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Characteristics of Strategies to Recruit Underrepresented U.S. Adult Populations in NIH-funded Clinical and Translational Research: Protocol of a Systematic Review

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Study protocol

Keywords: recruitment strategies, underrepresented populations, NIH-funded research, clinical trials, health equity, community engagement, translational research, public health research, systematic review, meta-analysis

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Characteristics of Strategies to Recruit Underrepresented U.S. Adult Populations in NIH-funded Clinical and Translational Research: Protocol of a Systematic Review

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ABSTRACT

Background: Since the enactment of legislation requiring inclusion of women and vulnerable populations in clinical research, subsequent policy updates have continued to broaden representation requirements across race, ethnicity, age, sex, socioeconomic status, geographic location, disability status, and other population characteristics that have been historically underrepresented in clinical and translational research. Despite this legislation, substantial disparities in research participation have persisted. These disparities limit the generalizability, external validity, and health equity impact of clinical and translational research findings. Documented barriers to recruitment include structural inequities rooted in systemic racism and historical injustices, medical mistrust, logistical constraints such as transportation and scheduling, language and cultural gaps between researchers and participants, digital divides limiting access to technology-based recruitment approaches, and geographic barriers affecting rural and remote populations. As a result, many studies have struggled to meet enrollment goals for populations that bear the greatest burden of health disparities.

Objective: This systematic review aims to synthesize and evaluate recruitment strategies used in NIH-funded clinical and translational research to engage underrepresented populations, focusing specifically on peer-reviewed studies that have evaluated the effectiveness of the strategies with comparators or controls.

Methods: We will conduct a systematic review following PRISMA-P 2015 guidelines. The peer-reviewed literature will be identified through searches of PubMed, Web of Science, Ovid, and EBSCOhost databases, including CINAHL, Race Relations, and others, and gaps will be filled using

Google Scholar, supplemented by forward and backward citation chasing. Using the Covidence workflow platform for systematic reviews, two independent reviewers will screen titles/abstracts, with a third reviewer resolving conflicts. The same approach will be implemented for full-text reviews. Critical appraisal of the corpus will be assessed using the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool. The overall certainty of evidence across the body of literature will be evaluated using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Framework. A primary narrative synthesis will be conducted, with meta-analysis performed where sufficient homogeneity is found.

Expected Outcomes: Findings will inform evidence-based recruitment practices and contribute to health equity in research participation.

Registration: This review was registered on the Open Science Framework:

10.17605/OSF.IO/BYS5G

Keywords: recruitment strategies, underrepresented populations, NIH-funded research, clinical trials, health equity, community engagement, translational research, public health research, systematic review, meta-analysis

INTRODUCTION

Background and Rationale

The passage of the National Institutes of Health's (NIH) Revitalization Act of 1993 and subsequent legislative updates over the past 30+ years have required the inclusion of women and vulnerable populations in clinical research.(1-4) Despite this mandate, disparities in research participation have persisted, limiting generalizability and the health equity impacts of findings.(5-8) In the 2022 National Academies of Sciences, Engineering, and Medicine Report, failure to achieve representation in research studies has "compounded health disparities" and "reinforced inequities" by continuing to not address the health needs of underrepresented groups.(5) Moreover, the 2024 AHRQ National Healthcare Quality and Disparities Report and the HHS Office of Inspector General 2024 Report both concluded that as studies continue to fall short of diverse or representative enrollment targets, there has been a systemic failure to produce "universally applicable medical evidence."(6, 7)

Fortifying this systemic failure have been considerable barriers to participation, including implicit biases and unfounded assumptions that the "hard to reach" is due to disinterest in research participation, or structural inequities like study designs with rigid exclusion criteria that prevent underrepresented individuals from participating.(5, 9, 10) A legacy of unethical research has fostered fear and historical mistrust in research as well as healthcare organizations and academic institutions for some communities.(11) Other examples of barriers, such as logistical constraints, language and cultural gaps, and limited accessibility to research sites,(12-16) have contributed to

the challenging environment of designing and evaluating recruitment strategies for research that can both address these barriers and attain representative enrollment goals.

