

Systematic Review Protocol (PRISMA-P Compliant)



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1. Document Identity & Purpose

Document Type:

Systematic Review Protocol (PRISMA-P 2015 Compliant)

Intended Audience:

- Peer-reviewed academic journals
- Systematic review methodologists
- Clinical researchers in cardiovascular medicine
- Health services and digital health policymakers

Context of Use:

This protocol outlines the planned methodology for conducting a systematic review evaluating **the impact of telemedicine on patient adherence in chronic heart failure (CHF)**. It provides a transparent, reproducible research plan to guide literature identification, screening, extraction, risk-of-bias assessment, and synthesis. The protocol follows **PRISMA-P 2015** reporting guidelines to ensure methodological rigor and eligibility for academic publication.

Compliance Statement:

This protocol has been developed in accordance with the **Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015** checklist.

Positioning Statement:

This sample demonstrates MedLexis' capability to design submission-ready systematic review protocols that meet academic publishing standards, incorporate advanced search strategies, and provide methodologically robust foundations for high-impact clinical research publications.

2. Title & Registration

2.1 Title of the Systematic Review

The Impact of Telemedicine on Patient Adherence in Chronic Heart Failure: A Systematic Review Protocol

2.2 Protocol Registration

PROSPERO Registration ID: CRD420250001 (Simulated)

The review will be prospectively registered in PROSPERO before data extraction to ensure methodological transparency and reduce the risk of bias.

3. Authors & Contributions

3.1 Author List (Simulated)

- Dr. A. Johnson, PhD
- Dr. L. Martinez, MD, MPH
- Dr. H. Tanaka, PhD
- MedLexis Research Support Unit (Simulated)

3.2 Affiliations

- Department of Digital Health & Outcomes Research, Northbridge University, USA
- Division of Cardiovascular Medicine, Westlake Medical Center, Canada
- Center for Evidence-Based Healthcare, Kyoto Research Institute, Japan
- MedLexis Scientific Writing & Research Services (Simulated)

3.3 Roles (CRediT Taxonomy)

- **Conceptualization:** Johnson, Martinez

- **Methodology:** Johnson, Tanaka
 - **Data Curation:** Martinez, MedLexis Research Support Unit
 - **Formal Analysis:** Tanaka
 - **Writing – Original Draft:** MedLexis Research Support Unit
 - **Writing – Review & Editing:** Johnson, Martinez, Tanaka
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4. Amendments

Any modifications to the methods described in this protocol will be documented in a dedicated amendment section in the final review manuscript and updated on PROSPERO as required.

Version Control Table (Simulated)

Version	Date	Description of Change	Author
1.0	Jan 2025	Initial protocol draft	MedLexis
1.1	Feb 2025	Methodology refinement	Johnson
1.2	Feb 2025	Search strategy update	Tanaka

5. Support & Conflicts of Interest

Funding / Support (Simulated)

This study is supported by an internal research grant from the **Center for Digital Health Innovation**, Northbridge University. Additional methodological support is provided by **MedLexis Scientific Writing & Research Services**.

Conflicts of Interest

The authors declare no conflicts of interest related to this protocol. MedLexis participation is limited to methodological and writing support and does not influence study design or outcomes.

6. Rationale

Chronic heart failure (CHF) remains a major global health burden, with high rates of morbidity, recurrent hospitalization, and long-term mortality. A central challenge in CHF management is **suboptimal patient adherence** to essential components of care, including medication regimens, self-monitoring behaviors, dietary recommendations, and scheduled clinical visits. Poor adherence is strongly linked to worse clinical outcomes and increased healthcare utilization.

Telemedicine has emerged as a potential strategy to improve adherence by enabling more frequent contact, remote monitoring, automated reminders, early detection of symptom changes, and enhanced patient engagement. While multiple studies suggest that telemedicine can support adherence in CHF populations, the evidence base is **heterogeneous**, varying in:

- Telemedicine modalities used
- Adherence definitions and measurement tools
- Clinical settings and patient characteristics
- Study designs and methodological rigor.

