Association and Agreement of Contact-Based Smartphone Photoplethysmography (PPG) Compared with Electrocardiography (ECG): A Protocol for a Systematic Review and Meta-Analysis

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Abstract

Background: Mobile health (mHealth), leveraging mobile devices for health measurement and promotion, is rapidly growing. Smartphone cameras can perform photoplethysmography (PPG) to estimate pulse rate (PR-PPG) and other features of the cardiac cycle. However, establishing the validity of PR-PPG is essential before it can be adopted for healthcare applications. There is a pervasive belief that PR-PPG is analogous to heart rate derived using electrocardiogram (HR-ECG), and we will conduct a systematic review and meta-analysis to support or challenge this supposition.

Objectives: To synthesise quantitative evidence on the validity of PPG derived from mobile devices (i.e. smartphones) for the assessment of compared to the gold standard ECG assessment of HR.

Methods: A comprehensive literature search will be performed on CINAHL Ultimate, MEDLINE, ScienceDirect, and Scopus using a predefined search strategy. All retrieved citations will be imported into Rayyan for screening and data management. A minimum of two independent reviewers will conduct the title and abstract screening, followed by two independent reviewers who will perform full-text screening and data extraction. All stages will be guided by predefined inclusion and exclusion criteria, which will be pilot tested to ensure consistency and reliability. Any discrepancies will be resolved through discussion with a third reviewer or during a research team meeting. Intra-rater reliability will be quantified at the title and abstract stage, and the full-text review stage using Cohen's Kappa. To ensure clarity and consistency in the presentation of study characteristics and findings, both narrative synthesis and tabular formats will be employed. This review will include studies that report the association and agreement between resting HR and PR from PPG utilising contact-based smartphone devices versus ECG as the gold standard. PPG signals will be obtained using a contact-based approach, defined as finger-on-camera measurements with the smartphone's built-in camera and flash. Studies will be excluded if they (a) do not use PPG utilising contact-based smartphone devices (b) compare PPG to another collection method other than ECG, or (c) are review articles or case studies.

Results: In order to inform clinical procedures and future studies, the results will contain data on PR-PPG and HR-ECG association (correlations) and agreement (Bland-Altmans), sampling devices, and operating systems. This project is unfunded, and the initial screening is expected to start in Q1 2026, with results published in Q1 2027.

Conclusions: This review will provide a comprehensive understanding of the association and agreement between PR-PPG and HR-ECG. The findings may inform future adoption of PR-PPG and HR-ECG with insight into device or setting characteristics for best agreement or association.

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Keywords: Photoplethysmography; PPG; mobile; heart rate; validity.

Introduction

Photoplethysmography (PPG) has been widely employed over several decades for the diagnosis, monitoring, and screening of various diseases and disorders, offering clinically relevant physiological insights [1–4]. The term "photoplethysmography" derives from its functional components: “photo” (light), “plethysmo” (volume), and “graphy” (recording) [5]. Initially introduced by Hertzman in 1937 to detect blood volume changes [4,6], PPG operates by measuring either transmitted (transmissive PPG) or reflected (reflective PPG) light as it interacts with biological tissues [7]. This technique relies on the optical properties of tissue, including absorption, scattering, and transmission [8]. Transmissive PPG detects light that has passed through relatively thin tissue regions, such as the fingers, toes, or earlobes. In contrast, reflective PPG captures light that is scattered back from the skin, which results in a reduction in detected light intensity [9]. While transmissive PPG generally provides more stable signal quality[10], reflective PPG offers greater versatility in terms of measurement site, enabling its application in anatomical regions such as the forehead, wrist, carotid artery, and esophagus—locations where transmissive PPG is less feasible [11–14].

Photoplethysmography operates based on the Beer–Lambert Law, which describes the attenuation of light intensity as a function of the extinction coefficient, concentration of the absorbing medium, and the optical path length through which light travels [15]. Leveraging this principle, a range of PPG devices are utilised in clinical settings to measure physiological parameters such as pulse rate, a key vital sign [7]. Clinically, PPG is commonly employed to monitor cardiac-induced fluctuations in blood volume within microvascular beds at peripheral anatomical sites including the finger, forehead, earlobe, and toe [16,17].

