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Comparing technology and health coaching for blood pressure control

Submission date	Recruitment status	[ ] Prospectively registered
14/04/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/05/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/05/2023	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

In the US, nearly 50% of adults have blood pressure (BP) over 140/90 mmHg, and many have uncontrolled hypertension associated with increased risks for cardiovascular disease. Many medical groups are not well-resourced to support hypertensive patients in making lifestyle changes; lay health coaches trained in health coaching can help support them. This study aims to investigate health coaching benefits to improve health for more individuals. The study will create a robust partnership with a local medical group to use their existing hypertension registry to identify research subjects with uncontrolled hypertension, including regular meetings and communication with the partner; and, design and run an effectiveness study to compare behavior and lifestyle change interventions to reduce systolic BP in a group of research subjects with uncontrolled hypertension.

Who can participate?

Healthy adult volunteers aged between 18-80 years old who were told in the last 12 months that their BP was over 140/90 mmHg

What does the study involve?

Participants are recruited via patient portals, mailing lists from the patient populations of a local federally-qualified health center, local hospital system, and community flyering. Patients or community members, who are interested, contact the study. These individuals will be screened for eligibility; if they are eligible and provide informed consent, they become participants in the study. Participants are randomly allocated to one of two Arms during intake. Each participant (both Arms) is in the study for a period of 9 months, starting from the day of their intake survey and BP measurements. In Arm 1, participants are paired with health coaches and given digital BP cuffs with coaching sessions or check-ins every 2-4 weeks. In Arm 2, participants are given the names of suggested mobile applications for lifestyle change and general health education information. Participants in both Arms complete follow-up surveys and submit BP measurements at 6-month and 9-month marks. Once a participant completes the 9-month survey and BP measurements, they have completed their time working with the study.

What are the possible benefits and risks of participating?

Participants in both Arms may benefit directly by receiving health education and access to

technology during the initial visit. Arm 1 participants may benefit by receiving a digital BP cuff and learning to measure their own BP at home, counseling to help them with lifestyle behavior change, and coaching on home blood pressure monitoring and readings. This research may benefit other people with high BP in the future if it is demonstrated that lay coaching is an effective tool for supporting the management of high blood pressure. The main risks are coaching being misinterpreted as “medical care,” participant-coach pairs not being a good fit, and hypertension possibly being stigmatized. Therefore, consent forms and all communications announce that this is a study and not part of routine care. Participants can be reassigned to a different coach if they are not satisfied with the initial pairing, and compassionate coaching is coupled with the assurance that participant information is kept as confidential as possible.

Where is the study run from?
Health Research for Action (HRA), an affiliated research center of the School of Public Health at the University of California, Berkeley (USA). The study took place in the HRA office space before COVID-19, then virtually and in a local health system after the COVID-19 pandemic.

When is the study starting and how long is it expected to run for?
February 2019 to June 2023

Who is funding the study?
Dr Jeffrey Thomas Stroke Shield Foundation (JTSSF) (USA)

Who is the main contact?
Dr Susan L. Ivey, Director of Research, Health Research for Action, sivey@berkeley.edu (USA)

Contact information

Type(s)
Principal investigator

Contact name
Dr Susan Lee Ivey

ORCID ID
https://orcid.org/0000-0002-8921-7032

Contact details
School of Public Health
2121 Berkeley Way West
University of California
Berkeley, California
United States of America
94720-1650
+1 510-643-1883
sivey@berkeley.edu

Type(s)
Public

Contact name
Dr Susan Lee Ivey

Contact details
School of Public Health
2121 Berkeley Way West
University of California
Berkeley, California
United States of America
94720-1650
+1 510-643-1883
sivey@berkeley.edu

Type(s)
Scientific

Contact name
Dr Susan Lee Ivey

Contact details
School of Public Health
2121 Berkeley Way West
University of California
Berkeley, California
United States of America
94720-1650
+1 510-643-1883
sivey@berkeley.edu

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A comparative effectiveness study of technologies to promote blood pressure control

Study objectives
Does self-monitoring of blood pressure + health coaching reduce systolic blood pressure more than general lifestyle advice and the use of an app?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2019, University of California, Berkeley (Office for Protection of Human Subjects, 1608 Fourth Street, Suite 220, MC 5940, Berkeley, CA 94710-1749, USA; +1 510-642-7461; ophs@berkeley.edu), ref: 2019-04-12136

Study design
Interventional (two-arm unmasked) randomization 1:1 allocation single-center study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Hypertension

Interventions
ARM A: Subjects in intervention Arm A receive a full 9 months of health coaching (including in person and telephone contact), lifestyle education, and support for home blood pressure monitoring (the study provides the digital monitor), with home BP data to be collected on their own monitor or through a community-facing portal feature supported through the American Heart Association's Check.Change.Control https://www.heart.org/en/health-topics/high-blood-pressure/find-highblood-pre ssure-tools--resources/check-change-icontroli-community-partner-resources. Note that we do not receive data/output from Check.Change.Control, as it is only for the subjects' personal use or to coordinate with their medical team. Participants receive reminder letters before the 6-month and 9-month data collection dates.

