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DOCUMENT DATE (IRB APPROVAL):

17-Jan-2024

NCT NUMBER:

NCT04863378

OFFICIAL STUDY TITLE:

Efficacy of a Technology-Based Multimodal Brain Health Intervention for Older African Americans

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STUDY00022363

Protocol Title

Efficacy of a Technology-Based Multimodal Brain Health Intervention for Older African Americans

Objectives

The Sharing History through Active Reminiscence and Photo-imagery (SHARP) programs are a culturally relevant, celebratory, multimodal approach to maintaining brain health through physical, social, and reminiscence activity. This study intends to:

Aim 1) Refine existing SHARP digital technology and test feasibility and efficacy of new biomarkers.
Aim 2) Using the technology refined in Aim 1, develop 10 walking routes and 30 Memory Markers for gentrifying neighborhoods in Oakland.

Background

Black Americans have a higher risk than other Americans of cognitive decline, including Alzheimer's disease.[1,2] Depression and anxiety, modifiable risk factors, exacerbate decline in Black Americans[3] and increase risk of progression from mild cognitive impairment (MCI) to dementia.[4] Lifestyle and psychological interventions, including multimodal approaches to physical activity, social engagement, and Reminiscence Therapy (RT), may mitigate risk and promote brain health. Neighborhood walking and social engagement decrease anxiety and depression,[5,6] linked to higher cognitive function and slower cognitive decline.[3,7] Systematic reviews and meta-analyses of RT effectiveness in older adults show it improves loneliness, anxiety and depression.[8-10] However, most research has involved predominantly White older adults.[11] A lack of validated, culturally specific, multimodal approaches to empower physical, social, and reminiscence activity for Black adults contributes to ongoing untreated or poorly managed deficits in physical and social activity. Ultimately the results are poorer physical, social, cognitive, and mental health. Cognitive health experts identify this need for culturally specific strategies.[12,13] An intervention's cultural milieu is critical, as in gentrifying neighborhoods wherein remaining Black residents experience cultural displacement and decreased neighborhood social cohesion,[14,15] contributing to diminished physical and social activity important for brain health.[16]

Black communities in Portland and Oakland, are being displaced through rapid gentrification.[20,21] Gentrification- related displacement of family, neighbors, and familiar services degrades neighborhood interdependence endangers opportunities for social engagement,[22] and reduces motivation to engage in neighborhood-based physical and social activity important for cognitive health and successful aging in place.[16] Dwindling social networks lead to depression and anxiety, related to more rapid cognitive decline and increased Alzheimer's disease and related dementias (ADRD) risk.[16] This style of SHARP study engages the population most vulnerable to gentrification and ADRD. SHARP integrates brain-healthy behaviors of walking, social engagement, and Reminiscence Therapy (RT) to address multiple modifiable cognitive decline risk factors including isolation, depression, and anxiety.[17]

Regular walking slows global cognitive decline[23] and has contributed to reversion to normal cognition from mild cognitive impairment (MCI).[24] MRI studies of healthy and MCI older adults showed that physical activity, including walking, had a protective effect on brain structures sensitive to neurodegeneration (i.e., AD pathology), and physical activity interventions sustained for as little as 3-6 months had protective effects on the hippocampus, important for memory.[25] Social engagement sustains or improves cognitive reserve.[25] Less social engagement is

associated with greater amyloid-β-related preclinical Alzheimer's cognitive composite (PACC) score decline while higher social engagement is associated with relative preservation of PACC scores.[26] RT is an empirically validated therapeutic treatment effective with older adults for improving (and preventing) anxiety, loneliness, depressed mood,[27-30] life satisfaction and quality of life.[31] RT promotes coping,[32] important for older Black adults adjusting to neighborhood changes.17 Group RT, proposed for this KL2, reduces depressive symptoms in AD patients,[33] and in African Americans.[34] Technology enabled RT, as proposed here, improves social interaction,[35,36] and has retained older adult participation.[37]

Study Design

This is a feasibility study. For Aim 1 Triads will walk the SHARP application's one-mile looped routes 3 times per week for 16 weeks. Participants continuously wear an actigraph watch and sleep on an under the mattress sleep sensor. Routes have Memory Markers, GPS-triggered images of local Black history and culture, to prompt conversational reminiscence as triads walk. The app records route, date, pace, distance, time, and conversation, auto-uploaded to our secure database on a protected OHSU server. The study team will refine app data collection, navigational interface and prompt display, the route programming platform, and any confusing navigation and prompts per feedback in pilots.

For Aim 2 the study team will conduct focus groups with 4 Black community stakeholders to identify cultural landmarks. Those interviews will be used to prompt image acquisition and the creation SHARP routes in Oakland California.

Study Population

a) Number of Subjects

For Aim 1 three triads (n=9 individuals aged >65; n=6 cognitively healthy, 3 Mild Cognitive Impairment (MCI) will be enrolled. We expect to consent and screen up to 18 people to find 9 people who are eligible.