For the last few decades, a growing body of literature has addressed recruitment and retention strategies,(17-29) and several systematic reviews have examined specific approaches.(30-42) However, to our knowledge, no prior systematic review has focused exclusively on NIH-funded clinical and translational research studies that not only describe but also evaluate their recruitment strategies through a comparative or controlled study design. While community-engaged approaches, culturally tailored outreach, and partnerships with trusted organizations were frequently described, the evidence supporting their effectiveness has remained fragmented across disciplines and lacked a common methodology to evaluate the approaches.(43-62)

By applying rigorous methodology, quality assessment, and, where appropriate, quantitative synthesis, this systematic review seeks to identify the most effective, evidence-based recruitment practices and to strengthen health equity in research participation by prioritizing evaluation and accountability.

Objectives

Our primary research questions focuses on recruitment strategy characteristics and their success overall, as well as with varying populations. They included:

Primary Questions

➢ What recruitment strategies have been evaluated in NIH-funded clinical and translational research to engage underrepresented populations?
➢ What are the characteristics of successful recruitment strategies? Which specific methods (e.g., community engagement, financial incentives, technology-based recruitment) are most effective? What role do culturally tailored approaches, trusted messengers, and community partnerships play in recruitment success?
➢ What barriers contribute to unsuccessful recruitment efforts? What are the most commonly reported challenges (e.g., mistrust, logistical constraints, socioeconomic barriers)? How do recruitment failures vary by population group (e.g., racial/ethnic minorities, rural residents, low-income individuals)?
➢ How do participant characteristics influence recruitment success? What recruitment strategies are most effective for different population subgroups? Are there differences in recruitment success based on race, sex, age, income, education, or geographic location?

Our secondary research questions addresses implementation considerations:

Secondary Questions
➢ How do recruitment strategies compare in terms of cost-effectiveness, feasibility, and sustainability?

➢ Are there significant differences in recruitment success between high cost vs. low-cost approaches?
➢ What recruitment strategies require long-term investment to maintain participant engagement?

Our primary outcome variables includes recruitment success, retention and engagement, and participant diversity. For recruitment success, these variables are enrollment rate, total number of participants recruited, and time to recruitment completion. For retention and engagement, these variables are retention rate, dropout rate, and adherence to study protocols. For participant diversity, the variables were population characteristic representation relative to study enrollment goals. Independent variables and interventions are types of recruitment strategies, such as community engagement, digital/technology-assisted, institutional/provider-referrals, financial incentives, and tailored messaging. Other independent variables include recruitment style (active vs. passive), recruitment setting (clinical or community), use of theory in design and implementation, and source of recruitment. Covariates may include participant characteristics such as race, ethnicity, sex, income, education completion level, age, geographic location, and barriers to recruitment including historical distrust, burden of participation, low awareness of research opportunities, socioeconomic constraints, and logistical challenges.

The following *a priori* hypotheses were formulated to guide the interpretation of findings:

- Community-based engagement strategies (e.g., partnerships with community leaders, faith-based organizations, and community health workers) will demonstrate more success than passive approaches (e.g., broad media advertisements, unsolicited clinical referrals). This expectation is consistent with previous literature on trusted messengers and tailored outreach.(5, 63-65)
- Digital and social media recruitment strategies will show mixed effectiveness, with higher engagement among younger participants and lower engagement among older adults and lower-income populations. We expect that little-to-no access to technology or distrust in research will impact enrollment.
- Financial incentives will be associated with increased enrollment but may not necessarily improve retention. Prior research suggests that sustained engagement is likely influenced by non-monetary factors such as trust, perceived relevance of research, and study burden.(5, 13, 66)
- Community-based participatory research (CBPR) approaches and implementation science frameworks will demonstrate higher recruitment and retention rates than traditional clinical trials, reflecting trust-building and co-design elements found in participatory models.
- Culturally tailored strategies will demonstrate greater enrollment success over one-size-fits-all approaches, specifically for racial/ethnic priority populations and non-English-speaking populations.

METHODS

Protocol Registration and Reporting

This protocol was registered on Open Science Framework, registration number **10.17605/OSF.IO/BYS5G**, and is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P 2015) guidelines (see PRISMA-P Checklist located before Appendices).(67, 68) Any substantive deviations from the registered protocol will be transparently documented and reported.