Existing reviews either combine adherence with broader outcomes (e.g., hospitalization or mortality) or evaluate mixed cardiovascular populations, limiting clarity on **adherence-specific effects** in CHF. No recent, adherence-focused systematic review has comprehensively evaluated **the impact of telemedicine interventions on adherence outcomes specifically in adult CHF populations**, despite the rapid expansion of telehealth technologies.

This review is therefore necessary to:

- Summarize the current evidence using transparent, reproducible methodology
- Clarify the magnitude and consistency of adherence benefits.
- Identify which telemedicine modalities show the strongest impact.
- Inform future research and clinical implementation strategies.

7. Objectives

Overall Objective

To systematically evaluate the impact of telemedicine interventions on patient adherence in adults with chronic heart failure.

Connection to PICOS

- **Population:** Adults (≥ 18 years) diagnosed with chronic heart failure (NYHA class II–IV)
- **Intervention:** Telemedicine modalities, including remote monitoring, video consultations, mobile applications, telephone follow-up, or digital adherence tools
- **Comparator:** Standard in-person care, usual care, or no telemedicine intervention
- **Outcomes:** Measures of adherence (medication adherence, visit adherence, self-monitoring adherence)
- **Study Designs:** Randomized controlled trials, cohort studies, or quasi-experimental studies

Primary Objective

- To determine whether telemedicine interventions improve **medication adherence** in adults with chronic heart failure compared with standard care.

Secondary Objectives

1. To evaluate the effect of telemedicine on **self-monitoring adherence**, including weight monitoring, blood pressure logging, and symptom tracking.
2. To assess the impact of telemedicine on **clinic-visit adherence** or scheduled follow-up adherence.

3. To compare adherence outcomes across **different telemedicine modalities**.
 4. To explore whether patient characteristics (age, disease severity, comorbidities) modify adherence outcomes.
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8. Eligibility Criteria (PICOS Framework)

Participants (P)

- **Inclusion:** Adults (≥ 18 years) diagnosed with chronic heart failure (NYHA II–IV)
- **Exclusion:** Pediatric populations, acute heart failure, post–acute HF hospitalization only, mixed cardiovascular populations unless CHF data are separable

Interventions (I)

Telemedicine interventions, including but not limited to:

- Remote physiological monitoring
- Video consultations
- Telephonic follow-up
- Smartphone or digital health applications
- Automated reminders or digital adherence tools

Comparators (C)

- Standard in-person care
- Usual care
- No telemedicine

- Non-digital interventions

Outcomes (O)

Eligible studies must report at least one adherence-related measure:

- Medication adherence (e.g., MPR, PDC, pill count, validated scales)
- Self-monitoring adherence (weight, BP, symptom logs)
- Visit adherence/follow-up adherence.

Study Designs (S)

- Randomized controlled trials (RCTs)
- Non-randomized controlled studies (quasi-experimental designs)
- Prospective or retrospective cohort studies

Excluded:

- Cross-sectional studies
- Case series/case reports
- Reviews, editorials, or opinion papers
- Studies without an adherence outcome

Inclusion/Exclusion Criteria Table

Category	Inclusion Criteria	Exclusion Criteria
Population	Adults (≥18) with CHF, NYHA II–IV	Pediatric, acute HF, non-CHF unless data separable

Intervention	Telemedicine-based intervention	Non-digital interventions only
Comparator	Standard care, usual care, no telemedicine	None
Outcomes	Any adherence-related measure	No adherence outcomes reported
Study Design	RCTs, cohorts, quasi-experimental	Cross-sectional, case reports, reviews
Language/Date	English; no limit on publication year	Non-English language, unless translation is available

9. Information Sources

The systematic review will use a comprehensive and multi-source search strategy to ensure complete coverage of the literature on telemedicine and patient adherence in chronic heart failure.

9.1 Electronic Databases

The following databases will be searched from inception to the date of search execution:

- PubMed/MEDLINE
- Embase (Elsevier)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- CINAHL (EBSCOhost)

These databases cover biomedical, nursing, allied health, and controlled trial literature essential for adherence-related research.

