The EMBER Trial for Weight Management Engagement

NCT05424081

July 1, 2021

Title : The EMBER Trial for Weight Management Engagement
Approval Period: **Draft**

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Modification

1. Summarize your proposed changes.

As previously discussed, we would like to amend this protocol to extend to the funded trial, which has the same goal and almost all of the same methods as the pilot. Therefore, we are also requesting to change the title of the IRB proposal to the title of the new grant. The two largest changes are to add a site (Houston VA Medical Center) and to have outside assessors complete follow-up assessments to ensure study staff remain blinded to participant randomization.

We have a waiver of using the VA central IRB and a single IRB waiver under review. We will not recruit Houston participants until we have/upload an approval letter from their IRB. We will not transfer data to/from the outside assessor until all procedures are approved by VA ISOs, ACOS, and other necessary parties.

2. Indicate Level of Risk

No Change

3. Update the Conflict of Interest (COI) section if any changes in COI have been made since the last protocol submission.

N Is there a change in the conflicting interest status for any existing personnel on this protocol?

Protocol Director

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Jessica Yelena Breland		PhD		Clinical Assistant Professor (Affiliated) [VAPAHCS]
Department	5722	**Phone**		**E-mail**
Psych/General Psychiatry and Psychology (Adult)		650-493-5000x 22105		jessica.breland@va.gov
CITI Training current				Y

Admin Contact

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Rakshitha Mohankumar		BA		RA
Department		**Phone**		**E-mail**
		650-493-5000		rakshitha.mohankumar@va.gov
CITI Training current				Y

Investigator

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Susan Frayne		MD		Professor-Med Ctr Line
Department	5475	**Phone**	(650) 617-2690	**E-mail**
Med/Primary Care and Population Health		650-493-5000		susan.frayne@va.gov
CITI Training current				Y

Other Contact

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Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Department		**Phone**		**E-mail**
CITI Training current				

Academic Sponsor

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Department		**Phone**		**E-mail**
CITI Training current				

Other Personnel

Name Christine Timko		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.** Clinical Professor (Affiliated) [VAPAHCS]
Department		**Phone** (650) 493-5000		**E-mail** Christine.Timko@va.gov
CITI Training current				Y

Name Ivan Georgiev Raikov		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.** Research Engineer
Department		**Phone**		**E-mail** iraikov@stanford.edu
CITI Training current				Y

Name Deloras Natasha Puran		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Department Psych/Public Mental Health & Population Sciences		**Phone**		**E-mail** Deloras.Puran@va.gov
CITI Training current				Y

Participant Population(s) Checklist	**Yes/No**
• Children (under 18)	N
• Pregnant Women and Fetuses	N
• Neonates (0 - 28 days)	N
• Abortuses	N
• Impaired Decision Making Capacity	N
• Cancer Subjects	N

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- Laboratory Personnel N
- Healthy Volunteers N
- Students N
- Employees N
- Prisoners N
- Other (i.e., any population that is not specified above) Y
- International Participants N

Please enter the countries separated by comma

Study Location(s) Checklist Yes/No

- Stanford University
- Clinical & Translational Research Unit (CTRU)
- Stanford Hospital and Clinics
- Lucile Packard Children's Hospital (LPCH)
- VAPAHCS (Specify PI at VA) Y

Breland

- Other (Click ADD to specify details) Y

Location / Country	Location	Contact Name	Contact Phone	Contact Email	Permission ?	Engaged?
Houston, Texas	US	Terri Fletcher	713-440-4490	terrib@bcm.edu	N	Y

General Checklist

Multi-site Yes/No

- Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role.(e.g., multi-site clinical trial) Y
- Is Stanford the coordinating institution or are you the lead investigator for this multi-site study? Y

Site Name	Contact Name	Contact Phone	Contact Email	Permission?	Engaged?
Houston VAMC	Terri Fletcher	713-440-4490	terrib@bcm.edu	N	Y

Collaborating Institution(s) Yes/No

- Are there any collaborating institution(s)? A collaborating institution is generally an N

institution that collaborates equally on a research endeavor with one or more institutions.

Cancer Institute	**Yes/No**
• Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol).	N

Clinical Trials	**Yes/No**
• Investigational drugs, biologics, reagents, or chemicals?	N
• Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)?	N
• Investigational Device / Commercial Device used off-label?	N
• IDE Exempt Device (Commercial Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Devices)	N
• Will this study be registered on# clinicaltrials.gov? (See Stanford decision tree)	Y
• Is Stanford responsible for ClinicalTrials.gov registration? (See Stanford decision tree) NCT#	N

Tissues and Specimens	**Yes/No**
• Human blood, cells, tissues, or body fluids (tissues)?	N
• Tissues to be stored for future research projects?	N
• Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see https://sites.stanford.edu/ico/mtas	N

Biosafety (APB)	**Yes/No**
• Are you submitting a Human Gene Transfer investigation using a biological agent or recombinant DNA vector? Please review the Administrative Panel on BioSafety website form more information.	N
• Are you submitting a Human study using biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies.	N
• Are you submitting a Human study using samples from subjects that are known or likely to contain biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies.	N

Human Embryos or Stem Cells	**Yes/No**
• Human Embryos or Gametes?	N

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• Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells)	N

