UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title	Implementation Strategies for Self-Measured Blood Pressure Monitoring in Racially and Ethnically Diverse Populations (InS2PiRED)
Principal Investigator (Person in charge of this study)	Elaine Khoong, MD, MS - Principal Investigator Department of Medicine elaine.khoong@ucsf.edu
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Clinicaltrials.gov National Clinical Trial (NCT) Number	NCT06871462

1. Why have I been given this document?

To see if you are interested in taking part in a research study. A research study is a planned project being done to learn more about a topic.

2. Do I need to take part in this research study?

No. Taking part in research is voluntary. If you don't want to take part, there will be no penalty and you will not lose your current benefits. The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding.

3. This section describes key information to consider about this study.

3.1. Why is this study being done?

This study is being done to compare two kinds of home blood pressure checking. We want to learn if one method is more helpful in improving high

blood pressure. We also want to learn if different types of training and support will help nurses, pharmacists, medical assistants, and doctors better treat high blood pressure.

3.2. How long would I be in this study? How many study visits are there?

You would be in this study for about 12 months. There are three study visits: one at the beginning of the study, one during the study, and one when the study is over.

We will follow up on your medical records for up to 18 months after the study is over.

If you are randomly assigned to one of the groups (see Section 7 for more information), you will be asked to attend four group sessions as well. These are different from study visits. These group sessions will be in person or online (e.g., Zoom) and will provide education on how to manage high blood pressure, as well as a chance to learn from other patients who also have high blood pressure.

3.3. What are the procedures with the most risk in this study?

The procedure with the most risk in this study is not having timely follow-up.

3.4. What risks and discomforts are most severe? What risks and discomforts are most common?

Possible risks and discomforts of this study that are most severe are not having timely follow-up.

Possible risks and discomforts of this study that are most common are:

- Physical discomfort or pain with using blood pressure cuff

3.5. Are there benefits to taking part in this study?

You may or may not benefit from participating in the study. The information learned from this study may help others in the future.

3.6. What are my other options if I don’t want to take part in this study?

You may or may not benefit from participating in the study. The information learned from this study may help others in the future.

3.7. What is the usual care for my condition?

The usual care for your condition is getting your blood pressure taken inperson at your doctor's office.

4. How many people will take part in this study?

About 330 will take part in this study at all research sites.

5. Who is paying for this study?

This study is being paid for by the Agency for Healthcare Research and Quality.

6. Do any UCSF researchers of this study have financial interests that I should know about?

No.

7. What are the research procedures of this study?

First, your medical record will be reviewed to see whether you are eligible for the study. We will look for the following:

- Must be 18 years or older, have had at least two hypertensive blood pressure readings (≥140/90 mmHg) in the past 18 months, including the most recent reading, and be able to provide informed consent.
- No medical condition that might complicate home blood pressure monitoring (such as pregnancy, acute myocardial infarction or stroke in the past 12 months, end-stage renal disease on dialysis, stage D heart failure, active treatment for cancer (except for nonmelanoma skin cancers), dementia, on active hospice care, or with serious behavioral health condition impeding participation (e.g., schizophrenia)).

7.1. Study Procedures

If you qualify for the study, you will need to have the following procedures.

- Informed consent signed
- Baseline survey completed
- Receive and use blood pressure (BP) monitor for 12 months ○ You will receive a BP monitor from CareSimple. The BP monitor will The BP monitor will upload your readings onto a private cloud that you can access by downloading the CareSimple app on your smartphone.
  You may keep the device even after the study is over.
  - ○ We'd like you to engage in blood pressure measurement at a frequency your care team recommends. If your blood pressure is above your goal, they may recommend that you measure twice a day.
    Once your blood pressure is lower, it may just be once a week.
- CareSimple will save data such as your name, blood pressure values, contact information that you choose to provide, and other information related to your health that you choose to provide, such as dietary preferences and smoking behaviors.
- Data is stored on private databases in the U.S.
- Only authorized study staff will have access to this data. Data is accessible only by logging into the CareSimple platform which requires log-in credentials that the user creates, and only authorized users will get a link to set up credentials.
- Your data will be stored for 24 months, then destroyed after.
- Randomization: This study has different groups. You will be put into a group by chance. How your group is chosen is like flipping a coin or rolling dice.
  - ○ If you are in **group 1,** you will receive training on how to use a blood pressure monitor, SMS text or app messages about hypertension management, and training about how to transmit blood pressure values to your care team.
  - ○ If you are in **group 2,** you will receive the same strategies as group 1, in addition to receiving support and SMS text or app messages to encourage you to engage support persons and attend group sessions. You will be asked to attend four group education sessions that are inperson or online. You may attend more than four group sessions if you'd like. Your caregiver is also welcome to attend.
- During the study, we will ask you to complete a phone-administered survey to understand how much patients need to spend (e.g., time, resources, money) to manage their hypertension. The survey will take about 30 – 45 minutes and we will ask you the survey questions over the phone. We will audio record the interview for accuracy. Recordings will not be tied to your information and will be deleted upon study completion.