9.2 Grey Literature Sources

Grey literature will be included to reduce publication bias:

- ProQuest Dissertations & Theses

- OpenGrey
- Conference abstracts from cardiology and digital health meetings
- Government/agency reports (e.g., AHRQ, WHO digital health documents)

9.3 Clinical Trial Registries

To identify ongoing or unpublished studies:

- **ClinicalTrials.gov**
- **WHO International Clinical Trials Registry Platform (ICTRP)**
- **EU Clinical Trials Register**

9.4 Time Restrictions

No publication-year limits will be applied to maximize inclusion, given the evolving nature of telemedicine technologies.

9.5 Language Restrictions

Searches will be restricted to **English-language publications** due to resource constraints for translation.

10. Search Strategy

10.1 Full Electronic Search Strategy

PubMed (Sample Search String)

("Telemedicine"[Mesh] OR telemedicine OR "telehealth" OR "remote monitoring" OR "mHealth" OR "mobile health" OR "eHealth" OR "digital health" OR "video consultation" OR "telephone follow-up")
AND

("Heart Failure"[Mesh] OR "chronic heart failure" OR "congestive heart failure" OR CHF OR "left ventricular dysfunction")

AND

(adherence OR "treatment adherence"[Mesh] OR "medication adherence" OR compliance OR "self-monitoring" OR "follow-up adherence")

Embase (Sample Search String)

('telemedicine'/exp OR telemedicine OR telehealth OR 'remote monitoring'/exp OR 'digital health' OR 'mobile health' OR mhealth)

AND

('heart failure'/exp OR 'chronic heart failure' OR CHF OR 'left ventricle failure')

AND

(adherence OR 'medication adherence'/exp OR 'treatment compliance' OR self-monitoring OR 'follow-up adherence')

Boolean Logic, MeSH Terms & Keywords

- Combined controlled vocabulary terms (MeSH, Emtree)
- Synonyms and free-text keywords
- Filters: none for year; English language included
- Search strings will be adapted for each database's syntax.

Search Updates

The search will be updated:

- Immediately before final data extraction
- Again, before manuscript submission
Updates ensure inclusion of recently published telemedicine studies.

10.2 Hand-Searching Plan

Reference Lists

- Screen reference lists of all included studies
- Screen reference lists of relevant systematic reviews

This captures studies missed by database indexing.

Key Journals

Targeted searches in high-yield journals:

- *Journal of Cardiac Failure*
- *European Journal of Heart Failure*
- *Telemedicine and e-Health*
- *Journal of Medical Internet Research (JMIR)*

Conference abstracts from major cardiology meetings (AHA, ESC) will also be reviewed.

11. Data Management & Study Selection Process

11.1 Study Screening Workflow

Stage 1 — Title and Abstract Screening

- Two reviewers will independently screen titles and abstracts.
- Studies failing to meet basic PICOS criteria will be excluded.
- Any disagreements will be resolved through discussion or by a third reviewer.

Stage 2 — Full-Text Screening

- Eligible abstracts will undergo full-text evaluation by two independent reviewers.
- Reasons for exclusion at this stage will be documented.

Stage 3 — PRISMA Flow Diagram

A PRISMA flow diagram will be prepared to illustrate:

- Number of records identified
- Screening outcomes
- Eligibility results
- Final included studies

This will be completed after the selection process.

11.2 Use of Software Tools (Simulated)

The following tools will support data management and workflow efficiency:

- **Rayyan** for title/abstract screening
- **Covidence** for full-text review and risk-of-bias tracking
- **EndNote** or **Zotero** for reference management and duplicate removal

All software use will adhere to PRISMA-P documentation standards.

12. Data Collection Process

A structured and reproducible data collection strategy will be used to ensure methodological rigor.

12.1 Standardized Data Extraction Form

A standardized data extraction form will be developed before data collection. The form will include fields for study characteristics, participant demographics, intervention details, adherence outcomes, and risk-of-bias variables. The form will be designed to capture both qualitative and quantitative data in alignment with PRISMA-P requirements.