Veterans Affairs (VA)	**Yes/No**
• The research recruits participants at the Veterans Affairs Palo Alto Health Care System(VAPAHCS).	Y
• The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes.	Y
• The research is sponsored (i.e., funded) by VAPAHCS.	N
• The research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities.	Y
• The research is conducted using any property or facility of VAPAHCS.	Y

Equipment	**Yes/No**
• Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000)	N
• Medical equipment used for human patients/subjects also used on animals?	N
• Radioisotopes/radiation-producing machines, even if standard of care? http://www.stanford.edu/dept/EHS/prod/researchlab/radlaser/Human_use_guide.pdf More Info	N

Payment	**Yes/No**
• Subjects will be paid/reimbursed for participation? See payment considerations.	Y

Funding	**Yes/No**
• Training Grant?	N
• Program Project Grant?	N
• Federally Sponsored Project?	Y
• https://doresearch.stanford.edu/policies/research-policy-handbook/definitions-and-types-agreements/specialized-categories-sponsored-p Industry Sponsored Clinical Trial?	N

Funding

Funding - Grants/Contracts			
Funding Administered By :	VA	**SPO # (if available) :**	
Grant # (if available) :	CDA15-257	**Funded By (include pending) :**	VA HSRD

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Principal Investigator : breland

Grant/Contract Title if different from Protocol Title :
Patient-Centered Strategies to Engage Veterans in Behavioral Health Treatments

Y For Federal projects, are contents of this protocol consistent with the Federal proposal?
N Is this a Multiple Project Protocol (MPP)?
N Is this protocol under a MPP?

Funding Administered By : VA **SPO # (if available) :**
Grant # (if available) : IIR 19-422 **Funded By (include pending) :** VA HSR&D
Principal Investigator : Jessica Breland

Grant/Contract Title if different from Protocol Title :
The EMBER Trial for Weight Management Engagement

Y For Federal projects, are contents of this protocol consistent with the Federal proposal?
N Is this a Multiple Project Protocol (MPP)?
N Is this protocol under a MPP?

Funding - Fellowships

Gift Funding

Dept. Funding

Other Funding

Resources :

a) Qualified staff.

Please state and justify the number and qualifications of your study staff.

Jessica Breland, MS, PhD is the Protocol Director, the grant's Principal Investigator, and is an investigator at the VA Palo Alto. She has clinical and research experience related to weight loss, weight loss treatments, health disparities, and qualitative interviews.

Susan Frayne, MD, MPH, Co-Protocol Director, is a Professor of Medicine at Stanford University and an investigator at the VA Palo Alto's Center for Innovation to Implementation. She has extensive clinical and research experience. She is an expert in primary care and women's health.

Deloras Puran, MPH, Program Manager, has experience managing and conducting qualitative and quantitative research.

Christine Timko, PhD, Co-Investigator, is a Clinical Professor (affiliated) at Stanford University and an investigator at the VA Palo Alto's Center for Innovation to Implementation. She is a psychologist extensive experience in Veteran-related research.

Psychology Intern (generic position), this person will be a VA Palo Alto psychology intern participating in a research rotation (usually 6 months), they will be clinical psychology doctoral candidates with experience in research design and analysis, including consent processes. Their name and other information will be

added/removed in RDIS at the start and end of the rotation.

Ivan Raikov is staff at Stanford University/Ci2i and a programmer with experience accessing/using VA data sources (e.g., CDW).

Rakshitha Mohankumar is a VA employee with recruitment, consent, data entry, and other research support experience.

b) Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

Staff have completed all mandatory annual training courses(e.g., VA Privacy and Information Security Awareness and Rules of Behavior, VA Privacy and HIPAA Training, CITI Training). The PI meets personally with all study staff on an intensive basis during their first month in the position, to assure that they understand all components of their roles, including data management procedures, data security procedures, etc.

c) Facilities.

Please describe and justify.

VA Palo Alto Health Care System
The VA Palo Alto Health Care System (VAPAHCS) will serve as the main research facility; research team members are all based at VAPAHCS.

Center for Innovation to Implementation

The Center for Innovation to Implementation (Ci2i) is a VA HSR&D Center of Innovation (COIN) located at VAPAHCS. Ci2i staff include over 30 core investigators who conduct numerous forms of health services research and have expertise in administrative database analyses, implementation science, behavioral health, qualitative research, intervention design and evaluation, longitudinal analyses, and multi-level analyses.

With regards to relevant technology, Ci2i has a centralized server and mass data storage that is firewalled and encrypted. The secure system is hosted and managed by VA OIT (Office of Information technology). There are daily backups as well as monthly full system back-ups, along with other state of the art security features, such as a locked server room with alarms.

d) Sufficient time.

Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.

We anticipate that this research will take approximately 3.5 years to complete, including presentation of findings and manuscript preparation.

e) Access to target population.

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

We plan to recruit 470 veteran participants out of over ten thousand veterans with obesity who use the VA Palo Alto & Houston Healthcare Systems, we do not anticipate difficulty meeting recruitment goals.

f) Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as

a consequence of the research when applicable. Please describe these resources.