For Aim 2 the study team will interview 4 Black community stakeholders in Oakland.

b) Inclusion and Exclusion Criteria

Aim 1

Eligibility Criteria

1) Self-identified African American,
2) Age $\geq$ 65 years old,
3) Reside or resided for $\geq$10 years in Portland's historically Black neighborhoods (to be familiar with Memory Markers about this area),
4) Able to ambulate independently.
5) Meeting Cognition Criteria
   (a) Participants (n=3) with MCI will meet criteria consistent with those defined by Jak et al.[16] and with the criteria outlined by the NIA-Alzheimer's Association workgroup,[17] OR
   (b) Participants without cognitive impairment (n=6) will have a Montreal Cognitive Assessment (MoCA) score $\geq$ 24 (and not meet MCI criteria). Participants' cognitive function should allow them to get to and from walk locations independently or with minimal assistance.
6) Cognitive function allows independent (or minimally assisted) travel to and from walk locations
7) In-home reliable broadband internet (for weekly online surveys).
8) Ability to read, speak, and understand English

Exclusion Criteria

1) Self-reported or clinically diagnosed dementia
2) Significant disease of the central nervous system
3) Severely depressed (CES-D score > 16), significantly symptomatic psychiatric disorder
4) Advanced cardiovascular disease that would make walking difficult, including history of congestive heart failure
5) Unstable insulin-dependent diabetes mellitus, received diagnosis Type 1 Diabetes, started insulin within past 3 months, hospitalized for hypoglycemia within past 6 months.

Aim 2

For the individual community stakeholder interviews, any participants identifying as Black community stakeholders will be enrolled, as referred to the PI by UC Davis' David Johnson and by African American Museum and Library at Oakland.

c) Vulnerable Populations

Eligibility criteria require that participants have normal cognition or MCI, based on the Montreal Cognitive Assessment (MoCA). Subjects with MCI have no more than minimal cognitive impairment are not decisionally impaired and are fully able to provide informed consent. No vulnerable populations will be included.

d) Setting

Orientation, and walking (aim 1) will take place in the historically Black neighborhoods of N/NE Portland. Analysis of the app, digital biomarkers, and survey data will be done at OHSU. The stakeholder interviews will be done in-person (and by phone if the first option is not available) by the study team and will occur in community settings in Oakland.

e) Recruitment Methods

Aim 1 Participants will be enrolled from similar studies, for example The NIA-Oregon Center for Aging and Technology's Life Lab cohort and the African American Dementia and Aging Project (a cohort study of the NIA-Layton Aging & Alzheimer's Disease Center, of which there are 62 eligible participants, 19 who currently have MCI). Participants will also be recruited from existing SHARP study networks within Portland's Black community who may or may not be currently enrolled in other ORCATECH studies. Other sources of recruitment include churches, community organizations (Passin Art African American theatre group friends and family; AARP Portland African American Chapter; Delta Sigma Theta Sorority and others; Men's Health Project, Black Men's Coalition, African American Health Coalition) and by word of mouth.

Aim 1 Participants may also be recruited through PreSERVE Coalition for African American Memory and Brain Health community events and the Coalition's partners who serve a large African American contingent and who have already demonstrated interest in the SHARP program: Providence Elderplace, Urban League of Portland, AARP Portland Chapter, Delta Sigma Theta Sorority, The Portland Chapter of The Links, Inc. Triads in will be formed by participants inviting eligible friends to join their team and/or by the research team matching participants. Every effort will be made to match triads of similar fitness level and walking speed. Participants will also be recruited via announcements from the SHARP Community Advisory Board and PreSERVE Coalition for African American Brain Health.

For Aim 2 participants will be identified by representatives from UC Davis Alzheimer's Disease Center and the African American Museum Library at Oakland (AAMLO).

Aim 1 Participants will be compensated $15 gift card per weekly online survey and $25 gift card per focus group, totaling up to $435 per each of 9 participants. Aim 2 participants will be compensated $50 gift card per interview.

f) Consent Process

For Aim 1 participants' permission will first be obtained via a paper information sheet in person or in the mail, or electronically using REDCap to conduct a MoCA to screen for eligibility. If the participant meets inclusion criteria, a second consent form describing the remainder of the study procedures will be given to the participant. The study team will find a time and place agreeable to the participant to review the details of the consent form either in person, over the phone or through OHSU approved videoconferencing software. The study team will assess subject consent comprehension by asking questions to confirm the potential participant understands the following:

- Nature of the research and the information relevant to his/her participation;
- Consequences of participation for the subject's own situation, especially concerning the subject's health condition;
- The difference between research and clinical care (avoiding therapeutic misconception);
- Available alternatives to participation and their consequences;
- Potential risks involved in the study;
- Procedures to follow if he/she experience discomfort or wishes to withdraw; and
- The voluntary nature of participation.