Eligibility Criteria and PICO Framework

To be eligible for inclusion in this systematic review, the study design must include an evaluation of recruitment or retention strategies for underrepresented populations in clinical and translational research. Studies must conduct in, or focus on, populations residing within the United States. Studies that have non-U.S. population data will also be included if the U.S. populations are reported as a discrete, analyzable subset. Priority population data must consist of adults, ages 18 and older, that can be independently analyzed from populations <18 years of age. The study design must include a comparison element, such as randomized controlled trials (RCTs), cross-sectional, cohort, quasi-experimental, program evaluation, or clinical trials. All studies must be peer-reviewed, and be funded by NIH in general, or by a specific National Institute or Center. Studies must be published in English, and preprints from recognized repositories are acceptable.

Exclusion criteria includes any basic science studies or early-phase clinical trials focused exclusively on efficacy and safety endpoints without attention to recruitment evaluation, animal or veterinary studies, grey literature such as perspective papers, dissertations, theses, white papers, editorial commentaries, systematic reviews, scoping reviews, protocols, conference proceedings, research reported as in-progress, research reporting only preliminary findings, research where final results are unavailable, or non-NIH-funded studies. Studies that describe recruitment strategies without assessing or evaluating their effectiveness through a comparative design will be excluded. If studies exclusively prioritize children or adolescents (<18 years of age), or studies with adult population data that cannot be disaggregated, or studies in which consent and participation decisions are made solely by parents or caregivers on behalf of dependent participants, they will also be excluded.

The review is structured around the PICO (Population-Intervention-Comparison-Outcome) components listed in Table 1.(69)

Table 1. PICO Framework

PICO Element	Description
Population (P)	Underrepresented populations in clinical and translational research, including racial/ethnic minorities, low-income individuals, rural residents, older adults, individuals with disabilities, LGBTQIA+ individuals,

	immigrants, and other groups with documented underrepresentation in NIH-funded research
Intervention (I)	Recruitment and retention strategies used to engage underrepresented populations, including community-based outreach, culturally tailored approaches, financial incentives, digital or social media recruitment, provider referral, and other active or passive methods
Comparison (C)	Studies comparing two or more recruitment strategies, or comparing an active recruitment strategy against a passive or standard-of-care comparator
Outcome (O)	Recruitment success (enrollment rate, total enrollment, time to completion), retention and engagement (retention rate, dropout rate, protocol adherence), participant diversity relative to study enrollment goals, and reported barriers and facilitators

Information Sources and Search Strategy

A comprehensive multi-database search will be conducted across the following sources: PubMed (NIH/NLM interface), Ovid (MEDLINE and PsycINFO), Web of Science, EBSCOhost/CINAHL and Health and Medicine databases, and Google Scholar. Although PubMed and Ovid databases share the same core MEDLINE dataset, utilizing both will be considered best practice in systematic reviews as they function as distinct platforms with unique content and search functionalities.(70) PubMed will be selected for its extensive collection of biomedical, clinical, and public health

literature, as well as robust MeSH term filtering capabilities.(71, 72) Ovid will be selected for access to high-quality biomedical and social science databases relevant to both qualitative and quantitative recruitment research.(72, 73) Web of Science will be selected for its multidisciplinary coverage across scientific disciplines including social sciences and healthcare.(72) EBSCOhost including CINAHL, Race Relations, AgeLine, as well as their "Health and Medicine" and "Social Sciences" databases will be selected for nursing, allied health, and community-based recruitment strategy literature.(72) Google Scholar will be used as a gap-check source, as this database has broad, interdisciplinary coverage, including studies not indexed in primary databases.(72) Search strategies are iteratively refined in collaboration with the University Libraries at Virginia Tech's Evidence Synthesis Services Team, which will provide guidance on search strategy development, MeSH term utilization, and hedge tool application.(74, 75)

Search queries are developed around the following concepts: (1) strategy or intervention terminology (e.g., strategy, intervention, implementation, outcome); (2) recruitment and enrollment terminology (e.g., recruit, retain, retention, enroll); (3) health disparities and population descriptors using the NIH health disparity hedge tool, customized with additional terms like BIPOC and Indigenous population; and (4) study design filters (e.g., randomized controlled trial, observational study, evaluation study). A limiter of English language will be included, however no publication year limit will be set. EBSCOhost and Ovid searches will be structured with similar conceptual categories without MeSH constraints, using the following core terms: strategy, intervention, recruitment, enrollment, evaluation, research, trial, and study. Google Scholar will be searched using a simplified query: "strategy AND recruitment AND (marginalized OR underrepresented) AND NIH". The full query strings for PubMed, incorporating

MeSH terms and Title/Abstract fields across all relevant population and study design descriptors, Ovid, EBSCOhost, and Web of Science can be found in Appendices A-D to this protocol.