We do not believe that participants in this minimal risk study will require medical or psychological resources. However, in the event they do, they will be referred to appropriate VA veteran health services.

g) Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

Coordination with other site will be done via email, phone, and video conferencing. Dr. Breland and the research coordinator will visit Houston in Y1 to ensure site staff have adequate training and to understand the Houston clinical context. Dr. Fletcher (Houston Site PI) will travel to Palo Alto in Y4 to help interpret results and plan future trials. Meeting Structure: Dr. Breland will lead monthly meetings with all co-investigators (weekly with Dr. Fletcher during Y1-Y2), and weekly meetings with research staff. Dr. Breland will meet weekly with the study coordinator. The coordinator will meet regularly with research assistants at both sites to guide training, recruitment, and progress. Dr. Breland will meet regularly with biostatistician, Dr. Boothroyd. Davis Research: We propose that this (or similar) company conduct blinded post assessments. Communication will include weekly calls / reports, and Stata files sent quarterly.

Adverse outcomes, unexpected problems, and/or protocol modifications will be reported to Dr. Breland immediately and reported to regulatory bodies as appropriate (e.g., IRBs, DSMB). As described elsewhere, we will complete interim analyses at n=200, with results reported to the DSMB.

Expedited Form

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

1. N **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
   - a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   - b) Research on medical devices for which
     - i) an investigational device exemption application (21 CFR Part 812) is not required; or
     - ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. N **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
   - a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   - b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. N **Prospective collection of biological specimens for research purposes by non invasive means.**

4. N **Collection of data through non invasive procedures (not involving general anesthesia or sedation)**

routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
b) weighing or testing sensory acuity;
c) magnetic resonance imaging;
d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Y **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

6. Y **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. Y **Research on individual or group characteristics or behavior(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

1. Purpose

a) In layperson's language state the purpose of the study in 3-5 sentences.

We will test the effectiveness and collect preliminary information that may help in its future implementation of EMBER, a patient-facing, self-help tool to increase weight loss treatment engagement. In this two site study we will recruit patients (n=470) from the VA Palo Alto Health Care System (VAPAHCS) in Palo Alto, CA and the Houston VA Medical Center (VAMC) in Houston Texas.

b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

We hope to learn about the effectiveness EMBER, i.e., whether it increases weight loss treatment engagement among veterans. This information is important because many veterans have obesity and increasing weight management engagement could lead to weight loss and subsequent improvements in morbidity and quality of life.

c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)

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Because we are testing EMBER, a tool to increase engagement in weight loss treatments, we need to include patients for whom the tool is intended.

2. Study Procedures

a) Please SUMMARIZE the research procedures, screening through closeout, which the human subject will undergo. Refer to sections in the protocol attached in section 16, BUT do not copy the clinical protocol. Be clear on what is to be done for research and what is part of standard of care.

Recruitment

We will recruit participants via batched opt-out letters (see attachment), which will include the consent form, and follow-up phone calls. These participants will be identified via the VA Informatics and Computing Infrastructure (VINCI).
VINCI is a VA HSR&D resource center that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It can provide us with a list of veterans who meet our inclusion/exclusion criteria.

If a VINCI programmer cannot provide us with a list, we will have another programmer create the cohort on VINCI.

We expect to send roughly 2,000 letters, based on a 10-30% response rate in prior work.

We will oversample women veterans to ensure adequate representation. In addition, we will track the race/ethnicity and age of participants. If we do not obtain adequate representation of any of the aforementioned groups, we may oversample the group(s).

We are requesting a full wavier of HIPAA for this study, to cover the access to PHI prior to screening, after screening (but before enrollment in the study), and also data collected after enrollment in the study.

Potential participants will be screened over the phone to determine whether they meet eligibility criteria. If they meet criteria via self-report, we will then use CPRS/VistAWeb to screen clinical records and confirm eligibility, if necessary, which may occur before and after mailings for participants recruited via mail.

We will inform primary care clinic directors that we are conducting this study (via email) and ask them to let us know if they have any questions or concerns.

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CONSENT

Once a participant is deemed eligible and they remain interested in participating, we will complete the verbal consent process over the phone. We are requesting a waiver of documentation of consent as it would be an undue burden for participants in this minimal risk study. Veterans will be given adequate time to review the consent and ask questions before verbally giving consent over the phone. If the veteran does not have the consent sheet, it will be resent or read verbatim over the phone. We may also direct potential participants to website that displays the consent form. If the person obtaining consent believes the veteran cannot give consent, the process will be terminated.

Baseline questionnaires: After the consent process, participants will complete the following questionnaires over the phone (see section 16 attachments):
- Baseline Questionnaire (demographics, motivation, knowledge, weight management beliefs/behaviors/outcomes, and preferences)
- Screen for Disordered Eating (Maguen et al)
- Stanford Leisure-Time Activity Categorical Item (L-Cat)
- Brief Illness Perception Questionnaire (Brief-IPQ)
- VR-12 (SF-12 for Veterans)
- PHQ-9

Staff will enter participant responses directly into Qualtrics. Participants will not use Qualtrics as all assessments are completed over the phone. This method will ensure complete data entry at the time of assessment and reduce the number of paper records.

Randomization: Participants will then be randomized 1:1 to the intervention or control arm, stratified by site and gender. To conceal allocation, the randomization algorithm will allocate stratum-specific participants to arms within randomly generated block sizes.

Participants in the control arm will be provided with information about available VA Palo Alto or Houston Programs via the modality of their choice (i.e., paper or online; see attachment). Participants in the treatment arm will be provided with a link to the web version of the self-help tool (via mail and/or verbally) or mailed a paper version of EMBER, depending on their preference. All participants will receive the Participant Letter (attachment 16).