ARM B: Subjects in intervention Arm B receive an initial educational outreach intervention at baseline intake (Time 0), which includes a description of lifestyle changes that can improve BP (AHA materials about high blood pressure are provided), provision of a physical activity or lifestyle app/website to match their goal (see list uploaded), and blood pressure rechecks by the research team at 6 and 9 months. There is no contact with subjects in between data collection time points except for the reminder letters for 6-month and 9-month visits. This arm is "on their own with their free app/website." During the pandemic, we substituted alternative ways to submit blood pressure readings for Arm B because the university did not permit in-person data collection between March 2020 and October 2020.

ARM A AND B: Both groups also continue receiving usual care from their physician/health care team as per guidance from their primary care doctor. We emphasize this repeatedly. Student coaches provide consistent lifestyle coaching (motivational interviewing, support calls, help setting goals) and are not expected to monitor any of the person's medical care. They are trained to use a digital blood pressure cuff and to train the Arm A subjects to use their home digital monitor and an appropriately sized cuff. They will encourage the subjects to call any home BP readings over 180/110 mm Hg to their own physician's office. Coaches have regular contact with subjects and discuss lifestyle changes and home BP readings with their participants. Since March 2020, we have had a protocol to use virtual BPs as data during the COVID-19 pandemic since the coaches already trained people in Arm A to do their own BPs. We added the choice to submit other measured blood pressures (nurse, physician, pharmacist) during the shelter-in-place period if participants chose not to have a measured BP in person.

WHO? We recruited residents from Alameda and Contra Costa counties (California) who had been diagnosed with high blood pressure. These people are 18-80 years of age, including men /women/diverse populations, and have had at least one medical visit in the last 12 months and have a measured BP of >140/90 mm Hg (defined as "uncontrolled hypertension") posted in the practice's registry. We only included English speakers during the initial phase of the research, but later added a small group of Spanish speakers. We did not include pregnant women as hypertension is managed differently in pregnancy. In order to use the Check.Change.Control portals or apps, subjects had to either have access to a smartphone or to a computer. To participate in any walking/stretching (advice on physical activity) they were screened for readiness using the PAR-Q physical activity readiness. Subjects can still participate in dietary, smoking cessation, or stress reduction goals regardless of ability/disability for ambulation so this would not exclude them from the study. Beginning in March 2021, Spanish-speaking people from Alameda and Contra Costa counties who had been diagnosed with high blood pressure were recruited. We used the same eligibility guidelines that were used for our English-speaking participants. In June 2021, we believed that it was safe to move the recruitment age back to age 75 given lower rates of COVID and high rates of vaccination. In Jan 2022, we increased the age maximum to 80 years of age as nearly all seniors in our area were immunized.
HOW? Prior to the pandemic onset, the head of Population Health at Lifelong Medical Care (a federally qualified health center) collaborated with us to select the original sample of eligible people from an existing hypertension registry. All persons during this stage were drawn from the practice's registry; Lifelong sent a flier about the study (we received no patient data). As the pandemic unfolded, we added a second partnership with Washington Hospital and Health System (WHHS) the following year. They sent letters inviting people to participate. We also put up flyers in local communities to maintain additional recruitment strategies to reach an adequate sample size.

At practice sites, we provided a recruitment letter template that each practice mailed/messaged to eligible patients. People who get a flier from the medical practice/site then call UCB's recruitment warmline, leaving information on voicemail if they would like to participate or are instructed that they can email the project. During certain daytime hours, staff are available to answer calls, but there was available voicemail if people call after regular working hours. Participants calling hear either the recorded voicemail about the study (with an opportunity to leave contact information for staff to call back) or staff will pick up the phone and go through the eligibility criteria. Staff call individuals who leave contact information back during regular working hours ~ 5 days/week. Once we have the potential subject on the phone, the staff assesses eligibility for the study using the screening criteria above, including assessing English language fluency and the person's understanding that this is a research study with 2 arms that involves randomization ("an equal chance to get one intervention or the other"). If ineligible, we will thank them for their time and will not retain any personal information. If the subject is eligible, volunteers for the study, and agrees to randomization, staff or students then fully consent eligible individuals for randomization at that time and schedule a visit for intake for either Arm A or B. We offered options to come in for that consent and randomization process too, prior to the pandemic. All eligibility, consenting, randomization, and surveys were re-created in virtual formats (online or via telephone) for use during the pandemic. In March 2021, we expanded social media recruitment methods by reaching out to CBOs, churches, and other local organizations. In April, we uploaded a social media recruitment message template to introduce the study via email or phone call and asked organizations to post on their social media outlets (e.g., Facebook, Twitter, etc). If willing to post, organizations were provided study recruitment information in a social media-friendly format.

RANDOMIZATION. Participants were randomized using a random number generator with 1:1 randomization to 2 arms. If people were eligible and volunteered, we conducted the

randomization after consent to be randomized using a random number generator. There were equal chances to be randomized to A or B arms (1:1 allocation).