If a potential subject cannot sufficiently answer these questions, they will not be enrolled. Subjects will be reminded participation is voluntary and research is will not replace regular care. Once all questions have been answered the participant be invited sign the consent form.

Participants will also have the opportunity to complete a remote consent process. A paper consent form and stamped and pre-addressed envelope will be mailed to participants. The study team will complete the consent conversation described above over the phone or through OHSU approved videoconferencing software. Once all questions have been answered the participant will sign the consent form and mail it back to the study team. A copy of the signed consent form will be given to the subject immediately over email and in paper copy as soon as possible.

If participants elect to complete the consent process electronically, the study team will complete the consent conversation described above over the phone or through OHSU approved videoconferencing software. Once all questions have been answered the participant will sign the electronic consent form. A copy of the signed form will be will be given to the subject during orientation. REDCap will be used for completion of electronic consent forms. Oregon Center for Aging and Technology personnel trained in REDCap survey will build and test the consent surveys.

After consent, participants will receive a Welcome Letter via email, and the PI (Dr. Croff) will contact each participant via telephone to introduce herself and offer a personalized welcome.

Modifications to the Consent Process

For the screening MoCA we are requesting a waiver of documentation of consent. These interviews present no more than minimal risk to participants. The purpose of the study, procedures, risks, benefits, and alternatives will be discussed. Subjects will be given adequate time to ask questions before the test begins.

The stakeholder interview participants will be provided an information sheet. We are requesting a waiver of documentation of consent. These interviews present no more than minimal risk to participants. The purpose of the study, procedures, risks, benefits, and alternatives will be discussed. Subjects will be given adequate time to ask questions before the interview starts.

Procedures

AIM 1 Cognitive Screening

After consenting to complete cognitive screening for eligibility using the Montreal Cognitive Assessment (MoCA), the MoCA will be administered by trained personnel either in person using paper copy in a private location convenient to the participant or remotely via OHSU approved teleconference platforms and according to the MoCA guidelines for remote testing at https://www.mocatest.org/remote-moca-testing/ The MoCA may be used, reproduced, and distributed without permission by universities, clinics, hospitals, and health professionals. Participants' scores will be explained to them, and given to them on a piece of paper for their reference, and they will be told if they are eligible to participate in the study.

Baseline Surveys

After the MoCA, and with the Research Coordinator/Assistant present, consented participants will take baseline surveys (Demographic, Technology Use, Health, PSQI (Pittsburgh Sleep Quality Index) on a study-provided Chromebook, via a secured REDCap or Qualtrics platform. Weight and blood pressure will be measured in a private setting.

AIM 1

After consent has been obtained, participants will be given an actigraph watch, sleep sensor, and Chromebook on which to access weekly online surveys. Participants will receive instruction about these devices either individually or in a group setting, either in person or via phone or teleconference. These devices will collect baseline data for up to 8 weeks. Prior to commencing neighborhood walking at approximately study week 8-9, participants will attend a 1.5-hour orientation and training session, held in a neighborhood setting close to our first route's starting point (N. Williams Ave and NE Stanton Street).

The purpose of the training session is to:

- Introduce participants to the program and to one another.
- Answer any participant questions or concerns.
- Assist as needed to pair participants with walking partners.
- Establish walking schedules for each triad.
- Instruct participants on the use of technologies deployed:
- Demonstrate and instruct how to use the SHARP walking application (figure 3).
- Conduct an orientation walk with small-groups to familiarize participants with using the mobile walking application while on a real walking route.
- Baseline surveys may be administered at orientation if there were barriers to completing surveys during the consent visit.

Triads of adults will walk 3x/week for 16 weeks in North Portland's gentrifying neighborhoods, using the SHARP application. Walks will take up to 45 minutes. A tablet will be programed with the 72 mile long looped routes. To mitigate data loss and maintain walking despite any technology failures, triads have a back-up mini-binder of paper-copy routes (approximately same dimensions as on-screen versions) and a digital recorder (Olympus DM-720) clipped onto a participant's clothing or worn around their neck in a lanyard-style pouch. On at least one walk per triad video will be recorded in order to capture how participants interact with the tablet during walks. Recordings (video and voice) will be used for quality assurance, and some recordings (video and/or voice) may be used on the study's website to build awareness about healthy cognitive aging among Black/African Americans in Oregon. Each SHARP route has 3 Memory Markers, GPS-triggered images and questions of local Black history and culture that engage walkers in conversational reminiscence about Black life, history, and culture. The app records route, date, pace, distance, time, and conversation. Using the SHARP app, each participant checks in at walk start so individual engagement is trackable. A member of the research team will accompany groups during the first three walks, and more as needed.

Participants will wear an actigraph watch (Withings) on the non-dominant wrist to assess physical activity and sleep. A wireless, unobtrusive under-the-mattress sensor (Emfit QS) captures sleep quality and HR variability. This device enhances and validates sleep data collected by the actigraph watch. Weight will be obtained with a wireless bioimpedance bathroom scale. On a study provided Chromebook at home, a weekly survey via an ORCATECH established Qualtrics Survey Platform captures (1) Internal states (loneliness, low mood, pain level), (2) health events (falls, illness, ED and hospital visits, medication changes), and (3) cognition (episodic memory by querying past-week routes/memory markers). Survey completion times over the study's duration is another measure of cognitive change.

