risk and protective factors influence outcomes, accounting for demographic and socioeconomic variables. Alternative models will be compared using a set of model fit indices, including root-mean-square error of approximation, Tucker-Lewis index, and various fit statistics as described by Bentler and Bonett [129], and Hu and Bentler [130].

Ethical Considerations

All study protocols and procedures have been approved by the San Diego State University institutional review board (HS-2023-0142) on July 28, 2023. All procedures are in accordance with the ethical standards of the institutional and national research committees and with the Helsinki declaration and its later amendments or comparable ethical standards. Verbal and written informed consent have been and will be obtained from all participants included in the study following a thorough individual study onboarding process carried out by research team members, conducted via online videoconferencing software. Participants are informed that their involvement in the study is voluntary and that they may withdraw at any time without penalty. Certain personal details (eg, name, mailing address, postal code, email, and phone number) are collected for study administration. To maintain privacy, only authorized research personnel trained in data protection and confidentiality have access to identifiable information. Electronic files are stored on secure, encrypted servers with restricted access, and identifiers are kept separate from research data. All data transfers are encrypted, and data will be permanently deleted once they are no longer required for research purposes. Confidentiality protections are explained during the informed consent process.

Results

This study was funded in September 2023 by the National Institute of Mental Health (R01MH133484; to EDS). The RADIANT study was launched in October 2023, and phase 1 interviews were initiated in April 2024 and were conducted through October 2024 until thematic saturation was reached. Rapid qualitative analysis was conducted between November 2024 and January 2025 to inform phase 2 survey programming. Formal analysis of the qualitative data is currently ongoing, and findings will be submitted for peer-reviewed publication. The phase 2 baseline survey was finalized in January 2025, and recruitment for phase 2 began in early February 2025. Enrollment is expected to continue through December 2025. Phase 2 cohort participants are expected to complete all follow-up assessments by December 2027.

Discussion

Principal Findings

This will be the first longitudinal prospective study of IPV and HPC engagement for gender diverse populations, allowing us to better understand potential mechanisms between IPV and HIV risk and protective factors. We will assess multiple forms of IPV, including TNB-specific (eg, controlling gender expression), psychological, sexual, emotional, and physical, unlike most studies that have focused on physical and sexual forms of abuse. Broader research on IPV suggests that psychological and emotional abuse also have significant impacts [56,131-134]. Yet, these forms of abuse and their effects are understudied among TNB persons [2,3,33]. Our approach to measuring IPV includes both victimization and perpetration, helping to address a significant gap in the existing literature, which has often overlooked IPV perpetration among TNB individuals and focused primarily on their experiences as victims [2]. Additionally, our study introduces a novel focus on the chronicity of IPV, as well as partner characteristics and relationship contexts in which violence occurs. Unlike most prior research, which typically assesses IPV over broad time frames such as lifetime or past year, our design allows for the examination of patterns over time—such as repeated episodes,

changes in intensity, and the progression or reduction of violence.

In taking a multidimensional, longitudinal assessment of TNB-specific IPV and HPC outcomes among TNB persons, this study will be able to examine how the associations between IPV and HPC vary for transfeminine, transmasculine, and nonbinary individuals. We will assess the interaction of multiple syndemic factors among specific gender identity groups. We build on a methodological design that we have refined over several previous studies, including a similar longitudinal IPV study with sexual minority men [55]. This will allow us to explore the unique and common effects of different kinds of stigmas and supportive factors on HIV risk and HIV prevention outcomes pertaining to the TNB population.

A longitudinal approach allows us to assess the temporality of associations between IPV and HPC engagement and heterogeneous phenotypes therein. This study will allow us to distinguish between TNB individuals who experience IPV concurrently with low engagement in the HPC and those whose IPV precedes declines in HPC engagement or increased HIV risk behaviors. We will also be able to evaluate whether greater engagement in affirming, comprehensive HPC services is associated with reductions in IPV over time [135]. The longitudinal design provides the opportunity to track changes in potential mediators and moderators—such as gender identity, mental health conditions, psychosocial stressors, social support, and resilience factors—across multiple time points. While a longitudinal approach is essential for capturing these complex dynamics, it also requires a sufficiently large and diverse sample, along with adequate follow-up duration, to meaningfully examine how IPV and HIV risk evolve across different TNB subgroups and relationship types—goals that are central to this study.

Another facet of the research will focus on resiliency and protective factors for IPV and HIV prevention within the lived experiences of TNB persons. Resiliency factors such as coping skills and social support have been linked to reduced HIV-risk behavior and increased HIV testing and PrEP use [15,136,137]. Informed by both of our qualitative and quantitative data, we expect to build upon existing research by examining potential protective roles of resilience at the individual level, such as coping skills [110,138-140], social support from within one's social network [141-144], positive self-esteem [145,146], stable employment [147-149], spirituality [150-152], adaptive coping skills [153,154], and emotional regulation [145,155,156], and at the community level, such as TNB role models and TNB-specific support networks [157-159], in buffering against the magnitude of stress- and trauma-related harm resulting from IPV. Many facets of resiliency are modifiable; therefore, understanding how resilience, coping skills, social network characteristics, and social support serve to buffer against IPV among TNB is imperative to developing culturally appropriate and strength-based interventions.

Limitations and Strengths

This study has several limitations that are important to acknowledge. First, data on both IPV victimization and perpetration will be based on self-reports, which may introduce bias. Perpetration may be underreported due to concerns about potential legal implications, while victimization could be underreported as a result of social desirability or stigma. To help address these challenges, in-depth qualitative interviews will be used to gain insight into how best to assess both victimization and perpetration in the context of romantic relationships among TNB persons. The prospective design of the study also enables us to assess how current IPV experiences influence downstream outcomes related to HPC engagement. Second, our assessment of perceived social support, a potential buffering factor in the relationship between IPV and HPC-related outcomes, is based on an egocentric measure that captures individuals' perceptions of support from various members of their social networks (eg, peers, family, and coworkers). While this approach may have limitations, egocentric data collection using validated tools is a well-established and widely accepted methodology in research.

Despite these limitations, this study is grounded in a rigorous methodological approach and has strong potential for public health impact. Our interdisciplinary team brings extensive expertise in prospective cohort study design, IPV research, HIV prevention among sexual and gender minority populations, and advanced statistical modeling. We will collect data on exposures, moderators, and outcomes at multiple time points, allowing for a comprehensive analysis of dynamic relationships over time. Importantly, this study will yield actionable findings to inform the development of targeted interventions aimed at reducing both IPV and gaps in HPC engagement among TNB persons. To our knowledge, this will be the first study of its kind to produce the scientific evidence necessary to guide intervention strategies that address these intersecting health risks, aligning with priorities outlined in the National Institutes of Health Strategic Plan for HIV and HIV-Related Research.

Conclusions

The RADIANT study will be designed and implemented with a high degree of scientific rigor and has the potential for greatly increasing the understanding of the pathways by which specific forms of IPV have direct and indirect effects on HIV- and STI-related outcomes. Through the development of actionable recommendations for intervention design, this study is positioned to be the first to generate the foundational evidence needed to guide effective strategies aimed at mitigating the dual harms of IPV and HIV among TNB individuals. These findings will address a critical gap in the field and contribute meaningfully to national efforts to end the HIV epidemic.

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Authors' Contributions

EDS: conceptualization, methodology, investigation, resources, writing, review and editing, supervision, funding acquisition
KJH: conceptualization, methodology, investigation, review and editing, funding acquisition
AO: conceptualization, methodology, investigation, review and editing, funding acquisition
AS: methodology, survey development, investigation, review and editing
AR: methodology, survey development, protocol development, investigation, review and editing
RL: methodology, survey development, qualitative protocol development, data collection and analysis, review and editing
SC: manuscript preparation, review and editing
SDL: survey design, data documentation, coding, cleaning, and preparation for analysis; manuscript preparation, review and editing
BJ: project management, supervision of data collection, review and editing
RD: data coding and analysis, preparation of tables and results, review and editing
JW: survey design and programming, data collection, review and editing
CS: development of recruitment materials, qualitative protocol development, data collection and analysis, review and editing
AB: qualitative protocol development, data collection and analysis, review and editing
GJW: conceptualization, methodology, supervision, review and editing, funding acquisition

Conflicts of Interest

None declared.

References

1. Anderson VN. Trans prejudice and its potential links to IPV among trans people. In: Russell B, editor. Intimate Partner Violence and the LGBT+ Community: Understanding Power Dynamics. Cham: Springer; 2020:91-110.
2. Peitzmeier SM, Malik M, Kattari SK, Marrow E, Stephenson R, Agénor M, et al. Intimate partner violence in transgender populations: systematic review and meta-analysis of prevalence and correlates. Am J Public Health 2020;110(9):e1-e14. [doi: 10.2105/AJPH.2020.305774] [Medline: 32673114]
3. Stephenson R, Todd K, Gamarel KE, Bonar EE, Peitzmeier S. Development and validation of a scale to measure intimate partner violence among transgender and gender diverse populations: protocol for a linear three-phase study (Project Empower). JMIR Res Protoc 2020;9(11):e23819 [FREE Full text] [doi: 10.2196/23819] [Medline: 33242022]
4. James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The report of the 2015 US transgender survey. National Center for Transgender Equality. 2016 Dec. URL: https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf [accessed 2025-11-12]
5. El-Bassel N, Mukherjee TI, Stoicescu C, Starbird LE, Stockman JK, Frye V, et al. Intertwined epidemics: progress, gaps, and opportunities to address intimate partner violence and HIV among key populations of women. Lancet HIV 2022;9(3):e202-e213 [FREE Full text] [doi: 10.1016/S2352-3018(21)00325-8] [Medline: 35151376]
6. Heintz AJ, Melendez RM. Intimate partner violence and HIV/STD risk among lesbian, gay, bisexual, and transgender individuals. J Interpers Violence 2006;21(2):193-208. [doi: 10.1177/0886260505282104] [Medline: 16368761]
7. Mimiaga M, Hughto JMW, Biello KB, Santostefano CM, Kuhns LM, Reisner SL, et al. Longitudinal analysis of syndemic psychosocial problems predicting hiv risk behavior among a multicity prospective cohort of sexually active young transgender

