Systematic Review Protocol: Accuracy of Photoplethysmography-Based Heart Rate Monitoring Devices

PROSPERO Registration Details

Title: Diagnostic Accuracy of Photoplethysmography-Based Heart Rate Monitoring Devices: A Systematic Review and Meta-Analysis

Registration: PROSPERO CRD4202XXYYYYY (to be submitted)

Protocol Version: 1.0

Date of Submission: [Current Date]

1. Background and Rationale

1.1 Clinical Context

Photoplethysmography (PPG) technology has emerged as a non-invasive method for heart rate monitoring, integrated into wearable devices, fitness trackers, and smartphone applications. As mobile health expands, understanding the reliability of PPG-based heart rate detection compared to electrocardiography (ECG) reference becomes crucial for clinical decision-making and personal health monitoring.

1.2 Knowledge Gap

While individual validation studies exist, there is no comprehensive synthesis evaluating PPG device accuracy across different implementations, populations, and conditions. This systematic review addresses this gap by quantifying PPG performance relative to ECG gold standard.

1.3 Aims and Objectives

Primary Aim:

To conduct a systematic review and meta-analysis evaluating the accuracy of photoplethysmography-based heart rate monitoring devices compared to electrocardiography gold standard.

Specific Objectives:

1. **Accuracy Quantification:** Pool measures of agreement (bias, limits of agreement, correlation)
2. **Subgroup Analysis:** Performance across device types, populations, and conditions
3. **Heterogeneity Assessment:** Identify sources of variability in PPG accuracy
4. **Quality Evaluation:** Assess methodological quality and risk of bias
5. **Clinical Implications:** Provide evidence-based guidance for PPG use

2. Methods

2.1 Review Design

- **Study Type:** Systematic review with meta-analysis
- **Design:** Diagnostic/test accuracy study
- **Reporting Standards:** PRISMA 2020, Cochrane Handbook
- **Registration:** PROSPERO (forthcoming)

2.2 Eligibility Criteria

Inclusion Criteria

1. **Population:** Any population with heart rate measurements
2. **Index Test:** PPG-based heart rate monitoring devices (wrist-worn, finger, smartphone, etc.)
3. **Reference Standard:** Electrocardiography (ECG)
4. **Outcome:** Quantitative accuracy measures (MAE, RMSE, Pearson correlation, Bland-Altman limits)
5. **Study Design:** Validation studies comparing PPG to ECG
6. **Language:** English
7. **Publication Period:** 2010-2025 (modern PPG technology)

Exclusion Criteria

1. **Non-PPG Devices:** Non-photoplethysmography based HR monitoring
2. **No ECG Reference:** Studies without ECG comparison
3. **Insufficient Data:** No quantitative accuracy metrics reported
4. **Animal Studies:** Non-human subjects
5. **Case Reports:** Individual subject reports without systematic methods

2.3 Information Sources and Search Strategy

Electronic Databases

1. PubMed/MEDLINE (1946-present)
2. EMBASE (1974-present)
3. Cochrane Central Register (CENTRAL)
4. IEEE Xplore Digital Library (1900-present)
5. Scopus (Additional validation)

Additional Sources

- Google Scholar (first 200 results)
- ClinicalTrials.gov
- WHO ICTRP registry
- Reference lists from included studies

Search Strategy

The search strategy will combine terms for PPG technology, heart rate monitoring, and validation studies:

Primary Search String:

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("photoplethysmography" OR "photoplethysmograph*" OR "PPG") AND ("heart rate" OR
"pulse rate" OR "HR") AND ("accuracy" OR "validation" OR "reliability" OR
"comparison") AND ("electrocardiogram" OR "ECG" OR "EKG")
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2.4 Study Selection and Data Extraction

Study Screening

- **Level 1 (Title/Abstract):** Independent dual review
- **Level 2 (Full-Text):** Dual review with consensus
- **Data Extraction:** Standardized form with duplicate extraction

Data to Extract

- Study characteristics (design, population, setting)
- Device specifications (PPG wavelength, sampling rate, processing algorithm)
- Accuracy metrics (MAE, RMSE, correlation coefficient r, Bland-Altman bias and LoA)
- Subgroup data (rest vs exercise, healthy vs diseased populations)
- Quality assessment items

2.5 Risk of Bias Assessment

Tool: Adapted QUADAS-2 for device validation studies

Domains:

1. **Patient Selection:** Representative population
2. **Index Test:** PPG measurement protocol
3. **Reference Test:** ECG measurement standardization
4. **Flow and Timing:** Measurement synchronization

2.6 Data Synthesis

Meta-Analysis Methods

- **Models:** Random-effects models for pooled estimates
- **Software:** R with metafor package, Stata
- **Effect Measures:** Mean absolute error (MAE), standardized mean difference
- **Heterogeneity:** I^2 statistic, subgroup analyses

Subgroup Analyses

- **Device Type:** Wrist-worn, finger, smartphone PPG
- **Population:** Healthy adults, athletes, patients with conditions
- **Activity Level:** Rest, moderate exercise, intense exercise
- **Device Brand/Model:** Grouped by manufacturer characteristics

2.7 Certainty of Evidence (GRADE)

Assessment of confidence in estimates across risk of bias, inconsistency, indirectness, imprecision, and publication bias domains.

2.8 Publication Bias

- Funnel plots
- Egger's test
- Trim-and-fill analysis when appropriate

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3. Timeline (Estimated)

Phase	Timeline	Activities
Protocol	Month 1	PROSPERO registration, finalization
Searches	Month 2	Database searches, deduplication
Screening	Months 3-4	Title/abstract, full-text review
Extraction	Months 5-6	Data extraction, quality assessment
Synthesis	Months 7-8	Meta-analysis, GRADE assessment
Writing	Months 9-10	Manuscript preparation
Submission	Month 11	Journal submission

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4. Limitations and Amendments

Protocol amendments will be documented and justified.

This protocol outlines a systematic approach to evaluate PPG-based heart rate monitoring accuracy, providing evidence for clinical and consumer health applications.