Additionally, an holistic measure of subjective sleep quality will be assessed using the Pittsburg Sleep Quality Index (PSQI), which assesses average patterns of sleep over the prior 30 days. The PSQI will be administered prior to the initiation of the walking program, and at week 4, 8, and 16-weeks into the program.

The study team will also conduct intermittent participant-researcher discussions (focus groups) at or near week 4, week 8, and week 16. Additionally, intermittent observational sessions throughout the 16 weeks, and surveys at focus group time points evaluate technology adoption, examine barriers to technology adoption and needed logistical refinements. MoCa testing will be repeated at month 4. At month 1, 3, and 6 will gather participant perspectives on program logistics and motivation factors. A brief exit interview via phone, teleconference, or in person as appropriate will capture barriers to program continuation with any withdrawing participants.

AIM 2

The study team will consult with representatives from UC Davis Alzheimer's Disease Center and the AAMLO to identify Black community stakeholders. 1 hour interviews will be held to gather details on salient cultural landmarks and themes. Interviews will follow a list of question prompts to collect information about historical figures and events. Follow up questions will be asked for clarity. We may also collect date and place of birth from interview participants as it is likely these stakeholders will live or have lived in Oakland area. When the interviews are transcribed any personal information beyond name, date and place of birth will be redacted. These interviews will be audio and video recorded. The study team will work with AAMLO to gather images documenting local Black history.

SHARP routes will then be created using the collected images and themes. Route creation will involve (1) assign images to identified themes, (2) design questions that resonate with images and themes, (2) identify images associated with specific addresses, (3) use Google Maps Street

View to locate addresses and configure 1-mile, looped routes, (4) Program routes and Memory Markers into the SHARP application using the ORCATECH platform[17] (5) walk routes to test various factors, and (6) refine routes.

Data and Specimens

g) Handling of Data and Specimens

AIM 1

Participant data will be labeled using a unique identifier (randomly generated numeric code). The information linking the code with participant names will be kept separate from research records. Only study personnel will have access to this information. All records will be stored in files in locked locations; computer files will be stored in on password-protected university systems. Firewall protections and password-restricted access will be used to prevent computer based breaches of privacy, per OHSU policy.

Walking route and conversational data is auto-uploaded to our secure database on a protected OHSU server. Study staff will use this data to refine the app including improvements to navigational interface and prompt display, the route programming platform.

Actigraph data are sent via Bluetooth LE to the OHSU hub computer, which securely transmits data to the Withings (HTTPS) and ORCATECH (VPN) servers. If the hub computer is unable to transmit data upon collection, data are cached locally in a MySQL table until internet connection is restored. Under the mattress Data is transmitted to the Emfit servers via HTTPS. Data are transferred to ORCATECH servers daily via Emfit API calls. Survey data are stored on Qualtrics servers, polled by ORCATECH servers via API calls.

AIM 2

The interview data, recordings, and images documenting Oakland local black history will be stored in an OHSU database. Access to these folders will be limited to the study team. Interviews may also be recoded and transcribed. If participants request interview recordings their contact information such as email will be collected during the interview. Contact information will be stored in this database.

h) Sharing of Results with Subjects

For Aim 1 participants some individual results will be immediately available for participants to review (walking data, weight). The survey data and aggregate data will not be directly shared with participants.

Data collected	Shared with Participants?	Comments
a. Baseline, intermittent, and post-intervention data on health and behavior collected via surveys	No	These will be for researcher use only.
b. Suggestions for improving program design gathered from surveys and focus groups	Yes	Survey data will be anonymous. Focus group data, by nature, will not be. As we make adjustments during the pilot year based on these data, we will let participants know we have taken their perspectives into account.

c. Narrative data from group walking	Yes	Select narratives will be posted on a project website and accessible to study participants and the public at large.
d. Walking data from the SHARP mobile application (number walks completed, average pace, distance)	Yes	This data will be visible immediately following group walks. We plan to anonymously share small-group walking data with the group at large.
e. Montreal Cognitive Assessment (MoCA) results	Yes	Score will be shared immediately with participant and explained by a trained assessor.
f. Blood pressure	Yes	Reading will be shared immediately with participant and explained by a trained assessor.
g. Weight	Yes	Weight will be shared immediately with participant.
h. Sleep sensor data	Yes	Sleep data will be shared with participants at select points throughout the study and at study end.
i. Actigraph watch data	Yes	Activity data will be shared with participants at select points throughout the study and at study end.
j. Technology Use Survey	Yes	Anonymous technology Use Data will be shared with participants in report-back presentations – as part of describing the sample demographics

For Aim 2 participants a copy of the interview audio and/or video recording will be shared with participants if they request this. An email address will be collected during the interview in order to share the recording. Results of the interviews will not be shared with participants, as the creation of SHARP routes is in an early phase.

i) Data and Specimen Banking

Data from Aim 1 and Aim 2 will be stored for future research in the ORCATECH repository and coded as described in the ORCATECH repository protocol (eIRB#6845). Study data including Aim 1 survey, walk, audio, activity data, sleep and focus group data will be stored for future use. Interview audio and/or video recordings and transcripts for Aim 2 will be stored for future use.