Since the introduction of the first iPhone in 2007, smartphones have become ubiquitous worldwide and are increasingly recognised as practical tools for data collection, addressing several limitations inherent in traditional methods [18]. Conventional health monitoring typically involves periodic, scheduled clinical visits, which may fail to capture dynamic physiological changes that occur longitudinally or during routine daily activities [3,19,20]. In this context, smartphones equipped with integrated cameras offer a cost-effective alternative for PPG acquisition, eliminating the need for additional external devices such as wearables [21].

Consequently, smartphone-based PPG has the potential to extend access to underserved populations, particularly those facing demographic, geographic, or socioeconomic barriers to healthcare access and delivery [22–24]. The adoption of mobile health (mHealth) technologies has accelerated in recent years, particularly following the COVID-19 pandemic, which underscored the utility of remote and prospective health and symptom monitoring [21,25–27]. As such, the increasing prevalence of smartphone-enabled telemedicine is likely to persist and may play a significant role in advancing global health equity, aligning with targets outlined in the United Nations Sustainable Development Goals (UN SDGs), specifically SDG 3: Good Health and Well-being [28,29].

Smartphone PPG can estimate resting pulse rate through the measurement of distal pulse rate (PR) at rest, and whilst completing other activities such as exercise or cognitive tasks [7]. While smartphone-based PPG can measure resting PR through peripheral pulse detection, accuracy hinges on proprietary algorithms that are often undisclosed in the literature. The lack of algorithmic transparency can hinder reproducibility and trust in the results. This is problematic given the proliferation of mHealth, and therefore the necessity that technologies are reliable and valid compared to gold standard measurements prior to universal adoption [30]. An earlier meta-analysis by De Ridder *et al.* [31] showed that smartphone PPG could yield results consistent with ECG, pulse oximetry, and radial pulse measurements. However, they identified significant variability due to sample characteristics, environmental conditions, and the diversity of smartphone hardware. Their review also reflected on the outdated technology assessed at the time, such as iPhone 5 and Galaxy S4 models. Subsequent technological advancements, including higher-resolution cameras and improved sensors, warrant an updated synthesis of the evidence [21]. Our recent scoping review [3] identified ten studies directly comparing PR-PPG and HR-ECG but did not quantify their agreement or association. This protocol aims to address

that gap by conducting a rigorous meta-analysis of studies evaluating the association and agreement between smartphone-based PR-PPG and HR-ECG.

Review questions:

Primary research question: What is the level of association and agreement between pulse rate derived from smartphones PPG and heart rate derived from ECG at rest?

Secondary research questions:
1. Does device type or operating system (e.g., iOS vs. Android) influence the association and agreement of PR-PPG?

2. What is the methodological quality and risk of bias among included studies?

We hypothesise that smartphone-derived PR-PPG may provide a valid alternative to HR-ECG at rest. Nonetheless, the current evidence base is likely to be limited and methodologically heterogeneous due to variations in device specifications, study design, and participant characteristics.

Methods

Eligibility Criteria

Participants

The eligibility criteria were assessed by PICO (Population, Intervention, Comparison, and Outcome) framework. For the Population component, we will only accept studies that involve humans. For the Intervention component, as this is an analysis of association and agreement, rather than a magnitude of change, there will be no intervention *per se*. However, this systematic review will investigate studies that measure PR-PPG via front or rear facing camera of a smartphone by contact-based, and HR-ECG. Contact-based smartphone PPG was defined as a finger-on-camera measurement using the device's built-in camera and flash. Participants placed the fingertip over the camera lens while the flash illuminated the skin to capture PPG signals. Non-contact methods such as facial video PPG were not included in this study. We will restrict inclusion to studies that report agreement or correlation, and we will not compute association or agreement from summary data. For the Comparison (C) component, the

inclusion of a control group is not necessary in this analysis. In terms of outcome measures, resting pulse rate ($b \cdot min^{-1}$) from PR-PPG and resting heart rate ($b \cdot min^{-1}$) from HR-ECG will be reported in the original studies. Moreover, to quantify association and agreement, studies must report a correlation coefficient (Pearson's, concordance correlation coefficient [CCC] or inter-class correlation coefficient [ICC]) or a Bland-Altman analysis between PR-PPG and HR-ECG.

The following exclusion criteria will apply: Studies utilising external devices (e.g., medical sensors, wearables) connected to smartphones for data acquisition; Papers that do not assess the validity of PR-PPG against HR-ECG as an outcome measure. Only original research articles presenting at least preliminary quantitative findings will be included. Qualitative studies, case reports, and literature reviews will not be eligible for inclusion in this review.