women in the United States. J Acquir Immune Defic Syndr 2019;81(2):184-192 [FREE Full text] [doi: 10.1097/QAI.0000000000002009] [Medline: 30839380]
8. Brennan J, Kuhns LM, Johnson AK, Belzer M, Wilson EC, Garofalo R, Adolescent Medicine Trials Network for HIV/AIDS Interventions. Syndemic theory and HIV-related risk among young transgender women: the role of multiple, co-occurring health problems and social marginalization. Am J Public Health 2012;102(9):1751-1757 [FREE Full text] [doi: 10.2105/AJPH.2011.300433] [Medline: 22873480]
9. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006-2017. Am J Public Health 2019;109(1):e1-e8 [FREE Full text] [doi: 10.2105/AJPH.2018.304727] [Medline: 30496000]
10. Magno L, Silva LAV, Veras MA, Pereira-Santos M, Dourado I. Stigma and discrimination related to gender identity and vulnerability to HIV/AIDS among transgender women: a systematic review. Cad Saude Publica 2019;35(4):e00112718 [FREE Full text] [doi: 10.1590/0102-311X00112718] [Medline: 30994744]
11. White Hughto JM, Reisner SL, Pachankis JE. Transgender stigma and health: a critical review of stigma determinants, mechanisms, and interventions. Soc Sci Med 2015;147:222-231 [FREE Full text] [doi: 10.1016/j.socscimed.2015.11.010] [Medline: 26599625]
12. CDC's 2013 HIV surveillance report. Centers for Disease Control and Prevention. 2015 Feb 24. URL: https://www.hiv.gov/blog/cdcs-2013-hiv-surveillance-report-now-available-online [accessed 2025-11-11]
13. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis 2013;13(3):214-222. [doi: 10.1016/S1473-3099(12)70315-8] [Medline: 23260128]
14. Ogunbajo A, Storholm ED, Ober AJ, Bogart LM, Reback CJ, Flynn R, et al. Multilevel barriers to HIV PrEP uptake and adherence among Black and Hispanic/Latinx transgender women in southern California. AIDS Behav 2021;25(7):2301-2315 [FREE Full text] [doi: 10.1007/s10461-021-03159-2] [Medline: 33515132]
15. Storholm ED, Ogunbajo A, Nacht CL, Opalo C, Horvath KJ, Lyman P, et al. Facilitators of PrEP persistence among Black and Latinx transgender women in a PrEP demonstration project in southern California. Behav Med 2024;50(1):63-74 [FREE Full text] [doi: 10.1080/08964289.2022.2105794] [Medline: 35993278]
16. Maragh-Bass AC, Kiplagat S, Lavari S, Sastre F, Devieux JG, Jimenez D, et al. Barriers to accessing and engaging in HIV preventive care and pre-exposure prophylaxis experienced by transgender women in Florida. Int J Environ Res Public Health 2024;21(3):376 [FREE Full text] [doi: 10.3390/ijerph21030376] [Medline: 38541377]
17. Sullivan P, Brixner D, Lam JT, Hsiao A. Overcoming barriers to HIV prevention: population health considerations on optimizing PrEP access. Am J Manag Care 2024;30(11 Suppl):S207-S215 [FREE Full text] [doi: 10.37765/ajmc.2024.89654] [Medline: 39652788]
18. McCann E, Brown M. Vulnerability and psychosocial risk factors regarding people who identify as transgender. a systematic review of the research evidence. Issues Ment Health Nurs 2018;39(1):3-15. [doi: 10.1080/01612840.2017.1382623] [Medline: 29286841]
19. Yang C, Huang Y, Newman PA. A qualitative systematic review of stigma, violence, victimization, and associated coping among transgender people engaged in sex work. Trauma Violence Abuse 2025;26(3):582-597. [doi: 10.1177/15248380241284586] [Medline: 39394694]
20. Marrow E, Malik M, Pantalone DW, Peitzmeier S. Power and control, resistance and survival: a systematic review and meta-synthesis of the qualitative literature on intimate partner violence against transgender individuals. Soc Sci Med 2024;342:116498. [doi: 10.1016/j.socscimed.2023.116498] [Medline: 38227997]
21. Henry RS, Perrin PB, Coston BM, Calton JM. Intimate partner violence and mental health among transgender/gender nonconforming adults. J Interpers Violence 2021;36(7-8):3374-3399 [FREE Full text] [doi: 10.1177/0886260518775148] [Medline: 29779457]
22. Storholm ED, Huang W, Ogunbajo A, Horvath KJ, Reback CJ, Blumenthal J, et al. Gender-based violence and post-traumatic stress disorder symptoms predict HIV PrEP uptake and persistence failure among transgender and non-binary persons participating in a PrEP demonstration project in southern California. AIDS Behav 2023;27(2):745-759 [FREE Full text] [doi: 10.1007/s10461-022-03807-1] [Medline: 36053404]
23. Dang M, Scheim AI, Teti M, Quinn KG, Zarwell M, Petroll AE, et al. Barriers and facilitators to HIV pre-exposure prophylaxis uptake, adherence, and persistence among transgender populations in the United States: a systematic review. AIDS Patient Care STDS 2022;36(6):236-248 [FREE Full text] [doi: 10.1089/apc.2021.0236] [Medline: 35687813]
24. Walker JK. Investigating trans people's vulnerabilities to intimate partner violence/abuse. Partner Abuse 2015;6(1):107-125. [doi: 10.1891/1946-6560.6.1.107]
25. Akande M, Del Farno A, Adrian H, Fogwell NT, Johnson DM, Zlotnick C, et al. 'Sometimes, we don't know if we're getting abused': discussions of intimate partner violence and HIV risk among transgender women. Cult Health Sex 2023;25(9):1101-1115. [doi: 10.1080/13691058.2022.2134929] [Medline: 36309824]
26. Ingold KA, Teasdale B. Explaining the relationship between intimate partner violence victimization and human immunodeficiency virus status in transgender and nonbinary individuals. J Interpers Violence 2024;39(15-16):3373-3395 [FREE Full text] [doi: 10.1177/08862605241230551] [Medline: 38345002]

27. King WM, Restar A, Operario D. Exploring multiple forms of intimate partner violence in a gender and racially/ethnically diverse sample of transgender adults. J Interpers Violence 2021;36(19-20):NP10477-NP10498. [doi: 10.1177/0886260519876024] [Medline: 31526070]
28. Sevelius JM, Keatley J, Calma N, Arnold E. 'I am not a man': trans-specific barriers and facilitators to PrEP acceptability among transgender women. Glob Public Health 2016;11(7-8):1060-1075 [FREE Full text] [doi: 10.1080/17441692.2016.1154085] [Medline: 26963756]
29. Wilson EC, Jin H, Liu A, Raymond HF. Knowledge, indications and willingness to take pre-exposure prophylaxis among transwomen in San Francisco, 2013. PLoS One 2015;10(6):e0128971 [FREE Full text] [doi: 10.1371/journal.pone.0128971] [Medline: 26039511]
30. Teng F, Sha Y, Fletcher LM, Welsch M, Burns P, Tang W. Barriers to uptake of PrEP across the continuum among transgender women: a global scoping review. Int J STD AIDS 2023;34(5):299-314. [doi: 10.1177/09564624231152781] [Medline: 36793197]
31. Sevelius J, Glidden DV, Deutsch M, Welborn L, Contreras A, Salinas A, et al. Uptake, retention, and adherence to pre-exposure prophylaxis (PrEP) in TRIUMPH: a peer-led PrEP demonstration project for transgender communities in Oakland and Sacramento, California. J Acquir Immune Defic Syndr 2021;88(S1):S27-S38 [FREE Full text] [doi: 10.1097/QAI.0000000000002808] [Medline: 34757990]
32. Nunn A, Brinkley-Rubinstein L, Oldenburg CE, Mayer KH, Mimiaga M, Patel R, et al. Defining the HIV pre-exposure prophylaxis care continuum. AIDS 2017;31(5):731-734 [FREE Full text] [doi: 10.1097/QAD.0000000000001385] [Medline: 28060019]
33. Peitzmeier SM, Hughto JMW, Potter J, Deutsch MB, Reisner SL. Development of a novel tool to assess intimate partner violence against transgender individuals. J Interpers Violence 2019;34(11):2376-2397. [doi: 10.1177/0886260519827660] [Medline: 30735080]
34. Peitzmeier SM, Wirtz AL, Humes E, Hughto JM, Cooney E, Reisner SL, American Cohort to Study HIV Acquisition Among Transgender Women (LITE). The transgender-specific intimate partner violence scale for research and practice: validation in a sample of transgender women. Soc Sci Med 2021;291:114495 [FREE Full text] [doi: 10.1016/j.socscimed.2021.114495] [Medline: 34710821]
35. Singer M. AIDS and the health crisis of the U.S. urban poor; the perspective of critical medical anthropology. Soc Sci Med 1994;39(7):931-948. [doi: 10.1016/0277-9536(94)90205-4] [Medline: 7992126]
36. Operario D, Nemoto T. HIV in transgender communities: syndemic dynamics and a need for multicomponent interventions. J Acquir Immune Defic Syndr 2010;55(Suppl 2):S91-S93 [FREE Full text] [doi: 10.1097/QAI.0b013e3181fbc9ec] [Medline: 21406995]
37. Poteat T, Scheim A, Xavier J, Reisner S, Baral S. Global epidemiology of HIV infection and related syndemics affecting transgender people. J Acquir Immune Defic Syndr 2016;72(Suppl 3):S210-S219 [FREE Full text] [doi: 10.1097/QAI.0000000000001087] [Medline: 27429185]
38. Meyer IH. Prejudice, social stress, and mental health in lesbian, gay, and bisexual populations: conceptual issues and research evidence. Psychol Bull 2003;129(5):674-697 [FREE Full text] [doi: 10.1037/0033-2909.129.5.674] [Medline: 12956539]
39. Testa RJ, Michaels MS, Bliss W, Rogers ML, Balsam KF, Joiner T. Suicidal ideation in transgender people: gender minority stress and interpersonal theory factors. J Abnorm Psychol 2017;126(1):125-136. [doi: 10.1037/abn0000234] [Medline: 27831708]
40. Hendricks ML, Testa RJ. A conceptual framework for clinical work with transgender and gender nonconforming clients: an adaptation of the minority stress model. Prof Psychol Res Pract 2012;43(5):460-467. [doi: 10.1037/a0029597]
41. Lefevor GT, Boyd-Rogers CC, Sprague BM, Janis RA. Health disparities between genderqueer, transgender, and cisgender individuals: an extension of minority stress theory. J Couns Psychol 2019;66(4):385-395. [doi: 10.1037/cou0000339] [Medline: 30896208]
42. Rich AJ, Salway T, Scheim A, Poteat T. Sexual minority stress theory: remembering and honoring the work of Virginia Brooks. LGBT Health 2020;7(3):124-127. [doi: 10.1089/lgbt.2019.0223] [Medline: 32053038]
43. Brooks VR. Minority Stress and Lesbian Women. Lexington, MA: Lexington Books; 1981.
44. Goldenberg T, Kahle EM, Stephenson R. Stigma, resilience, and health care use among transgender and other gender diverse youth in the United States. Transgend Health 2020;5(3):173-181 [FREE Full text] [doi: 10.1089/trgh.2019.0074] [Medline: 32923667]
45. Stall R, Friedman M, Catania JA. Interacting epidemics and gay men's health: a theory of syndemic production among urban gay men. In: Unequal Opportunity: Health Disparities Affecting Gay and Bisexual Men in the United States. England: Oxford Academic; 2008:251-274.
46. Stall R, Paul JP, Greenwood G, Pollack LM, Bein E, Crosby GM, et al. Alcohol use, drug use and alcohol-related problems among men who have sex with men: the urban men's health study. Addiction 2001;96(11):1589-1601. [doi: 10.1046/j.1360-0443.2001.961115896.x] [Medline: 11784456]