12.2 Pilot Testing the Extraction Form

The extraction form will be pilot-tested using **three randomly selected studies**. Pilot testing aims to:

- Ensure clarity and completeness of extraction fields
- Identify inconsistencies
- Allow refinement before full extraction begins.

Modifications will be made as necessary based on pilot findings.

12.3 Two-Reviewer Independent Extraction

Two reviewers will independently extract data from all included studies.

- Data will be recorded separately and then compared.
- This minimizes extraction errors and reduces subjective bias.

12.4 Resolution of Discrepancies

Any discrepancies between reviewers will be resolved:

1. Through discussion and consensus
2. With arbitration by a third reviewer if agreement cannot be reached

A log will be maintained documenting all disagreements and resolutions for transparency.

13. Data Items

The following data fields will be extracted from each study. All items reflect the requirements of a high-quality systematic review on adherence outcomes in CHF.

13.1 Study Characteristics

- Study title
- Authors
- Year of publication
- Country
- Study design (RCT, cohort, quasi-experimental)
- Setting (hospital, outpatient clinic, community-based)

13.2 Participant Details

- Sample size
- Mean/median age
- Sex distribution
- Heart failure classification (NYHA class)
- Comorbidities (if reported)
- Inclusion/exclusion criteria

13.3 Telemedicine Modality

- Type of telemedicine intervention (remote monitoring, video visits, mobile app, telephone, mixed modalities)

- Frequency and duration of intervention
- Technology components (e.g., sensors, wearable devices, messaging systems)

13.4 Adherence Measures

- Medication adherence (e.g., MPR, PDC, pill counts, validated scales)
- Self-monitoring adherence (e.g., frequency of weight/BP logs)
- Visit adherence (scheduled follow-up completion)
- Any composite adherence score

Measurement tools, definitions, and thresholds for adherence will be documented as reported.

13.5 Outcomes

- Primary adherence outcomes
- Secondary clinical outcomes (if related to adherence), such as:
 - Rehospitalization
 - Emergency visits
 - Patient-reported adherence barriers or facilitators

13.6 Funding Sources

- Study funding statements
- Industry vs. non-industry sponsorship

13.7 Conflicts of Interest

- Author disclosures

- Industry involvement
 - Potential conflicts relevant to telemedicine tools or devices
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14. Outcomes & Prioritization

This review focuses specifically on adherence-related outcomes in CHF. Outcomes are prespecified and hierarchized to prevent selective reporting.

14.1 Primary Outcome

Change in medication adherence, measured using:

- Medication Possession Ratio (MPR)
- Proportion of Days Covered (PDC)
- Pill counts
- Electronic monitoring
- Validated self-report scales (e.g., Morisky Medication Adherence Scale)

Medication adherence is prioritized due to its strong linkage to clinical outcomes in CHF management.

14.2 Secondary Outcomes

1. Self-Monitoring Adherence

Adherence to recommended daily weight monitoring, BP monitoring, symptom logging, or use of telemonitoring tools.

2. Clinic-Visit Adherence

Completion of:

- Scheduled follow-up visits
- Telemedicine check-ins
- Guideline-recommended monitoring appointments

3. Rehospitalization Related to Adherence

- CHF-related rehospitalization rates
- Emergency department visits
(Only if explicitly linked to adherence behavior)

4. Patient-Reported Adherence Behaviors

- Self-reported adherence barriers
- Engagement with telemedicine tools
- Satisfaction with telemedicine-supported care

These outcomes provide important qualitative context to adherence measurement, especially in chronic disease populations.

15. Risk of Bias Assessment

A structured risk-of-bias evaluation will be conducted to assess the methodological quality of included studies.

15.1 Randomized Controlled Trials (RCTs)

Risk of bias for RCTs will be assessed using the **Cochrane Risk of Bias 2 (RoB 2) tool**, evaluating the following five domains:

1. Bias arising from the randomization process
2. Bias due to deviations from intended interventions

3. Bias due to missing outcome data
4. Bias in the measurement of the outcome
5. Bias in the selection of the reported result

Each domain will be rated as:

- Low risk
- Some concerns
- High risk

Overall risk-of-bias judgments will follow RoB2 standards.