Search strategy

This meta-analysis will be performed in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The study protocol has been registered on the Open Science Framework (OSF) and can be accessed via: https://doi.org/10.17605/OSF.IO/83V7A. Any deviations from this protocol during the review will be documented with justifications and timestamps to ensure full transparency, and searches will be updated close to analysis.

A comprehensive search strategy has been developed to strike a balance between thorough coverage and practical scope, ensuring methodological rigor. Four electronic databases will be searched: CINAHL Ultimate, MEDLINE, ScienceDirect,Scopus, and EMBASE.. These databases were selected for their relevance across health sciences, biomedical research, signal processing, and behavioural science. CINAHL Ultimate is included for its strong representation of allied health literature. MEDLINE, accessed via EBSCOhost, provides authoritative sources in biomedical and cardiovascular research. ScienceDirect was chosen for its wide range of journals covering computational and physiological aspects of PPG. Scopus is used for its comprehensive indexing and citation tracking capabilities. Embase was searched because it offers broader, deeper, and more clinically oriented coverage than many other databases, especially for medical, pharmaceutical, and health-related research. In addition to peer-

reviewed literature, grey literature will be searched. This includes preprint servers (e.g., MedRxiv, arXiv), theses and dissertations (ProQuest), conference proceedings (e.g., Web of Science), and institutional repositories like DSpace. Citation chaining will also be used by examining reference lists and citing articles (via Google Scholar and CrossRef), along with CoCites to identify related work through citation patterns. The search strategy will be refined iteratively if it produces excessive irrelevant records, with adjustments made to keyword combinations, Boolean logic, and subject headings. Known relevant studies will be used to test the sensitivity and specificity of the search. If required data are missing or unclear, the corresponding authors will be contacted using a standardised template. Follow-up emails will be sent two and four weeks after the initial message if no reply is received. All correspondence will be logged and summarised in the manuscript and supplementary materials. A final search update will be conducted prior to manuscript submission if more than six months have passed since the initial search.

Search Terms

Example Boolean string (Scopus):

TITLE-ABS-KEY ("heart rate" OR hr) AND TITLE-ABS-KEY (photoplethysmography OR ppg OR "remote ppg" OR "camera-based ppg" OR "remote photoplethysmography" OR "camera based photoplethysmography") AND TITLE-ABS-KEY (smartphone* OR "mobile phone" OR "mobile device" OR camera* OR "smartphone photoplethysmography" OR "phone-based ppg" OR "smartphone ppg") AND TITLE-ABS-KEY (electrocardiogram OR ecg OR ekg OR electrocardiography) AND TITLE-ABS-KEY (validity OR valid OR accuracy OR agreement OR correlation OR reliability)

The example search string includes Scopus syntax; these terms and syntax will be adapted across all the databases that are planned to be searched. The search period will begin in 2007 to ensure inclusion of early studies related to the first smartphone models (e.g., iPhone released in 2007) through the end of 2025. The review will focus on correlation coefficients comparing heart rate estimates from PPG to ECG. Supplementary data will include study setting, participant demographics, smartphone model, app characteristics, sampling frequency, camera specifications, ECG details, and environmental conditions during data collection.

Study/Source of Evidence Selection

All references retrieved from the database search will be imported into Rayyan [32], where duplicate entries will be automatically identified and removed. The screening process will take place in two stages: (1) title and abstract screening, and (2) full-text screening.

In both stages, two independent reviewers will apply *a priori* inclusion and exclusion criteria. Reviewers will work in a blinded manner, with Rayyan's platform enabling independent decisions without revealing each other's judgments. Disagreements will be flagged automatically and resolved through discussion. If consensus cannot be achieved, a third reviewer will serve as an adjudicator.

To improve consistency, a calibration phase will be conducted prior to formal screening. Reviewers will test the inclusion/exclusion criteria on a sample of records to align interpretation and application. Inter-rater reliability will be evaluated using Cohen's Kappa statistic, which measures agreement beyond chance. This metric will be calculated at both the abstract and full-text screening phases. Screening decisions and bibliographic metadata will be exported in RIS and CSV formats and archived in an open-access repository (e.g., OSF) at the time of submission or acceptance.

Data Extraction

Prior to full-scale data extraction, a pilot phase will be conducted where all reviewers independently extract data from a small subset of studies (5–10%). This exercise will be used to refine the extraction template and standardise the approach.

