

Telephone-Based Patient Outreach to Improve Home Blood Pressure Monitoring in Chronic Hypertension

Statistical Analysis Plan

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1. Abbreviations and Definitions

- **BP:** Blood Pressure
- **CI:** Confidence Interval
- **GLM:** Generalized Linear Model
- **IPW:** Inverse Probability Weighting
- **ITT:** Intention-to-Treat
- **RCT:** Randomized Controlled Trial
- **SAP:** Statistical Analysis Plan
- **SBP:** Systolic Blood Pressure

2. Introduction

2.1 Preface

This study is a randomized controlled trial designed to evaluate the efficacy of a proactive phone call intervention in improving patient compliance with home blood pressure (BP) logs. Regular home BP monitoring is essential for optimal hypertension management, yet return rates of these logs to clinical charts remain low.

2.2 Scope of Analysis

This SAP details the methodology for evaluating the primary outcome (presence of the BP log in the clinical chart) and the secondary outcome (systemic reduction in systolic blood pressure) at a 90-day follow-up period.

3. Study Objectives and Endpoints

3.1 Study Objectives

The primary objective is to measure the effectiveness of a proactive phone call reminder compared to standard care in increasing the proportion of patients who successfully return a home BP log to their clinical chart. The secondary objective is to evaluate if the intervention facilitates better short-term blood pressure control.

3.2 Endpoints

- **3.2.1 Primary Endpoint:** The presence of a completed home BP log in the patient's clinical chart at the 90-day post-intervention chart review (Binary: Yes / No).
- **3.2.2 Secondary Endpoints:** 1. Change in Systolic Blood Pressure (Δ SBP) from baseline to the most recent follow-up visit.
2. Completion of a follow-up office visit (Updated BP recorded).

4. Study Methods

4.1 General Study Design and Plan

This is a 1:1 randomized controlled trial comparing a proactive telephone intervention against standard clinical care. Chart reviews are conducted at 90 days post-intervention.

4.2 Study Population

Patients indicated for home blood pressure monitoring.

4.3 Randomization

Patients are randomized equally into the Intervention Arm and the Control Arm.

5. Sample Size and Power Calculations

Prior to the initiation of the study, the true baseline return rate of home BP logs in standard care was unknown. The investigators established a priori goal to detect a 15% improvement in home blood pressure log use between the intervention and control.

Because the baseline rate was unknown, the investigators estimated that a target sample size of 150 patients (75 per arm) should be sufficient to detect this clinical difference.

6. General Analysis Considerations

6.1 Timing of Analyses

Final analysis is performed 90 days after the intervention phase is complete.

6.2 Analysis Populations

- **Full Analysis Population (Intention-to-Treat - ITT):** All randomized subjects are evaluated in their original randomized groups, representing the unadjusted baseline ITT population.
- **IPW-Adjusted Population:** The full ITT population, mathematically weighted using Inverse Probability Weighting to properly account for patients who did not yet follow up (missing data), as outlined in Section 6.4.

6.3 Covariates

Baseline covariates utilized in the adjustment models include:

- Baseline Systolic Blood Pressure (Continuous)
- History of completing a BP log in the prior 5 years (Binary: Yes/No)
- Treatment Group Assignment

6.4 Handling Missing Data

At the 90-day evaluation, patients without an updated chart entry due to pending PCP appointments represent right-censored data. Because dropping these patients violates ITT principles, missingness will be addressed via **Inverse Probability Weighting (IPW)**. A logistic regression model will predict the probability of observation based on baseline covariates. The inverse of these probabilities will be used as weights in the primary efficacy analysis to calculate the adjusted success rates for the full ITT cohort.

7. Summary of Study Data

All continuous variables (e.g., SBP) will be summarized using mean, standard deviation, and non-missing sample size. Categorical variables (e.g., Baseline Log History) will be reported as frequencies and percentages.

8. Efficacy Analyses

8.1 Primary Efficacy Analysis

The primary analysis will evaluate the difference in log return rates strictly using the ITT frameworks defined in Section 6.2.

- **Base ITT Model:** An unadjusted analysis where any missing data (pending visits) is strictly categorized as a treatment failure (Outcome = No). Differences will be tested via a Chi-square test of independence.
- **IPW-Adjusted ITT Model:** A weighted Generalized Linear Model (GLM) with a binomial family and logit link will be applied to the data, utilizing the IPW weights derived in Section 6.4. The risk difference, standard error, 95% Confidence Interval, and p-value for the treatment effect will be reported.

8.2 Secondary Efficacy Analysis

The secondary analysis will evaluate the clinical impact of the intervention on actual blood pressure management.

- **Blood Pressure Reduction:** An Analysis of Covariance (ANCOVA) will be utilized to compare the mean change in Systolic Blood Pressure (SBP) between the intervention and control groups, adjusting for baseline Systolic Blood Pressure as a covariate. This analysis will be restricted to the sub-population of patients who successfully completed a follow-up office visit and had updated vitals recorded.

9. Safety Analyses

Adverse events related to the intervention or standard care (if any) will be reported descriptively. No formal statistical comparative safety analysis is planned for this behavioral intervention.

10. Reporting Conventions

P -values ≥ 0.001 will be reported to 3 decimal places; p -values less than 0.001 will be reported as " < 0.001 ". The threshold for statistical significance is set a priori at $\alpha = 0.05$. Confidence intervals will be calculated at the 95% level. To comprehensively evaluate the clinical significance of the findings, the 95% CIs will be actively evaluated against the 15% MCID threshold to assess potential clinical relevance, particularly in the event of null p -values.

11. Quality Assurance of Statistical Programming

Analyses will be conducted using Python 3.x (libraries: pandas, numpy, scipy.stats, statsmodels). Data cleaning steps, missing data imputation models (IPW), and GLM regressions will be documented in a reproducible codebase.