Additional forward and backward citation chasing will be conducted using the Citationchaser platform (shinyapps.io) to identify studies not captured by database searches.(76) References found in the final corpus bibliographies will also be added to Covidence for screening.(77)

Search validity will be assessed by verifying that known key studies are retrieved, reviewing the initial set of retrieved articles against the research question and inclusion criteria, and iteratively adjusting keywords, Boolean operators, and search filters. An ESS librarian advisor will test and provide feedback on search queries, with particular attention to the use of health disparity hedges and MeSH terms.(74, 75)

Study Selection

All search results will be imported into Covidence software for systematic reviews.(78) The program manages de-duplication, screening workflows, and inter-rater reliability scoring. Screening will proceed in two stages: Title and Abstract (T/A) Screening and Full Text (FT) Review. In T/A screening, two independent reviewers will screen all titles and abstracts against the inclusion and exclusion criteria. A third reviewer serves as a tiebreaker for all conflicts. In FT review, full texts of all studies passing the T/A screens are independently reviewed by two reviewers. Conflicts will be resolved by a third reviewer. All remaining sources after FT review will be retained for data extraction. To minimize bias, reviewers will be blinded to each other's

decisions at each stage. All screeners will attend the University Libraries at VT's ESS team systematic review and meta-analysis (SRMA) trainings and will participate in pilot screening rounds prior to full screenings. Conflict resolution discussions will be conducted in weekly or bi-weekly virtual or in-person team meetings.

The primary exclusion criteria applied during screening will be geographic exclusion (studies conducted solely outside the United States), wrong population (study population exclusively children or adolescents under 18), wrong study design (no comparator for evaluating recruitment/retention strategies), and wrong outcomes (strategies described but not assessed or evaluated).

Data Collection and Extraction

Extraction Template and Domains

A data extraction template will be developed and customized within Covidence (see Appendix E). Two independent reviewers will extract data from each included study, with a third reviewer facilitating consensus decisions. The following data will be extracted:

- Bibliographic and study metadata: title, lead author name, institutional affiliation, contact information, country of study, study start and end dates, study design, and NIH funding mechanism or institute.

- Study context and population: aim of the study, population of interest and inclusion/exclusion criteria for participant recruitment, population characteristics such as race, ethnicity, age, sex identity, sexual orientation, income, education completion level, geographic location (rural/urban/suburban), disability status, and other vulnerable populations.
- Recruitment strategy data: description of each recruitment strategy, comparison or control conditions, incentives offered and any barrier-reduction assistance provided, setting of recruitment (healthcare, community, online), level of community engagement (e.g., CBPR involvement or health behavior theories or models utilized).
- Outcomes: total number enrolled, sample size, retention rate, dropout rate, adherence to study protocols, reported barriers to recruitment, and study limitations as reported by authors.

Data extraction will proceed through training, pilot extraction, full extraction, reliability verification, and final review stages. In the training stage, all reviewers will be trained on the protocol, the extraction template, and quality assessment tools. Alignments on criteria interpretation will be established through discussion. In the pilot extraction stage, two reviewers independently will extract data from 10 selected studies. A third reviewer will facilitate consensus discussion and input the final agreed-upon extractions. During the full extraction stage, all remaining eligible studies will be extracted by the same two independent reviewers using the customized template. For the reliability verification stage, the extracted data from both reviewers will be compared, with discrepancies resolved through discussion and, when necessary, adjudication by a third reviewer. In the final review stage, extracted data will be reviewed for

completeness and accuracy, organized into analytical categories and coded in preparation for synthesis.