In the main extraction phase, two reviewers will independently extract data using a structured and pre-tested form. Extracted variables will include correlation coefficients and mean bias and limits of agreement between PR-PPG and HR-ECG, participant demographics, smartphone specifications, ECG characteristics, and data collection procedures. As we will include correlation coefficients and Bland-Altman analysis, these tests will report both r values (-1 to 1), and agreement values (in bpm or Hz), it is important to outline our harmonisation strategy. Where a study reports HR or PR in Hz, we will apply the following formula:

$$\text{Hz} = \frac{\text{bpm}}{60}$$

During the risk of bias assessment, the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) will be employed independently by two reviewers. QUADAS-2 evaluates four domains: patient selection, index test, reference standard, and flow and timing. Each domain will be rated as low, high, or unclear risk of bias, and applicability concerns were assessed for patient selection, index test, and reference standard.

Disagreements will be resolved through consensus or by involving a third adjudicator. Any ambiguities in reported data will be flagged for discussion. Missing values will be marked as "NR" (not reported), and no estimations will be made unless explicitly stated. All data entries will be double-checked by a second reviewer for accuracy. Where appropriate, AI-assisted tools may be used to support metadata extraction or to highlight relevant text, but all final data entries will be manually reviewed and verified. Reconciliation logs and resolution steps will be documented throughout the process. Data collection will adhere to PRISMA and Cochrane Handbook guidelines. Finalised data will be formatted for meta-analysis and saved using a standardised file naming convention. These files will also be uploaded to the OSF repository.

Details on each included study will be systematically documented, beginning with key bibliographic information such as the study title, authors, publication year, journal name, and study setting (e.g., academic or clinical environments). Further extracted information will include total sample size, participant demographics (age, sex, health status, skin pigmentation), country of study, smartphone model and specifications (e.g., camera resolution, flash use), application name and whether it is proprietary commercial application, open-source software, or custom-developed code, sampling rate of the PPG signal, camera orientation used (front vs. rear-facing), channel used in data computation, ECG equipment used, electrode placement details, and ECG processing methods, environmental conditions and participant preparation (e.g., posture, breathing instructions, dietary control), duration of recording, and number of measurement trials.

In addition to the above, the extraction form will capture relevant statistical outcomes, such as correlation coefficients, confidence intervals, mean bias, limits of agreement and any additional reported metrics that relate to association of agreement. Risk of bias for each study will be evaluated using the QUADAS-2 tool, with domain-specific judgments recorded and justified.

To ensure data accuracy, each extraction will be independently performed by two reviewers. Their entries will be compared side-by-side, with discrepancies resolved through consensus. If a resolution cannot be reached, a third reviewer will arbitrate. All final decisions and justifications will be recorded in a reconciliation log. Each data extraction file will follow a standardised naming convention (e.g., StudyID_Initials_Extraction.xlsx) and be uploaded to the OSF repository upon completion. Once finalised, the cleaned and verified dataset will be formatted for meta-analysis and made available for public access alongside the manuscript, unless restricted by publisher guidelines.

Data Analysis and Presentation

The analysis will utilise the Fisher r-to-z transformed correlation coefficient as the primary outcome measure of association. The analysis will utilise the pooled mean difference and limits of agreement as the primary outcome measure of agreement. A random-effects model will be applied to the data, with all analyses performed in R Studio using the *metafor* package. Weltz et al. [33] proposed that when conducting a meta-analysis involving Fisher r-to-z transformed correlation coefficients, especially in the presence of study heterogeneity, employing a random-effects model with appropriate variance estimation techniques yields more reliable and generalisable results compared to fixed-effects models. Therefore, random effects models will be utilised. Subgroup analyses will only be performed when there are at least five studies per subgroup. Meta-regression will require a minimum of ten studies per covariate to reduce risk of overfitting. Tests for funnel plot asymmetry will only be conducted when the meta-analysis includes ten or more studies, as recommended by the Cochrane Handbook. Sensitivity analyses will be interpreted cautiously when the evidence base is small.