EMBER, the self-help tool: Both the paper and online versions of the self-help tool help veterans consider the pros and cons of weight loss and weight management treatments by using the decisional balance exercise that is

common in Motivational Interviewing. In addition, the tool will help veterans set a concrete goal to engage in a weight loss treatment. The tool IS NOT a weight loss treatment, instead it is meant to engage veterans in existing treatments. The paper version of the tool is attached (section 16). Treatments will be specific to those available in Palo Alto and Houston.

The online versions of the tool and control materials are hosted on Qualtrics, which is a HIPAA compliant survey website. Access to Qualtrics is provided through Stanford. Qualtrics will collect data on participants' IP addresses, answers to tool questions, and length of time on the website. See section 16 for screenshots.

10-day call: Roughly 10 days after mailing patients study materials, study staff will complete a call with participants to understand whether they used study materials and to review study materials with participants, if necessary. 10-day call guides are provided in Section 16. These calls will be audio recorded to assess fidelity.

Follow-up questionnaires: Eight weeks and 24 weeks after the tool is sent, an outside company will call participants to have them complete the following questionnaires (see attachments):
- Follow-up Questionnaire (weight loss, thoughts about tool/control materials, weight, height, motivation, self-efficacy)
- Screen for Disordered Eating (Maguen et al)
- Stanford Leisure-Time Activity Categorical Item (L-Cat)
- Brief Illness Perception Questionnaire (Brief-IPQ)
- VR-12 (SF-12 for Veterans)
- PHQ-9

Participants who we cannot be reached by phone for follow-up calls will be sent the lost to follow-up letter.

VINCI/CPRS/VISTAweb-based follow-up: The primary outcome, whether participants used a weight loss treatment by 2-month follow-up. This is defined as visits in MOVE! or nutrition clinics, recreation therapy visits, Vida app use.

Using VINCI, we will also collect information on participants' height and weight at baseline, two months, and six months. We will collect information on mental and physical health diagnoses as well as hospitalizations and death (for adverse event reporting). Therefore, we are requesting an amendment of HIPAA authorization to be able to access these limited portions of

participants' medical records.

Payment: Veterans will receive $20 per questionnaire related study contact (baseline, 2-month, 6-month) for a possible total of $60.

b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.

Participation represents minimal risk for participants given that they will be told they can withdraw from the study at any time. Veterans will receive very basic information on behavioral weight management treatment options and questions do not differ substantially from what could be asked in usual care settings.

c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 13). Submit a debriefing script (in section 16).

n/a

d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.

We plan to record the 10-day phone call, which we may also transcribe. The primary use for these recordings is to assess treatment fidelity. However, de-identified written quotations may be used in manuscripts and presentations.

e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).

n/a

f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

n/a

g) Study Endpoint. What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?

We plan to complete interim analyses at n=200. We propose using the conservative O'Brien-Fleming approach to determine whether the study should be stopped at the interim (α = 0.0054 for the interim analysis and 0.0492 for the final analysis) as we do not expect to see effects at n=200. For futility at interim, we propose a conditional power approach where we stop for futility if the conditional power is below 10%.

If we do not not see effects at interim, we will complete analyses of the primary outcome once we have 2-month follow-up data for the full sample. Analyses for secondary outcomes will be completed once the full sample completes the 6-month questionnaires.

3. Background

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a) Describe past experimental and/or clinical findings leading to the formulation of the study.

As we have shown, almost 80% of veterans using the Veterans Health Administration (VHA) have overweight or obesity (1). While almost 95% are offered a weight loss treatments, only about 10% use one (2).

Motivational Interviewing is an empirically supported, patient-centered method for enhancing motivation by exploring and resolving ambivalence (3). While no self-help motivational interviewing tools exist for weight loss treatment engagement, there is support for self-help versions of motivational interviewing in other contexts (4-8). Therefore, we believe EMBER, a motivational, self-help tool could help engage veterans in weight loss
treatments.

1. Breland, J.Y., Phibbs, C. S., Hoggatt, K. J., Washington, D. L., Lee, J., Haskell, S., Uchendu, U. S., Saechao, F. S., Zephyrin, L. C., & Frayne, S. M. (2017). The Obesity Epidemic in the Veterans Health Administration: Prevalence among Key Populations of Women and Men Veterans. Journal of General Internal Medicine, 32(1): 11-17. doi: 10.1007/s11606-016-3962-1.

2. Littman AJ, Damschroder LJ, Verchinina L, Lai Z, Kim HM, Hoerster KD, Klingaman EA, Goldberg RW, et al. National evaluation of obesity screening and treatment among veterans with and without mental health disorders. General hospital psychiatry. Jan-Feb 2015;37(1):7-13.

3. Miller WR, Rollnick S. Motivational Interviewing: preparing people for change. 2nd. ed. New York, NY: The Guildford Press; 2002.

4. Hester RK, Squires DD, Delaney HD. The Drinker's Check-up: 12-month outcomes of a controlled clinical trial of a stand-alone software program for problem drinkers. J Subst Abuse Treat. 2005;28(2):159-69.

5. Ondersma SJ, Svikis DS, Schuster CR. Computer-based brief intervention a randomized trial with postpartum women. Am J Prev Med. 2007;32(3):231-8.