Data Analysis

Highly frequently observed data used in this study allow us to generate person-specific distributions of each activity feature (digital biomarkers) within a short interval (e.g., 1st 4 weeks) at baseline. Using the individual specific distribution, we identify person-specific thresholds sensitive to underlying changes (e.g., 1 SD below person specific daily step counts based on data from baseline 4 weeks). We will examine the frequency of observing this significant departure from their own baseline distribution over time. Using deviations from each subject's own distribution enhances signal-to-noise. This approach substantially reduces required sample sizes verses using group norms. Data will be important for refining statistical power needed for the future multicenter SHARP intervention.

We will also assess technology adherence. The activity watch is to be continuously worn; time not worn is tracked. The sleep mat is a one-time install/uninstall; we anticipate high adherence. Technologies, adherence and acceptance are validated;[45,46] we will consider adherence and, as technologies collect duplicate data, will cross compare sleep and nighttime activity. Feasibility criterion will be 80% adherence to protocol and data generation (watch, sleep mat, weekly questionnaire) over 24 weeks. Participant

acceptability and satisfaction (ease, technology obtrusiveness) will be assessed using an ORCATECH 5-point Likert scale.

Privacy, Confidentiality and Data Security

Study data as described in the procedures and data handling sections will be stored on a secure, password protected OHSU server. Access to data will be restricted to study personnel. Access to data will require OHSU ID/password authentication. Paper files will be stored in locked filing cabinets in restricted access offices at OHSU. OHSU's Oregon Center for Aging and Technology (ORCATECH) will program appropriate security measures on study provided chrombooks. The chromebooks will be password protected and access to sites other than the study surveys will be blocked. The study team will follow OHSU Information Security Directives and institutional policy to maintain the confidentiality and security of data collected in this study. As this is a federally funded study, we have obtained a Certificate of Confidentiality.

Risks and Benefits

j) Risks to Subjects

Aim 1

There is a risk of falls, near, falls or traffic related incidents. These are a risk whenever walking on public sidewalks. To minimize these risks, marked crosswalks are used for crossing main thoroughfares, and majority of each walk is routed on side streets with less traffic. Walks were created and piloted using strategies to minimize risks, considering aspects that may contribute to unsafe or difficult walking conditions: crime, construction/other obstructions, sidewalk conditions, traffic, presence of marked crosswalks, and down/uphill grade. Our identifiable weekly health update will capture any falls and other health-related conditions, such as Emergency Department visits, for safety monitoring.

Participants will be trained to stop while manipulating the tablet (the SHARP application is designed so that participants typically do not need to manipulate the tablet once walking begins), and to stop if they feel any dizziness or shortness of breath. Falls and near-falls are surveyed weekly, as part of the safety focus of this study. Additionally, intermittent check-ins query safety-related issues, including sidewalk conditions, and safety-related suggested revisions. Routes will be revised as needed in response to safety hazards noted during the course of the research.

Participants may become physically tired during walking. Upon walk-start at log-in to the SHARP walking application, participants check-off a reminder to stop whenever feeling dizzy, faint, short of breath, chest pains, or fatigued. Additionally, participants are trained in orientation and reminded periodically through intermittent check-in calls to rest when fatigued. In developing routes, staff consider grocery stores and public buildings/spaces with restrooms and points of rest. Subjects will be routinely reminded that participation is entirely voluntary and that they can discontinue the research at any time.

Participants may become sad, upset, and angry, or experience other unpleasant emotional disturbances as a result of walking by and/or reminiscing about spaces important to the African American community that are no longer present due to or threatened by gentrification.

Other risks include getting lost, and breech of GPS-tracking confidentiality. Participants walk in triads guided by a GPS-linked visual map with navigational instructions and audible and vibratory alerts for turns. Should technology fail, triads also carry a paper back-up copy of

routes. Routes have few turns for easier navigability, and are loops that start and end at the same location.

Focus group data, and focus group surveys will be anonymous. Weekly online health update surveys and recorded conversational reminiscence sessions while walking will be identifiable. Online health updates record safety-related queries like falls and ED visits are thus critical to identify participant respondents for safety monitoring. Recorded conversational reminiscence is identifiable because participant identities are central to the oral history archive this study produces as a community deliverable.