To identify potential outliers and influential studies, studentised residuals and Cook's distances will be examined [34]. Studies with studentised residuals exceeding the $100 \times (1 - 0.05/(2 \times k))$th percentile of the standard normal distribution (applying a Bonferroni correction with two-sided $\alpha = 0.05$ for k studies) will be flagged as potential outliers. Studies with Cook's distances greater than the median plus six times the interquartile range of Cook's distances will be deemed influential. Outliers and influential studies will be retained in the primary analysis but flagged for sensitivity analyses to assess their impact on pooled estimates. Funnel plot asymmetry will be assessed using the rank correlation test [35] and regression test [36], where the standard error of observed outcomes serves as the predictor. Heterogeneity will be

evaluated through I^2, *Cochran's Q*, and tau^2 statistics. Where possible, subgroup analyses will explore variability in PR-PPG validity based on factors such as operating system, participant characteristics (e.g., age, sex), and study design.

Moderator analyses will investigate the influence of PPG parameters and participant traits on outcomes, while sensitivity analyses will test the effects of risk of bias. Additional sensitivity checks will consider the impact of excluding high-risk studies, approaches to missing data, and methodological quality. Provided sufficient data, meta-regression will examine relationships between continuous variables and effect sizes. Results will be displayed using forest and funnel plots. Conclusions concerning association will be based on effect sizes, with overall effect sizes of $r > 0.9$ (approximately $z > 1.5$) considered valid. For context, $r = 0.70$ is typically regarded as very large and roughly corresponds to $z = 0.8$. Conclusions concerning agreement will be based on bias and limits of agreement (Bias<1 $b \cdot min^{-1}$ and LoA<5 $b \cdot min^{-1}$=Excellent agreement; acceptable for medical-grade; Bias<3 $b \cdot min^{-1}$ and LoA<10 $b \cdot min^{-1}$=Acceptable for general PR monitoring, may be borderline for medical-grade; Bias>5 $b \cdot min^{-1}$ or LoA>10 $b \cdot min^{-1}$=Poor agreement, not clinically interchangeable). High heterogeneity ($I^2 > 50\%$) will warrant cautious interpretation and further exploration through subgroup or moderator analyses. Confidence in conclusions will be guided by the QUADAS-2 framework depending on quality of accuracy.

Results

In order to inform clinical procedures and future studies, the results will contain data on PR-PPG and HR-ECG association (correlations) and agreement (Bland-Altmans), sampling devices, and operating systems. This project is unfunded, and the initial screening is expected to start in Q1 2026, with results published in Q1 2027.

A summary of the study selection procedure is given in Figure 1. This process is now explicitly detailed to ensure consistency and transparency during study selection.

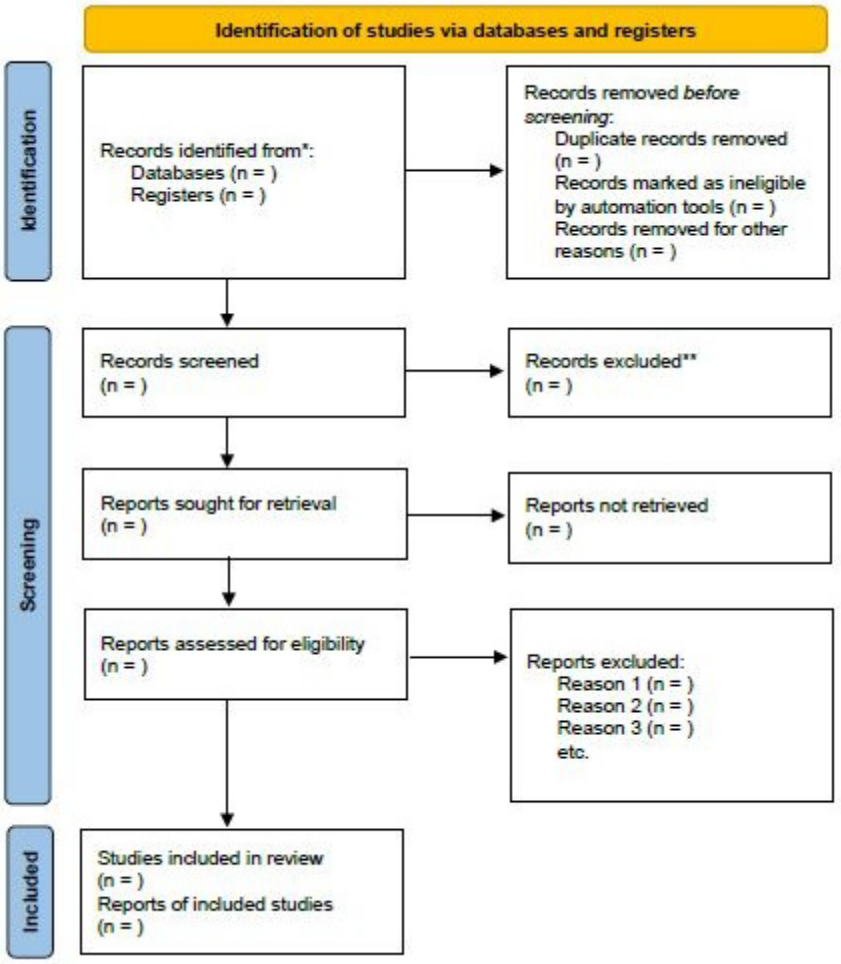

Figure 1. The PRISMA flow diagram which visually summarises the screening process.

