

#20174025 - Mi Propio Camino: Personalized approaches to improve blood pressure control

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Expedited	Approved	Feb 03, 2023	--
Expiration Date	Initial Approval Date	Initial Review Type	
Jun 07, 2025	Apr 16, 2021	Expedited	

Feedback

Approval Comment

The IRB Approval Letter and any approved documentation (e.g. stamped consent forms) can be downloaded in the Attachments section of the protocol.

Protocol Amendment Form

Amendment Instructions

Specify the type of submission:

TRANSLATION: This is a translation that does not require changes to the IRB approved protocol (non-English speakers already approved)

Translations

Select the level of risk for your approved protocol:

Exempt/Expedited (minimal risk)

Exempt/Expedited (minimal risk) studies: The IRB will accept documents translated by an **individual fluent** (credentials, certifications, education, native language fluency, etc.) in a given language.

Is there a translation certification or a letter from the translator available as a separate attachment?

Yes

End of translation form!

Project Details

Specify the study title (**this title should not exceed more than 100 words**):

Mi Propio Camino: Personalized approaches to improve blood pressure control

Lead Researcher/Investigator:

John T Billimek

Enter the Lead Unit:

IR-7115 - HEALTH POLICY RESEARCH (Lead Unit)

Project Screener

Submit a Human Subject Protocol for UCI Institutional Review Board (IRB) Review

Will this protocol be reviewed under a sIRB process?

No, there is no reliance involved. UCI serves as the IRB of record

Are the research procedures limited to the use/analysis of identifiable private information and/or identifiable biospecimens (no subject contact)?

No

Select the required [level of review](#) for this protocol:

Minimal Risk (Expedited)

Check all sites where UCI investigator(s) will conduct research activities (e.g., recruitment, informed consent, and research procedures including accessing identifiable, private information about participants):

UCI Facilities or Sites (e.g. school, hospital or clinics, etc.)

Provide a non-technical summary of the project that can be understood by IRB/hSCRO members with varied research backgrounds, including non-scientists and community members (**this summary should not exceed more than 250 words**):

28% of patients who are prescribed medications to control their high blood pressure never fill the first prescription, and another 28% discontinue the medication within the first year. Many of these patients are reluctant to start the new medication because they feel the drugs are not likely to work for them, or may cause harm to them in the future. Yet very few patients discuss the concerns they have about their medications with the doctor, or even report that they have stopped taking the medication. The proposed pilot study will examine the feasibility of a mobile health software application called MediCom to improve patient-provider communication regarding concerns about medications, and to help address patients' hypothetical concerns about a treatment that is new to them. The MediCom application will allow patients, with clinical supervision, to use mobile devices to record their medication taking behavior, blood pressure and symptoms of common side effects each day for a trial period. At the end of the period, this monitoring data will be downloaded and compiled into an intuitive report that the patient and a pharmacist can review during a follow-up visit to guide a personalized discussion of the benefits and disadvantages of continuing the medication. First, in a series of pilot studies (Study 1, 2 and 3), we will examine whether patients find the application and symptom monitoring protocol feasible and acceptable, and to gather preliminary data on patients' medication-related beliefs, medication adherence, and blood pressure control to guide the design of a definitive effectiveness trial for the intervention. Then, we will conduct the definitive effectiveness trial (Study 4) to determine the effect of Mi Propio Camino (MPC), a 4-session group education intervention employing the MediCom mHealth software to improve blood pressure medication adherence by addressing negative beliefs about medications. MPC will be compared to a traditional 4-session blood pressure group education class. The primary endpoint of medication adherence will be assessed at 6-month follow-up.

IRB Protocol Instructions

- For research with a Master Protocol or with a detailed project proposal, specify this in the protocol and an abbreviated protocol will be generated.
- Submit all new and/or revised supporting documents in the Protocol Attachments section near the end of the protocol.
- The Lead Researcher (LR) is responsible for maintaining all supplemental documentation (as indicated in the form) in the research records. This documentation may be requested by Human Research Protections for quality assurance review.

For regulatory or institutional guidance:

- Visit [Human Research Protections](#)
- Contact the [Human Research Protections staff](#)

For technical issues or questions:

- Visit the [Kuali Research Protocols \(KRP\) User Guide](#)
- Contact [Electronic Research Administration \(ERA\)](#)

Type of Research

The purpose, specific aims or objectives of the research is:

Biomedical

The research protocol is:

Investigator-Initiated

Does the investigator-initiated study have any industry support?

No

Does this study include a Master Protocol or detailed project proposal?

No

Is this study an extension of a UCI IRB approved study (e.g., resubmission of ongoing exempt research; Open Label Extension) or is it otherwise related to a UCI IRB approved study?

No

Does this research meet the definition of a [clinical trial](#) that requires adherence to [Clinicaltrials.gov](#)?

Yes

If currently available, provide the [CT.gov](#) registration NCT # (Enter 8-digit sequence of numbers only):

04585594

Specify the rationale for [Clinicaltrials.gov](#) registration:

NIH-funded Clinical Trial

STOP! All clinical trials must be conducted under the auspices of an Organized Lead Unit (OLU). Please update. Go to Project Details and choose the appropriate OLU for the trial.

Level of Review

[Minimal Risk](#) - No more than minimal risk to subjects

Select the applicable category(ies):

- 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves
- 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
- 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Expedited Category 5¹ materials that:

have previously been collected for nonresearch purposes

Study Funding

Select the funding source(s) (**check all that apply**):

Department or campus funds (includes department support, unrestricted funds, start-up funds, personal funds, campus program awards, etc.)

Grant/Contract

Undergraduate Research Opportunities Program (UROP)

Select the sponsor type(s) (**check all that apply**):

Health and Human Services (HHS) (includes National Institutes of Health (NIH))

List below all extramural proposals or awards that will support the study (if applicable):

IMPORTANT! Skip this table if extramural funding is not available.

Sponsor Name

NIH/NHLBI

Title of Proposal/Award (if different from study title):

Mi Propio Camino (My Own Way): Addressing negative beliefs about medication to improve adherence among Hispanic adults with hypertension

Proposal or Award #:

R01 HL142964

Sponsor Name

NIH/NHLBI

Title of Proposal/Award (if different from study title):

Mi Propio Camino (My Own Way): Addressing negative beliefs about medication to improve adherence among Hispanic adults with hypertension

Proposal or Award #:

R56 HL142964

Scientific/Scholarly Review

Is the research Sponsor-Initiated?

No

Is the research cancer-related?

No

The proposed research qualifies as minimal risk research. The Department Chair, Division Chief, or Institute Director provides assurance that the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known.

Check here to confirm the above assurance

Potentially Hazardous Materials

If any of the following hazardous materials are involved in this research please check below:

N/A

--

Other UCI Committee Reviews

Check all ancillary committees that apply:

N/A

Study Team

Study Team:

- **List only study team members who are engaged in human subjects research below.**
 - Administrative Contact (AC): Do not add ACs to the study team table. To add ACs, navigate to the Permissions tab on top-right-hand-side of form. All ACs must complete the requisite [Human Research Protections CITI Training](#).
- Lead Researcher (LR): LRs must meet requirements specified on the [Lead Researcher Eligibility page](#) for study to be approved.
 - Select 'Oversight of Research' along with other applicable duties.
 - Select 'Full Access'.
- Faculty Sponsor (FS): FSs are required when the person serving the LR role is not qualified to serve as LR-- the FS must be eligible to be LR.
 - Select 'Oversight of Research' along with other applicable duties.
 - Select 'Full Access'.
- Co-Researcher (CR): CRs are faculty, staff, students and other academic appointees who the LR considers to be key personnel for conducting the research study. These individuals work closely with the LR to design, conduct, and/or report on the research.
- Research Personnel (RP): List RP as required per the [Research Personnel Heat Map](#). For those RP who do not need to be listed on the protocol, they may be tracked by alternative methods, see below.
- **IMPORTANT!** Do NOT list non-UCI researchers below, in the Permissions tab at top or on the [Study Team Tracking Log](#) (or equivalent); instead, follow the [Single IRB Reliance \(sIRB\)](#) process.
- [Collaborative Institutional Training Initiative \(CITI\) Human Research Protections Training Courses](#)
 - Confirm CITI training is complete and current for all study team members.
 - Incomplete or expired CITI training will delay IRB approval.
 - For more information, visit HRP [Training and Education](#).

Researcher

John T Billimek

Training

GCP - Social and Behavioral Research Best Practices for Clinical Research - Basic Course
06/26/20 - 06/26/23

! Expired

Biomedical Investigators - Basic Course
03/21/16 - 03/20/21

! Expired

Social/Behavioral Investigators - Basic Course
05/16/17 - 05/15/22

! Expired

Biomedical Investigators - Refresher Course
12/03/21 - 12/02/26

To promote the objectivity of the research, all researchers are required to disclose their **related disclosable financial interests**, per the [IRB COI Policy](#). If you have any questions about the COI process in general, contact the [COI](#) team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

PhD

Position/Title

Assistant Professor

Department

IR-6096 - FAMILY MEDICINE (Lead Unit)

Affiliation

UCI Faculty

Researcher Role

Lead Researcher

Permissions

Full Access

Duties

Oversight of Research

Research Procedures

Screen/Recruit Subjects

Finalize Informed Consent

Access/Analyze Identifiable Information

Describe additional research procedures below:

He will oversee all aspects of the proposed study including study design, supervision of the research procedures, study personnel, analysis and interpretation of study results. He will lead team meetings, monitor study progress, train personnel in research procedures, and work with project staff to ensure regulatory compliance with IRB procedures, safety monitoring and adverse event reporting to all required parties.

Specify relevant training and experience for the referenced duties/responsibilities:

He will have primary responsibility for overseeing the data collection at the study clinics, including serving as the liaison for all field operations, and training and supervising the research staff. Proficient in Spanish, Dr. Billimek also will oversee the development and translation of the intervention and control materials by native speakers. As the lead statistical expert for the Health Policy Research Institute, he will have access to study identifiable data, and will oversee data analysis, and manuscript preparation in conjunction with other the study investigators.

Researcher

David Bruce Kilgore

Training

GCP - Social and Behavioral Research Best Practices for Clinical Research - Basic Course
09/18/20 - 09/18/23

GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA focus) - Basic Course
08/11/17 - 08/11/20

! Expired

Social/Behavioral Investigators - Refresher Course
01/25/22 - 01/24/27

Social/Behavioral Investigators - Basic Course
06/03/16 - 06/02/21

! Expired

To promote the objectivity of the research, all researchers are required to disclose their **related disclosable financial interests**, per the [IRB COI Policy](#). If you have any questions about the COI process in general, contact the [COI](#) team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

MD

Position/Title

Clinical Professor

Department

IR-7453 - MEDICINE

Affiliation

UCI Faculty

Researcher Role

Co-Researcher

Permissions

Full Access

Duties

Oversight of Research

Research Procedures

Screen/Recruit Subjects

Finalize Informed Consent

Access/Analyze Identifiable Information

Describe additional research procedures below:

Dr. Kilgore is a Family Medicine Physician with extensive expertise in community engaged research and developing culturally congruent health promotion interventions in diverse low-income communities including Latino communities in Southern California.

Specify relevant training and experience for the referenced duties/responsibilities:

Proficient in Spanish, Dr. Kilgore will provide clinical oversight to the study, will participate in the intervention development activities, screening/recruiting of participants, and will participate in data analysis and preparation of manuscripts. As needed, he may also finalize informed consent for some participants. Finally, as an experienced provider in group patient education activities, Dr. Kilgore will lead, alongside a Group Facilitator, group education activities in the study intervention, and will train and supervise the Group Facilitators that will co-lead these education sessions.