6. Ondersma SJ, Svikis DS, Thacker LR, Beatty JR, Lockhart N. Computer-
delivered screening and brief intervention (e-SBI) for postpartum drug use: a randomized trial. J Subst Abuse Treat. 2014;46(1):52-9.

7. Pemberton MR, Williams J, Herman-Stahl M, Calvin SL, Bradshaw MR, Bray RM, Ridenhour JL, Cook R, et al. Evaluation of two web-based alcohol interventions in the U.S. military. J Stud Alcohol Drugs. 2011;72(3):480-9.

8.Serowik KL, Ablondi K, Black AC, Rosen MI. Developing a benefits counseling website for Veterans using Motivational Interviewing techniques. Computers in Human Behavior. 2014;37:26-30.

b) Describe any animal experimentation and findings leading to the formulation of the study.

n/a

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4. Radioisotopes or Radiation Machines

a) List all standard of care procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all research procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study. More Info

Identify Week/Month of study	Name of Exam	Identify if SOC or Research

b) For research radioisotope projects, provide the following radiation-related information:

Identify the radionuclide(s) and chemical form(s).

For the typical subject, provide the total number of times the radioisotope and activity will be administered (mCi) and the route of administration.

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

c) For research radiation machine projects, provide the following diagnostic procedures:

For well-established radiographic procedures describe the exam.

For the typical subject, identify the total number of times each will be performed on a single research subject.

For each radiographic procedure, provide the setup and technique sufficient to permit research subject dose modeling. The chief technologist can usually provide this information.

For radiographic procedures not well-established, provide FDA status of the machine, and information sufficient to permit research subject dose modeling.

d) For research radiation machine projects, provide the following therapeutic procedures:

For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research participants's medical condition or whether it is being performed because the research participant is participating in this project.

For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

5. Devices

a) Please list in the table below all Investigational Devices (including Commercial Devices used off-label) to be used on participants

b) Please list in the table below all IDE Exempt Devices (Commercial Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Devices) to be used on participants.

6. Drugs, Reagents, or Chemicals and Devices

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a) Please list in the table below all investigational drugs, reagents or chemicals to be administered to participants.

b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to participants.

7. Medical Equipment for Human Subjects and Laboratory Animals

If medical equipment used for human patients/participants is also used on animals, describe such equipment and disinfection procedures.

n/a

8. Participant Population

a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii)the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

Participants will be 470 VAPAHCS and Houston VAMC patients (235 at each site). Participants will have obesity as the goal of the tool is to engage such patients in weight loss treatments.

b) State the age range, gender, and ethnic background of the participant population being recruited.

The veteran participant population will generally reflect the age and ethnicity of VA Palo Alto & Houston patients with obesity. We will oversample women to ensure their participation, given their low representation among VA users.

c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.

Vulnerable subjects will be included in so far as they are representative of the patient population in VA. These individuals are likely to include individuals with mental health conditions. Because previous work tells us women veterans have a higher rate of mental health conditions than men veterans, it is important that we not exclude these vulnerable subjects. Also to the extent that they are represented in VA populations, participants may include employees, pregnant women, elderly, and economically disadvantaged individuals.

No children are included in this study, as it is a study of adult veterans.

d) If women, minorities, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).

Women and minorities are included. We will not include children as they do not receive care at VHA.

e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it. Please see Stanford University policy.

We are not specifically recruiting employees or students.

f) State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.

No enrollees will be healthy volunteers as obesity is an inclusion criterion.

g) How will you identify and recruit potential participants about the research study? (E.g., by: chart review; notified by treating physician; response to ad). All final or revised recruitment materials, flyers, etc. must be submitted to the IRB for review and approval before use. You may not contact potential participants prior to IRB approval. See Advertisements: Appropriate Language for Recruitment Material.

We will use patient mailing lists from VINCI for recruitment, which will be used to send batched opt out letters to potential participants.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Veterans:
1. Primary care patient who uses PAVAHCS or Houston VAMC
2. Have obesity (BMI >= 30)

Identify exclusion criteria.

Veterans:
1. Age 80 or older
2. Documentation of a suicide attempt in the past 30 days
3. Hospitalization in the past 30 days
4. Documentation or other evidence of cognitive impairment
5. VA weight loss program use in past 2 years
6. Self-repot from potential participant that they will not be in town for the majority of the 2 months following baseline
7. Self-report from potential participant they plan to leave VA Palo Alto or Houston VAMC within the next 6 months
8. Under age 18

i) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a waiver of authorization for recruitment (in section 15).

1. VINCI will provide a list of potential participants meeting inclusion/exclusion criteria.
2. We will mailed batched opt-out letters to these Veterans
3. We may call those who do not opt out to see if they are interested and eligible (see phone script, attachments). Eligibility will be assessed with the Phone Screen (see attachments).

j) Describe how you will be cognizant of other protocols in which participants might be enrolled. Please explain if participants will be enrolled in more than one study.

We will ask participants if they are participating in other studies that might preclude their participation in our work. The present study does not require participants to not enroll in other studies.

k) Payment/reimbursement. Explain the amount and schedule of payment or reimbursement, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See payment considerations

Participants will be paid $20 per study contact for total possible compensation of $60.

l) Costs. Please explain any costs that will be charged to the participant.

None

m) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.