LEAD: The lead provider is Dr. Susan L. Ivey, MD, MHSA who is trained and board-certified in family medicine (American Board of Family Medicine; ongoing every 10 years; most recent certification from ABFM is 2015-2025). She also has a Master's in Health Services Administration with 2 years of postdoctoral research training. She trained the project director in all research procedures and in all COVID-related protection policies. Both Dr Ivey and Ms Vien completed the University of California, Berkeley, COVID protection policies (certification). All students and investigators are trained in human subject protection (CITI certified). All students undergo training in the use of the digital blood pressure cuff and how to coach a participant to use the digital device regularly. Similarly, all students are trained in motivational interviewing techniques for lifestyle change (physical activity, healthy diet, smoking cessation, sodium reduction). Students are tested on motivational interviewing use following training using vignettes tailored for common study scenarios. Students are only allowed to coach after they have successfully demonstrated competence on at least 2 vignettes. If they do not succeed in the first test, they are retested after reinforcement training. Students also received training in the use of protective equipment when face to face with participants during COVID, were asked to undergo weekly testing when coaching or doing data collection, and were provided with all PPE (masks, gloves, hand gel, face shields) during the peak of the pandemic. We also asked students to receive vaccination against COVID to protect participants.

DELIVERY: The modes of delivery for our interventions were a mixture of face-to-face, internet, and over the telephone. The intervention was provided primarily in an individual setting. In intervention arm A, each of the participants was matched to a personal health coach. The health coach provided the health-coaching intervention throughout the study period and met regularly with the participant. While intake appointments happened in person at the beginning of the study period, the COVID-19 pandemic, especially during the shelter-in-place that started in March 2020 in Berkeley, CA, prevented in-person appointments from happening. Thus, most meetings between health coaches and participants took place remotely either via the telephone or the Internet since the beginning of the shelter-in-place order during the pandemic. The intervention consisted of motivational interviewing sessions and check-in sessions between the health coach and participants. The interventions allowed the health coaches to help their participants identify behavioral goals at the beginning of the study period, and work towards their respective goals throughout the 9-month study period.

LOCATION: Prior to the COVID-19 pandemic, participants were enrolled and consented to have their initial surveys and BP recording at Health Research for Action (HRA), a research center at UC Berkeley, CA, USA. Following the shelter-in-place order in March 2020, in Berkeley, CA, our study was restricted from new enrollment for 7 months. After enrollment restarted in Oct. 2020, we re-started our in-person appointments between participants and health coaches in 4 locations: Washington Hospital Healthcare System (WHHS) in Fremont, CA, our study location at HRA, UC Berkeley, at Dr Ivey's medical office in Berkeley, and in outdoor settings adjacent to the UC Berkeley campus (public meeting spaces as mutually agreed on by our health coaches and participants). However, since the COVID-19 pandemic, most of our intervention administration (i. e., motivational interviewing and intake appointments between participants and health coaches) still occurred virtually with permission from the IRB. Remote locations where the intervention occurred consisted of telephones and over the Internet.

Intervention Type
Behavioural

Primary outcome(s)
Change in systolic blood pressure measured using an FDA-approved digital blood pressure device with a cuff used on the upper arm at baseline (0 months), 6, and 9 months

Key secondary outcome(s))
Lifestyle changes measured using survey responses at baseline (0 months), 6, and 9 months:
1. Dietary behaviors measured using the Self-care of Hypertension Inventory (SC-HI) scales of maintenance, monitoring, and management
2. Physical activity measured as minutes of physical activity per week

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Aged between 18-80 years old
2. Previously told blood pressure was over 140/90 in last 12 months in a physician visit
3. From Alameda or Contra Costa County, CA
4. Speaks English or Spanish
5. Able to provide consent for themselves

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
124

Key exclusion criteria
1. Pregnant women
2. Being treated for cancer
3. Cognitive impairment that prevents giving their own consent

Date of first enrolment
17/10/2019

Date of final enrolment
28/07/2022

Locations

Countries of recruitment
United States of America

Study participating centre
UC Berkeley School of Public Health
Health Research for Action
2199 Addison Way
Suite 435 University Hall
University of California, Berkeley
Berkeley, California
United States of America
94720-7360

Sponsor information

Organisation
Dr. Jeffrey Thomas Stroke Shield Foundation

ROR
https://ror.org/051bjph87

Funder(s)

Funder type
Charity

Funder Name
Dr. Jeffrey Thomas Stroke Shield Foundation

Alternative Name(s)
Jeffrey Thomas Stroke Shield Foundation, Stroke Shield Foundation, Dr Jeffrey Thomas Stroke Shield Fdn, Dr Jeffrey Thomas Stroke Shield Foundation, Stroke Shield Fndn, The Stroke-Shield Foundation, JTSSF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			09/05/2023	No	Yes
Participant information sheet			09/05/2023	No	Yes
Participant information sheet			09/05/2023	No	Yes
Participant information sheet			09/05/2023	No	Yes
Participant information sheet			09/05/2023	No	Yes