Researcher

Sergio Gago Masague

Training

GCP - Social and Behavioral Research Best Practices for Clinical Research - Basic Course
01/24/22 - 01/23/25

Social/Behavioral Investigators - Refresher Course
05/30/18 - 05/29/23

! Expired

To promote the objectivity of the research, all researchers are required to disclose their **related disclosable financial interests**, per the [IRB COI Policy](#). If you have any questions about the COI process in general, contact the [COI](#) team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

Other

Degree Other

please update

Position/Title

assistant professor

Department

IR-8061 - COMPUTER SCIENCE

Affiliation

UCI Faculty

Researcher Role

Co-Researcher

Permissions

Full Access

Duties

Oversight of Research

Research Procedures

Access/Analyze Identifiable Information

Describe additional research procedures below:

Dr. Gago Masague is a project scientist and expert in human-computer interaction who will contribute to all aims of the project. He led the development of the MediCom web application and mHealth smartphone app that will be used in the study, and will lead the effort to adapt and maintain the applications for the proposed study intervention.

Specify relevant training and experience for the referenced duties/responsibilities:

Dr. Gago Masague will work with students and project personnel on analyzing and improving the software applications and implementing the feedback collected from patients and health care providers. With the other investigators, Dr. Gago Masague will assist in analyzing the results of the study and he will contribute to article and conference presentations.

Are RP tracked outside the approved protocol, in accordance with the [RP Heat Map](#)?

Yes, RP are tracked on a Study Team Log or other comparable log

Supplemental Documents

Does this study include supplemental documents?

No

Background & Purpose of the Research

Describe the purpose, specific aims or objectives and specify the hypotheses or research questions to be studied:

Study 1 has two specific aims: ● Aim 1: assess the feasibility and acceptability of the MediCom software application and medication experience monitoring protocol for Latino patients with high blood pressure. ● Aim 2: Collect pilot data on beliefs about medications, medication adherence and blood pressure control to guide the design of a definitive effectiveness trial. Questionnaire study entitled Study 2 (potential participants: 300) Study 2 aims to investigate perceptions patients may have about controlling blood pressure, concerns patients may have about taking medications, and experiences discussing concerns about medications with health providers. Study 3 aims to examine the feasibility and acceptability of a brief, multi-session educational intervention employing mHealth and small group discussions to address concerns patients might have about strategies to improve blood pressure control. Study 4 aims to evaluate the effectiveness of a culturally appropriate intervention in a randomized controlled trial comparing two sets of group education sessions that differ in the focus on addressing negative beliefs about medications and through employing mHealth.

Provide the scientific or scholarly rationale for the research and describe the relevant background information and the specific gaps in current knowledge that this study intends to address:

Background Information More than 50% of patients with chronic health conditions exhibit medication nonadherence.¹ That is, they do not take their medications as prescribed. Many low-income patients, and patients from ethnic minority populations have unfavorable beliefs about medications (e.g., believing they do not need them, that alternative therapies are superior, or that the medication will cause side effects).² Patients who have more negative beliefs about medications—both in terms of specific experiences with the medication, and general, hypothetical concerns, are less likely to adhere to their medication therapy.³ As a result, many patients are reluctant to start a new medication, or are curious to know how their body would react if they discontinue it¹, but few patients discuss these kinds of beliefs with their providers.⁴ Mobile symptom monitoring has been employed as a patient-centered approach to guide a productive patient-provider discussion about a specific individual's response to a medication—in terms of treatment response, side effects and treatment burden.⁵ Rather than discussing “average effects” of a medication in the population, this approach allows a provider and patient to have an informed discussion of the specific effect of the medication on that individual patient. **Gaps in knowledge** Although the connection between beliefs and medication adherence is well established, the utility of mobile symptom monitoring to help guide patient-provider discussion about medications to promote more positive beliefs is not well-studied. We posit that, for patients who have concerns about hypothetical consequences of taking a specific medication, having a concrete discussion about the patient's actual response to a drug may result in more positive beliefs about the medication, and consequently, better adherence. Or if the experience is unfavorable, it may encourage the patient and physician to try different options until a satisfactory drug is selected.

Provide relevant preliminary data (animal and/or human):

Unpublished data from a recently completed pilot study conducted by the Lead Researcher at UC Irvine Health suggest that the majority of Latino patients taking medication for diabetes rate hypothetical concerns such as worry about future adverse as their largest concern, whereas relatively few patients report concerns about adverse effects that they have actually experienced. Focus groups conducted by the Lead Researcher with patient advisory group of Latino patients with chronic health conditions at the study clinic indicate that patients would be interested to try mobile symptom monitoring to improve communication with the provider about concerns about medication. The MediCom application We have developed a web-based application called MediCom that can aggregate data from multiple mobile health monitoring devices, and a protocol for patients to self-monitor their experience with a specific medication. The MediCom web-based application and the accompanying SymTrack mobile symptom monitoring application are described in Appendix K. In short, the MediCom software is used to integrate data collected by patients about their own health and behaviors from multiple sources. For this study, we will invite patients to collect data about their experiences trying to lower their blood pressure using (1) a mobile diary application (SymTrack) that we developed, (2) a portable blood pressure cuff, (3) a wearable activity and sleep tracker and (4) a pill bottle cap monitor to track medication-taking. Each of these devices are described in Appendix K. Users can then display visualizations of day-to-day changes (as a line graph) and summary displays (as a bar graph showing averages across multiple days) of the patient's experiences with medication-taking, blood pressure, symptoms, physical activity, and sleep quality. More importantly, relationships between the observed variables can be presented in an intuitive display to show, for example, trends in blood pressure control over time, or comparisons of the patient's monitoring data on days they took their medication versus days they did not take it. The software allows providers and patients to access and visualize the data on their own, or for a designated user approved by the provider and patient to facilitate access to the data visualizations. The feasibility of this protocol and the application have not yet been evaluated. To guide development of an intervention employing the application, we aim to conduct a pilot study to assess the feasibility of the approach, and gather preliminary data to guide the design of a subsequent effectiveness trial.

Preliminary Data from Studies 1, 2 and 3: Study 1 protocol adherence data: We approached 18 Spanish-speaking community health center patients we

approached to pilot test the mHealth protocol, of whom 10 (56%) consented to complete two group discussions with a 7 to 14 day home monitoring period in-between. During these home monitoring periods, the protocol adherence was excellent with 92/102 (90%) of the scheduled home BP readings recorded, and 96/102 (94%) of the scheduled diary entries completed. Nine of ten (90%) of participants completed at least one phone contact between the two group discussions. Almost all participants of the pilot test were very interested to continue home monitoring after the dry run was over, and asked to be included in the RCT. Study 2 baseline questionnaire data: We recently deployed the baseline questionnaire in English and Spanish to be collected on tablets and have begun to collect questionnaires from participants. Of the 31 patients we have approached in the clinic, 27 (87%) met all eligibility criteria of whom 26 (96%) consented and completed the questionnaire. 50% have BMQ scores above the threshold for “very negative beliefs”, and 46% reported intentional nonadherence related to beliefs, similar to the rates we observed in a prior study of beliefs and adherence in Hispanic patients with diabetes.⁶ We have asked the last 20 participating patients if they would be interested to be contacted about the upcoming RCT, and all 20 (100%) said yes. Study 3 focus group findings: We have convened four focus group sessions with Spanish-speaking community members and patients affected by hypertension. In all four groups, participants expressed enthusiasm about the project, citing the importance of empowering individuals with home monitoring tools and skills to communicate and build mutual trust with the doctor. They made numerous valuable suggestions about the project, including that successful recruitment depends more on the personal relevance of the study to participants (including the control group) rather than a monetary incentive on its own, that the amounts of the monetary incentives for participants are appropriate, that providing a BP monitor for participants at the end of the study would enhance engagement, and while there was lots of interest in using a smartphone app, they recommended also having a paper version of the diary available. We have implemented all of these suggestions into the study plan.

Describe the primary outcome variable(s), secondary outcome variables, and predictors and/or comparison groups as appropriate for the stated study objectives/specific aims:

Study Measures Primary Outcome: Medication-related beliefs. Beliefs will be assessed with the Beliefs about Medications Questionnaire (BMQ).¹⁰ The BMQ has been translated into Spanish, validated in Spanish-speaking adults with chronic health conditions, and been successfully used in other studies.

Secondary Outcomes: Medication adherence. The main outcome variable is medication nonadherence, which will be assessed in two ways. First, daily adherence (percent of doses taken) will be assessed with the MEMS bottle cap monitors during the 4 week outcome assessment period and with a validated 11-item self-report adherence measure that is used in current practice.⁷

Blood pressure control: Systolic and diastolic blood pressure will be measured during the study visit using an automatic sphygmomanometer (blood pressure cuff).

Feasibility/Acceptability: Feasibility will be assessed by counting the proportion of days that the patient completed entries in the mobile symptom diary application (Symtrack, see Appendix K). Time to complete each study visit will also be recorded. Acceptability will be assessed with a short post-session survey asking patients for ratings of ease-of-use and usefulness of the monitoring devices. The research team and a subset of patients will be interviewed about their experience with the application for insights on its strengths and weaknesses. (Nov 2018)

This IRB e-modification is to add an additional set of study measures as part of "Study 2" in this on-going investigation. Study 2 will consist of the recruitment of up to 300 adults with uncontrolled hypertension to complete a questionnaire. This procedure of administering the questionnaire will be done at the clinic by a member of the study team. These participants will also have their most recent blood pressure measurements extracted from the electronic health record. The measurements that are extracted will include blood pressure measurements and other relevant cardiometabolic indicators (HbA1C lipids and Body Mass Index), sociodemographic information (age, gender, ethnicity, race, language preference, health insurance type) and healthcare utilization (number of outpatient and inpatient visits, prescription medications, and performance of recommended health management processes). Study 2 will not include the use of the approved mHealth devices from Study 1. Study 2 measures will be:

Primary Outcome: Medication-related beliefs. Beliefs will be assessed with the Beliefs about Medications Questionnaire (BMQ).¹⁰ The BMQ has been translated into Spanish, validated in Spanish-speaking adults with chronic health conditions, and been successfully used in other studies. (Same as Study

1) Secondary Outcomes: Medication adherence. The main outcome variable is medication nonadherence, which will be assessed with a validated 11-item self-report adherence measure that is used in current practice.⁷ (Same questionnaire measure as Study 1, however the MEMS pill bottle cap monitors will not be used in Study 2). Blood pressure control: Unlike Study 1, blood pressure control will be assessed by extracting, from the electronic health record, all blood pressure measurements collected in the 12 month up to and including the date of the study visit. Other cardiometabolic indicators (HbA1C lipids and Body Mass Index) will be extracted from the medical record, sociodemographic information (age, gender, ethnicity, race, language preference, health insurance type), and healthcare utilization (number of outpatient and inpatient visits, prescription medications, and performance of recommended health management processes). Study 3 measures will be: Primary Outcome: Medication-related beliefs. Beliefs will be assessed with the Beliefs about Medications Questionnaire (BMQ).¹⁰ Same as Study 2. Secondary Outcomes: Medication adherence. The main outcome variable is medication nonadherence, which will be assessed with a validated 11-item self-report adherence measure that is used in current practice.⁷ Same as Study 2. Feasibility/Acceptability: Feasibility will be assessed by counting the proportion of study visits attended, proportion of days that the patient completed entries in the mobile symptom diary application (Symtrack, see Appendix K). Time to complete each study visit will also be recorded. Acceptability will be assessed with a short post-session survey asking patients for ratings of ease-of-use and usefulness of the monitoring devices. The research team and a subset of patients will be interviewed about their experience with the application for insights on its strengths and weaknesses. (May 2019) This IRB e-modification is to add an additional set of study measures as part of "Study 4" in this on-going investigation. Study 4 measures will be: Primary Endpoint: Daily Adherence (objective) will be assessed with the Medication Event Monitoring System (MEMS) pill bottle cap monitors, an objective "standard" measure for pill-taking behavior. Daily adherence is defined as the proportion of days that the prescribed number of doses was taken by patient during a 30-day period. Same as Study 1. Secondary Outcomes: Medication-related beliefs. Beliefs will be assessed with the Beliefs about Medications Questionnaire (BMQ).¹⁰ Same as Study 3. Daily Adherence (subjective): Will be assessed with a validated measure, the Morisky Medication Adherence Scale (8-item MMAS). Medication-related knowledge: Will be assessed with two measures, adapted from validated measured the

Medication Knowledge Questionnaire (MKQ) to assess patients level of information about their medications and the PROMIS Self-Efficacy for Managing Chronic Conditions Manage Medications/Treatment scale to assess behavioral skills. Blood pressure control: Systolic and diastolic blood pressure will be measured during the study visit using an automatic sphygmomanometer (blood pressure cuff). Same as Study 1. Self-Efficacy: Self-Efficacy will be assessed through the Medication Adherence Strategies Inventory (ASI), measuring activation of behavioral strategies for adherence.