We estimate the length of the study to be 3.5 years, with analysis of participant data occurring throughout. Regarding participant involvement, screening should take ~10 minutes, consent should take ~ 15 minutes, baseline and follow-up assessments should take ~ 30 minutes each. The 10 day follow-up call should take ~30 mins. Time spent using the tool should take roughly 15 minutes.

9. Risks

a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the participant it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.)

The risks of the Investigational devices.

n/a

The risks of the Investigational drugs. Information about risks can often be found in the Investigator's brochure.

n/a

The risks of the Commercially available drugs, reagents or chemicals. Information about risks can often be found in the package insert.

n/a

The risks of the Procedures to be performed. Include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

n/a

The risks of the Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy) and associated risks.

n/a

The risks of the Physical well-being.

n/a

The risks of the Psychological well-being.

There is a risk that confidentiality of study data could be breached. This is minimized by procedures described below. Because the study involves data related to mental health status and other private health information, inappropriate release of information could be psychologically detrimental to subjects in the study.

The risks of the Economic well-being.

There is a risk that confidentiality of study data could be breached. This is minimized by procedures described below. Because the study involves data related to mental health status and other private health information, inappropriate release of information could be economically detrimental to subjects in the study insofar as it would affect employment opportunities.

The risks of the Social well-being.

There is a risk that confidentiality of study data could be breached. This is minimized by procedures described below. Because the study involves data related to mental health status and other private health information, inappropriate release of information could be socially detrimental to subjects.

Overall evaluation of Risk.

Low - innocuous procedures such as phlebotomy, urine or stool collection, no therapeutic agent, or safe therapeutic agent such as the use of an FDA approved drug or device.

b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Provide an explanation as to why the research must be completed at this location and complete the [LINKFORINTERNATIONALREASEARCHFORM] International Research Form. If not applicable, enter N/A.

n/a

c) Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.

The study team will be responsible for implementation of any and all reasonable steps to minimize disclosure of identifiable patient information.

Access to identifiable information will be limited to people who require such access to perform the stated research. Any participant data whether identifiable or not will be held in strictest confidence, with the need for confidentiality taking precedence over considerations of economy or convenience.

The following policies will be enforced to ensure that participant privacy is protected.

Confidentiality Precautions for VA staff:
The following precautions will be implemented to maintain the confidentiality of identifiable information stored at VA:

*Electronic data containing confidential identifiers will be stored on VA Servers, these servers will be behind VA firewalls and accessed via a secured remote computing environment. The remote computing environment will enable data analysis to be done directly on VA servers. No data will be moved to local PC hard drives.

* All data are backed up regularly by the facility Office of Information Technology (OIT) or by VA staff responsible for regional or national servers.

* All computer workstations and servers are secured in locked offices.

* All computers are protected with "sign-on" passwords. Password strength is assured by facility policy.

* Small amounts of data with PII on paper, if any, will be kept in a locked file cabinet in a locked office and retained per VHA rules.

* OIT seeks to stay current with standards and technologies for security management, and makes recommendations when new security technology is released.

* The research team will:
o Comply with all VA information security program policies, procedures, and practices.
o Participate in required VA security awareness training
o Report all security incidents immediately to the system or facility ISO (information security officer) and their immediate supervisor.
o Comply with orders from the VA CIO (chief information officer) directing specific activities in the event that a security incident occurs.

Responses to research assessments will be reviewed in real time. In the event that a participant expresses

suicidal ideation on the PHQ item 9, the P4 screener may be used to assess risk (attachment, 16; answers to the P4 will not be saved for research purposes). The PI will be notified (she is a licensed psychologist) and will be available to speak with the participant and/or consult with research staff, if necessary. Concern for the participant's well-being and encouragement for seeking help will be expressed, and suggestions for where help can be sought will be offered using the appropriate local resource (e.g., local VA). Staff will have the capability of directly connecting suicidal participants to a 24-hour suicide hotline (Veterans Crisis Line).

Davis Research an outside assessment company that will conduct the 2 and 6-month follow-up assessments, has worked on VA research in the past also has established security procedures to ensure the integrity of VA data. Further, their staff are trained to respond to suicidal ideation, including transferring participants to the Veterans Crisis Line and contacting the PI.

d) Explain the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant Also discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.

The experiment will terminate 6 months after the final participant is sent the self-help tool. Analyses will take the remaining study period.

10. Benefits

a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.

Results may not directly benefit participants, however, if
they do engage in a weight loss
treatment, they may lose weight and have related health improvements.

11. Privacy and Confidentiality

Privacy Protections

a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

We are requesting a waiver of documentation of consent as the consent
process and all other study procedures will be conducted over the phone.

Study staff will be in a private room when talking to participants.

Potential and actual participants will be contact by postal mail
and phone.

If any participants leave a telephone message, VA voicemail is
password protected. Desktop/email access and voicemail passwords are
required to be changed on a regularly scheduled basis per VA protocol.

Confidentiality Protections

b) Specify PHI (Protected Health Information). PHI is health information linked to HIPAA identifiers (see above). List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol. Be consistent with information entered in section 15a.

Names
Social Security numbers
Telephone numbers
Addresses, including zip code
Dates associated with care
Date of birth
Internet Protocol (IP) address numbers/URLs
Voice recording
age
gender
depressive symptoms
disordered eating behaviors
quality of life
diagnoses
height
weight
health service use
Patient ICN

c) You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See http://med.stanford.edu/datasecurity/ for more information on the Data Security Policy and links to encrypt your devices.