47. Warner DM, Mehta AH. Identifying and addressing barriers to transgender healthcare: where we are and what we need to do about it. J Gen Intern Med 2021;36(11):3559-3561 [FREE Full text] [doi: 10.1007/s11606-021-07001-2] [Medline: 34254221]
48. Klein A, Golub SA. Increasing access to pre-exposure prophylaxis among transgender women and transfeminine nonbinary individuals. AIDS Patient Care STDS 2019;33(6):262-269. [doi: 10.1089/apc.2019.0049] [Medline: 31166785]
49. Reisner SL, White Hughto JM, Pardee D, Sevelius J. Syndemics and gender affirmation: HIV sexual risk in female-to-male trans masculine adults reporting sexual contact with cisgender males. Int J STD AIDS 2016;27(11):955-966 [FREE Full text] [doi: 10.1177/0956462415602418] [Medline: 26384946]
50. Meyer IH. Resilience in the study of minority stress and health of sexual and gender minorities. Psychol Sex Orientat Gend Divers 2015;2(3):209-213. [doi: 10.1037/sgd0000132]
51. Testa RJ, Habarth J, Peta J, Balsam K, Bockting W. Development of the gender minority stress and resilience measure. Psychol Sex Orientat Gend Divers 2015;2(1):65-77. [doi: 10.1037/sgd0000081]
52. Restar A, Minalga BJ, Quilantang MI, Adamson T, Dusic E, van der Merwe L, et al. Mapping community-engaged implementation strategies with transgender scientists, stakeholders, and trans-led community organizations. Curr HIV/AIDS Rep 2023;20(3):160-169 [FREE Full text] [doi: 10.1007/s11904-023-00656-y] [Medline: 37012537]
53. Wolf EJ, Harrington KM, Clark SL, Miller MW. Sample size requirements for structural equation models: an evaluation of power, bias, and solution propriety. Educ Psychol Meas 2013;76(6):913-934 [FREE Full text] [doi: 10.1177/0013164413495237] [Medline: 25705052]
54. Holloway IW, Traube DE, Kubicek K, Supan J, Weiss G, Kipke MD. HIV prevention service utilization in the Los Angeles House and Ball communities: past experiences and recommendations for the future. AIDS Educ Prev 2012;24(5):431-444 [FREE Full text] [doi: 10.1521/aeap.2012.24.5.431] [Medline: 23016504]
55. Storholm ED, Siconolfi DE, Wagner GJ, Huang W, Nacht CL, Sallabank G, et al. Intimate partner violence and HIV prevention among sexual minority men: protocol for a prospective mixed methods cohort study. JMIR Res Protoc 2022;11(11):e41453 [FREE Full text] [doi: 10.2196/41453] [Medline: 36378519]
56. Understanding and addressing violence against women: intimate partner violence. World Health Organization. 2012 Nov 27. URL: https://www.who.int/publications/i/item/WHO-RHR-12.36 [accessed 2025-11-11]
57. Stephenson R, Finneran C. The IPV-GBM scale: a new scale to measure intimate partner violence among gay and bisexual men. PLoS One 2013;8(6):e62592 [FREE Full text] [doi: 10.1371/journal.pone.0062592] [Medline: 23755098]
58. Postmus JL, Plummer S, Stylianou AM. Measuring economic abuse in the lives of survivors: revising the scale of economic abuse. Violence Against Women 2016;22(6):692-703. [doi: 10.1177/1077801215610012] [Medline: 26508530]
59. Stephenson R, Chavanduka TMD, Sullivan SP, Mitchell JW. Pre-exposure prophylaxis stigma and beliefs in the efficacy of pre-exposure prophylaxis: an analysis of a cross-sectional survey of male couples in the United States. J Assoc Nurses AIDS Care 2022;33(4):406-420. [doi: 10.1097/JNC.0000000000000315] [Medline: 34812796]
60. Stephenson R, Chavanduka TMD, Sullivan SP, Mitchell JW. Dyadic influences on pre-exposure prophylaxis (PrEP) use and attitudes among male couples. AIDS Behav 2022;26(2):361-374. [doi: 10.1007/s10461-021-03389-4] [Medline: 34331608]
61. Stephenson R, Chavanduka TMD, Sullivan S, Mitchell JW. Partner support and communication for pre-exposure prophylaxis (PrEP) use among male couples. Arch Sex Behav 2022;51(5):2549-2562. [doi: 10.1007/s10508-021-02118-1] [Medline: 34799830]
62. Crowe A, Overstreet NM, Murray CE. The intimate partner violence stigma scale: initial development and validation. J Interpers Violence 2021;36(15-16):7456-7479. [doi: 10.1177/0886260519834095] [Medline: 30866696]
63. Weiss NH, Duke AA, Overstreet NM, Swan SC, Sullivan TP. Intimate partner aggression-related shame and posttraumatic stress disorder symptoms: the moderating role of substance use problems. Aggress Behav 2016;42(5):427-440 [FREE Full text] [doi: 10.1002/ab.21639] [Medline: 26699821]
64. National HIV Behavioral Surveillance System (NHBS) Round 5 Survey (2017-2019). 2025. URL: https://www.cdc.gov/hiv/pdf/statistics/systems/nhbs/NHBS_CRQ_R5_IDU5.pdf [accessed 2025-11-11]
65. Sullivan PS, Zahn RJ, Wiatrek S, Chandler CJ, Hirshfield S, Stephenson R, et al. HIV prevention via mobile messaging for men who have sex with men (M-Cubed): protocol for a randomized controlled trial. JMIR Res Protoc 2019;8(11):e16439 [FREE Full text] [doi: 10.2196/16439] [Medline: 31730043]
66. Siegler AJ, Wiatrek S, Mouhanna F, Amico KR, Dominguez K, Jones J, et al. Validation of the HIV pre-exposure prophylaxis stigma scale: performance of Likert and semantic differential scale versions. AIDS Behav 2020;24(9):2637-2649 [FREE Full text] [doi: 10.1007/s10461-020-02820-6] [Medline: 32157490]
67. Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. Office of Management and Budget. 2024 Mar 29. URL: https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and [accessed 2025-11-11]
68. Pillai D, Artiga S. Revisions to federal standards for collecting and reporting data on race and ethnicity: what are they and why do they matter? Kaiser Family Foundation. 2024 Apr 30. URL: https://www.kff.org/racial-equity-and-health-policy/