AIM 2

Interviews with individual community stakeholders in Oakland will be identifiable. Any personal health information beyond name, date and place of birth will be anonymized from any transcription, as well as any other information the interviewee wishes to anonymize beyond these required anonymities.

k) Potential Benefits to Subjects

Participants will not directly benefit from this research beyond potential increased or maintained cognitive and physical fitness from regular walking and social engagement from engaging in study activities.

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Statistical Analysis Plan

Statistical analysis. The analytic methodology adopts that of Dodge et al.,[1] (mentor for this KL2), designed specifically to take advantage of high frequency digital biomarker data and intra-individual distributions. Highly frequently observed data used in this study allow us to generate person-specific distributions of each activity feature (digital biomarkers) within a short interval (e.g., 1st 4 weeks) at baseline. Using the individual specific distribution, we identify person-specific thresholds sensitive to underlying changes (e.g., 1 SD below person-specific daily step counts based on data from baseline 4 weeks). We will examine the frequency of observing this significant departure from their own baseline distribution over time. Using deviations from each subject's own distribution enhances signal-to-noise. This approach substantially reduces required sample sizes verses using group norms. Data will be important for refining statistical power needed for the future multicenter SHARP intervention. **Technology adherence.** The activity watch is to be continuously worn; time not worn is tracked. The sleep mat is a one-time install/uninstall; we anticipate high adherence. Technologies, adherence and acceptance are validated;[2,3] we will consider adherence and, as technologies collect duplicate data, will cross compare sleep and nighttime activity. Feasibility criterion will be 80% adherence to protocol and data generation (watch, sleep mat, weekly questionnaire) over 16 weeks. Participant acceptability and satisfaction (ease, technology obtrusiveness) will be assessed using an ORCATECH 5-point Likert scale.

1. Dodge, H.H., et al., Use of High-Frequency In-Home Monitoring Data May Reduce Sample Sizes Needed in Clinical Trials. *PLOS ONE*, 2015. **10**(9): p. e0138095.
2. Huysmans, D., et al., Evaluation of a Commercial Ballistocardiography Sensor for Sleep Apnea Screening and Sleep Monitoring. *Sensors* (Basel, Switzerland), 2019. **19**(9): p. 2133.
3. Mercer, K., et al., Acceptance of Commercially Available Wearable Activity Trackers Among Adults Aged Over 50 and With Chronic Illness: A Mixed-Methods Evaluation. *JMIR mHealth and uHealth,* 2016. **4**(1): p. e7-e7.

IRB Approved: 1/10/2024
Approval Expires: 1/15/2027

OREGON HEALTH & SCIENCE UNIVERSITY

STUDY00022363

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Efficacy of a Technology-Based Multimodal Brain Health Intervention for Older African Americans

PRINCIPAL INVESTIGATOR: Raina Croff Ph.D. *(503) 494-4362*

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

PURPOSE: The purpose of this study is to refine a physical and cognitive health program for African Americans aged 65 and older. We also want to collect feedback including if the program is convenient, engaging, and culturally relevant.

DURATION: Your participation in the study will last for 6 months and take about 30 minutes per week for the first 2 months and 3 hours per week for the remaining 4 months. There will be 5 visits with the study team and up to 48 group walks.

PROCEDURES: If you decide to participate, activities will include wearing a watch that measures your activity, using an under-the-mattress sleep sensor, and completing online surveys weekly. After a period of up to 8 weeks, activities will also include taking walks in small groups 3 times per week. Those will include recorded conversations about your memories. We will also ask you to participate in up to 3 focus group sessions.

RISKS: As you will be walking outside there is a risk of falls, near, falls or traffic related incidents. There is a risk of loss of confidentiality

BENEFITS: You will not directly benefit from taking part in this research.

ALTERNATIVES: You may choose not to participate in this study, may receive standard treatment or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

OREGON HEALTH & SCIENCE UNIVERSITY

STUDY00022363

Research Consent and Authorization Form

TITLE: Efficacy of a Technology-Based Multimodal Brain Health Intervention for Older African Americans

PRINCIPAL INVESTIGATOR: Raina Croff, PhD 503-494-4362

STUDY COORDINATOR: Patrice Fuller, BS 503-494-2367

WHO IS PAYING FOR THE STUDY?: National Center for Advancing Translational Sciences (NCATS)
WHO IS PROVIDING SUPPORT FOR THE STUDY?: The OHSU Layton Aging & Alzheimer's Disease Center and the Oregon Center for Aging and Technology are providing support for this study.

WHY IS THIS STUDY BEING DONE?:
You have been invited to be in this research study because you are Black/African American, age 65 or older, who has lived in or is living in the historically Black neighborhoods of North Portland or Northeast Portland.

The purpose of this study is to develop a physical and cognitive health program for African Americans aged 65 and older in Portland. In this study, we will test how possible it is to do a program like this, and test how well program technology works. We will also find out how culturally relevant the program is to Black/African Americans in Portland, and we will learn whether people find the program interesting and engaging.