List up to ten relevant references/articles to support the rationale for the research:

1. Kettani, F.-Z. et al. Impact of a better adherence to antihypertensive agents on cerebrovascular disease for primary prevention. *Stroke* 40, 213–220 (2009).
2. Bailey, J. E., Wan, J. Y., Tang, J., Ghani, M. A. & Cushman, W. C. Antihypertensive Medication Adherence, Ambulatory Visits, and Risk of Stroke and Death. *J GEN INTERN MED* 25, 495–503 (2010).
3. Billimek, J. & Sorkin, D. H. Food insecurity, processes of care, and self-reported medication underuse in patients with type 2 diabetes: results from the California Health Interview Survey. *Health Serv Res* 47, 2159–2168 (2012).
4. Ngo-Metzger, Q., Sorkin, D. H., Billimek, J., Greenfield, S. & Kaplan, S. H. The Effects of Financial Pressures on Adherence and Glucose Control among Racial/Ethnically Diverse Patients with Diabetes. *J Gen Int Med* 27(4), 432–7 (2012).
5. Fischer, M. A. et al. Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions. *J GEN INTERN MED* 25, 284–290 (2010).
6. Steiner, J. F. et al. Sociodemographic and Clinical Characteristics Are Not Clinically Useful Predictors of Refill Adherence in Patients With Hypertension. *Circ Cardiovasc Qual Outcomes* 2, 451–457 (2009).
7. Billimek, J. & August, K. J. Costs and Beliefs: Understanding Individual- and Neighborhood-Level Correlates of Medication Nonadherence Among Mexican Americans With Type 2 Diabetes. *Health Psychol* 33, 1602–5 (2014).
8. Design and Implementation of N-of-1 Trials: A User's Guide. (Agency for Healthcare Research and Quality (US), 2014). at <<http://www.effectivehealthcare.ahrq.gov/N-1-Trials.cfm>>
9. Morisky, D. E., Ang, A., Krousel-Wood, M. & Ward, H. J. Predictive Validity of a Medication Adherence Measure in an Outpatient Setting. *The Journal of Clinical Hypertension* 10, 348–354 (2008).
10. Jimenez, K, Vargas C, Garcia K, Guzman H, Angulo M, and Billimek J. "Evaluating the Validity and Reliability of the Beliefs About Medicines Questionnaire in Low-Income, Spanish-Speaking Patients With Diabetes in the United States." *The Diabetes Educator* 43, no. 1 (February 2017): 114–24.

Subject Population(s) (Individuals/Records/Biospecimens)

Check all subject populations/data sources that apply to the research:

Adults Competent to Provide Informed Consent

Subjects who are unable to communicate in English

UCI Inpatients or Outpatients (Receiving Diagnosis/Treatment/Surgery)

Maximum and Expected Number of Persons/Records/Biospecimens to be Enrolled

1. Click "Add Line" button above Enrollment Table to add a Category/Group
 - a. To change visibility of columns, click "Columns" button above Enrollment Table and select which Column rows to view.
2. Specify the maximum and expected numbers of individual-level information and/or biospecimens to be accessed/analyzed within each Category/Group

Category/Group

Study 1. Adult Spanish or English-speaking primary care patients

Age Range

Over 18 years old

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected

128

Number Expected to Complete the Study or Needed to Address the Research Question

72

Category/Group

Study 2. Adult Spanish or English-speaking primary care patients

Age Range

Over 18 years old

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected

700

Number Expected to Complete the Study or Needed to Address the Research Question

500

Category/Group

Study 3. Adult Spanish or English speaking primary care patients

Age Range

Over 18 years old

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected

60

Number Expected to Complete the Study or Needed to Address the Research Question

36

Category/Group

Study 4. Adult Spanish or English speaking primary care patients who participated in study 2 (questionnaire study)

Age Range

Over 18 years old

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected

500

Number Expected to Complete the Study or Needed to Address the Research Question

400

Will this study only take place at UCI and does not involve other sites?

Yes

Eligibility Factors (Inclusion/Exclusion Criteria)

1. Click "Add Line" button above Eligibility Factors Table to add a inclusion/exclusion criteria
 - a. To change visibility of columns, click "Columns" button above Eligibility Factors Chart and select which Column rows to view.
 2. Identify the factors for limited eligibility and provide a scientific rationale. Include additional rows for factors, as needed.
-

Category/Group Eligibility

Adult Spanish or English-speaking primary care patients

Inclusion Criteria

Hispanic adults (age 18+), speaking English or Spanish, with blood pressure > 140/90 mmHg and currently receiving care at the UC Irvine Health Ambulatory Clinics.

Exclusion Criteria

Diagnosis of with stage 4 or 5 chronic kidney disease (CKD)

Is eligibility based on age, gender, pregnancy/childbearing potential, social/ethnic group, or language spoken (e.g., English Speakers only)?

Yes

Limited Eligibility Factors (Special Populations)

1. Click "Add Line" button above Limited Eligibility Factors Table to add a special population
 - a. To change visibility of columns, click "Columns" button above Limited Eligibility Factors Table and select which Column rows to view.
2. Identify the special populations and provide a scientific rationale. Add additional rows, as needed.

Eligibility Limited to the Following Factors

Age

Specify the rationale for this group:

Over 18 years old

Pre-Screening and Determining Eligibility without Informed Consent

Will Identifiable information be obtained for the purpose of screening, recruiting, or determining eligibility of prospective subjects?

No

Recruitment Methods

Will this study involve **NO** direct contact with participants (i.e., passive observation of public behavior)?

No

Indicate all methods that will be used to recruit subjects for this study:

Recruitment Method

Clinicaltrials.gov

Confirm that the ClinicalTrials.gov statement is in all applicable consent documents

Recruitment Method

Study team will contact potential subjects who have given prior permission to be contacted for research studies

Specify how these individuals granted permission and enter HS#:

Permission was granted by indicating their preference to be contacted for future studies in the Study 2 consent form under this protocol, IRB #20174025

Recruitment Method

Other recruitment methods

Specify 'Other' recruitment methods:

Study team members will approach their own patients, students, employees for participation in the study.

Informed Consent Process

Does this study involve the creation, use, or disclosure of **Protected Health Information (PHI)**?

Yes

Methods of [Health Insurance Portability and Accountability Act \(HIPAA\)](#) Authorization

Identify the HIPAA authorization process (**Check all that apply**):

Partial waiver of HIPAA authorization for screening/recruitment purposes only.
Signed authorization obtained prior to further access to PHI

Methods of [Informed Consent](#)

Identify the consent or assent process as applicable for each participant population (**check all that apply**):

Paper-based signed informed consent/assent

Paper-based Signed Informed Consent

Indicate the paper-based signed informed consent/assent (**check all that apply**):

Signed Informed Consent

Does this recruitment method include all subjects?

Yes

REQUIRED! Submit the Adult Consent Form, Child [Assent Form](#) and/or Parental Permission Form in the Attachments Section.

Circumstances of Consent

Indicate the location where the consent process will take place (**check all that apply**):

Group setting

Other

Private room

Waiting room

Specify 'Other' location:

In a group setting (for study 4, Informed Consent will be finalized at the first intervention group session)

Specify how the research team will assure that subjects, their parents, or their legally authorized representative (LAR) have sufficient time to consider whether to participate in the research:
Subjects or their LAR will be allowed to take home the unsigned consent form for review prior to signing it

What type of consent process will be used for **Non-English Speaking Participants**?

The English version of the consent materials will be translated for non-English speaking participants or their LAR once IRB approval is granted. An interpreter will be involved in the consenting process

Indicate how non-English speaking subjects or their LAR will be consented in their language and who will be responsible for interpreting and facilitating the informed consent discussion for the non-English speaking subjects:

At least one member of the study team is fluent in the language that will be used for communication, and that study team member(s) will be available during emergencies.

Waiver of HIPAA Authorization

You requested a Partial Waiver of HIPAA Authorization

When a partial waiver is requested, the Lead Researcher is requesting the HIPAA research authorization be waived for a portion of the study, such as a waiver for subject identification or recruitment purposes.

Please specify for what purpose the partial waiver is requested:

A partial waiver is needed for the subject identification process to determine patient eligibility for the study.

Justification for a Waiver of HIPAA Authorization

Does the use or disclosure of personal health information involve more than minimal risk?

No

Would the granting of the waiver adversely affect privacy rights and welfare of the individuals whose records will be used or disclosed?

No

Explain (justify) the answer:

Records will only be used to determine subject eligibility for the study and will be kept in a secure location.

Could the research practicably be conducted without a waiver of HIPAA authorization?

No

Explain the answer:

It would not be practical to identify eligible subjects without access to medical records data.

Could the research practicably be conducted without access to, use or disclosure of the personal identifiers listed in the PHI question?

No

Explain the answer:

The research could not practicably be completed without access. A proper screening is required to ensure only eligible patients can enroll in the study.

Are the privacy risks reasonable relative to the anticipated benefits of the research?

Yes

Describe the risk/benefit analysis performed to explain the answer above:

There are minimal privacy risks involved in the research. The benefits of PHI use for subject recruitment include the ability to practicably conduct the research with potential societal benefits. All study identifiable information will be stored electronically in REDCap and all hard copy versions of the study data will be kept in a secure and location in the office of the lead researcher. PHI used for recruitment purposes will be destroyed as soon as the study team has verified the eligibility status of the individual whose PHI will be used.

Describe the plan to protect the personal identifiers from improper use and disclosure (i.e., describe data security methods):

To minimize the risk, PHI will be screened and used to generate a list of individuals eligible for recruitment to the study, with contact information. Aggregate data on the number of cases screened, and the number screened positive with basic aggregated descriptors (such as mean age, gender mix) etc. will be stored for purposes of documenting methodological rigor. The list of eligible individuals will be stored on a secured, password protected server behind the UC Irvine Health firewall, and will not include any health related information. As soon as recruitment status is determined, all individual-level health information will be deleted, leaving only a list of potential subjects with contact information, therefore leaving no PHI being stored.