revisions-to-federal-standards-for-collecting-and-reporting-data-on-race-and-ethnicity-what-are-they-and-why-do-they-matter/ [accessed 2025-11-11]
69. 2019 Survey – English – Paper Version. Trans PULSE Canada. URL: https://transpulsecanada.ca/wp-content/uploads/2021/05/Survey-EN-Paper-Full-2021-05-27.pdf [accessed 2025-11-11]
70. Participant provided information. All of Us Research Program. URL: https://allofus.nih.gov/get-involved/participation [accessed 2025-11-11]
71. Smith TW. General Social Surveys (1972-2018): Cumulative Codebook. Chicago, IL: National Opinion Research Center; 2019.
72. Measuring financial well-being: a guide to using the CFPB Financial Well-Being Scale. Consumer Financial Protection Bureau. 2015. URL: https://www.consumerfinance.gov/data-research/research-reports/financial-well-being-scale/ [accessed 2025-11-11]
73. U.S. household food security survey module: six-item short form. Economic Research Service, USDA. 2024 May. URL: https://ers.usda.gov/sites/default/files/_laserfiche/DataFiles/50764/short2024.pdf?v=77152 [accessed 2025-11-11]
74. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). Medical Care 1992;30(6):473-483. [doi: 10.1097/00005650-199206000-00002]
75. 2020 National Health Interview Survey (NHIS) Questionnaire – Interview Module: Adult. National Center for Health Statistics. 2020. URL: https://www.cdc.gov/nchs/nhis/documentation/2020-nhis.html [accessed 2025-11-11]
76. Quarter 1 2015 Questionnaire, question numbers Q7, Q8, Q8b. Health Reform Monitoring Survey (HRMS). 2015. URL: https://www.urban.org/policy-centers/health-policy-center/projects/health-reform-monitoring-survey [accessed 2025-11-11]
77. Jowett SL, Seal CJ, Barton JR. The short inflammatory bowel disease questionnaire is reliable and responsive to clinically important change in ulcerative colitis. Am J Gastroenterol 2001;96(10):2921-2928. [doi: 10.1016/s0002-9270(01)03244-0]
78. 2019 National Survey on Drug Use and Health (NSDUH): CAI Specifications for Programming [English Version]. Substance Abuse and Mental Health Services Administration. URL: https://www.icpsr.umich.edu/web/NAHDAP/studies/32722 [accessed 2025-11-11]
79. Rusbult CE. A longitudinal test of the investment model: the development (and deterioration) of satisfaction and commitment in heterosexual involvements. J Pers Soc Psychol 1983;45(1):101-117. [doi: 10.1037//0022-3514.45.1.101]
80. Miller RS, Lefcourt HM. The assessment of social intimacy. J Pers Assess 1982;46(5):514-518. [doi: 10.1207/s15327752jpa4605_12] [Medline: 16367633]
81. Anderson SR, Johnson LN, Miller RB, Barham CC. The Couple Relationship Scale: a brief measure to facilitate routine outcome monitoring in couple therapy. J Marital Fam Ther 2022;48(2):464-483. [doi: 10.1111/jmft.12541] [Medline: 34269484]
82. Kurdek LA. The deterioration of relationship quality for gay and lesbian cohabiting couples: a five‐year prospective longitudinal study. Pers Relat 2005;3(4):417-442. [doi: 10.1111/j.1475-6811.1996.tb00125.x]
83. Sternberg RJ. A triangular theory of love. Psychol Rev 1986;93(2):119-135. [doi: 10.1037//0033-295x.93.2.119]
84. Futris TG, Campbell K, Nielsen RB, Burwell SR. The communication patterns questionnaire-short form: a review and assessment. Fam J 2010;18(3):275-287. [doi: 10.1177/1066480710370758]
85. Pulerwitz J, Gortmaker SL, DeJong W. Measuring sexual relationship power in HIV/STD research. Sex Roles 2000;42(7-8):637-660. [doi: 10.1023/a:1007051506972]
86. Schulz U, Schwarzer R. Soziale Unterstützung bei der Krankheitsbewältigung: Die Berliner Social Support Skalen (BSSS) [Social support in coping with illness: the Berlin Social Support Scales (BSSS)]. Diagnostica 2003;49(2):73-82. [doi: 10.1026//0012-1924.49.2.73]
87. Adverse childhood experience questionnaire for adults. California Surgeon General's Clinical Advisory Committee. 2020 May 5. URL: https://www.acesaware.org/wp-content/uploads/2022/07/ACE-Questionnaire-for-Adults-De-identified-English-rev.7.26.22.pdf [accessed 2025-11-11]
88. Schnarrs PW, Dorri AA, Yockey RA, Stone AL, Russell ST, Rosenberger JG. The sexual and gender minority adverse childhood experiences scale. Am J Prev Med 2023;65(6):1050-1058. [doi: 10.1016/j.amepre.2023.08.006] [Medline: 37572853]
89. Harris KM, Udry JR. National Longitudinal Study of Adolescent to Adult Health (Add Health), 1994-2018 [Public use]. Carolina Population Center, University of North Carolina–Chapel Hill. URL: https://addhealth.cpc.unc.edu/data/public-use-data-sets/ [accessed 2025-11-11]
90. Krieger N, Smith K, Naishadham D, Hartman C, Barbeau EM. Experiences of discrimination: validity and reliability of a self-report measure for population health research on racism and health. Soc Sci Med 2005;61(7):1576-1596 [FREE Full text] [doi: 10.1016/j.socscimed.2005.03.006] [Medline: 16005789]
91. Schutt RK, Goldfinger SM. Homelessness, Housing, and Mental Illness. Cambridge: Harvard University Press; 2011.
92. Link BG, Susser E, Stueve A, Phelan J, Moore RE, Struening E. Lifetime and five-year prevalence of homelessness in the United States. Am J Public Health 1994;84(12):1907-1912. [doi: 10.2105/ajph.84.12.1907] [Medline: 7998628]
93. Mujahid MS, Diez Roux AV, Morenoff JD, Raghunathan T. Assessing the measurement properties of neighborhood scales: from psychometrics to ecometrics. Am J Epidemiol 2007;165(8):858-867. [doi: 10.1093/aje/kwm040] [Medline: 17329713]

94. Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord 2009;114(1-3):163-173. [doi: 10.1016/j.jad.2008.06.026] [Medline: 18752852]
95. Prins A, Bovin MJ, Kimerling R, Kaloupek DG, Marx BP, Kaiser AP, et al. Primary care PTSD screen for DSM-5 (PC-PTSD-5). U.S. Department of Veterans Affairs. 2015. URL: https://www.ptsd.va.gov/professional/assessment/screens/pc-ptsd.asp [accessed 2025-11-11]
96. Kroenke K, Spitzer RL, Williams JB, Monahan PO, Löwe B. Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. Ann Intern Med 2007;146(5):317-325. [doi: 10.7326/0003-4819-146-5-200703060-00004] [Medline: 17339617]
97. Hughes ME, Waite LJ, Hawkley LC, Cacioppo JT. A short scale for measuring loneliness in large surveys: results from two population-based studies. Res Aging 2004;26(6):655-672 [FREE Full text] [doi: 10.1177/0164027504268574] [Medline: 18504506]
98. Hawthorne G. Measuring social isolation in older adults: development and initial validation of the friendship scale. Soc Indic Res 2006;77(3):521-548. [doi: 10.1007/s11205-005-7746-y]
99. DSM-5-TR Self-Rated Level 1 Cross-Cutting Symptom Measure—Adult. American Psychiatric Association. 2013. URL: https://www.psychiatry.org/getmedia/e0b4b299-95b3-407b-b8c2-caa871ca218d/APA-DSM5TR-Level1MeasureAdult.pdf [accessed 2025-11-11]
100. LEVEL 2—Sleep Disturbance—Adult (PROMIS—Sleep Disturbance— Short Form). American Psychiatric Association. 2013. URL: https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM5_Level-2-Sleep-Disturbance-Adult.pdf [accessed 2025-11-11]
101. Gross JJ, John OP. Individual differences in two emotion regulation processes: implications for affect, relationships, and well-being. J Pers Soc Psychol 2003;85(2):348-362. [doi: 10.1037/0022-3514.85.2.348] [Medline: 12916575]
102. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Arch Intern Med 1998;158(16):1789-1795. [doi: 10.1001/archinte.158.16.1789] [Medline: 9738608]
103. NIDA-Modified ASSIST V2.0. National Institute on Drug Abuse. URL: https://nida.nih.gov/ [accessed 2025-11-11]
104. Baber KM, Tucker CJ. The social roles questionnaire: a new approach to measuring attitudes toward gender. Sex Roles 2006;54(7-8):459-467. [doi: 10.1007/s11199-006-9018-y]
105. Sevelius JM, Chakravarty D, Dilworth SE, Rebchook G, Neilands TB. Measuring satisfaction and comfort with gender identity and gender expression among transgender women: development and validation of the psychological gender affirmation scale. Int J Environ Res Public Health 2021;18(6):3298 [FREE Full text] [doi: 10.3390/ijerph18063298] [Medline: 33806834]
106. Meyer IH, Frost DM, Narvaez R, Dietrich JH. Project STRIDE methodology and technical notes. Project STRIDE. 2006. URL: https://www.columbia.edu/~im15/method/stridemethod.pdf [accessed 2025-11-11]
107. Szymanski DM, Gonzalez KA. The role of resilience in sexual and gender minority mental health. In: Rothblum ED, editor. The Oxford Handbook of Sexual and Gender Minority Mental Health. Oxford: Oxford Academic; 2020:429-442.
108. Frost DM, Meyer IH. Measuring community connectedness among diverse sexual minority populations. J Sex Res 2012;49(1):36-49 [FREE Full text] [doi: 10.1080/00224499.2011.565427] [Medline: 21512945]
109. Chesney MA, Neilands TB, Chambers DB, Taylor JM, Folkman S. A validity and reliability study of the coping self-efficacy scale. Br J Health Psychol 2006;11(Pt 3):421-437 [FREE Full text] [doi: 10.1348/135910705X53155] [Medline: 16870053]
110. Wagnild GM, Young HM. Development and psychometric evaluation of the Resilience Scale. J Nurs Meas 1993;1(2):165-178. [Medline: 7850498]
111. Wagnild G. A review of the Resilience Scale. J Nurs Meas 2009;17(2):105-113. [doi: 10.1891/1061-3749.17.2.105] [Medline: 19711709]
112. Rosenberg M. The measurement of self-esteem. In: Society and the Adolescent Self-Image. New Jersey: Princeton University Press; 1965.
113. Restar A, Jin H, Operario D. Gender-inclusive and gender-specific approaches in trans health research. Transgend Health 2021;6(5):235-239 [FREE Full text] [doi: 10.1089/trgh.2020.0054] [Medline: 34993295]
114. Charmaz K. Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis. Thousand Oaks, CA: SAGE Publications; 2006.
115. Brod M, Tesler LE, Christensen TL. Qualitative research and content validity: developing best practices based on science and experience. Qual Life Res 2009;18(9):1263-1278. [doi: 10.1007/s11136-009-9540-9] [Medline: 19784865]
116. Cohen J. A coefficient of agreement for nominal scales. Educ Psychol Meas 1960;20(1):37-46. [doi: 10.1177/001316446002000104]
117. Creswell JW, Miller DL. Determining validity in qualitative inquiry. Theory Pract 2000;39(3):124-130. [doi: 10.1207/s15430421tip3903_2]
118. Palinkas LA, Aarons GA, Horwitz S, Chamberlain P, Hurlburt M, Landsverk J. Mixed method designs in implementation research. Adm Policy Ment Health 2011;38(1):44-53 [FREE Full text] [doi: 10.1007/s10488-010-0314-z] [Medline: 20967495]