15.2 Non-Randomized Studies

Non-randomized and quasi-experimental studies will be evaluated using **ROBINS-I** (Risk Of Bias In Non-randomized Studies—of Interventions).

Seven domains will be assessed:

1. Confounding
2. Participant selection
3. Classification of interventions
4. Deviations from intended interventions
5. Missing data
6. Measurement of outcomes
7. Selection of the reported results

Results will be categorized as:

- Low
- Moderate

- Serious
- Critical
- No information

15.3 Reviewer Process and Discrepancy Resolution

- Two reviewers will independently rate the risk of bias.
- Discrepancies will be discussed and resolved by consensus.
- Persistent disagreements will be adjudicated by a third reviewer.
- A risk-of-bias summary table and figure will be generated.

15.4 Sensitivity Analyses Related to Risk of Bias

To assess the robustness of findings, the following sensitivity analyses will be conducted when possible:

- Excluding studies with **high risk of bias** (RoB2)
- Excluding studies rated **serious/critical** (ROBINS-I)
- Assessing the effect of removing non-randomized studies
- Comparing results between low-risk and high-risk subgroups

These analyses help determine the stability of pooled estimates.

16. Data Synthesis

16.1 Quantitative Synthesis (Meta-analysis), If Appropriate

Meta-analysis will be performed if the included studies are sufficiently homogeneous in design, population, interventions, and outcome measures.

Effect Size Metrics

- **Continuous outcomes:** Mean Difference (MD) or Standardized Mean Difference (SMD)
- **Dichotomous outcomes:** Risk Ratio (RR) or Odds Ratio (OR), depending on reporting
95% confidence intervals will be calculated for all effect estimates.

Statistical Models

- A **random-effects model** (DerSimonian–Laird) will be used as the default due to expected heterogeneity across telemedicine modalities.
- Fixed-effect models may be explored in sensitivity analyses.

Assessment of Heterogeneity

- Statistical heterogeneity will be quantified using **I² statistics** and **Chi² tests**.
- Interpretation of I²:
 - 0–40%: might not be important
 - 30–60%: moderate
 - 50–90%: substantial
 - 75–100%: considerable

Planned Subgroup Analyses

If data allow, subgroup analyses may examine differences by:

- Telemedicine modality (remote monitoring vs. video vs. app-based)
- Heart failure severity (NYHA II vs. III/IV)
- Study design (RCT vs. observational)

- Duration of intervention (short-term vs. long-term)

Planned Sensitivity Analyses

- Removing studies at high risk of bias
- Removing outliers identified in forest plots
- Comparing random-effects vs. fixed-effect results
- Excluding very small sample studies (<50 participants)

These analyses strengthen confidence in the pooled findings.

16.2 Qualitative Synthesis (If Meta-analysis Is Not Feasible)

If statistical pooling is inappropriate due to heterogeneity in interventions, populations, or adherence measures, a structured narrative synthesis will be performed.

This will include:

- Tabular summaries of key study characteristics
- Thematic grouping of telemedicine modalities
- Descriptive comparison of adherence outcomes
- Identification of patterns, inconsistencies, and gaps in evidence

Narrative synthesis will follow guidance from the **Cochrane Handbook**.

17. Meta-Bias Assessment

17.1 Publication Bias

If ≥ 10 studies are included in the meta-analysis, publication bias will be assessed using:

- **Funnel plot symmetry**
- **Egger's regression test** (for continuous or log-transformed outcomes)
- **Begg's test** (as supplementary analysis)

Small-study effects will also be examined.

17.2 Selective Reporting Bias

Selective outcome reporting will be evaluated by:

- Comparing published outcomes to registry entries (ClinicalTrials.gov, ICTRP)
- Cross-checking methods sections vs. reported endpoints.
- Assessing reporting discrepancies using risk-of-bias tools (RoB2, ROBINS-I)

Studies with strong indications of selective reporting will be flagged in the risk-of-bias assessment and considered in sensitivity analyses.

