



GENERAL WRITTEN CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**TITLE OF STUDY: Comparative Effectiveness Study of Technologies to Promote Blood Pressure Control**

**INVESTIGATOR:**

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**PURPOSE:** You are being invited to participate in a research study conducted by the University of California, Berkeley. Participation in research is completely voluntary. The purpose of this study is to compare coaching and two different technologies that encourage healthy lifestyle changes. The study will be with people who have been diagnosed with high blood pressure. Your time on the study will take a total of about 4 or 8 hours depending on the group you are matched with. Risks or discomforts are low and include interrupting your daily schedule, feeling uncomfortable with the topics discussed, or getting injured while being more active. You may not directly benefit from this research study, however your blood pressure may improve if you choose to be in this study. If you agree to be in this study, you will be asked to do the following:

**PROCEDURES:** You will be "randomized" into one of the study groups described below. We will use a random number generator to randomly assign you to one of the two groups in this study. Randomization means that you are put into a group by chance. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in 1 of the 2 groups.

- If you are in Group 1, you will work with a student coach, get education about lifestyle changes you can make, and be taught how to use home blood pressure monitoring. You will also continue getting routine care from your doctor. You will come to the research center when you start the study to answer questions. At the first meeting, you will meet with a student coach who will discuss your lifestyle goals and will also train you to use a home blood pressure monitor and how to enter your blood pressures to keep track of them yourself. Once you choose a goal for lifestyle change, the coach will set up times to meet or call so they can support you and motivate you to reach your goal over the 9 month study. We expect you will meet with the coach about 6 times in person and have some telephone calls as well. Besides getting a student coach, nothing changes in the care you receive from your doctor. You will continue to have blood pressure checks at the

doctor's office when you go to get your routine care. In addition, you will be asked to regularly check your blood pressure at home with your home blood pressure monitor. If you are placed in Group 1, your participation in this study will take about 8 hours total over 9 months. The study will take place at our research center and at your home. During your first visit, you will be gifted a digital BP monitor, cuff, and user materials and the American Heart Association blood pressure numbers tracking system. The monitor and cuff you get at the first visit have a value of \$50. You will also receive \$25 gift cards from Amazon, Target, or Safeway (given based on gift card we have in stock) at each of the second and third visits.

- If you are in Group 2, you will receive lifestyle education at UC Berkeley and a physical activity/lifestyle change phone app or website. You will continue getting routine care from your doctor. You will come to the research center when you start the study to answer questions and have your blood pressure taken. The research assistant will go over ways you can reduce your blood pressure and help you choose a goal for the next 9 months. We will help you download an app on your phone or give you an online website to use related to the health goal you choose. This program lets you take your lifestyle changes into your own hands. We will schedule visits to recheck your blood pressure at months 6 and 9. Nothing changes in the care you have been told to receive from your doctor. You will continue to have your blood pressure checked at your doctor's office when you go to get your routine care. If you are placed in Group 2, your participation in this study will take about 4 hours total over 9 months. The study will take place at our research center. We will pay you \$50 as a gift card at the first visit and give you a \$25 gift card at each of the second and third visits from Amazon, Target, or Safeway, whichever we have available.

**BENEFITS:** You may not directly benefit from this research study, however your blood pressure may improve if you choose to be in this study. Also, the information you provide may help other people to control their high blood pressure in the future.

**RISKS:** If you choose to participate in this study, there is low risk to you.

- Physical risks: Student coaching may be misunderstood as regular medical care. To minimize this risk, we confirm student coaching is not medical care and does not replace scheduled appointments with your regular doctor.
- Injury risks: If you choose physical activity as a goal, you may be injured (example: falling while being active). To minimize this risk, we recommend if you are able to be active, to only participate in walking or stretching. We also will ask for permission to assess you for ability to be active. We will use PAR-Q, a Physical Activity Readiness Questionnaire, to assess your ability to be active. We will provide contact information for you to call if you are injured because of participating in this study and need medical treatment.
- Psychological risks: Blood pressure check-ins with the student coach could interrupt your daily routine or the student coach may not be the best fit for you. To minimize this risk, we will ask for your general experiences with your student coach, and we will connect you with a new student coach if your student coach is not a good match for you. Coming for blood pressure check-ups could interrupt your daily routine. To minimize this risk, we will work with you to schedule blood pressure checks with the research team that work for your daily routine.
- Social risks:

- You may feel a loss of privacy from working with us and giving us your health data or having a student coach in your home. To minimize these risks, we will keep the data you give us in a secure and safe place, and your student coach receives ongoing development and training to provide appropriate support.
- You may feel uncomfortable or upset by some topics that are discussed in the program, or you may feel judged for having high blood pressure. To minimize these risks, we will be sure that phone calls and face-to-face interactions with your student coach are in private, safe spaces chosen by you and your student coach.

**CONFIDENTIALITY:** As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk. Your participation in this study and anything you say will be kept as confidential as possible. Your doctor will not know if you participate or not. Your doctor will not receive information from the interview visits. We do everything we can to keep your name from being connected with results of this research study. Your name will not appear in any reports or statistics about the study. Your information will be kept in secure, protected files or locked cabinets. I will retain this data for up to 5 years after this study is over. The same measures described above will be taken to protect confidentiality of this study data. I will destroy anything with your name on it at the end of the 5 years.

**COMPENSATION:** In return for your time and effort, you will be compensated with \$100 or the equivalent of \$100 for participating in this study for a full 9 months.

**RIGHT TO REFUSE OR WITHDRAW:** *Participation in research is completely voluntary.* You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

**QUESTIONS:** If you have any questions or concerns about this study, you may contact Dr. Susan Ivey at (510) 462-2088 or email [health.research.action@gmail.com](mailto:health.research.action@gmail.com). If you have any questions or concerns about your rights and treatment as a research subject, you may contact the office of UC Berkeley's Committee for the Protection of Human Subjects, at 510-642-7461 or [subjects@berkeley.edu](mailto:subjects@berkeley.edu).

**CONSENT:** YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM AND OF THE MEDICAL RESEARCH SUBJECT'S BILL OF RIGHTS TO KEEP. THIS STUDY DOES NOT TAKE THE PLACE OF YOUR REGULAR MEDICAL CARE. IF YOU WISH TO PARTICIPATE IN THIS STUDY, PLEASE SIGN BELOW.

YOUR SIGNATURE BELOW INDICATES THAT YOU AGREE TO VOLUNTEER AS A PARTICIPANT IN THIS RESEARCH STUDY. **THIS DOES NOT TAKE THE PLACE OF YOUR REGULAR MEDICAL CARE.**

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Participant's Name (please print): \_\_\_\_\_

Signature of Participant: \_\_\_\_\_ DATE: \_\_\_\_\_

The purpose of the research study has been explained to me to my satisfaction. I have had the opportunity to ask questions and to have my questions answered. I voluntarily agree to participate in the research study. I understand this is a research study and not medical care. I will continue to seek the routine medical care as recommended by my medical doctor.

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**FOR RESEARCHER:**

Signature of Researcher: \_\_\_\_\_ DATE: \_\_\_\_\_

I have explained the material above to this participant and he/she acknowledge his/her understanding.