Describe the plan to destroy the personal identifiers at the earliest opportunity, or provide a health or research justification for retaining the identifiers:

As soon as recruitment status is determined for the list of individuals whose PHI is used, all individual-level health information will be deleted, leaving only a list of potential subjects with contact information, therefore leaving no PHI being stored. Members of this list of eligible individuals will be assigned a study identifier. Once an individual on the list has been contacted, and declined to participate in the study, all personal identifiers will be immediately deleted. For those that consent to the study, their contact information will be stored until he or she completes the study procedures or withdraws from the study, at which point the personal identifiers will be deleted.

Describe how potential subjects will be identified:

Potential participants are identified from the UCI Health Electronic Health Record using an automated query conducted by UC Irvine Health Enterprise Data and Analytics, selecting patients meetings the following criteria: -
INCLUDE if: ---Age 18-75 years ---Has a scheduled physician appointment in a UC Irvine Health Ambulatory Clinic in next 30 days ---Diagnosis of Hypertensive disease (ICD10 I10 OR ICD9 401) ---Most recent Systolic BP > or = 140 OR Most recent Diastolic BP > or = 90 ---Hispanic OR Non-Hispanic Ethnicity -
EXCLUDE if ---any Laboratory Result Glomerular Filtration Rate (GFR) <30 (But do not exclude if there is no GFR value) ---OR Stage 4 or 5 Chronic Kidney Disease (ICD10: N18.4 OR N18.5) ---OR End stage Renal disease (ICD10: N18.6) This query is run once per week, and the list of patients it generates is sent to the study team via the UCI Health Share Drive. The list includes only the following data elements, which are necessary to contact the patients to recruit them for the study: -Medical Record Number -Last Name and First Name - Ethnicity -Gender -Preferred language -Phone number -Date and time of upcoming UCI Health ambulatory clinic appointment -Appointment location - Appointment provider's name

Research Procedures

Check all boxes that apply to the research:

Analysis of Existing Identifiable or Coded Data, Specimens, Records, Charts, and Datasets

Surveys/Questionnaires/Interviews/Oral Histories

Will **deception or incomplete disclosure** be involved in the research?

No

Study Design

Include an explanation of the study design (e.g., randomized placebo-controlled, cross-over, cross-sectional, longitudinal, etc.) and, if appropriate, describe stratification/randomization/blinding scheme:

Study 1 Design: Longitudinal observational pilot study consisting of a 4 week observation period. Results from this pilot study will guide design of an intervention trial to determine the effect of the intervention on medication-related beliefs, medication adherence and blood pressure control. Study 2

Design: Cross sectional observational study examining topics including concerns patients have about taking medications, perceptions about controlling blood pressure, and experiences discussing concerns about medications with health providers. (May 2019) This IRB e-modification is to add an additional set of study procedures, "Study 4", in this on-going investigation.

Study 4 Design: Randomized controlled trial evaluating a culturally appropriate intervention to improve adherence to antihypertensive medications. To ensure balance on the "Beliefs about medications questionnaire (BMQ)" measure, randomization will be stratified by high versus low BMQ subgroup.

Provide precise definitions of the study endpoints and criteria for evaluation; if the primary outcomes are derived from several measurements (i.e., composite variables) or if endpoints are based composite variables, then describe precisely how the composite variables are derived:

Feasibility assessment: Study 1, 3 and 4 Protocol adherence will be assessed by counting the proportion of patients who successfully complete each stage of the protocol. Study 1, 3 and 4 Acceptability will be assessed with a short post-intervention satisfaction survey. Other outcomes for pilot study Study 1 and 4 Daily adherence (objective measure) will be assessed with Medication Event Monitoring System (MEMS) pill bottle cap monitors (MWV/WestRock), an objective, “gold-standard” measure for pill-taking behavior. MEMS caps can be affixed to a medicine bottle in place of the original cap to record each time the bottle is opened, indicating when the patient took the medication. Daily adherence is defined as the proportion of days that the prescribed number of doses was taken by the patient during a 30-day period. Study 1, 2 and 4. Daily adherence (self-report) will be assessed with a validated Spanish translation of the Morisky Medication Adherence Scale (8-item MMAS), coded dichotomously (low vs. high adherence) using published cutoffs. Study 1, 2 and 4. Medication-related beliefs will be assessed with the Beliefs about Medicines Questionnaire (BMQ). A Spanish translation of the BMQ has been validated for use by Latino patients in the U.S. Study 1, 3 and 4. Blood pressure will be measured by a trained research assistant using an automated sphygmomanometer. Study 2 and 3. Blood pressure control will be assessed by extracting, from the electronic health record, all blood pressure measurements collected in the 12 month up to and including the date of the study visit. The measurements that are extracted will include blood pressure measurements and other relevant cardiometabolic indicators (HbA1C lipids and Body Mass Index), sociodemographic information (age, gender, ethnicity, race, language preference, health insurance type) and healthcare utilization (number of outpatient and inpatient visits, prescription medications, and performance of recommended health management processes). (January 2023: Adding waist circumference measurement) Study 4. Waist circumference will be measured as a marker of cardiometabolic risk and allostatic load one time using the Multi-Ethnic Study of Atherosclerosis assisted (MESA-assisted) protocol. For the MESA assisted technique, a trained research assistant can complete the measurement or can coach the participant to complete the measurement. Prior to measurement, a study team member will remind the participant that they may opt out of the WC measurement, and will confirm that they consent to the measurement. The

measurement will be done in a private area, over street clothing using a measuring tape with Gulick spring attachment at the level of the umbilicus. Waist circumference measurements will be used for descriptive and exploratory analysis to add to external validity of the study, primarily by characterizing the distribution of waist circumference values within the study sample compared to other study populations. See: https://www.cdc.gov/nchs/data/series/sr_02/sr02_182-508.pdf (May 2019) Data from Studies 1, 2 and 3 have been used to inform the design of Study 4, a definitive effectiveness trial (RCT) evaluating the effect of the Mi Propio Camino intervention on daily medication adherence. Primary endpoint and secondary outcomes are listed below: Primary Endpoint: Daily Adherence (objective) will be assessed with the Medication Event Monitoring System (MEMS) pill bottle cap monitors, an objective "standard" measure for pill-taking behavior. Daily adherence is defined as the proportion of days that the prescribed number of doses was taken by patient during a 30-day period. Same as Study 1. Secondary Outcomes: Medication-related beliefs. Beliefs will be assessed with the Beliefs about Medications Questionnaire (BMQ).¹⁰ Same as Study 3. Daily Adherence (subjective): Will be assessed with a validated measure, the Morisky Medication Adherence Scale (8-item MMAS). Medication-related knowledge: Will be assessed with two measures, adapted from validated measures the Medication Knowledge Questionnaire (MKQ) to assess patients level of information about their medications and the PROMIS Self-Efficacy for Managing Chronic Conditions Manage Medications/Treatment scale to assess behavioral skills. Blood pressure control: Systolic and diastolic blood pressure will be measured during the study visit using an automatic sphygmomanometer (blood pressure cuff). Same as Study 1. Self-Efficacy: Self-Efficacy will be assessed through the Medication Adherence Strategies Inventory (ASI), measuring activation of behavioral strategies for adherence.

Statistical Considerations

Is a statistical analysis plan appropriate for this qualitative study design?

Yes

Describe the statistical methods for the stated specific aims and hypotheses. Your analysis plans should match the stated study specific aims and hypotheses:

The Specific Aims and study hypotheses for Study 4 are: Aim 1: To evaluate the efficacy of a theory-based intervention to modify negative medication beliefs and promote medication adherence through direct and vicarious experiences with a medication. --H1: The intervention, based on the tenets of the elaboration likelihood model (ELM) of persuasion, will increase patients' adherence to medication (primary endpoint) --H2: The intervention will reduce patients' negative beliefs about medications (secondary endpoint) --H3: The intervention will be associated with improved blood pressure control (secondary endpoint) --H4: Change in negative medication beliefs will mediate the impact of the intervention on patients' adherence to medication. (mediation analysis) --H5: The intervention effect will be significantly larger in the subgroup of patients with the most negative medication-related beliefs at baseline compared to those with more positive baseline beliefs. (moderation analysis) Aim 2: To test prospectively a theoretical model by which beliefs about medication at baseline predict subsequent use of behavioral strategies to improve adherence. --H6: Independent of intervention condition, beliefs at the conclusion of the intervention predict the use of behavioral strategies to improve adherence at 6-month follow-up. (secondary aim) The statistical plan and sample size calculations were developed in consultation with the Biostatistics, Epidemiology and Research Design (BERD) Unit under the Institute for Clinical and Translational Science (ICTS)

Describe the statistical method(s) that will be used to analyze the primary outcome(s) or endpoints:

H1: The primary endpoint, objective measure of MEDICATION ADHERENCE (% of doses adherent from MEMS cap measurement) at 6-month post intervention will be examined with an independent-sample t test for a mean difference between MPC and comparison groups.

If appropriate describe secondary or post hoc analyses of primary outcome(s) or other exploratory analysis and if necessary, provide a breakdown of the methods used per outcome or endpoint:

H2, 3, 4: Secondary endpoints include self-reported measure of adherence to medication at 30-days and 6-months post intervention, change in belief about medication from baseline to intervention conclusion), and change in systolic BP from baseline to 6-month post intervention. For each of these three hypotheses, independent-sample t tests will be used to test for differences in these study outcomes between intervention and comparison groups. H5: We will test this hypothesis of a moderation effect (wherein baseline medication beliefs act as an effect modifier on the interaction effect) using two-way analysis of variance (ANOVA), entering intervention group and baseline beliefs subgroup as the two factors in the analysis. We will also conduct exploratory analysis of the intervention effect stratified by medication beliefs subgroup using independent samples t-tests. H6: Use of behavioral strategies will be operationalized as use of at least one of the strategies assessed in the measure. Anticipating a threshold effect of beliefs, we will use Fisher's exact test to compare the proportion of participants using at least one strategy between individuals with positive versus negative beliefs, defined by median split. For all between group analyses (H1-6), balance on important sociodemographic, cardiometabolic, and health care utilization factors will be assessed between intervention and comparison group using t-tests and chi squared tests. When imbalance is found, t-test analyses will be corroborated with multiple regression analysis controlling for those imbalanced factors.

Sample Size Determination: Explain how the overall target sample size was determined (e.g., power analysis; precision estimation), providing justification of the effect size for the primary outcome based on preliminary data, current knowledge/literature and/or cost consideration; if appropriate, provide sample size justification for secondary outcomes. Power analysis should (at least) match the primary outcome/endpoint:

The study is powered on the primary endpoint. We aim to accrue an overall sample of $n=400$, evenly divided between the positive beliefs and negative beliefs subgroups due to the stratified randomization. To account for an estimated 20% attrition rate due to loss to follow-up at 6 month post intervention, a total of 500 patients will be randomized into the study intervention and control groups. Assuming a standard deviation for baseline adherence of 0.25, comparable to values observed in an RCT using the same outcome measure¹, a sample size of $n=400$ patients would yield 80% power to detect an intervention effect as small as 0.05 at 5% significance level in the entire sample, and an effect as small as 0.11 in each of the two subgroups (of $n=200$ each).