18. Confidence in Cumulative Evidence

The overall confidence in the body of evidence will be evaluated using the **GRADE (Grading of Recommendations, Assessment, Development, and Evaluations)** approach.

18.1 GRADE Domains Assessed

For each prespecified outcome (medication adherence, self-monitoring adherence, visit adherence), the following GRADE domains will be evaluated:

1. **Risk of Bias**
Based on RoB2 or ROBINS-I judgments.
2. **Inconsistency**

- Variability in effect sizes
- Overlap of confidence intervals
- I^2 heterogeneity statistics

3. Indirectness

- Applicability of study populations to CHF
- Alignment between the intervention and the research question
- Relevance of measured outcomes to adherence

4. Imprecision

- Wide confidence intervals
- Small sample sizes
- Low event rates (if dichotomous outcomes)

5. Publication Bias

- Funnel plot asymmetry
- Egger's test results (if applicable)

18.2 Certainty-of-Evidence Ratings

Each outcome will be graded as:

- **High:** Very confident that the true effect is close to the estimate
- **Moderate:** True effect likely close to the estimate, but possibility of substantial difference
- **Low:** Limited confidence; true effect may be substantially different
- **Very Low:** Very little confidence; true effect likely substantially different

A GRADE Summary of Findings (SoF) table will be produced for inclusion in the final review manuscript.

19. References

(All references below are simulated or generalizable academic citations appropriate for a portfolio sample.)

1. Smith J, Patel R. Telemedicine interventions and adherence outcomes in chronic disease management: A structured review. *J Med Internet Res*. 2023;25(4):e10245.
2. Hernandez L, Wong A. Digital remote-monitoring strategies for chronic heart failure: Trends and clinical impact. *Eur J Heart Fail*. 2024;26(1):55–66.
3. Thompson P, Lee S. Understanding adherence behaviors in chronic heart failure: A systematic overview. *Heart Lung*. 2022;51(3):411–420.
4. World Health Organization. WHO guideline: Recommendations on digital interventions for health system strengthening. 2019.
5. Cochrane Effective Practice and Organisation of Care (EPoC). Data collection form guidelines.
6. Moher D et al. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015. *Syst Rev*. 2015;4:1.
7. Guyatt GH, Oxman AD, et al. GRADE guidelines: A framework for rating certainty of evidence. *BMJ*. 2011;343:d5928.

20. Notes (Portfolio Value Statement)

Why Systematic Review Protocols Are High-Value Deliverables

Systematic review protocols are critical components of scholarly research and academic publishing. They:

- Ensure **methodological transparency**, preventing bias and improving reproducibility
- Increase acceptance likelihood in high-impact journals.
- Serve as the foundation for meta-analysis and evidence synthesis projects.
- They are often required by registries (e.g., PROSPERO) and ethically expected by research institutions

For clients—universities, research groups, and healthcare organizations—having a high-quality protocol significantly accelerates publication timelines and enhances research credibility.

MedLexis Methodology Expertise

This protocol showcases MedLexis' strengths in:

- Designing **robust, publication-compliant search strategies** across major databases
- Building **rigorous PICOS frameworks** and eligibility criteria
- Applying authoritative **risk-of-bias tools** (RoB2, ROBINS-I)
- Structuring precise **GRADE evidence assessments**
- Ensuring full alignment with **PRISMA-P 2015** and international academic standards

Such expertise positions MedLexis as a premium partner for research groups seeking evidence-based, methodologically sound, and publication-ready documentation.

How This Sample Demonstrates Premium Academic & Regulatory Writing Capability

- It reflects mastery of systematic review methodology and academic scientific writing.
- It integrates technical rigor with clarity, producing a document that is ready for journal submission.
- It demonstrates MedLexis' ability to guide full-cycle evidence synthesis projects—from protocol development to final manuscript.

- It showcases the agency's capacity to produce **high-value, billable research deliverables** that meet the expectations of universities, medical institutions, and global research teams.

MedLexis Portfolio Disclaimer

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