119. Lepkowski JM. Treatment of wave nonresponse in panel surveys. In: Panel Surveys. New York: John Wiley & Sons; 1989:348-374.
120. Little RJA, Rubin DB. Statistical Analysis With Missing Data. New York: John Wiley & Sons; 2002.
121. Xu D, Daniels MJ, Winterstein AG. Sequential BART for imputation of missing covariates. Biostatistics 2016;17(3):589-602 [FREE Full text] [doi: 10.1093/biostatistics/kxw009] [Medline: 26980459]
122. Willett JB, Bub KL. Structural equation modeling: latent growth curve analysis. In: Encyclopedia of Statistics in Behavioral Sciences. Sussex: John Wiley & Sons; 2005.
123. Muthén BO, Curran PJ. General longitudinal modeling of individual differences in experimental designs: a latent variable framework for analysis and power estimation. Psychol Methods 1997;2(4):371-402. [doi: 10.1037//1082-989x.2.4.371]
124. Willett JB, Sayer AG. Using covariance structure analysis to detect correlates and predictors of individual change over time. Psychol Bull 1994;116(2):363-381. [doi: 10.1037//0033-2909.116.2.363]
125. Berlin KS, Parra GR, Williams NA. An introduction to latent variable mixture modeling (part 2): longitudinal latent class growth analysis and growth mixture models. J Pediatr Psychol 2014;39(2):188-203. [doi: 10.1093/jpepsy/jst085] [Medline: 24277770]
126. Asparouhov T, Hamaker EL, Muthén B. Dynamic latent class analysis. Struct Equ Modeling 2016;24(2):257-269. [doi: 10.1080/10705511.2016.1253479]
127. Bollen KA. Structural Equations With Latent Variables. New York: John Wiley & Sons; 1989.
128. Storholm ED, Huang W, Siconolfi DE, Pollack LM, Carrico AW, Vincent W, et al. Sources of resilience as mediators of the effect of minority stress on stimulant use and sexual risk behavior among young black men who have sex with men. AIDS Behav 2019;23(12):3384-3395 [FREE Full text] [doi: 10.1007/s10461-019-02572-y] [Medline: 31273490]
129. Bentler PM, Bonett DG. Significance tests and goodness of fit in the analysis of covariance structures. Psychol Bull 1980;88(3):588-606. [doi: 10.1037//0033-2909.88.3.588]
130. Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. Struct Equ Modeling 1999;6(1):1-55. [doi: 10.1080/10705519909540118]
131. Dillon G, Hussain R, Loxton D, Rahman S. Mental and physical health and intimate partner violence against women: a review of the literature. Int J Family Med 2013;2013:313909 [FREE Full text] [doi: 10.1155/2013/313909] [Medline: 23431441]
132. Devries KM, Mak JY, Bacchus LJ, Child JC, Falder G, Petzold M, et al. Intimate partner violence and incident depressive symptoms and suicide attempts: a systematic review of longitudinal studies. PLoS Med 2013;10(5):e1001439 [FREE Full text] [doi: 10.1371/journal.pmed.1001439] [Medline: 23671407]
133. Coker AL. Does physical intimate partner violence affect sexual health? A systematic review. Trauma Violence Abuse 2007;8(2):149-177. [doi: 10.1177/1524838007301162] [Medline: 17545572]
134. Capaldi DM, Knoble NB, Shortt JW, Kim HK. A systematic review of risk factors for intimate partner violence. Partner Abuse 2012;3(2):231-280 [FREE Full text] [doi: 10.1891/1946-6560.3.2.231] [Medline: 22754606]
135. Neumann MS, Finlayson TJ, Pitts NL, Keatley J. Comprehensive HIV prevention for transgender persons. Am J Public Health 2017;107(2):207-212 [FREE Full text] [doi: 10.2105/AJPH.2016.303509] [Medline: 27997228]
136. Chen Y, Duncan DT, Issema R, Goedel WC, Callander D, Bernard-Herman B, et al. Social-environmental resilience, PrEP uptake, and viral suppression among young black men who have sex with men and young black transgender women: the neighborhoods and networks (N2) study in Chicago. J Urban Health 2020;97(5):728-738 [FREE Full text] [doi: 10.1007/s11524-020-00425-x] [Medline: 32468507]
137. Lelutiu-Weinberger C, English D, Sandanapitchai P. The roles of gender affirmation and discrimination in the resilience of transgender individuals in the US. Behav Med 2020;46(3-4):175-188 [FREE Full text] [doi: 10.1080/08964289.2020.1725414] [Medline: 32787726]
138. Hawkey AJ, Ussher JM, Liamputtong P, Marjadi B, Sekar JA, Perz J, et al. Trans women's responses to sexual violence: vigilance, resilience, and need for support. Arch Sex Behav 2021;50(7):3201-3222. [doi: 10.1007/s10508-021-01965-2] [Medline: 34697692]
139. Crann SE, Barata PC. “We can be oppressed but that does not mean we cannot fight oppression”: narratives of resilience and advocacy from survivors of intimate partner violence. J Interpers Violence 2021;36(17-18):8004-8026. [doi: 10.1177/0886260519848779] [Medline: 31079519]
140. Sanchez ML. The resilience experiences in non-binary survivors of intimate partner violence and sexual assault [Master’s Thesis]. The Ohio State University. 2019. URL: https://etd.ohiolink.edu/acprod/odb_etd/etd/r/1501/10?clear=10&p10_accession_num=osu1556796935295631 [accessed 2025-11-11]
141. Carlson BE, McNutt LA, Choi DY, Rose IM. Intimate partner abuse and mental health: the role of social support and other protective factors. Violence Against Women 2002;8(6):720-745. [doi: 10.1177/10778010222183251]
142. Machisa MT, Christofides N, Jewkes R. Social support factors associated with psychological resilience among women survivors of intimate partner violence in Gauteng, South Africa. Glob Health Action 2018;11(Suppl 3):1491114 [FREE Full text] [doi: 10.1080/16549716.2018.1491114] [Medline: 30270774]

143. Beeble ML, Bybee D, Sullivan CM, Adams AE. Main, mediating, and moderating effects of social support on the well-being of survivors of intimate partner violence across 2 years. J Consult Clin Psychol 2009;77(4):718-729. [doi: 10.1037/a0016140] [Medline: 19634964]
144. Sylaska KM, Edwards KM. Disclosure of intimate partner violence to informal social support network members: a review of the literature. Trauma Violence Abuse 2014;15(1):3-21. [doi: 10.1177/1524838013496335] [Medline: 23887351]
145. Mitchell MD, Hargrove GL, Collins MH, Thompson MP, Reddick TL, Kaslow NJ. Coping variables that mediate the relation between intimate partner violence and mental health outcomes among low-income, African American women. J Clin Psychol 2006;62(12):1503-1520. [doi: 10.1002/jclp.20305] [Medline: 16897697]
146. Bradley R, Schwartz AC, Kaslow NJ. Posttraumatic stress disorder symptoms among low-income, African American women with a history of intimate partner violence and suicidal behaviors: self-esteem, social support, and religious coping. J Trauma Stress 2005;18(6):685-696. [doi: 10.1002/jts.20077] [Medline: 16382436]
147. Crowne SS, Juon H, Ensminger M, Burrell L, McFarlane E, Duggan A. Concurrent and long-term impact of intimate partner violence on employment stability. J Interpers Violence 2011;26(6):1282-1304. [doi: 10.1177/0886260510368160] [Medline: 20587457]
148. Cunradi CB, Caetano R, Schafer J. Socioeconomic predictors of intimate partner violence among White, Black, and Hispanic couples in the United States. J Fam Violence 2002;17(4):377-389. [doi: 10.1023/a:1020374617328]
149. Staggs SL, Long SM, Mason GE, Krishnan S, Riger S. Intimate partner violence, social support, and employment in the post-welfare reform era. J Interpers Violence 2007;22(3):345-367. [doi: 10.1177/0886260506295388] [Medline: 17308203]
150. de la Rosa IA, Barnett-Queen T, Messick M, Gurrola M. Spirituality and resilience among Mexican American IPV survivors. J Interpers Violence 2016;31(20):3332-3351. [doi: 10.1177/0886260515584351] [Medline: 25948642]
151. Fowler DN, Rountree MA. Exploring the meaning and role of spirituality for women survivors of intimate partner abuse. J Pastoral Care Counsel 2009;63(3-4):1-13. [doi: 10.1177/154230500906300303]
152. Drumm R, Popescu M, Cooper L, Trecartin S, Seifert M, Foster T, et al. “God Just Brought Me Through It”: spiritual coping strategies for resilience among intimate partner violence survivors. Clin Soc Work J 2013;42(4):385-394. [doi: 10.1007/s10615-013-0449-y]
153. LaMartine S. Experiences of violence, victimization, and coping among African American transgender women [Dissertation]. University of La Verne. 2020. URL: https://researchworks.laverne.edu/esploro/outputs/doctoral/Experiences-of-Violence-Victimization-and-Coping/991004156102706311 [accessed 2025-11-11]
154. Sherman ADF, Balthazar M, Klepper M, Febres-Cordero S, Valmeekanathan A, Prakash D, et al. Approach and avoidant coping among black transgender women who have experienced violence: a qualitative analysis. Psychol Serv 2022;19(Suppl 1):45-61 [FREE Full text] [doi: 10.1037/ser0000581] [Medline: 34460276]
155. Iverson KM, Litwack SD, Pineles SL, Suvak MK, Vaughn RA, Resick PA. Predictors of intimate partner violence revictimization: the relative impact of distinct PTSD symptoms, dissociation, and coping strategies. J Trauma Stress 2013;26(1):102-110. [doi: 10.1002/jts.21781] [Medline: 23417878]
156. Smith PH, Murray CE, Coker AL. The coping window: a contextual understanding of the methods women use to cope with battering. Violence Vict 2010;25(1):18-28. [doi: 10.1891/0886-6708.25.1.18] [Medline: 20229691]
157. Bukowski LA, Hampton MC, Escobar-Viera CG, Sang JM, Chandler CJ, Henderson E, et al. Intimate partner violence and depression among Black transgender women in the USA: the potential suppressive effect of perceived social support. J Urban Health 2019;96(5):760-771 [FREE Full text] [doi: 10.1007/s11524-019-00355-3] [Medline: 31037482]
158. Kurdyla V, Messinger AM, Ramirez M. Transgender intimate partner violence and help-seeking patterns. J Interpers Violence 2021;36(19-20):NP11046-NP11069. [doi: 10.1177/0886260519880171] [Medline: 31596167]
159. Grocott LR, Schlechter TE, Wilder SMJ, O'Hair CM, Gidycz CA, Shorey RC. Social support as a buffer of the association between sexual assault and trauma symptoms among transgender and gender diverse individuals. J Interpers Violence 2023;38(1-2):NP1738-NP1761. [doi: 10.1177/08862605221092069] [Medline: 35466782]