Research Procedures

Provide a detailed chronological description of the clinical or treatment plan:

Study 1 - Pilot Study Overview Participants will complete two study visits approximately 30 days apart. They will be invited and trained to use inexpensive mobile devices (provided by the study team) to track their own medication taking, health behaviors, symptoms, side effects, and blood pressure changes for a 30-day “medication experience monitoring” period. Data from the mHealth devices will be aggregated and displayed to the patient and study team members for discussion using a web application previously developed by the investigators. Pilot data from the medication experience monitoring period and feasibility data collected at the end of the monitoring period will be analyzed. Medication experience monitoring period Initial visit (approximately 45 minutes) The first study visit will be held in a private room at the clinic. After obtaining informed consent, a member of the study team will administer a baseline questionnaire including the self-reported adherence measure and beliefs about medications questionnaire. A member of the study team will then provide each participant a “kit” consisting of four mHealth devices: • MEMS bottle cap monitors, • a wearable sleep/activity monitor (FitBit Charge HR), • a smartphone with the MediCom symptom diary app installed (or if they have their own compatible smartphone, will be allowed to load the symptom diary app on their own phone and use it for the study), and • a portable blood pressure (BP) monitor. A member of the study team will configure the kits and train the participants to use the devices. The symptom diary app will be configured for each patient to (1) track up to five symptoms of concern, selected by the patient (including symptoms they associate with hypertension and side effects they think may emerge), (2) track up to five lifestyle factors they think may impact their BP (e.g. eating salty foods), also selected by the patient and (3) send reminders to complete the symptom diary and BP reading at least once daily. The patient will be asked to place a 30-day supply of a tablet/capsule for a medication or supplement he or she is currently taking at least once per day in a labelled pill bottle with a MEMS cap monitor to track when each dose is taken. If a patient prefers not to place an actual active medication in the pill bottle, they may instead use a hard shelled candy or breath mint to simulate a medication for purposes of this pilot study. Study personnel will not handle patients’ medications. An appointment for the second and final study visit, approximately 30 days from the first, will be made at this time. Between visits Participants will be asked to carry the smartphone

and wear the sleep/activity monitor. They will be prompted by the smartphone app to measure BP at the same time each day at home with the portable BP monitor, and to complete the symptom & lifestyle tracking diary at least once daily. They will be asked to take their antihypertensive medications directly from the study pill bottles with MEMS cap monitors (rather than transferring the pills to a pill box) to track medication-taking. A member of the study team will call the patient twice per week to encourage them to follow the protocol, to ensure the devices are correctly charged and used, and to answer questions. If there are concerns about adverse effects, the study team member will page the participant's personal physician, or if unknown, the study physician (Kilgore) immediately to respond to the patient. Final visit (approximately 45 minutes) The patient will return to the clinic for a 30-Day Follow-Up Visit to return the mHealth devices and complete self-report adherence and beliefs questionnaire, the feasibility/acceptability questionnaire and BP measurement. A study team member will upload data from each of the mobile devices to the "MediCom" portal web server as a .csv file using a secure connection under SSL protocol and user/password identification. The .csv files will include no identifying information other than the participant's study identifier and time/date stamps for when each data element (e.g. blood pressure) was collected. The participant will be given \$80 in cash or gift card as compensation for their participation at the end of this final visit.

Study 2 - Questionnaire Study Overview Participants will complete one study visit in a private room at the clinic. After obtaining informed consent, a member of the study team will administer a baseline questionnaire including the self-reported adherence measure and beliefs about medications questionnaire. Blood pressure data will be abstracted from the electronic health record. The participant will be given a \$30 in cash or gift card as compensation for participation. Participants who complete the Study 2 Questionnaire study will be asked to grant permission to be contacted to be recruited for the Study 4 RCT.

Study 3 - Home Monitoring Pilot Study Overview Participants who completed Study 2 and granted permission to be contacted about future studies will be recruited to participate in Study 3. Study 3 participants will complete a brief educational intervention including 3 study visits, each of which is a group education session facilitated by two members of the study team—a primary care physician and a staff member acting as a Group Facilitator. The proposed study will evaluate a culturally appropriate and novel intervention to improve adherence to antihypertensive medications among low-income Hispanic/Latino Americans with diabetes and uncontrolled

hypertension. The intervention, called Mi Propio Camino (MPC, Spanish for “My Own Way”), empowers patients to (1) monitor their own individual experience with blood pressure lowering strategies (including BP changes and side effects), (2) discuss those experiences with peers and providers in a group education setting, and (3) engage in future discussion with their own primary physician providers about barriers and concerns about their BP-lowering approach. MPC will consist of 4 group education sessions, facilitated by a primary care physician and a trained Group Facilitator with three medication experience monitoring periods, one between Group Sessions 1 and 2, a second between Group Sessions 2 and 3 and a third between Group Sessions 3 and 4. Each Group Session includes three sections: a check-in, an educational activity, and a goal setting activity. Group Session 1 (3 hours). Participants will meet in a group activity room at the clinic with the Group Facilitator and physician, supported by the assistant project coordinator and student researchers. Patients will be asked to bring their BP medications to the session. The session will begin with discussion of the ground rules of the Group Session. These rules have been developed and are routinely used in group health education activities provided routinely at the study clinics. Group Session Ground Rules 1. Because it is a group discussion, confidentiality of what is shared during the session cannot be guaranteed. 2. Sharing of personal information is not mandatory 3. Others’ personal information should not be discussed outside of the Group Session. Activities for Group Session 1 include: 1) during check-in, discuss patients’ current BP-lowering strategies (including medications) and concerns about medications; 2) during the education activity, introduce principles of healthy eating (e.g. DASH diet) and ways to increase physical activity to complement medications to reduce BP; and 3) during goal-setting, identify a BP-lowering strategy, incorporating the patients previously prescribed medications (from their personal physicians as part of their usual care) with healthy lifestyle changes, that the patient is willing to try for a finite period. At the end of Session 1, the study team will provide each patient a “kit” of mHealth devices: MEMS pill bottle cap monitors, and a portable BP monitor. Each kit will be configured by a study team member. Further, the patients will be asked to install the SymTrack symptom tracking application (see Appendix K) to their own smartphone, or if they prefer, to carry a smartphone provided by the study team. Participants will be trained on how to use the devices. The symptom tracking app will be configured for each patient to 1) track up to five symptoms of concern, selected by the patient, 2) track up to five lifestyle factors they think may impact BP (e.g. eating salty foods), also selected by the

patient and 3) send reminders to complete the symptom diary and BP reading at least once daily. The study physician will teach patients how to place a 3-week supply of each BP medication in a labeled pill bottle with a MEMS cap monitor to track when doses are taken. Medication Experience Monitoring Period 1 (approximately 2 weeks). For the period in between Group Sessions 1, 2 and 3 (approximately 2-4 weeks), participants will be asked to carry the smartphone and track their medication-taking and blood pressures at home. The smartphone app will prompt them to measure BP at home once daily with the portable BP monitor. Prompts include a symptom and lifestyle tracking diary at least once daily. They will be asked to take their antihypertensive medications directly from the study pill bottles with MEMS cap monitors to track medication-taking. If the patients prefer to use a pill box organizer or to store their pills outside of a pill bottle, they will be asked to keep the empty pill bottle with the MEMS cap monitor next to their pill organizer and to simply open and close the empty bottle to record the pill-taking on the device. A coordinator or volunteer research assistant will call patients twice per week to encourage them to follow the protocol, to ensure the devices are correctly charged and used, and to answer questions. If concerns about adverse effects arise, a study team member will contact the patient's physician immediately to respond to the patient. Group Session 2 (2 hours). Patients will return to the group activity room and give their mHealth kits to the coordinator. Research assistants will ensure data are synced with the MediCom web portal (See Appendix K). During check-in, the facilitators will lead a discussion about the patients' experiences with the medications and lifestyle changes, and show the patients how to view their mHealth data on the smartphone to review their own adherence, changes in BP, and occurrence of symptoms of concern. During this time, patients will be invited to display their data on a large screen for group discussion about experiences, concerns, and strategies to maintain adherence. Participants will be reminded of the ground rules established in Group Session 1 that sharing of personal information is not mandatory and others' personal information should not be discussed outside of the GMV. During the education activity, facilitators will discuss questions about the role of herbal supplements in BP control, teach simple relaxation techniques and stress management strategies and review recommendations to support healthy sleep. During goal setting, the patients will opt to continue the BP lowering strategy they began after Session 1, or to make changes to their strategy, including adjustments to the medication regimen. Finally, the assistants will set up each patient's mHealth kit as in Session 1. Medication

Experience Monitoring Period 2 (approximately 2 weeks). Patients will repeat the Medication Experience Monitoring protocol for the BP-lowering strategy chosen in Group Session 2 until Group Session 3 is scheduled. Group Session 3 (2 hours). Similar to the prior session, Group Session 3 will begin with review of patients' mHealth data and their experiences with the regimen during check-in. The education activity will focus on behavioral strategies recommended by the American Heart Association to reduce forgetting and confusion about medications. During goal setting, patients will focus on setting a SMART goal incorporating medications with healthy lifestyle changes that the patient is willing to try or a finite period of time. Medication Experience Monitoring Period 3 (approximately 2 weeks). Patients will repeat the Medication Experience Monitoring protocol for the BP-lowering strategy chosen in Group Session 3 until Group Session 4 is scheduled. Group Session 4 (2 hours). Similar to the prior session, Group Session 4 will begin with review of patients' mHealth data and their experiences with the regimen during check-in. The education activity will focus on behavioral strategies recommended by the American Heart Association to reduce forgetting and confusion about medications. During goal setting, patients will have two options: 1) complete an additional monitoring period and GMV session (possibly with a new group of patients) to explore other BP-lowering strategies or 2) graduate from the intervention with encouragement to continue discussing concerns with their primary doctor. Finally, all mHealth devices will be collected from MPC patients by study team members. Participants will complete a follow-up questionnaire including the BMQ and medication adherence measures, and the post-intervention satisfaction survey. At the end of this session, the participants will be given \$100 in cash or gift card. Since all Study 3 participants will have completed Study 2 already, this amounts to a total of \$130 compensation for completing the two studies, which was considered to be appropriate compensation by an advisory group of community stakeholders who work with patients in this community. Completion of the above activities in Group Session 4 marks the end of the participant's participation in Study 3. (May 2019) This IRB e-modification is to add an additional set of study procedures, "Study 4", in this on-going investigation. Study 4 is an RCT comparing the IRB-approved MPC intervention (group education sessions augmented with mHealth) pilot tested in Study 3 to a comparison intervention (traditional group education sessions with no mHealth component). Study 4 RCT participants will be recruited from those individuals who completed the Study 2 questionnaire study. Study 4 - Intervention RCT Study 4 is similar to Study 3

using the same mHealth devices and study questionnaires, but including the following additions: (1) RCT design to randomly allocate participants to the MPC intervention (described in Study 3) or a comparison intervention, (2) a six-month follow-up visit. For completeness, both intervention conditions and all study procedures for Study 4 are described below.