Provide any additional information on ALL data security measures you are taking. You must use secure databases such as https://researchcompliance.stanford.edu/panels/hs/redcap RedCap. If you are unsure of the security of the system, check with your Department IT representative. Please see http://med.stanford.edu/irt/security/ for more information on IRT Information Security Services and http://www.stanford.edu/group/security/securecomputing/mobile_devices.html for more information for securing mobile computing devices. Additionally, any PHI data on paper must be secured in an locked environment.

By checking this box, You affirm the aforementioned. Y

Data will be stored on VA servers which are password protected,
backed up, and encrypted. We are requesting permission to store
identifiable patient information on VAPAHCS and/or Houston VAMC servers
as well as in VINCI so that we may mail recruitment letters.

d) Describe how data or specimens will be labeled (e.g. name, medical record number, study number, linked coding system) or de-identified. If you are de-identifying data or specimens, who will be responsible for the de-identification? If x-rays or other digital images are used, explain how and by whom the images will be de-identified.

Questionnaire responses will be stored in Qualtrics, which is approved
for PHI, and then
on a secure, password-protected VA server in a folder in which only
study personnel have access. Data files will be labeled with a
randomly selected unique study identifier number. The crosswalk
between unique study identifier and participant identifiers (name,
contact information, participation tracking database) will be
maintained in a separate folder; only staff with a need for crosswalk
information will have access to that file.

e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).

Access to identifiable information will be limited to the minimum necessary team members. Data held by research staff whether identifiable or not will be held in strictest confidence, with the need for confidentiality taking precedence over considerations of economy or convenience. Research staff will use, disclose, or request information to the minimum amount necessary required to perform their specific job function and to accomplish the intended research purpose. The same will be true for data held by Davis Research.

f) If data or specimens will be coded, describe the method in which they will be coded so that study participants' identities cannot be readily ascertained from the code.

Codes will be generated using a random number table and assigned at random. As noted above, the crosswalk file that links participants and codes will be kept in a separate file from other data sources and will only be available to study staff with a need for that information.

g) If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.

Dr. Breland will maintain the crosswalk file in an encrypted excel sheet on the secure server. As noted above, only necessary staff will have access to the crosswalk file.

h) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit.See http://www.stanford.edu/group/security/securecomputing/. http://www.stanford.edu/group/security/securecomputing/. Additionally, if you will be using or sharing PHI see https://uit.stanford.edu/security/hipaa https://uit.stanford.edu/security/hipaa.

We will transfer data by one of the following VA approved
mechanisms for secure transfer of data:
1. FedEx of media (e.g. CD or DVD) (password-protected, encrypted file;
password transmitted separately to recipient after receipt is confirmed)
2. Outlook email attachment additionally encrypted with VA approved PKI.
3. Direct file transfer over VA server behind the national VA firewall.
4. VA approved File transfer system (e.g., SAFE, RMS, SFTP)

We may also mail Veterans the payment form, if needed. We will discuss the process (we will mail form, they will return it completed) before we send the form with an addressed, stamped, return envelope.

i) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?

All staff are required to complete formal training regarding privacy and confidentiality. Provisions for disciplinary action including termination of employment in case of unauthorized disclosure are included as policy and are covered in the formal training process. All staff will maintain current required trainings.

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12. Potential Conflict of Interest

Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.

Financial Interest Tasks

Investigators	Role	Email	Has Financial Interest?	Date Financial Interest Answered	Date OPACS Disclosure Submitted	Date OPACS Review Completed
Jessica Yelena Breland	PD	jessica.breland@va.gov	N	10/19/2020		
Susan Frayne	COP D	susan.frayne@va.gov	N	10/20/2020		

13. Consent Background

13. 1 Waiver of Documentation EMBERtrial_Consentv1

Sponsor's Consent Version Number: (if any) :

a) Describe the informed consent process. Include the following.

i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)

ii) When and where will consent be obtained?

iii) How much time will be devoted to consent discussion?

iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?

v) What steps are you taking to minimize the possibility of coercion and undue influence?

vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

i) Dr. Breland, Ms. Mohankumar or other research staff will obtain consent. They are knowledgeable about this specific study and the consent process in general. ii) Consent will be obtained over the phone. iii) As much time as necessary will be devoted to the consent discussion, we anticipate it will take ~15 mins or less. iv) We will give potential participants ample time to ask questions. They will be welcome to think about participation and schedule another phone call to complete the consent process, if they prefer. v) We will remind potential participants that they are not required to participate and that their participation or non-participation will not affect their care. vi) n/a

b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter12.2 for guidance.

All participants will understand English as they are US veterans. Anyone needing assistance will be provided with accommodations.

c) What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

During recruitment we will exclude potential participants with cognitive impairment and if the person obtaining consent believes the potential participant is unable to give consent, the process will be terminated.

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Additional VA questions:

i) List the people to whom you have formally delegated responsibility to obtain informed consent, and state whether they have the appropriate training to perform this activity.

Dr. Breland, Ms. Mohankumar or other research staff will obtain consent. They are knowledgeable about this specific study and the consent process in general.

ii) Will legally effective informed consent be obtained from the participant or the participant's legally authorized representative (LAR) or both? If LAR, is it clear who can serve as LAR?