Quality Assessment

Our team will critically appraise the final corpus using the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative Studies.(77, 79) The EPHPP tool was selected because it was designed to be inclusive of multiple quantitative study designs and was validated for public health and community-based research contexts, offering advantages over tools designed solely for RCTs such as the Cochrane's Risk of Bias Tool.(80, 81) A template in Covidence (see Appendix F) will be customized to allow assessment of the included studies with the following EPHPP domains: selection bias (representativeness of the sample), study design (appropriateness of the design to the research question), confounders (presence and control of confounding variables), blinding (masking of participants, outcome assessors, or recruiters), data collection methods (validity and reliability of outcome measures), withdrawals and dropouts (rate and handling of attrition), intervention integrity (fidelity to the recruitment strategy as described), and intervention allocation and analysis (appropriateness of analytic approach). Each domain will be rated as STRONG, MODERATE, or WEAK, yielding a global quality rating per EPHPP guidelines. Two independent reviewers will complete quality assessments, with discrepancies resolved through consensus and third-party adjudication. No study will be excluded solely on the basis of its quality rating, however EPHPP ratings will inform interpretation of findings, sensitivity analyses, and weighting of evidence in narrative conclusions.

Following individual study appraisal, the GRADE Framework will be applied to evaluate the overall certainty of evidence across the body of included studies.(82) Evidence will be rated as HIGH, MODERATE, LOW, or VERY LOW certainty. Ratings will be downgraded based on the presence of serious risk of bias (information obtained from EPHPP scoring), important inconsistency across studies, indirectness of evidence, imprecision in effect estimates, or suspected publication bias. Ratings will be upgraded where a large magnitude of effect, a dose-response relationship, or the absence of plausible confounding was observed. GRADE assessments will be summarized in the Summary of Findings table in the main SRMA manuscript and will directly inform the strength of conclusions drawn in the synthesis.

Together these tools will provide complementary levels of appraisal: the EPHPP tool will assess individual study quality while GRADE will characterize the cumulative strength of evidence across the full corpus of included studies.

Data Synthesis

Our team anticipates heterogeneity in study designs, populations, recruitment contexts, and outcome reporting. The primary synthesis approach focuses on a structured, narrative synthesis. Studies will be grouped thematically by recruitment approach (e.g., community engagement, incentive, tailored messaging) and by priority population subgroup where sufficient evidence exists. Prior to synthesis, extracted data will undergo the following standardized transformations: standardization of recruitment outcomes (e.g., enrolled, not enrolled, sample size) to enable

cross-study comparability; categorical coding of recruitment strategies, including single and multiple-component strategies; classification of participation burden (high or low) and recruitment styles (active, passive, or mixed); coding of population characteristics using a standardized schema (e.g., A=Age, G=Gender, R=Race/Ethnicity); and extraction and tabulation of effect direction and magnitude for structured narrative synthesis where meta-analysis is not appropriate.

A random effects model may be considered due to a sufficient number of studies reporting comparable outcomes with adequate homogeneity in enrollment rates. Statistical heterogeneity will be assessed. A multiple linear regression will be deployed, and effect direction plots and summary tables will be employed in lieu of pooled estimates.

Where sufficient evidence exists, subgroup analyses will be conducted by priority population, sample pool source (healthcare, community, or other), study design, recruitment style (active, passive, or mixed), burden of participation (high or low), and type of recruitment strategy.

Because quantitative synthesis may include more than 10 studies, publication bias will be assessed using forest plot visualization and multiple linear regression (or meta-regression). Where meta-analysis is not conducted, publication bias will be qualitatively assessed by examining asymmetry in the distribution of positive versus null recruitment outcomes, and by evaluating patterns of selective outcome reporting within included studies.

Sensitivity analyses may not be conducted during the meta-analysis due to a possible inability to conduct pooled estimates and evaluating effect sizes. For narrative synthesis, robustness will be

evaluated by comparing conclusions including vs. excluding lower-quality studies, and by assessing whether key findings persisted across different study designs.

Missing Data

For studies with incomplete outcome reporting, missing statistics will be calculated from available data where possible, such as enrollment data derived from numerator and denominator. Due to several studies evaluating recruitment strategies being published separately from their respective parent studies, our team will be able to obtain missing data from parent study publications. When critical outcome data was absent without an alternative way to locate it, study authors will be contacted, however it may still not be recovered. In the instance where the missing data will not be recovered, it will be documented in the main SRMA manuscript, and the study will be included in the qualitative synthesis but excluded from quantitative analysis. The potential impact of missing data will be discussed as a limitation.

