Study Protocol and Statistical Analysis Plan

Post-Emergency Department Discharge Clinic Telehealth Program for Patients With Uncontrolled Hypertension: A Pilot Study

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Background and Rationale

Hypertension affects nearly half of adults in the United States and remains a leading risk factor for cardiovascular disease, stroke, and kidney disease. Despite the availability of effective treatments, blood pressure control rates have declined in recent years. Many individuals with uncontrolled hypertension lack consistent access to primary care and rely on emergency departments for healthcare.

The emergency department represents a critical point of contact with the healthcare system for many patients who do not have an established primary care provider. To address this gap in care, the University of Alabama at Birmingham established the Emergency Department Post-Discharge Clinic (ED-PDC), which provides follow-up care for patients discharged from the emergency department who do not have ongoing outpatient care.

Remote blood pressure monitoring and pharmacist-led hypertension management have been shown to improve blood pressure control in outpatient settings. Telehealth approaches may further reduce barriers to care, particularly for patients facing challenges related to transportation, healthcare access, or provider availability.

This pilot randomized study evaluates the feasibility of implementing a program that combines remote blood pressure monitoring with pharmacist-led telehealth visits among patients with uncontrolled hypertension seen in the ED-PDC.

Study Objectives

The goal of this pilot study is to evaluate the feasibility of implementing a remote blood pressure monitoring and pharmacist-led telehealth program for hypertension management among patients seen in the ED-PDC.

Primary Outcome

The primary outcome is the **total number of participants recruited and enrolled into the study** during the study period. This outcome serves as a measure of recruitment feasibility within the ED-PDC setting.

Other Pre-specified Outcome

An additional feasibility indicator is the **number of participants who attended the final study visit** conducted three months after randomization. This outcome reflects participant retention and completion of follow-up.

Although the primary focus of this pilot study is feasibility, blood pressure measurements and participant engagement with the intervention are collected to inform the design of future larger studies evaluating the clinical effectiveness of remote blood pressure monitoring and telehealth-based hypertension management.

Study Design

This study is a **pilot randomized interventional study** conducted at the University of Alabama at Birmingham.

Participants are randomized in a **parallel two-arm design** to either usual care or a remote blood pressure monitoring and telehealth intervention.

Study Characteristics

Study type: Interventional
Allocation: Randomized
Intervention model: Parallel assignment
Masking: None (open label)
Primary purpose: Treatment

Total enrollment: **24 participants**

Study duration for each participant: **3 months**

Study Population

Participants are recruited from the **Emergency Department Post-Discharge Clinic (ED-PDC)** at the University of Alabama at Birmingham.

The ED-PDC provides follow-up care for patients discharged from the emergency department who do not have an established primary care provider.

Eligibility Criteria

Inclusion Criteria

Participants must meet the following criteria:

- Age 18 years or older
- Seen in the Emergency Department Post-Discharge Clinic
- Blood pressure ≥130/80 mmHg and ≤160/100 mmHg
- English speaking
- Own a smartphone with video capability
- No established primary care provider

Exclusion Criteria

Participants will be excluded if they:

- Are pregnant or breastfeeding
- Work overnight or second shift schedules that would interfere with the intervention schedule

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Randomization

After eligibility confirmation and informed consent, participants are randomized in a **1:1 ratio** to one of two groups:

1. Usual care
2. Remote blood pressure monitoring plus pharmacist-led telehealth

Randomization assignments are generated prior to study initiation and implemented by the study coordinator.

Study Procedures

Enrollment Visit

Participants attend an enrollment visit at the ED-PDC where they:

- Provide informed consent
- Complete baseline questionnaires
- Undergo blood pressure measurement
- Are randomized to one of the two study arms

Participants receive educational materials regarding hypertension and blood pressure measurement.

Intervention Arm

Participants randomized to the intervention arm receive a **remote blood pressure monitoring program combined with pharmacist-led telehealth visits**.

Participants are provided with a **Withings BPM Connect Pro home blood pressure monitor**.

They are instructed to measure blood pressure:

- Twice in the morning
- Twice in the evening

Blood pressure measurements are automatically transmitted to the study team.

Participants receive **daily text message reminders** encouraging blood pressure monitoring.

Participants also participate in **weekly telehealth visits with a pharmacist** to review blood pressure readings and discuss medication management. Medication changes are overseen and approved by a collaborating physician.

The intervention continues for **12 weeks**.

Usual Care Arm

Participants randomized to usual care continue receiving routine clinical care as provided by their healthcare providers.

They return for a **single follow-up research visit at 3 months** after enrollment.

Follow-Up Visit

All participants attend a final research visit at approximately **3 months after enrollment**.

During this visit:

- Blood pressure is measured using standardized procedures
- Participants complete follow-up questionnaires
- Participants in the intervention group return the home blood pressure monitoring device

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Outcome Measures

Primary Outcome

Total number of participants recruited and enrolled into the study.

Other Pre-specified Outcome

Number of participants who attended the final study visit conducted approximately three months after randomization.

Statistical Analysis Plan

This study is designed as a **pilot randomized study** primarily intended to evaluate feasibility.

Analyses will therefore focus on **descriptive statistics**.

Baseline participant characteristics will be summarized using:

- Means and standard deviations for continuous variables
- Frequencies and percentages for categorical variables

The primary outcome, the total number of participants recruited, will be reported as the count of participants enrolled during the study period.

Participant retention will be summarized as the **number of participants who completed the final study visit**.

Given the small sample size typical of pilot studies, statistical analyses are not designed to formally test hypotheses regarding treatment effects. Data collected in this study will be used to inform the design and sample size calculations of future larger trials.

Ethical Considerations

This study was reviewed and approved by the **University of Alabama at Birmingham Institutional Review Board**.

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All participants provided written informed consent prior to participation.

Funding

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