Discussion

This systematic review and meta-analysis aims to be the first to provide an updated quantification of the association and agreement of PR-PPG compared to HR-ECG at rest. The rapid development in technology required continuous assessment of validity, and this meta-analysis will provide important findings, indicating whether PR-PPG can be used with confidence. There is a pervasive belief that PR-PPG is analogous to HR-ECG, and herein we will provide an updated systematic review and meta-analysis to support or challenge this supposition. We hypothesise that smartphone-based PR-PPG will demonstrate strong association and acceptable agreement with HR-ECG at rest. These findings would support the

potential of PR-PPG as a valid alternative for remote monitoring in clinical and non-clinical settings.

The decision to undertake a meta-analysis was driven by the need to evaluate the level of agreement between PR-PPG and HR-ECG, including modifying parameters such as frame rate, camera location, skin pigmentation, operating system. Moreover, if there is an absence of knowledge around modifying variables, this systematic review will provide opportunities for future research. By providing context to current findings, this research can guide future studies to concerning PR-PPG and its application. Previous reviews, such as De Ridder et al. [31], indicated that smartphone-based PR-PPG could approximate HR-ECG. However, these analyses were constrained by outdated technology and lacked detailed agreement metrics, limiting their clinical applicability. The De Ridder et al. [31] meta-analysis included studies published between 2009 and 2016, which means smartphone models assessed were from that era. These typically included early-generation devices such as the Apple iPhone 4 and iPhone 5 series (released in 2010 and 2012), the Samsung Galaxy S3 and S4 (released in 2012 and 2013), and other similar Android models from that period. These devices are now 10–15 years old, and their hardware (camera resolution, LED flash quality, processing power) is significantly outdated compared to current smartphones. This is why De Ridder's findings, while useful at the time, may not fully reflect the performance of modern devices with advanced sensors and algorithms. Our meta-analysis aims to address these gaps by including studies that use modern smartphones and operating systems, reflecting current technological capabilities. By quantifying agreement using Bland–Altman analysis alongside correlation measures, we will provide more robust assessment of interchangeability. Moreover, by exploring potential moderators, such as device type, operating system, and participant demographics, we will be able to better understand sources of variability.

This review has several strengths including a rigorous methodology following PRISMA-P guidelines and pre-registration, clear eligibility criteria using PICO framework, a comprehensive search strategy of multiple databases, robust screening and data extraction with dual independent reviewers with calibration and Cohen's Kappa for reliability, and use of structured extraction forms and QUADAS-2 for bias assessment. Our analysis plan includes random-effects meta-analysis using Fisher r-to-z transformation, outlier diagnostics, funnel

plot asymmetry tests, and moderator analyses. The main limitations are that of the original studies. These include potential ambiguity in reporting, heterogeneity in study design and reporting, selective reporting, and lack of algorithm transparency due to proprietary software. The results from this systematic review and meta-analysis could identify areas for future research such as lack of diversity in participants, potential for integration with telehealth and electronic health records, and device or OS-specific optimisation.

Project Timeline

The projected timeline for the study includes title and abstract screening from Q1 2026, followed by full-text screening in Q2 2026. Results are anticipated by Q3 2026, with publication in Q1 2027. Throughout this period, database searches will be regularly updated to capture any newly published studies meeting the inclusion criteria.

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None.

Conflicts of Interest

There are no conflicts of interest in this meta-analysis.

Data availability

This is a protocol paper, so no data are currently available. Once the study is complete, the dataset supporting the findings will be included in the main manuscript and Appendix.

Authors contributions

All authors contributed equally to the conceptualisation, preliminary search, search strategy, writing – original draft, review and editing. No generative AI was used in any portion of the manuscript generation

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol* Green text indicates completed.

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		

Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining

		data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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