Abbreviations

AFAB: assigned female at birth
AMAB: assigned male at birth
CAB: community advisory board
DBS: dried blood spot
HPC: HIV prevention continuum
IPV: intimate partner violence
LCM: latent curve model
PrEP: pre-exposure prophylaxis
RADIANT: Relationships And Dynamics—Improving Advocacy for Nonbinary and Trans
SEM: structural equation modeling
STI: sexually transmitted infection
TNB: transgender and nonbinary

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Examining the Relationship Between Alcohol Use Disorder and Glaucoma: Protocol for a Scoping Review

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Abstract

Background: Alcohol use disorder (AUD) is a condition characterized by uncontrollable alcohol use despite negative social, occupational, or health consequences. AUD affects major organ systems in the body, including the eyes, in different ways. Alcohol seems to have dose-dependent effects on intraocular pressure (IOP), with some quantities lowering IOP and promoting blood flow to the optic nerve head, whereas higher quantities are linked to cardiovascular disorders and systemic physiological changes affecting glaucoma development. Current research shows mixed findings on the correlation between alcohol consumption and glaucoma, and little has been investigated in the AUD population. This paper outlines a protocol for a scoping review that aims to characterize the literature on the connection between AUD and its related conditions, such as alcohol dependence and alcohol misuse, and glaucoma and its associated symptoms, including increased IOP, optic nerve damage, and vision loss.

Objective: The overarching goal of this scoping review is to synthesize an extensive overview of the current literature surrounding AUD or alcohol consumption and glaucoma. We aim to (1) map the existing literature on alcohol and glaucoma; (2) identify how alcohol consumption is associated with glaucoma; and (3) synthesize evidence concerning the association between AUD or alcohol consumption, including drinking frequency, quantity, and type, and glaucoma.

Methods: A biomedical librarian will conduct a systematic search of PubMed and MEDLINE, Embase, Web of Science, and CENTRAL. A 2-step process will be used to screen the results, using Covidence as the screening software. All unique records retrieved from the databases and those identified through supplemental searches will be screened by 2 reviewers independently using the eligibility criteria. This will be followed by data charting. This evidence synthesis will summarize findings in narrative and tabular formats.

Results: This scoping review was started in Covidence in November 2024 and is currently funded by the National Institutes of Health Intramural Research Program. The projected end date for data collection and submission is between November 2025 and January 2026.

Conclusions: This scoping review aims to clarify the mixed findings on the association between AUD or alcohol consumption and glaucoma. The findings will guide future research in this area.

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KEYWORDS

alcohol use disorder; AUD; glaucoma; alcohol abuse; alcohol consumption

Introduction

Rationale

Alcohol use disorder (AUD) is a condition characterized by uncontrollable alcohol use despite negative social, occupational, or health consequences. The National Institute on Alcohol Abuse and Alcoholism defines heavy drinking as consuming 5 or more drinks on any day or 15 or more per week for men and consuming 4 or more drinks on any day or 8 or more drinks per week for women [1]. According to the 2023 National Survey on Drug Use and Health, 28.1 million adults ages 18 years and older had AUD in the previous year [2]. “AUD” is a newer term, as the disorder was previously called “alcoholism.” This change occurred in 2013 with the release of the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* [3]. Due to this terminology shift, we will include various terms for alcohol consumption in our study. Alcohol consumption is

associated with risks of developing noncommunicable diseases such as liver and heart disease, cancers, and mental and behavioral conditions. The World Health Organization states that there is no form of alcohol consumption that is risk free [4]. The health effects of alcohol vary robustly based on the amount consumed. Excessive alcohol consumption can lead to alcoholic liver disease, cardiovascular disease, pancreatitis, cancers, psychiatric comorbidities, and more. Along with consumption levels, drinking patterns, such as light, moderate, and heavy drinking, strongly influence health outcomes [5].

The health consequences of alcohol are widely known as alcohol affects different major organs, including the eyes, based on a variety of factors, including age, sex, and other characteristics. For instance, chronic alcohol use has been reported to increase the risk of eye conditions such as age-related macular degeneration, diabetic retinopathy, cataract, optic neuropathy, retinal vascular and ocular surface diseases, and visual defects [6]. In a 2021 review of the literature, the risk of developing glaucoma from alcohol use was not clearly disclosed, but the review reinforced the need for investigation [6]. Glaucoma is an eye disease, as well as a group of eye diseases, that causes damage to the eye's optic nerve due to fluid buildup in the front part of the eye. It is the leading cause of blindness for individuals aged >60 years [7]. Those with ocular hypertension or high intraocular pressure (IOP) are at a higher risk of glaucoma.

Glaucoma is the main cause of irreversible blindness worldwide. It is estimated that over 100 million individuals will have glaucoma in 2040 [8]. Alcohol is a potential modifiable risk factor for glaucoma, with some harmful associations reported at consumption levels below current US and UK alcohol consumption guidelines [9]. Glaucoma has long been known to be associated with alcohol consumption [10], as well as other risk factors such as IOP, age, gender, genetics and family history, race, and myopia [11]. Studies reporting the effects of alcohol on IOP vary in consistency [12]. Some suggest alcohol use is associated with an increased risk of elevated IOP depending on demographics and glaucoma status [13]. Current literature on the association between alcohol consumption or AUD and glaucoma, including the various subtypes of the disease, shows variable findings [6,14,15]. For instance, some papers report that daily alcohol consumption is a protective factor, associated with a decreased risk of glaucoma [16], whereas other studies report that greater total alcohol consumption is associated with a higher risk of exfoliation glaucoma and exfoliation glaucoma status risk [17]. Another review examined evidence from 10 studies that reported that habitual alcohol use is associated with higher IOP, a risk factor for glaucoma [15]. Most literature on the association between alcohol use and glaucoma is inconsistent.

In this review, we hope to summarize the associations between alcohol use and glaucoma categorically by glaucoma type and quantity of alcohol consumption as a comprehensive overview of the literature. A scoping review will be conducted, rather than a systematic review or meta-analysis, because the existing literature on AUD and glaucoma has not been characterized; other than a 2021 scoping review on drug use and ocular effects [18], there does not appear to be a scoping review specifically related to this topic. Taking a scoping review approach allows us to map the breadth of current evidence on the link between different levels of alcohol consumption or an AUD diagnosis and glaucoma, identify gaps in knowledge, and clarify key concepts in this area. Our aim is to provide a comprehensive overview that can inform the design of future systematic reviews or quantitative syntheses where the evidence base is more developed [19,20].

Objectives

The primary research question and objectives of this review are to examine the existing literature on AUD, a relatively new term, and related alcohol use or consumption in relation to glaucoma risk. Our population of interest is individuals with AUD, alcohol misuse, alcohol abuse, and any terms that are synonymous with this condition. We plan to conduct a thorough review that also includes drinking patterns, demographics, and alcohol consumption levels.

Methods

We will follow the methods outlined in the *JBI Manual for Evidence Synthesis* [21] and use the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist [22] (Checklist 1) to report the completed review. This protocol was written using the PRISMA-ScR checklist as an outline, with additional information and details from Lely et al [23].

Eligibility Criteria

The eligibility criteria were established by the study team to ensure inclusion of a broad yet relevant body of literature on the association between AUD and glaucoma. We sought to capture empirical research across diverse populations and study designs while excluding sources that would not directly inform the research question. A summary of inclusion and exclusion criteria is presented in Textbox 1.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Studies on individuals aged ≥18 years
- Patient populations of men and women
- Articles published in English
- Studies that document a diagnosis of glaucoma (*International Classification of Diseases, 10th Revision* code H40)
- Published articles including the year 2014 and up to 2025
- Primary research articles (case-control studies; case series or case reports; cohort studies; controlled trials; cross-sectional studies; prospective, longitudinal, and follow-up studies; and randomized controlled trials)

Exclusion criteria

- Animal or nonhuman studies
- Studies on individuals with other ocular conditions or diagnoses
- Diagnoses of congenital glaucoma (childhood glaucoma), including juvenile open-angle glaucoma, and any induced glaucoma (eg, drug, steroid, or corticosteroid induced)
- Cost-benefit analysis studies
- Commentaries or opinions, editorials, and letters
- Gray literature (conference proceedings, dissertations, ongoing clinical trials, and preprints)

Search Strategy

The biomedical librarian (TS) will develop search strategies and incorporate team feedback on terminology. Four databases will be searched: PubMed, which includes MEDLINE (US National Library of Medicine); Embase (Elsevier); Web of Science Core Collection (Science Citation Index Expanded and Social Sciences Citation Index; Clarivate Analytics); and CENTRAL (Wiley). Search strategies include a combination of indexing terms (MeSH [Medical Subject Headings] and Emtree) and keywords (see Multimedia Appendix 1 for the complete search strategies). Concepts will be combined using the Boolean operators OR and AND, and the searches will be limited to English-language citations published since 2014. This date limit reflects diagnostic criteria as defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* [3]. The searches will be peer reviewed by another biomedical librarian independent of this scoping review team following Peer Review of Electronic Search Strategies guidance [24], and the complete searches for every database will be documented as supplementary materials in the final manuscript to improve validity and reproducibility. All results will be exported to EndNote (version 21; Clarivate Analytics) and uploaded to the Covidence screening software (Veritas Health Innovation [25]), with duplicate citations removed.