Overview

Participants who completed the Study 2 Questionnaire study and granted permission to be contacted about future studies will be recruited to participate in Study 4. Study 4 participants will be randomly allocated to complete either the MPC intervention or the comparison intervention, each of which consists of 4 biweekly sessions facilitated by members of the study team. The proposed study will evaluate a culturally appropriate and novel intervention to improve adherence to antihypertensive medication among low-income Hispanic/Latino adults with uncontrolled hypertension. The intervention, called *Mi Propio Camino* (MPC, Spanish for “My Own Way”), empowers patients to (1) monitor their own individual experience with blood pressure lowering strategies (including BP changes and side effects), (2) discuss those experiences with peers and providers in a group education setting, and (3) engage in future discussion with their own primary physician providers about barriers and concerns about their BP-lowering approach. The comparison intervention, will focus on information and behavioral skills but will not address negative beliefs through direct and vicarious experience using mHealth. Both intervention groups will consist of 4 group education sessions with two follow up appointments, at one month and six months post intervention sessions. MPC will be facilitated by a primary care physician and a trained Group Facilitator with three medication experience monitoring periods, one between Group Sessions 1 and 2, a second between Group Sessions 2 and 3 and a third between Group Sessions 3 and 4. The comparison intervention group will be facilitated by a trained Health Coach experienced in leading group education sessions with Spanish-speaking Latino patients with limited health literacy. Each Group Session includes three sections: education activities, goal setting and take home activities. Session 1 will include a discussion of ground rules and an ice breaker activity. In Sessions 2-4, check-in will include small group discussions of observations from the prior Personal Experience Monitoring Session. For participants randomized to MPC: Participants in the MPC condition will follow the procedure described for the 4 MPC intervention visits with Medication Experience Monitoring Sessions described in Study 3, above. In brief: Education activities will emphasize discussions to address commonly held negative beliefs about medications. For example, concerns about harms

vs. benefits will be addressed by focusing the ways medication and lifestyle work synergistically, the distinction between temporary symptoms/side effects and permanent harm, and how monitoring experiences with BP-lowering strategies helps individuals find a personalized approach that works for them. Concerns about provider overuse of medications or unwillingness to respond to patient concerns will be addressed by discussion about insights on how providers think about selecting BP lowering strategies and responding to side effects, and how bringing in information from home monitoring can empower patients to collaborate with their physician more effectively. Finally, based on our successful experience training Spanish-speaking patients to use the mHealth kits during our dry run sessions, we will dedicate a full hour of Session 1, to train participants to use the kits to complete the subsequent Personal Experience Monitoring Sessions. Goal setting focuses on setting a SMART goal incorporating medications with healthy lifestyle changes that the patient is willing to try for a finite period and monitor at home between GMV sessions. Although participants will be allowed to try a BP lowering strategy that does not involve medications, no participants in our dry run sessions have opted for this option. Take-home activity: Personal Experience Monitoring Period (2 weeks). At the end of GMV Session 1, the coordinator and assistants will provide each patient a “kit” of two mHealth devices: MEMS pill bottle cap monitors, a portable BP monitor, each configured by a member of the study team. Additionally, the patients will be given the option to (1) install the SymTrack symptom tracking application to their own smartphone, (2) to carry a smartphone provided by the study team or, (3) based on feedback from feasibility testing, use a paper-based diary to collect data that a study team member can input into the web portal. Participants will be trained on how to use the devices, include the appropriate protocol to take BP reliably, and asked to set a daily reminder (either in the app or on their own phone or watch) for a consistent time they think they will have 5 quiet minutes to complete the symptom diary and BP reading. The symptom diary app will be configured for each patient to track their BP, overall energy level, and up to five lifestyle factors they think may impact their BP (e.g. eating salty foods) selected by the patient. The study physician will teach patients to place a 2-week supply of each BP medication in a labeled pill bottle with a MEMS cap monitor to track when doses are taken. Participants will be asked to take their BP meds directly from the study pill bottles with MEMS caps (rather than transferring the pills to a pill box) to track medication-taking. A study team member will call patients twice between GMV sessions to encourage them to follow the protocol, to

troubleshoot the mHealth devices, and to answer questions. If concerns about adverse effects arise, a study team member will contact the patient's physician immediately to respond to the patient. During the monitoring period, participants will be asked to find a time once per day to sit quietly for 5 minutes, reflect on the day, and complete the diary. Then, they will follow the instructions in the kit to take their BP. When patients return to the group activity room for the next GMV session, they will give their mHealth kits to the research assistants, who will help compile and summarize the data for the patient. During check-in, the facilitator will lead a discussion about the patients' experiences with the medications and lifestyle changes, and show the patients how to view their mHealth data on the smartphone to review their own adherence, BP changes, and occurrence of symptoms of concern. Patients will be invited to display their data on a large screen for group discussion about experiences, concerns, and strategies to maintain adherence, and will be reminded of the ground rules established in Session 1. For participants randomized to the comparison intervention: Participants allocated to the comparison group will complete a traditional 4-session BP health education class, based on American Heart Association curriculum materials, developed under the supervision of the study physician, and similar to a class currently offered at the study site. Like the MPC Study Intervention, the comparison intervention will include 4 in-person sessions over two months, with take-home activities in between. Unlike the MPC intervention, the comparison intervention will focus on information and behavioral skills, but will not address negative beliefs through direct and vicarious experience using mHealth. Education activities. Instead of focusing on addressing negative beliefs, the Education Activities will include detailed presentations on the specific health threats (complications) associated with uncontrolled BP, and teaching seven specific lifestyle strategies related to the "Changes You Can Make to Manage High BP" described by the American Heart Association including healthy eating, physical activity, etc. In each session, behavioral strategies to reduce confusion/forgetting in medication-taking will be discussed. Goal-Setting (and subsequent Check-Ins) will focus on setting a SMART Goal for a behavioral change related to the subject of the day's lesson to implement in the Take-Home Activity. Take-Home Activity: Instead of Personal Experience Monitoring, the Take-Home activity in the comparison intervention will focus on implementing their SMART goal for a behavior change without offering the mHealth kit or explicit guidance about how to monitor one's experience with the strategy. They will receive two phone contacts during each interval

between In-Person Sessions to provide encouragement and help with problem-solving related to implementing the goals. Follow up visits One-month follow up. For session 4 in both groups, participants will be asked to bring a 30-day supply of their currently prescribed blood pressure medications and asked to take every dose of those medications for the next 30 days directly from the MEMS cap monitors to measure daily adherence for that period, the patient will return for a 30-Day Follow-Up Visit to return the MEMS cap, complete a blood pressure measurement and complete a brief questionnaire. Five-month follow-up. Approximately 5 months after session 4, patients will complete a second follow-up visit to complete a brief questionnaire and blood pressure measurement, and receive another MEMS pill bottle cap monitor with instructions for the second 30-day adherence monitoring session Six-month follow up. At six months post intervention sessions, the coordinator will meet the patient at the clinic to take a final blood pressure measurement, collect a final survey including self-reported adherence and complete a second 30-day adherence monitoring using MEMS caps, following the same procedure as for the one month follow up. Completion of the above activities over the six month follow up period marks the end of the participant's participation in Study 4.

Specify the total duration of a subject's participation in the study and clearly outline the duration of participation for each study visit and sub-study, as applicable:

Study 1. The subject will participate in two study visits, of approximately 45 minutes each, with a 30 day home monitoring period in between during which they will complete a daily smartphone diary, wear a Fitbit sleep/activity monitor and check their own blood pressure. Study 2. The subject will participate in one study visit, approximately 45 minutes in length. Study 3. The subject will participate in 3 study visits, consisting of interactive group education sessions lasting a total of approximately 7 hours. In between the study visits, they will complete three home monitoring periods of approximately two weeks each, during which they will complete a daily smartphone diary, will check their own blood pressure daily and will receive approximately two brief reminder calls per week. These home monitoring activities (at 5 minutes per day) and reminder calls (at 5 minutes per call) are expected to take no more than 4 hours in total for the whole study period. Study 4. Participants will attend four group education sessions over a period of approximately 1 month, and three follow up appointments, at 1 month, 5 months and 6 months after the last group education session. For the four group education sessions, Session 1 will be approximately three hours long, and Sessions 2 through 4 will be two hours long each. The one-month, five-month and six-month follow-up sessions will be approximately one hour each. In total, participants would spend approximately 15 hours engaged in study activities at the clinic over a seven-month span. Additionally, participants will complete home monitoring and follow-up phone calls outside the clinic totaling 5 hours. Combined, total participation time at clinic and at home will be 20 hours over the 7 months.

List data collection tools (e.g., measures, questionnaires, observational tool) below by clicking the 'Add Line' button. Include additional rows for study instruments, as needed:

The 'Columns' button allows you to display or hide columns in the Study Instrument List.

Name of Tool:

Beliefs about medicines questionnaire (BMQ)

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: the development and evaluation of a new method for assessing the cognitive representation of medication. *Psychology and health* 1999;14(1):1–24.

Name of Tool:

Morisky Medication Adherence Scale

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive Validity of A Medication Adherence Measure in an Outpatient Setting. *J Clin Hypertens (Greenwich)* 2008;10(5):348–54.

Name of Tool:

Medication Knowledge Questionnaire (MKQ)

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

Mayberry LS, Osborn CY. Empirical validation of the information-motivation-behavioral skills model of diabetes medication adherence: a framework for intervention. *Diabetes Care* 2014;37(5):1246–53.

Name of Tool:

PROMIS Self-Efficacy for Managing Chronic Conditions Manage Medications/Treatment scale

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

Gruber-Baldini AL, Velozo C, Romero S, Shulman LM. Validation of the PROMIS® measures of self- efficacy for managing chronic conditions. Qual Life Res 2017;26(7):1915–24.

Name of Tool:

Medication Adherence Strategies Inventory (ASI)

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

Boron JB, Rogers WA, Fisk AD. Everyday Memory Strategies for Medication Adherence. Geriatr Nurs 2013;34(5):395–401.

Name of Tool:

Safran Reasons for Nonadherence Scale

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

Safran DG, Neuman P, Schoen C, et al. Prescription drug cover- age and seniors: findings from a 2003 national survey. Health Aff (Millwood). 2005;Suppl Web Exclusives:W5.152-W5.166.

Name of Tool:

Demographics and other general items (full survey provided)

Is the data collection tool standardized or validated?

No, submit a copy of the draft or final tool in the Attachments Section

Name of Tool:

Arizona Lifestyle Index

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

Brooks A, Dodds S, Cook P, Maizes V, Lebensohn P. Psychometric Analyses of the Arizona Lifestyle Inventory: A Multi-Dimensional Integrative Medicine Measure to Assess Wellness Behaviors. The Journal of Alternative and Complementary Medicine. 2014 May 1;20(5):A133-.

Name of Tool:

InCharge Financial Distress/Financial Well-Being Scale

Is the data collection tool standardized or validated?

Yes

Please provide data collection tool citation:

AD Prawitz, ET Garman, B Sorhaindo , etal: Incharge financial distress/financial well-being scale: Development, administration, and score interpretation Fin Couns Plan 17: 34– 50,2006

Will this study require clinical items/ services from UC Irvine Health?

No

Does the research involve the use of [identifiable private information](#)?

Yes

Use of [Identifiable Private Information](#) as Part of the Main Study.

