Study Title: Building Engagement Using Financial Incentives Trial – Hypertension (BENEFIT-H)

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1. Study aim, background, and design

Remote patient monitoring (RPM) of blood pressure provides critical data upon which providers base treatment decisions and contributes to patients' sense of personal control and responsibility for hypertension self-management, with positive effects on disease control.[1] A recent meta-analysis demonstrated that smartphone application-based self-monitoring of hypertension-related behaviors has a clinically significant effect on blood pressure reduction.[2] Despite the strong evidence in support of these strategies for increasing patient engagement with preventive healthcare and chronic disease management, low intrinsic motivation among patients in real-world primary care settings may undermine their effectiveness. In light of low intrinsic motivation, extrinsic motivation in the form of financial incentives has been proposed to increase patient engagement with health behaviors.[3] The effectiveness of financial incentives for increasing patient engagement may depend on the timing (immediate vs. delayed payment) with which incentives are paid. The Louisiana Community Engagement Alliance (LA-CEAL) will pursue the following objective:

> **OBJECTIVE:** To determine the effectiveness of immediate vs. delayed payment of financial incentives for increasing engagement with remote blood pressure monitoring and improving blood pressure control in primary care patients.

To accomplish this objective, we will use a 2-arm randomized controlled trial design. FQHC patients who are aged 40 or older with uncontrolled blood pressure (n=50) will be identified through the electronic health records of our FQHC partners. Participants who meet eligibility criteria and enroll in the study will be randomized to one of two arms: **Arm 1** (delayed incentives) will receive a home blood pressure monitor and the app associated with that device, as well as instructions for using the device and app. They will receive financial incentives paid out at the end of the study for home blood pressure monitoring (up to $25/week for 8 weeks). **Arm 2** (immediate incentives) will receive the same device and app and will also be offered financial incentives paid out each week for home blood pressure monitoring (up to $25 per week for 8 weeks depending on completion of self-monitoring).

2. Subject Population

Using the following criteria, we will enroll up to 50 patients at partner FQHCs:

> Inclusion criteria: Age ≥40 years; receive care at a participating FQHC; taking blood pressure medication; uncontrolled blood pressure at most recent clinic visit (systolic blood pressure ≥130 mm Hg or diastolic blood pressure ≥80 mm Hg); ability to understand and speak English; able to access a smartphone

Exclusion criteria: currently participating in another clinical trial or research study on blood pressure; unable or unwilling to give informed consent

3. Procedure

At a screening visit, study staff will verify eligibility and obtain informed consent. Enrolled participants will complete a baseline questionnaire, have their height and weight measured, list the medications they currently take, and be given a home blood pressure monitor. Study staff will help participants to download the associated app, set up the device, and understand how and when to use it. Study staff will explain the financial incentives available for measuring their blood pressure. Participants will use the device for 2 months before completing a follow-up study visit. During those 2 months, study staff may contact participants to help with troubleshooting technical issues. Study staff will monitor regular data downloads from the RPM data portal and pay weekly incentives to the intervention group for completion of self-monitoring. The incentives for the control group will be paid out at the end of the study. Healthcare utilization and blood pressure data will be obtained from the participant's electronic health record. The primary outcome is the difference in self-monitoring completion between the two groups. All electronic data will be stored on secure cloud-based servers and accessed on HIPAA-compliant, encrypted, password-protected computers that are only accessible to the study staff.

4. Risks

The risk of physical, psychological, social, or legal harm associated with participation in all components of this study is minimal:

- Participants may find it inconvenient to take time to participate in the study. All study activities will be arranged at a time that is convenient for participants.
- There is a small risk of unauthorized disclosure of participants' responses, which will be prevented by following a strict protocol for data handling and rigorous training of study staff:
    - No direct identifiers (e.g., name, address) will be recorded on study forms. Identifying data used for participant recruitment will be kept separate from study data.
    - All electronic study records will be stored with password-protection. All paper study records will be locked in a secure study office. Data will be accessible only by study staff with approval from the PI.
    - The data will be retained without direct identifiers in a secure location for possible use in a future project, which will be consistent with the original research purpose.
    - Data may be shared with the NIH or other researchers upon request. Any data shared with the NIH or other researchers will not contain identifying information.
    - *Discomfort during blood pressure measurements:* Participants may experience temporary discomfort when having their blood pressure measured if the cuff puts pressure on the arm; this risk is similar to when a patient has his/her blood pressure measured by his/her healthcare provider. To reduce the risks of discomfort, study staff taking blood pressure measurements will be trained using the American Heart Association protocol and will make sure they are using a blood pressure cuff that is the right size and that the equipment is working properly.
    - If participants start taking their blood pressure medication more regularly in response to increased self-monitoring, they may experience symptoms from low blood pressure, including lightheadedness, dizziness, and fainting. If their blood pressure is low or they report symptoms of low blood pressure at a study visit, they will be instructed to seek care of healthcare provider and/or schedule an appointment with their healthcare provider.

5. Benefits

If the BENEFIT-H financial incentives are found to be effective at increasing engagement with remote blood pressure monitoring, individuals could benefit from that behavior. In addition, the knowledge gained from the study may benefit society in general by providing evidence to optimize a strategy to increase patient engagement with chronic disease self-monitoring and preventive healthcare, with ensuing benefits for reducing morbidity and mortality.

6. Remuneration

Participants who complete the baseline and follow-up study visits will receive remuneration in the form of a $50 gift card for each visit completed (up to $100).

In addition, both groups will receive up to $25/week for up to 8 weeks in gift cards for completing blood pressure monitoring (up to $200 over the 8-week study):

These financial incentives (immediate versus delayed) comprise the intervention being tested in this study.

7. Costs

There will be no costs to the participant for participating in this research study.

8. Consent process and documentation

Under a partial waiver of HIPAA authorization granted the Tulane IRB, FQHC partners will query their EHR systems and provide a list of eligible patients and their contact information to study staff, who contact patients, verify interest/eligibility through a telephone pre-screening, and schedule a screening/baseline visit for those meeting eligibility criteria. We will request a *waiver of documentation of consent* from the Tulane IRB for telephone pre-screening. Potential participants will attend an in-person screening visit, at which eligibility will be verified and consent and HIPAA authorization will be documented using signed forms.

REFERENCES

1. Artinian NT, Flack JM, Nordstrom CK, et al. Effects of nurse-managed telemonitoring on blood pressure at 12-month follow-up among urban African Americans. *Nursing research*. 2007;56(5):312-322.
2. Kassavou A, Wang M, Mirzaei V, Shpendi S, Hasan R. The association between smartphone app–based self-monitoring of hypertension-related behaviors and reductions in high blood pressure: Systematic review and meta-analysis. *JMIR mHealth and uHealth*. 2022;10(7):e34767.
3. Thirumurthy H, Asch DA, Volpp KG. The uncertain effect of financial incentives to improve health behaviors. *Jama*. 2019;321(15):1451-1452.