Study Selection

A 2-step process will be used to screen the results, using Covidence as the screening software. First, the titles and abstracts of all unique records retrieved from the databases and supplemental searches will be screened by 2 reviewers (FE and AH) independently using the eligibility criteria. A separate third reviewer (GRW) will resolve conflicts and, if necessary, discuss the conflict with at least one other reviewer to decide whether to include or exclude based on the eligibility criteria. Second, articles that meet the inclusion criteria after title and abstract screening will proceed to full-text screening. The PDFs of these articles will be obtained and uploaded into Covidence. Two reviewers (FE and AH) will independently screen the full texts using the same eligibility criteria. Conflicts will be resolved using the same process as before. Before working on the full review, reviewers will conduct a pilot of this 2-step process, including testing data extraction. For the pilot, the biomedical librarian (TS) will randomly select 50 articles from the completed searches and upload them to Covidence to test title and abstract screening and full-text screening steps with all reviewers (FE, AH, and GRW). On the basis of this pilot process, revisions or clarifications to the eligibility criteria, search strategies, and protocol will be made as needed.

Data Charting

Covidence, as well as Microsoft Excel, will be used for data collection. Covidence will be used to screen titles and abstracts to filter out publications for the full-text review stage and then, finally, obtain a collection of papers for data extraction. Microsoft Excel will be used to collect the necessary information via an extraction template for the scoping review (Table 1). Two reviewers (FE and AH) will independently collect data from each included article. One reviewer (GRW) will check all collected data and reconcile any discrepancies in them. If data are missing, we will contact the corresponding author and, if no reply is received, mark the data as either missing or not reported. Similar to the screening pilot, a pilot of the data collection step will be completed with 3 reviewers (FE, AH, and GRW) on a sample of 2 to 5 records taken from the screening pilot. Changes to the data items or data collection process will be documented in the protocol.

Table . Data charting for the included literature.

Data item domain and subdomain	Description
Document characteristics	
Document type	Primary research articles
Title	Title of the publication
Authors	Authors of the publication
Publication year	Year of publication
Full citation	Citation of the publication
DOI	DOI included
Web link	Link to online source
Study characteristics	
Design	Case-control study, case report or series, or cohort study, among others
Setting	For example, hospital; inpatient or outpatient
Location	Country of publication
Population	Study eligibility criteria
Sample size	Number of participants in the study
Study objectives	Study research question (if relevant)
Characteristics of AUD[a]	
Drinking frequency	For example, number of drinks in a day, week, or month
Type of liquor consumed	For example, beer, wine, liquor, and other types of alcoholic beverages reported
Alcohol consumption level	For example, light, moderate, or heavy alcohol consumption
Alcohol consumption assessment tool	For example, self-reported surveys, questionnaires, and other assessment tools
Characteristics of glaucoma	
Glaucoma subtype	Types of glaucoma, such as open angle or normal tensions
IOP[b] status or reading	For example, elevated, normal, or low (measured in mm Hg)
Co-use of substances	
Smoking (nicotine)	Smoking status: smoker, nonsmoker, or ex-smoker
Marijuana or cannabis	Marijuana or cannabis user, nonuser, or ex-user
Other outcomes	Any other study outcomes
Limitations	Limitations described by the authors and any other limitations identified
Implications and conclusions	Implications and conclusions as described by the authors
Vision characteristics	
Vision tests	IOP readings, OCT[c], visual field and acuity, gonioscopy, and pachymetry

[a]AUD: alcohol use disorder.

[b]IOP: intraocular pressure.

[c]OCT: optical coherence tomography.

Data Synthesis

As this is a scoping review, we will provide a narrative summary of our findings, including descriptive statistics on key data items. A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram will be used to document the disposition of results from the searches. We will include a table of key characteristics for the included studies and additional tables and figures for specific variables of interest as needed. We anticipate that studies may vary substantially in the details provided for alcohol consumption, such as providing intake in grams, drinks per day, or other unit of time or specific types of beverages, and we will describe consumption in the terms used in each study. We will synthesize findings while noting differences in exposure definitions and reference groups (eg, nondrinkers vs lowest intake category). Additionally, the studies

each analyze cohorts and conclude whether alcohol intake is or is not associated with the glaucoma outcome; although the highest intake amount in each cohort will vary between studies, it will always be more relevant to each paper's analyzed reference or control group (typically nondrinkers). We will synthesize findings noting this variability. Studies will also be categorized thematically and stratified into subgroups. Specifically, we will classify the included studies by (1) glaucoma subtype (eg, primary open-angle glaucoma, angle closure, or other specified types) and (2) drinking patterns (eg, light, moderate, or heavy) and alcohol consumption quantities as defined by each study.

This structured approach will allow us to identify recurring themes, highlight areas of evidence concentration versus gaps, and provide a comprehensive overview of the existing literature.

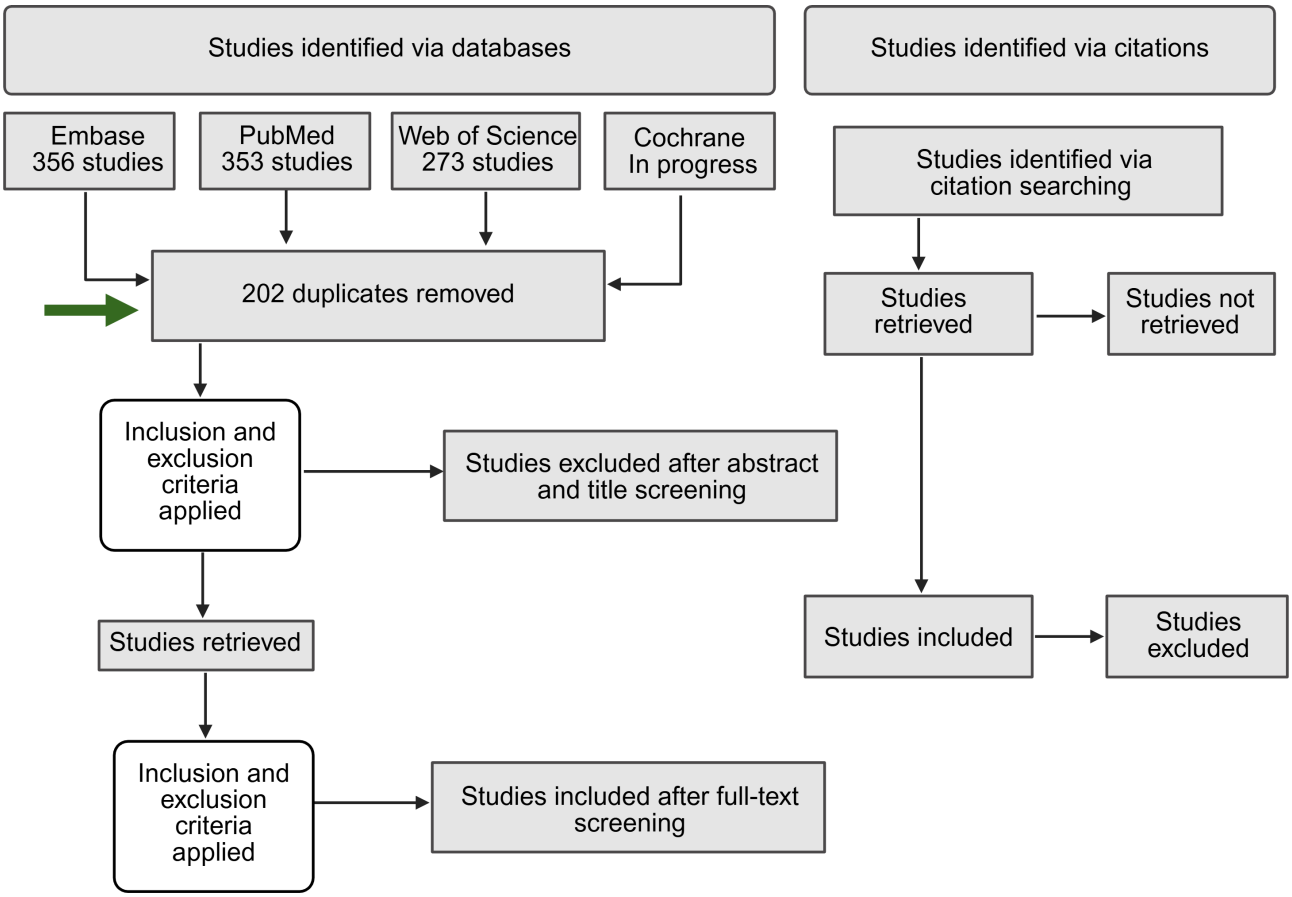
Ethical Considerations

This review does not require ethics approval. We expect results from this scoping review to identify gaps in the current literature and encourage future research regarding patient advisement on the risks of alcohol consumption and the development of glaucoma. This review does not have any stakeholders. Results will be disseminated through peer-reviewed publications and conferences.

Results

This scoping review was started in Covidence in November 2024 and is currently funded by the National Institutes of Health's Intramural Research Program. The database searches were completed and imported into Covidence and, in total, produced 982 papers, with 6 (0.6%) duplicates removed manually and 192 (19.6%) removed via Covidence for a total of 202 (20.6%) duplicates removed. Title and abstract screening of the remaining 780 articles is currently taking place. We will also be using the Cochrane database for our search, which may adjust these numbers and our screening process for the final manuscript. The projected end date for data collection and submission is between November 2025 and January 2026. The results will be presented in a final manuscript in relation to our research aims. We included a preliminary PRISMA-ScR flow diagram with our current database searches and a green arrow indicating our current project status (Figure 1). The final manuscript will include an updated PRISMA-ScR flow diagram, extraction table, and narrative description of our findings.