7.2. Follow-up procedures

After the study ends, the study team will continue to review your medical record for 18 months to see how you are doing.

7.2.1. Where do the procedures happen?

Study procedures will be done at the San Francisco Health Network.

7.2.2. Will clinically relevant research results be shared with me?

Yes, if you have an abnormally high or low blood pressure reading, we will alert you and your care team.

8. What are the risks of this study?

Risks related to this study include:

- **Randomization risks:** You might be put into a group that receives something that is not as effective as another group.
- **Timely follow-up** for patients with abnormally high or low blood pressure readings
- Discomfort with **using blood pressure cuff**
- If randomly assigned to Group 2, discomfort **with attending group sessions**

9. Will I be paid if I take part in this study?

Yes, you will be paid in return for your time and effort. The amount you will be paid depends on which study activities you're asked to complete.

A company called Greenphire is working with this study to pay participants. Greenphire will need to collect some personal information (name, email address, mailing address, date of birth, and phone number) from you to set up your payment account.

If you are randomly assigned to **Group 1,** you will be paid $120 in total.

- Baseline visit: $30
- Patient cost interview: $25
- Exit visit: $65

If you are randomly assigned to **Group 2**, you can earn up to $150 in total. In addition to the baseline and exit visits, you will be paid for each group session you attend. If you attend more group sessions, you will not receive more incentives. If your caregiver attends, they will not receive incentives.

- Baseline visit: $30
- Patient cost interview: $25
- Group session 1: $10
- Group session 2: $10
- Group session 3: $10
- Group session 4: $30
- Exit visit: $35

10. Will I be reimbursed for expenses if I take part in this study?

This study does not involve any expenses to research participants.

11. How will my information be used?

Researchers will use your information to do this study. Once the study is done, we may use your information for other research studies in the future. We may share it with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information.

12. How will information about be kept confidential?

If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. However, we cannot guarantee total privacy. Some information from your medical records may be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. People involved with your future care and insurance may become aware that you participated in this study. They may see information added to your medical record. Study tests and information obtained from you will be part of your research records. This information may be added to your medical record. Your personal information may be given out if required by law. Information from this study may be published or presented at scientific meetings. If it is, your name and other personal information will not be used.

12.1. Who may review my research information?

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the Sponsor (Agency for Healthcare Research and Quality)

13. Does this study involve testing of diseases and conditions that must be reported to the public health department?

No, this study does not involve testing for reportable diseases and conditions.

14. What happens if I am injured or feel harmed because I took part in this study?

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

14.1. Treatment and Compensation for Injury

If you get hurt because of this study, the University of California will give you medical treatment that you need. You might have to pay for this treatment, or your insurance might pay for it. It depends on different things. The University or the study sponsor might pay for the medical costs instead. But usually, they don't pay for other things besides medical care if you get hurt. If you want to know more, call the office of the Institutional Review Board at 415476-1814.

15. Are there any costs to me for taking part in this study?

No. There is no cost to you or your insurer if you take part in this study. However, you may need to pay for items such as parking and transportation.

You or your insurer will be billed for the costs of any usual medical care you receive outside of this study. You will also be responsible for any deductibles or co-payments for these usual medical care costs.

16. Can I stop being in the study if I want to?

Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team so they can discuss any risks of stopping with you. They can tell you what follow-up care and testing could be most helpful. The study team will help you stop your participation safely.

If you stop being in the study, any data we have already collected will remain part of the study records. The study team may still get information from your medical records if it is important to the study. This information may include information like laboratory results, treatment courses, or health outcomes. If you do not want this information to be collected after you decide to stop being in the study, you must tell the study team.

17. Can I be removed from the study by the Principal Investigator?

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

18. What are my rights if I take part in this study?

You may choose to take part or not to take part in this study. It's your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Leaving the study will not affect your medical care. You can still get your medical care from our institution. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

19. Who can answer my questions about this study?

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 415-476-1814.

19.1. Where can I get more information about this study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

20. Consent

You will be given a copy of this form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say “No” to this study now or at any point without penalty.

If you wish to take part in this study, please sign below.

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent

_____ _____