This study will last for about 6 months. During that time, you will participate for 30 minutes per week for up to 8 weeks, then about 3 hours every week. This study requires 4 visits with the study team and up to 48 group walks.

We are asking you to provide information for a data bank, also called a repository. This information will be stored indefinitely and may be used and disclosed in the future for other research studies.

We expect to screen up to 18 people to find 9 who will participate in the study.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

You will:

- Complete eligibility screening, including a **brief cognitive assessment** that you will repeat at the end of the study.
- Fill out a **demographics questionnaire** at the start of the study
- Fill out a basic **health questionnaire** at the beginning and end of the study These forms ask about your dietary habits, exercise habits, mental health and wellbeing (mood), past and current health conditions, height, weight, and tobacco and alcohol consumption.
- Fill out a brief sleep questionnaire at the start of the study, at weeks 4 and 8, and at the end of the study.
- Fill out a Technology Use Survey at the start of the study
- Attend an **orientation session**. At the orientation, walking groups will be formed and you will be given instructions for how to use program technology. The orientation session will last about 1.5 hours.
- Go on **three walks per week** in a small group in N/NE Portland. Each walk will last 30-45 minutes. Your group's pace and speed will be recorded.
- Complete weekly surveys about your health, memory, and mood electronically on a study provided chromebook.
- Weight yourself on a study provided wireless bathroom scale
- Participate in **three focus groups**. In the focus groups, you and other participants will share their impressions of and experiences participating in the program. At the start of each focus group, you and other participants will each fill out a brief questionnaire about their thoughts on the study's design and program technology. Though we will not ask you specific questions about your health history in focus groups, you may choose to reveal private health information during group conversation
- Complete a **30-minute exit interview** if you leave the study prior to its end. Exit interviews may be in-person, telephone, or via teleconference as appropriate.

	Visit 1 Month 1	Month 2	Visit 2 Month 3	Visit 3 Month 4	Visit 4 Month 5	Visit 5 Month 6
Consent Discussion & eligibility screening	X					
Cognitive assessment	X					X
Demographic Questionnaire	X					
Baseline Health Questionnaire	X					X
Sleep Questionnaire	X	X	X	X	X	X
Technology Use Questionnaire	X					
Weight, blood pressure	X					X

Weekly Health Update	X	X	X	X	X	X
Focus Group & Survey				X	X	X
Orientation for group walks			X			
Weekly walks (3x/wk) with recorded conversation			X	X	X	X

The following table shows an example of what a typical week of participating in this study may be like:

Example Week			
	Monday	**Wednesday**	**Friday**
Activity	 Group walk with memory-based conversation	 Group walk with memory-based conversation	 Group walk with memory-based conversation
Duration	45 minutes	45 minutes	45 minutes
Technology	Continuously wear an activity watch		
	Sleep on an under-the-mattress sleep sensor		
			Weekly Online Survey (15 minutes)

The information and recordings collected as part of this study will become part of a data bank, also called a repository. This information will be stored indefinitely. In the future, your information may be given to researchers for other research studies. The information will be labeled as described in the ***Who Will See My Personal Information?*** section.

During this study you will be audio-recorded and you may be periodically video-recorded. We will use the audiotapes for educational materials and research publications. Group conversations on walks will be audio-recorded and may be periodically video recorded. Recordings (video and voice) will be used for quality assurance, and some recordings (video and/or voice) may be used on the study's website to build awareness about healthy cognitive aging among Black/African Americans in Oregon. If your recordings are used on the website, your identity WILL BE disclosed, as identity is an important part of the historical archive we are hoping to build from participant narratives in this study. Information about you that would be disclosed could be your first and last name, age, and current and/or past neighborhood of residence, and dates of residence in inner North and Northeast Portland.

- Walking conversations will be audio-recorded and you WILL BE identifiable.
- Any audio or transcribed walking conversations used on the health education website or in presentations WILL BE identifiable.
- We may use some voice recordings (no video) for future research, such as improving speech recognition software so that it can be more accurate for use with other Black/African Americans who may have similar speech patterns. If recordings are used for this purpose, your identity WILL NOT be disclosed and you will remain ANONYMOUS. Rather, any voice recordings used for this research purpose will have all identifying information removed.

WILL I RECEIVE RESULTS FROM THE TESTING IN THIS STUDY?

The research staff conducting your cognitive assessment will write down your assessment score for you to discuss with your provider if you wish. You will have access to the data that is visible to you while being collected. This includes walk data (number of walks complete, average pace), weight, blood pressure, sleep sensor, and activity data. We will share the suggestions for improving program design gathered from surveys and focus groups.

Baseline, post intervention, and weekly survey data will not be shared with you. The results of research tests will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:
Voice and video recordings used in this study and on this study's website are not anonymous. Thus, you may be recognized from these recordings.

Although we take steps to maintain confidentiality of all study information, there is a risk of loss of confidentiality of other information collected about you during the study. Your information will be stored for future research. If your health data or survey results were to be accidentally released, it might be possible that the information we will gather about you as part of this research repository could

become available to an insurer or an employer, or a relative, or someone else outside the approved research.