Figure 1. PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) flowchart for the scoping review process.



Discussion

Anticipated Findings

This scoping review is anticipated to reveal information linking alcohol consumption, including AUD diagnoses, to glaucoma. Evidence on this link has been heterogeneous at best. While some studies suggest that habitual alcohol intake is associated with elevated IOP or increased glaucoma risk, others have reported null or even protective associations. We expect that our mapping of the literature will highlight considerable

variability in how alcohol exposure and glaucoma outcomes are defined and measured, which has likely contributed to the inconsistency of findings to date.

Our work will build on individual studies by providing a comprehensive overview of how alcohol use, from general consumption to clinically defined AUD, has been studied in relation to glaucoma and its subtypes. By consolidating and categorizing this evidence, the scoping review will clarify methodological patterns, illuminate conceptual gaps, and identify areas in which future systematic reviews or meta-analyses may be warranted. The aim of this work is to provide a comprehensive synthesis of the extensive literature on glaucoma and alcohol consumption, addressing the conflicting findings that have been reported. By thoroughly summarizing all relevant data, we intend to clarify the existing literature and address any gaps.

Comparison to Prior Work

Previous studies have examined the relationship between alcohol and multiple other eye diseases with a brief overview of glaucoma but have been ultimately inconclusive or needed more information [6]. This review will add an extensive overview of the relationship between alcohol use and glaucoma, adding to existing findings by including details of alcohol consumption levels, drinking patterns, glaucoma types, and whether an association between alcohol use and glaucoma was statistically found. This offers a clear picture of the current knowledge on the association between alcohol use and glaucoma.

Strengths and Limitations

A strength of this review is that it includes a comprehensive search method across multiple scientific databases for peer-reviewed literature to include in our review. Additionally, we will include literature that has been published in the last 10 years for the most up-to-date discoveries. Conducting a scoping review such as this one and following guidance from the PRISMA checklist and comprehensive search terms will increase transparency and reproducibility for future reviews. This approach offers an extensive overview of the most current knowledge on this topic.

We aim to be comprehensive in our scoping review; however, several limitations should be noted. First, we plan to synthesize data on glaucoma-related measures, such as IOP, optical coherence tomography, and visual field tests. These measures may not be consistently reported across the studies. It is also important to consider that alcohol consumption may be reported in varying ways between papers, which might limit comparability across studies. Second, restricting our review to English-language publications introduces the possibility of language bias as relevant studies published in other languages may be missed. Third, as with any review, there is potential for publication bias as studies with null or negative findings may be less likely to appear in the published literature. Fourth, even though our date limit of including literature from the past 10 years, from 2014 onward, may strengthen our study by including more up-to-date discoveries, it may also be a limitation due to missing important information or perspectives published prior to 2014. Finally, our exclusion of qualitative studies may introduce selection bias as insights from lived experience and patient perspectives will not be represented. Therefore, when evaluating the existing literature, we plan to take a holistic approach while also including any specific and relevant findings.

Dissemination Plans

The dissemination methods for the findings of this scoping review will include publication in a peer-reviewed journal, which will start with manuscript submission planned for December 2026. Presentations at conferences both nationally and internationally are also planned, likely taking place before or around the time of manuscript submission.

Conclusions

We intend to review the vast amount of literature related to the association between AUD and glaucoma to provide a summary of current knowledge and an evidence-based resource that may benefit physicians, patient care teams, and other health professionals in advising, treatment, and preventative care. While synthesizing the breadth of evidence, we will concurrently identify gaps in the literature, thus identifying areas that require future focused research efforts.

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Data Availability

Data sharing is not applicable to this paper as no datasets were generated or analyzed during this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategies.
[DOCX File, 20 KB - resprot_v14i1e76050_app1.docx]

Checklist 1
PRISMA-ScR checklist.
[DOCX File, 18 KB - resprot_v14i1e76050_app2.docx]

References

1. Understanding alcohol drinking patterns. National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism. 2025. URL: https://www.niaaa.nih.gov/alcohols-effects-health/alcohol-drinking-patterns [accessed 2025-12-12]
2. National Survey on Drug Use and Health. URL: https://nsduhweb.rti.org/respweb/homepage.cfm [accessed 2025-12-12]
3. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition: American Psychiatric Association; 2013. URL: https://www.psychiatry.org/psychiatrists/practice/dsm [accessed 2025-12-12]
4. Alcohol. World Health Organization. 2024. URL: https://www.who.int/news-room/fact-sheets/detail/alcohol [accessed 2025-12-12]
5. Hendriks HFJ. Alcohol and human health: what is the evidence? Annu Rev Food Sci Technol 2020 Mar 25;11:1-21. [doi: 10.1146/annurev-food-032519-051827] [Medline: 32209032]
6. Karimi S, Arabi A, Shahraki T. Alcohol and the eye. J Ophthalmic Vis Res 2021;16(2):260-270. [doi: 10.18502/jovr.v16i2.9089] [Medline: 34055263]
7. Understanding glaucoma: symptoms, causes, diagnosis, treatment. American Academy of Ophthalmology. 2024. URL: https://www.aao.org/eye-health/diseases/what-is-glaucoma [accessed 2025-12-12]
8. Kang JM, Tanna AP. Glaucoma. Med Clin North Am 2021 May;105(3):493-510. [doi: 10.1016/j.mcna.2021.01.004] [Medline: 33926643]
9. Stuart KV, Luben RN, Warwick AN, et al. The association of alcohol consumption with glaucoma and related traits: findings from the UK Biobank. Ophthalmol Glaucoma 2023;6(4):366-379. [doi: 10.1016/j.ogla.2022.11.008] [Medline: 36481453]
10. Pexczon JD, Grant WM. Glaucoma, alcohol, and intraocular pressure. Arch Ophthalmol 1965 Apr;73:495-501. [doi: 10.1001/archopht.1965.00970030497009] [Medline: 14270135]
11. McMonnies CW. Glaucoma history and risk factors. J Optom 2017;10(2):71-78. [doi: 10.1016/j.optom.2016.02.003] [Medline: 27025415]
12. Grant A, Roy-Gagnon MH, Bastasic J, et al. Alcohol consumption, genetic risk, and intraocular pressure and glaucoma: the Canadian longitudinal study on aging. Invest Ophthalmol Vis Sci 2023 Jul 3;64(10):3. [doi: 10.1167/iovs.64.10.3] [Medline: 37405759]
13. Song JE, Kim JM, Lee MY, Jang HJ, Park KH. Effects of consumption of alcohol on intraocular pressure: Korea National Health and Nutrition Examination Survey 2010 to 2011. Nutrients 2020 Aug 12;12(8):2420. [doi: 10.3390/nu12082420] [Medline: 32806703]
14. Kang JH, Willett WC, Rosner BA, Hankinson SE, Pasquale LR. Prospective study of alcohol consumption and the risk of primary open-angle glaucoma. Ophthalmic Epidemiol 2007;14(3):141-147. [doi: 10.1080/09286580601187963] [Medline: 17613849]
15. Stuart KV, Madjedi K, Luben RN, et al. Alcohol, intraocular pressure, and open-angle glaucoma: a systematic review and meta-analysis. Ophthalmology 2022 Jun;129(6):637-652. [doi: 10.1016/j.ophtha.2022.01.023] [Medline: 35101531]
16. Fujita A, Hashimoto Y, Matsui H, Yasunaga H, Aihara M. Association between lifestyle habits and glaucoma incidence: a retrospective cohort study. Eye (Lond) 2023 Nov;37(16):3470-3476. [doi: 10.1038/s41433-023-02535-7] [Medline: 37076689]
17. Hanyuda A, Rosner BA, Wiggs JL, Negishi K, Pasquale LR, Kang JH. Long-term alcohol consumption and risk of exfoliation glaucoma or glaucoma suspect status among United States health professionals. Ophthalmology 2023 Feb;130(2):187-197. [doi: 10.1016/j.ophtha.2022.08.023] [Medline: 36041586]
18. Proulx V, Tousignant B. Drugs of abuse and ocular effects. Clin Exp Optom 2021 Jul;104(5):567-578. [doi: 10.1080/08164622.2021.1878852] [Medline: 33722158]
19. Munn Z, Peters MD, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol 2018 Nov 19;18(1):143. [doi: 10.1186/s12874-018-0611-x] [Medline: 30453902]
20. Peters MDJ, Marnie C, Colquhoun H, et al. Scoping reviews: reinforcing and advancing the methodology and application. Syst Rev 2021 Oct 8;10(1):263. [doi: 10.1186/s13643-021-01821-3] [Medline: 34625095]
21. Aromataris E, Lockwood C, Porritt K, Pilla B, Jordan Z. JBI Manual for Evidence Synthesis: JBI; 2024. URL: https://synthesismanual.jbi.global.https://doi.org/10.46658/JBIMES-24-01 [accessed 2025-12-12]
22. Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018 Oct 2;169(7):467-473. [doi: 10.7326/M18-0850] [Medline: 30178033]

23. Lely J, Morris HC, Sasson N, et al. How to write a scoping review protocol: guidance and template. Open Science Framework. 2023. URL: https://osf.io/ym65x/overview [accessed 2025-12-12]
24. McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS peer review of electronic search strategies: 2015 guideline statement. J Clin Epidemiol 2016 Jul;75:40-46. [doi: 10.1016/j.jclinepi.2016.01.021] [Medline: 27005575]
25. Covidence. URL: www.covidence.org [accessed 2025-12-15]

Abbreviations

AUD: alcohol use disorder
IOP: intraocular pressure
MeSH: Medical Subject Headings
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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