Indicate the types/sources of identifiable private information (**Check all that apply**):

UCI Health Medical Records

Indicate whether the information was originally collected for research purposes:

Not originally collected for research

Explain how the information were originally collected (e.g., clinical care):

Routine clinical care

Provide a complete list of the data points, variables, and/or information that will be collected (i.e. data abstraction form):

Or specify variables or information required here:

The study team will request specific patient information/data from UCI Health Honest Broker Services. The dataset will contain the following data elements:

1. Sociodemographic characteristics: To describe the sample and to use as covariates in data analysis -Age -Gender -Race/ethnicity -Preferred language - Marital status -Health insurance type
2. Healthcare utilization: To account for differential utilization of health services when testing study hypotheses. - Number of inpatient stays -Total inpatient length of stay -Number of emergency department visits -Number of scheduled ambulatory primary care appointments -Number of attended ambulatory primary care appointments - Dates of the following preventive services: --All COVID-19 vaccine doses --All influenza vaccination doses --A1C test --Lipid panel --Kidney function testing --Diabetic Foot exam --dilated eye exam
3. Cardiometabolic Indicators: To assess the secondary endpoint of blood pressure control and account for differences in cardiometabolic risk factors when testing study hypotheses - Blood pressure -Laboratory data for a two-year period: --Lipid panel results (LDL; HDL; Total cholesterol; Triaglycerides) --Hemoglobin A1C -Body Mass Index Each result will be listed in a separate row for all study patients.
4. Chronic health conditions: To account for patients' disease burden in the analysis, the dataset will include a list of relevant diagnoses noted in the medical record to allow us to compute the Charlson comorbidity index score. The following diagnoses, and any available comorbidity summary scores, will be included in the dataset: --Myocardial infarction/heart disease --Congestive heart failure --Peripheral vascular disease --Dementia --Cerebrovascular disease --Chronic lung disease -Connective tissue disease --Ulcer --Chronic liver disease --Diabetes --Hemiplegia --Moderate or severe kidney disease -- Diabetes with end organ damage --Tumor --Leukemia --Lymphoma --Moderate or severe liver disease --Malignant tumor and metastasis
5. Medication orders: To validate patient reported and objectively collected medication adherence data, and to account for differences in treatment intensity in analysis of study outcomes, all medication orders noted in the EMR will be included, each in a separate row, identified by a study identifier. The data elements to include will be: --Date of medication order/prescription (NOTE: all dates will be converted into "Days From Start of Observation Period" so that no actual dates will be stored in the dataset). --Type of order (e.g. initiate, refill, discontinue) -- Medication brand name --Medication generic name(s) (combination medications may include more than one generic medication) --Medication class(es) --Number of units ordered (e.g. number of pills prescribed) --Dose

count (number of units per dose, e.g. take ____ pills...) --Dose frequency (number of times per day to be taken) --Unit dose (e.g. milligrams per pill/unit) --Dose form (pills, injectable, ointment, inhaler, etc.) --Notes (special instructions like "take with food") Once the data are obtained, the investigator will conduct data analyses to describe the sample and the distribution of study variables, and to test the study hypotheses. please update

Specify the time-frame of the data to be accessed (e.g. January 2002 to 2024):

All results noted in the medical record for the 1-year period before the consent date and for two years after the final study visit date will be included, with the date of the test and the result (NOTE: all dates will be converted into "Days From Start of Observation Period" so that no actual dates will be stored in the dataset), and the study identifier.

This study will use medical records, indicate the source:

Study team will access their own UCI patients' records and abstract data directly from those records

Does the research involve the use of identifiable biospecimens?

No

Sharing Results with Subjects

Will Individual results be shared with subjects?

No

Will overall study results will be shared with subjects?

N/A, final study results will not be shared with subjects

Risk Assessment

Risks and Discomforts

1. Describe and assess any reasonably foreseeable risks and discomforts associated with each procedure for each subject population – physical, psychological, social, legal or other:

2. If this study will involve the collection of identifiable private information, even temporarily, for which the disclosure of the data outside of the research could reasonably place the subjects at risk, include the risk of a potential breach of confidentiality:

Breach of Confidentiality: Study 1, 2, 3 and 4. Because we are operating in a clinic setting, consent documents and data collection instruments will be transported from the clinic to the research offices.

Study 1, 3 and 4. Participants will also be collecting health data using mobile health devices.

Therefore, there is a minimal, but non-zero, risk that participant data stored at the research offices or stored/transmitted using the mobile devices could be compromised. From prior experience in similar studies, we expect the frequency to be rare (<1%).

Study 3 and 4. Because the study intervention involves voluntary group discussion of health matters, we cannot assure that confidentiality will be maintained for information that participants choose to disclose in front of others. This potential for disclosure of personal information by other group participants is assumed in routine patient group health education activities that are routinely held at the study clinic.

Study 1, 2, 3 and 4.

Discussion of potentially sensitive issues. During the pre-visit session, the patient and study team member could discuss health issues or personal issues that raise concern for the patient. From prior experience in similar studies, we expect the frequency to be rare (<1%).

Discuss what steps have been taken and/or will be taken to prevent and minimize any risks/potential discomforts to subjects:

Breach of confidentiality. Study 1, 2, 3 and 4. To minimize this risk, all data collection instruments will be assigned unique study identifiers. Identifiers, including patient's name, address, telephone number and study identifier will be stored electronically in REDCap, a secure web-based research platform, with access limited to key study personnel. All study personnel will be trained in confidentiality protocol procedures. All hard copy versions of study data collection materials will be transported in a locked briefcase, and maintained in secure, locked, filing cabinets, in offices of the lead researcher. For Study 3, because the study intervention involves voluntary group discussion of health matters, we cannot assure that confidentiality will be maintained for information that participants choose to disclose in front of others. For this reason, we discuss and establish ground rules at the beginning of each group session for the study intervention, indicating that: 1. Because it is a group discussion, confidentiality of what is shared during the session cannot be guaranteed. 2. Sharing of personal information is not mandatory 3. Others' personal information should not be discussed outside of the Group Session. Study 1, 2, 3 and 4. Data collected using mobile devices or stored on any 3rd party server other than REDCap will be identified only by the participant's study identifier, both on the devices themselves, and on the study's "MediCom" web server. In addition, data will be protected as it moves along the communication pathways (from participant to server) using a secure protocol: Secure Sockets Layer (SSL). All users and admin accounts to access and manage the web services are password protected. Data will also be stored securely in a central database hosted in a server at Calit2 as part of the UCI network, which stores and encrypts the information retrieved from the devices. This server is behind the UCI Firewall. The server is protected by automatic updates, antivirus and monitoring of activities and users. Study 1, 2, 3 and 4. Discussion of potentially sensitive issues. Because the research encounters will occur at the patient's medical clinic, they will have the opportunity to address any such issues with a health providers on staff at the clinic.

Certificate of Confidentiality

Is the research partially or wholly funded by NIH (including [NIH Institutes and Centers](#)), or does the research involve identifiable sensitive information that require CoC protections?

No

Potential Benefits

Is there the prospect of a direct benefit anticipated for subjects?

Yes

Describe the potential benefits subjects may expect to receive from participation in this study:

Potential benefits include learning about medication adherence, beliefs about medication, and one's own changes in blood pressure over time. Studies 3 and 4 also offers the opportunity for participants to learn about recommended strategies to manage blood pressure and to communicate with their personal doctors about concerns and barriers they face in managing blood pressure.

Specify the expected potential societal/scientific benefit(s) of this study:

Study 1, 2 , 3 and 4 have the expected societal benefit of increasing understanding of health related beliefs that may influence medication adherence. Further, Studies 1, 3 helps establish the feasibility of using mobile devices to help address negative hypothetical beliefs about medications, which will guide future investigations of this approach. Study 4 has the expected societal/scientific benefit of testing a theoretically grounded health education intervention designed to address negative beliefs about medications to improve adherence to blood pressure medications and subsequent blood pressure control in a population facing significant disparities on these outcomes.

Alternatives to Participation

Describe the alternatives to participation in the study available to prospective subjects. Include routine (standard of care) options as well as other experimental options, as applicable (**check all that apply**):

No alternatives exist. The only alternative to study participation is not to participate in the study

Participant Compensation

Will subjects be compensated?

Yes

Specify whether compensation is applicable and, if so, the method, amount and schedule of compensation (**Check all that apply**):

Other

Specify 'Other' compensation method:

Cash or gift card (depending on patient preference)

Other schedule:

Other

Specify the 'Other' compensation 'Other' schedule:

Study 1. Subjects will be compensated with the following schedule and amounts: Total compensation of up to \$80 will be offered for participation. \$20 will be handed to patient at completion of the first study visit and \$60 will be handed to the participant at completion of the second visit. Study 2. \$30 cash/gift card will be given to patient at completion of the study procedure in person. Study 3. \$100 will be given to patient at completion of the study procedure, in person. (January 2023) - To provide greater incentive to participate and respond to great barriers to participation since the start of the COVID-19 pandemic, total compensation for Study 4 is being increased from \$180 to \$240 dollars, following the schedule of payments listed below. Study 4. Subjects will be compensated with the following schedule and amounts. Total compensation up to \$240 will be offered for participation and completion of study components. -\$40 will be handed to patient upon completion of session 1. -\$10 will be given upon completion of session 2. -\$10 will be given upon completion of session 3. -\$40 will be given upon completion of session 4 -\$40 at completion of 1 month follow up visit and \$100 upon completion of 6 month follow up. Compensation to participants will be handed in person. Because all Study 4 participants will have already completed Study 2, please note that the total compensation for Study 4 is in addition to compensation the participants will have received for Study 2.

Will the 'Other' compensation method include all subjects?

Yes

Will subjects be reimbursed for out-of-pocket expenses?

No

Participant Costs

Will subjects or their insurers be charged for study procedures?

No

Confidentiality of Research Data

Information and/or Biospecimens Storage

Indicate how information and/or biospecimens (including signed consent forms) will be stored
(**check all that apply**):

Information will be maintained electronically. Information will be password protected and maintained in an encrypted format

Information will be maintained on an UCI enterprise cloud platform

Encrypted Format

Specify where the information will be maintained electronically:

In addition to the Enterprise cloud platforms listed below, P4 data will also be stored securely behind password protection on: REDCap, UCI Qualtrics, UCI Protected Research Environment server

Enterprise Cloud Platform

For [enterprise cloud storage](#), select the location that adheres to the UCI [Protection Level](#) required for the research information:

Microsoft OneDrive

Microsoft Teams

Microsoft SharePoint

Microsoft OneDrive

Will subject/patient identifiers be collected or retained?

Yes

Subject/Patient Identifiers

Will any subject/patient identifiers be collected or retained for data analysis, recruitment, consenting and/or compensation (**check all that apply**)?

All elements of dates (except year) for dates that are directly related to an individual: birth date, admission date, discharge date, death date, and all ages over 89

All geographic subdivisions smaller than a state: street address, city, county, precinct, ZIP code, and geocodes

Email addresses

Medical record numbers

Names

Telephone numbers

Will a code be used to link subject/patient identifiers with the information and/or biospecimens?

A code will be used. Subject/Patient identifiers will be kept separately from the information and/or biospecimens. The code key will be destroyed at the earliest opportunity, consistent with the conduct of this research

Will research data/biospecimens be transported or maintained on portable devices (e.g., laptop, smartphone, external hard drive, etc.)?

No

Specify who will have access to subject/patient identifiable information/biospecimens as part of this protocol (**check all that apply**):

Authorized UCI personnel (such as the research team) and appropriate institutional officials: such as the Office of Human Research Protections (OHRP) Regulatory entities such as the Food and Drug Administration (FDA), the National Institutes of Health (NIH)

Specify whether subject/patient identifiers be disclosed in presentations and/or publications:

Subject/Patient identifiers will be disclosed. Text regarding the disclosure will be included in the consent document and specific permission to disclose will be discussed with subjects/patients

Specify how long all subject/patient identifiers will be retained. This includes identifiers stored in paper format, stored electronically as well as video recordings, audio recordings, photographs, etc.:

Other

Specify 'Other' time frame and provide rationale:

Participants will be asked to indicate on the Consent Form whether they grant permission for our study team to contact them about future studies. Time frame: For those participants who grant this permission, we will maintain their personal identifiers and contact information until the end of this study protocol. Rationale: Maintaining this information will allow us to reduce potential participant burden by eliminating the need to collect questionnaire data multiple times for subjects participating in more than one of the sub-studies. It also gives greater flexibility to participants by allowing them to participate in the sub-studies that are most relevant to them on a schedule they choose.