Criteria for Drawing Conclusions

Conclusions will be drawn based on consistency of findings across multiple studies, magnitude and direction of recruitment effects, quality of the methods in contributing evidence per the EPHPP ratings, presence of plausible functional and process explanations such as community trust, cultural competence, and CBPR principles, statistical significance in meta-regression

findings, and the overall certainty of evidence determined by the GRADE framework. Strong or robust conclusions require consistent findings across multiple moderate- or strong-quality studies. Tentative or qualified conclusions will be applied where evidence is limited, inconsistent, or predominantly derived from weak-quality studies. For tentative or qualified conclusions, the findings will be considered solely hypothesis-generating.

ANTICIPATED LIMITATIONS

Heterogeneity is anticipated across included studies in terms of how evaluations of recruitment strategies are implemented, as this is not a common practice. Defining underrepresented populations may also vary, making direct comparisons complicated. Available evidence has already documented limitations in quality of representativeness, justification of study methods, reliability and validity of data collection methods, potential for bias, and data analysis. Many of the studies are expected to be retrospective or secondary aims in which much of the data may not be reported adequately. Limiting to only NIH-funded studies may cause findings to not be generalizable to research conducted under other federal agencies or private funding sources with distinct inclusion mandates and reporting requirements.

EXPECTED CONTRIBUTIONS

This systematic review is expected to make meaningful contributions to health equity research and clinical and translational methods for recruitment. By focusing on NIH-funded studies, the findings are expected to inform future study design, help researchers and funders identify evidence-based best practices, and highlight persistent gaps warranting further investigation.

REVIEW TEAM DECLARATIONS

Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable

Availability of data and materials: All phases of this project including screening, full-text review, data extraction, and quality assessment, will be managed within the Covidence software platform, with supplemental tracking in Microsoft Excel. Extracted datasets, coding frameworks such as data dictionaries, EPHPP quality assessment scores, GRADE summary of findings tables, and analytic scripts from R will be stored in an Open Science Framework repository. The following data will be made publicly available upon publication or project completion, with no embargo period anticipated: CSV files of all references retrieved from databases with associated metadata and screener decisions; data extraction spreadsheet; EPHPP quality assessment scores and GRADE evidence certainty ratings; Analytic scripts from R version 2025.09.1. Data will be shared under a CC-BY 4.0 (Creative Commons Attribution 4.0 International) license, permitting unrestricted use and modification with appropriate attribution. No sensitive data is anticipated that would require access restrictions. All deviations from the registered synthesis plan will be

transparently documented and version-controlled through OSF project updates. Analytical software will include Covidence (screening and extraction management), Microsoft Excel (data organization and tabulation), and R (statistical analysis and correlation assessment).

Competing Interest: No competing or conflicts of interest have been identified among any members of the review team.

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Expert Consultation: The University Libraries at Virginia Tech's Evidence Synthesis Services Team provided integral support throughout the review process, including guidance on search strategy development, MeSH term optimization, hedge tool utilization, and systematic review and meta-analysis training. An evidence synthesis librarian advisor reviewed and provided iterative feedback on all database query strings.

AUTHOR CONTRIBUTIONS: AAH contributions: draft and edit protocol manuscript, create the review workflow in Covidence, register the review in OSF, design, test, and iterate the search strategies, work with librarian advisor to refine search strategies and protocol design, format all search results through EndNote and convert to XML to upload to Covidence, screen all search

results, review all studies through full-text review, extract studies, assess studies utilizing EPHPP tool and GRADE framework, data clean-up and coding for analysis, and submit manuscript for publication. KAJ contributions: advise with search strategies, tiebreaker for screen conflicts, review full-text articles, extract studies, assess studies utilizing EPHPP tool, verify information in data clean-up before meta-analysis and edit manuscript. SE contributions: screen all search results, verify information in data clean-up before meta-analysis, and edit manuscript. KH contributions: mentor project from outset, including search strategies, eligibility criteria, judge conflicts for both screening and full-text phases, make consensus decisions during data extraction and quality assessment phases, and edit manuscript.

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