Conversing with fellow participants and research staff about your personal memories and experiences living and working in North and Northeast Portland are an essential part of this program. You may feel discomfort in sharing some memories. You do not have to share any memories that you do not feel comfortable sharing.

Neighborhood walks take place in the historically Black neighborhoods of Portland which are undergoing intense gentrification. You may feel discomfort talking about and experiencing the changes as you walk through these areas.

Neighborhood walks take place on public city sidewalks, so there may be unknown risks or potential for injury from uneven walking surfaces, construction, or other unanticipated factors within the neighborhood environment. To minimize these risks, marked crosswalks are used for crossing main thoroughfares, and majority of each walk is routed on side streets with less traffic. Walks were created and piloted using strategies to minimize risks, considering aspects that may contribute to unsafe or difficult walking conditions.

This study requires walking at a moderate pace. You may feel discomfort walking at a moderate pace if you are newly starting or returning to physical exercise after a period of time not being active. Upon walk-start at log-in to the walking application, you will be reminded to stop whenever feeling dizzy, faint, short of breath, chest pains, or fatigued. Additionally, you will be trained in orientation and reminded periodically through intermittent check-in calls to rest when fatigued.

BENEFITS:
You will not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit people in the future.

ALTERNATIVES:
You may choose not to be in this study.

WHO WILL SEE MY PERSONAL INFORMATION?:
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Data including voice and video recordings will be stored on password-protected computers, and will only be accessible to approved study staff.

If your recordings are published online for historical purposes, information about you that may be disclosed includes: first and last name, age, and current and/or past neighborhood of residence, and dates of residence in inner North and Northeast Portland, and you may be identified in your voice and video recordings, but other personal information we collect about you will be kept private.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study. Additionally, your data will be stored in a repository for future research

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, The National Center for Advancing Translational Sciences (NCATS), and the funder's representatives
- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records.

We may also share your information with other researchers, who may use it for future research studies, in which cases your identifying information will be removed.

We will not release information about you to others not listed above, unless required or permitted by law. Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities.

When we send information outside of OHSU, it may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your permission.

To help us protect your privacy, we have obtained a Certificate of Confidentiality to protect your privacy even from people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Another exception is information about child or elder abuse or neglect and harm to yourself or others or communicable disease reporting. Note that this doesn't prevent you from releasing the information yourself.

Data from this study may be shared with other investigators for future research studies. A code number will be assigned to you and to the information about you. Only the investigators and people involved in the conduct of the study will be authorized to link the code number to you. Other investigators who may receive samples of your information for research, such as voice recordings, and data from the demographic survey and from the two health surveys will be given only the code number which will not identify you.

Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities.

We may continue to use and disclose your information as described above indefinitely.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT? Information including any videotapes and audiotapes about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?: There will be no cost to you or your insurance company to participate in this study.

You will be given a $15 gift card per completed weekly online survey (up to $360 for all 24 weekly online surveys), and $25 gift card per focus (up to $75 for all three focus groups). The total possible compensation for engaging in all study surveys and activities is $435 per participant.

You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet.

We may request your social security number in order to process any payments for participation.

Payment received as compensation for participation in research is considered taxable income for a research subject. If payments are more than $600 in any one calendar year, OHSU is required to report this information to the Internal Revenue Service (IRS). Research subject payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research subject and a copy will be sent to the IRS.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Raina Croff, PhD, at 503-494-2367.

If you are injured or harmed by the study procedures, you will be treated. OHSU and NCATS do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

WHERE CAN I GET MORE INFORMATION?:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact PI Raina Croff 503-494-4362 or Patrice Fuller at 503-494-2367.

This research has been approved and is overseen by an Institutional Review Board ("IRB"), a committee that protects the rights and welfare of research subjects. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?
We will ask you to walk with your group 3 times per week and discuss your memories. Additionally it is important that you complete the weekly surveys and wear the activity watch.

DO I HAVE TO TAKE PART IN THIS STUDY?
Your participation in this study is voluntary. You do not have to join this or any research study.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

During this study you may be photographed and videotaped. You will be audiotaped. We will use the photographs, videotapes, or audiotapes for educational materials and research publications.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join this study, or if you withdraw early from the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Dr. Raina Croff
Layton Aging and Alzheimer's Disease Center
Oregon Health & Science University
3181 SW Sam Jackson Pk Rd – CR 131
Portland, OR 97239

croff@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If you withdraw from the program prior to the end of the 6 month program period, we will ask you to complete an exit interview with the study staff about your experience in the program.

If you decide you no longer want to participate in this research, we will stop collecting information from you and any devices that send data to us. We will remove

your name and any other identifiers from your information, but material already collected will not be destroyed and we will continue to use it for research.

You may be removed from the study if the investigator or funder stops the study, or if you do not follow study instructions.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:
Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date