Research Information and/or Biospecimens Retention

Indicate how long research information/biospecimens will be retained:

Other

Specify time frame and provide the rationale for research information and/or biospecimens retention:

Will be retained for six years as this research involves Protected Health Information (PHI) (e.g., IRB documentation, consent/assent forms – NOT the actual PHI). Investigators must destroy PHI at the earliest opportunity, consistent with the conduct of this study, unless there is an appropriate justification for retaining the identifiers or as required by law.

Will research information and/or biospecimens be shared?

No

Attachments

If required documentation is not provided, the submission is incomplete and your Application will be returned to you. Be sure to upload each document as required. If changes are needed, go back to the sub-section to revise your selections.

Maximum file size is 30MB

All UCI templates are available on the Human Research Protections [Applications & Forms page](#) or Human Stem Cell Research [Applications & Forms page](#).

To access approval documents where UCI will rely on another IRB, including commercial IRBs, visit their respective online portals. Frequently used commercial IRB portals include:

- WIRB Copernicus Group's [WCG IRB Connexus](#)
- Advarra's [CIRBI](#)
- SMART [Online Reliance System \(ORS\)](#)

Attachment

2017-4025 APPENDIX K MEDICOM APPLICATION 05-23-18_NORMAL_333168.DOC

Attachment Type

Other

File Comments

Reference Only

File Name

Status (IRB/hSCRO Use Only)

Attachment

2017-4025 APPENDIX K SYMTRAK MOBILE SYMPTOM DIARY 05-23-
18_NORMAL_333169.DOC

Attachment Type

Other

File Comments

Reference Only

File Name

Status (IRB/hSCRO Use Only)

Attachment

2017-4025 APPENDIX K FITBIT CHARGE HR. 05-23-18_NORMAL_333170.DOC

Attachment Type

Other

File Comments

Reference Only

File Name

Status (IRB/hSCRO Use Only)

Attachment

[2017-4025 APPENDIX K BP MONITOR 05-23-18_NORMAL_333171.DOC](#)

Attachment Type

Other

File Comments

Reference Only

File Name

Status (IRB/hSCRO Use Only)

Attachment

[2017-4025 APPENDIX K MEMS CAP 05-23-18_NORMAL_333172.DOC](#)

Attachment Type

Other

File Comments

Reference Only

File Name

Status (IRB/hSCRO Use Only)

Attachment

[2018-4025 PRODUCT BROCHURE - FITBIT CHARGE HR 05-23-18_NORMAL_333173.PDF](#)

Attachment Type

Medical Device Instructions (User Manual/Product Brochure)

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

[2018-4025 PRODUCT BROCHURE - OMRON BLOOD PRESSURE MONITOR 05-23-18_NORMAL_333174.PDF](#)

Attachment Type

Medical Device Instructions (User Manual/Product Brochure)

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

[2018-4025 PRODUCT BROCHURE - MEMS 05-23-18_NORMAL_333175.PDF](#)

Attachment Type

Medical Device Instructions (User Manual/Product Brochure)

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

[2017-4025 DATA ABSTRACTION SHEET 05-23-18_NORMAL_333178.DOCX](#)

Attachment Type

Data Collection Tool/Instrument

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

[2017-4025 FEASIBILITY SURVEY 05-23-18_NORMAL_333180.DOCX](#)

Attachment Type

Other

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

APPENDIX K - MEDICOM DATA AGGREGATION AND WEB PORTAL SOFTWARE 07-05-19_NORMAL_363003.DOCX

Attachment Type

Other

File Comments

Reference Only

File Name

Status (IRB/hSCRO Use Only)

Attachment

2017-4025 PHONE AND EMAIL 12-12-18_APPROVED_346851.PDF

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2017-4025 PHONE AND EMAIL SCRIPT (SPANISH) 04-05-19_APPROVED_356468.PDF

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[MPC_BASELINE_QUESTIONNAIRE.PDF](#)

Attachment Type

Data Collection Tool/Instrument

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

[20174025 PHONE RECRUITMENT SCRIPT 03-23-22.DOCX](#)

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 PHONE RECRUITMENT SCRIPT 03-23-22.PDF](#)

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[ENGLISH MPC FLYER.PDF](#)

Attachment Type

Recruitment Material

File Comments

Stamped English Version

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 STUDY 2 AND 4 RECRUITMENT FLYER 03-23-22.PDF](#)

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 SPANISH STUDY 2 AND 4 RECRUITMENT FLYER 03-23-22.PDF](#)

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 SPANISH STUDY 2 CONSENT FORM 09-23-22.DOCX](#)

Attachment Type

Translated Consent Form

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 UCI HIPAA FORM 6-8-22.DOCX](#)

Attachment Type

HIPAA Research Authorization Form

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 IRB APPROVAL LETTER 6-8-22.PDF](#)

Attachment Type

UCI IRB Approval Letter

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 SPANISH HIPAA FORM.DOCX](#)

Attachment Type

HIPAA Research Authorization Form

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

[20174025 SPANISH STUDY 2 CONSENT FORM + HIPAA 09-23-22.PDF](#)

Attachment Type

Translated Consent Form

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 SPANISH STUDY 4 CONSENT FROM + HIPAA 2-2-23.PDF](#)

Attachment Type

Translated Consent Form

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 STUDY 2 MAIN CONSENT \(QUESTIONNAIRE STUDY\) 6-8-22 \(5\).PDF](#)

Attachment Type

Consent Form

File Comments

English study 2 consent form approved

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 STUDY 2 MAIN CONSENT \(QUESTIONNAIRE STUDY\) 6-8-22.DOCX](#)

Attachment Type

Consent Form

File Comments

English study 2 word doc

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 SPANISH STUDY 4 CONSENT FORM 2-2-23.PDF](#)

Attachment Type

Translated Consent Form

File Comments

Updated consent form to match the compensation in that was updated in the English consent form for study 4

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[TRANSLATOR LETTER_TANYA_01312023.PDF](#)

Attachment Type

Other

File Comments

Translator letter

File Name

Status (IRB/hSCRO Use Only)

Attachment

[20174025 STUDY 4 MAIN CONSENT 01-25-2023.PDF](#)

Attachment Type

Consent Form

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 STUDY 4 MAIN CONSENT 01-25-2023.DOCX](#)

Attachment Type

Consent Form

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[20174025 AMENDMENT APPROVAL LETTER 01-25-2023.PDF](#)

Attachment Type

UCI IRB Approval Letter

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

[SPANISH MPC FLYER.PDF](#)

Attachment Type

Recruitment Material

File Comments

Stamped Spanish Version

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

ENGLISH MPC FLYER.DOC

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

SPANISH MPC FLYER.DOC

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Lead Researcher Certification

Investigator's Assurance

As Lead Researcher, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for research involving human subjects.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. The information provided in this application has been discussed and shared with my Department Chair. Any requests for changes based on this discussion are included in this application upon submission or will be initiated by the research team either during the IRB review process or via an amendment.
3. All named individuals on this project have read and understand the procedures outlined in the protocol and their role on the study.
4. All named individuals on this project have completed the required [Educational research tutorials](#) and have been made aware of the "Common Rule" ([45 CFR Part 46](#)), applicable Food and Drug Administration (FDA) regulations ([21 CFR Parts 50, 56, 312 and 812](#)), have read the [Belmont Report](#), and [UCI's Federalwide Assurance \(FWA\)](#) that are available on the [Human Research Protections Program \(HRP\) website](#).
5. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.
6. I understand that, if the study described in this IRB application is supported by a federal award or used as a basis for a proposal for funding, it is my responsibility to ensure that the description of human subjects activities in the proposal/award is identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to assure the proposal/award and application are identical in principle.

I and all co-investigators and research personnel agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following:

1. Obtaining the legally effective informed consent of all human subjects or their legally authorized representatives (unless waived) and using only the currently approved, stamped consent form (if applicable).
2. Per federal regulations, once a human research study has received IRB approval, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation except when necessary to avoid an immediate, apparent hazard to a subject. See [Reporting of Unanticipated Problems](#).
3. Reporting any unanticipated problems involving risk to subjects or others, including protocol violations per UCI IRB policy. In addition, HIPAA privacy violations must be PROMPTLY disclosed to the UCI Privacy Officer. There are time requirements for reporting these breaches of confidentiality, which, if not met, may result in monetary damages to the researcher and the institution.
4. Responding appropriately to subjects' complaints or requests for information about the study; and reporting to the IRB any subject complaints that are not resolvable by the study team.

5. Promptly providing the IRB with any information requested relative to the project.
6. Assuring the appropriate administration and control of investigational test articles (i.e., investigational drugs, biologics or devices) by a qualified investigator or other appropriate individual or entity (e.g., UCI Health pharmacy), and assuring use and maintenance of an Investigational Drug/Biologic Accountability Log or Device Accountability Log.
7. Registering applicable clinical trials with clinicaltrials.gov. For more information about this topic, visit the [ClinicalTrials.gov](https://clinicaltrials.gov) web page or the HRP webpage. **The consequences of not meeting the registration and reporting requirements include monetary damages to the researcher and the institution.**
8. Obtaining continuing review prior to study expiration (I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all human research activities must cease until IRB approval is obtained).
9. Promptly and completely complying with an IRB decision to suspend or terminate its approval for some or all research activities.

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- . Submitting to a routine review of human subject research records. The [Compliance & Privacy Office](#) at UCI Health performs ongoing routine reviews of open biomedical research protocols, in an effort to ensure in part that human subject research activities are conducted in accordance with regulations, laws and institutional policies regarding the protection of human subjects. In addition, the HRP unit of the Office of Research has developed the Education Quality and Improvement Program (EQUIP). Through EQUIP, HRP staff conduct periodic quality improvement monitoring and educational outreach.

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- . For clinical trials initially approved by the IRB on or after January 21, 2019, posting one (1) IRB-approved clinical trial consent form at a publicly available federal website. The consent form must be posted after recruitment closes, and no later than 60 days after the last study visit. For additional guidance, refer to the [OHRP FAQs on Informed Consent](#).

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- . Filing a final report with UCI HRP at the conclusion of this project.

As the Lead Researcher, I assure all of the above

Financial Disclosure

Investigators' Disclosure of Financial Interest

In order to inform research subjects of circumstances that may affect their decision to participate in this study, all researchers are required to disclose their financial interests with outside institutions.

The Lead Researcher of the protocol must ask the following question of all study team members:

"Do you, your spouse/registered domestic partner, and dependent children together have any disclosable financial interests (i) that would reasonably appear to be affected by the research; or (ii) in entities whose financial interests would reasonably appear to be affected by the research?"

A member of the study team who answers in the affirmative will be contacted by the Conflict of Interest Oversight Committee (COIOC) to obtain additional information regarding their specific financial interest(s).

IMPORTANT! If there has been a change in the financial disclosures of the LR or the study team, please also request a 'Change in Financial Interests'.

As Lead Researcher, I certify that the disclosures for all study team members are accurate

End of form. Please review responses for accuracy and completeness.

Please ignore the Admin Details Section below. This section is for IRB/hSCRO use only.

Administrative Details Form

Project Status

Committee:

IRB D

Project Status:

Approved

Date of Project Determination:

December 31, 1969

Amendment Status:

Approved

Date of Amendment Determination:

February 2, 2023

Date of ERA Transcription:

January 19, 2022

Pre-2018 Common Rule:

No

Date of Transition to 2018 Common Rule:

December 31, 1969