Informed consent will be obtained from the participant.

iii) Will the circumstances of the consent process minimize the possibility of coercion or undue influence and provide the prospective participant or their representative sufficient opportunity to consider whether to participate?

As noted above, we will take several steps to minimize the possibility of coercion or undue influence, including: *Giving potential participants as much time as needed to discuss their consent, we expect the process to take about 15 minutes. *Giving potential participants ample time to ask questions. They will also be welcome to think about participation and schedule another phone call to complete the consent process, if they prefer. *Reminding potential participants that they are not required to participate and that their participation or non-participation will not affect their care.

iv) Will the circumstances of the consent process minimize the possibility of coercion or undue influence?

Yes, see previous answer.

v) Will the information being communicated to the participant or the representative during the consent process exclude any exculpatory language through which the participant or the representative is made to waive or appear to waive the participant's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agent from liability for negligence (e.g. I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research)?

Participants will not be asked to waive any rights.

vi) Please confirm that the consent form is on the VA Form 10-1086

Select one of the following regulatory criteria for a waiver of documentation (signature) and provide a protocol-specific justification:

1)		**45 CFR 46.117(c)(i). For research that is not subject to FDA regulation, the only record linking the participants and the research would be the consent document,and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.**
2)	Y	**45 CFR 46.117(c)(ii). For research that is not subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**
3)		**45 CFR 46.117(c)(iii). For research not subject to FDA regulation, if subjects or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.**
4)		**21 CFR 56.109(c)(1). For research that is subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**

Rationale for above selection:

We will be asking participants to use a tool to increase their weight loss treatment engagement as well as for information regarding their health beliefs and behaviors. We are also asking for permission to obtain information about diagnoses and treatment use from their medical record. All procedures are related to actions that might be asked during a normal clinical encounter for which a consent would not be required outside a research context.

13. 2 Waiver of Documentation EMBERtrial_PhoneScreenv1

Sponsor's Consent Version Number: (if any) :

Title : The EMBER Trial for Weight Management Engagement
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a) Describe the informed consent process. Include the following.

i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)

ii) When and where will consent be obtained?

iii) How much time will be devoted to consent discussion?

iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?

v) What steps are you taking to minimize the possibility of coercion and undue influence?

vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

i) Dr. Breland, Ms. Mohankumar or other research staff will obtain consent. They are knowledgeable about this specific study and the screening process in general. ii) Screening will be done over the phone. iii) As much time as necessary will be devoted to the screening discussion, we anticipate it will take ~5 mins or less. iv) We will give potential participants ample time to ask questions. They will be welcome to think about participation and schedule another phone call to complete the screening process, if they prefer. v) We will remind potential participants that they are not required to participate and that their participation or non-participation will not affect their care. vi) n/a

b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter12.2 for guidance.

All participants will understand English as they are US veterans. Anyone needing assistance will be provided with accommodations.

c) What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

During recruitment we will exclude potential participants with cognitive impairment and if the person obtaining consent believes the potential participant is unable to give consent to screening, the process will be terminated.

Additional VA questions:

i) List the people to whom you have formally delegated responsibility to obtain informed consent, and state whether they have the appropriate training to perform this activity.

, Ms. Mohankumar or other research staff will obtain consent. They are knowledgeable about this specific study and the consent and screening process in general.

ii) Will legally effective informed consent be obtained from the participant or the participant's legally authorized representative (LAR) or both? If LAR, is it clear who can serve as LAR?

Informed consent will be obtained from the participant.

iii) Will the circumstances of the consent process minimize the possibility of coercion or undue influence and provide the prospective participant or their representative sufficient opportunity to consider whether to participate?

As noted above, we will take several steps to minimize the possibility of coercion or undue influence, including: *Giving potential participants as much time as needed to discuss their consent/screening, we expect the process to take about 15 minutes. *Giving potential participants ample time to ask questions. They will also be welcome to think about participation and schedule another phone call to complete the screening process, if they prefer. *Reminding potential participants that they are not required to participate and that their participation or non-participation will not affect their care.

iv) Will the circumstances of the consent process minimize the possibility of coercion or undue influence?

Yes, see previous answer

v) Will the information being communicated to the participant or the representative during the consent process exclude any exculpatory language through which the participant or the representative is made to waive or appear to waive the participant's legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agent from liability for negligence (e.g. I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research)?

Participants will not be asked to waive any rights.

vi) Please confirm that the consent form is on the VA Form 10-1086

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Select one of the following regulatory criteria for a waiver of documentation (signature) and provide a protocol-specific justification:

1)		**45 CFR 46.117(c)(i). For research that is not subject to FDA regulation, the only record linking the participants and the research would be the consent document,and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.**
2)	Y	**45 CFR 46.117(c)(ii). For research that is not subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**
3)		**45 CFR 46.117(c)(iii). For research not subject to FDA regulation, if subjects or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.**
4)		**21 CFR 56.109(c)(1). For research that is subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**

Rationale for above selection:

We will be asking participants questions to determine their eligibility for a study.

14. Assent Background (less than 18 years of age)

15. HIPAA Background

15. 1 Waiver of Authorization waiver of authorization

a) **Describe the Protected Health Information (PHI) needed to conduct the research. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STRIDE, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.**

This waiver of authorization is requested for access to PHI data collected after enrollment in the study since the VA does not recognize an "Alteration of Authorization". We plan to collect the following PHI: Names Social Security numbers Telephone numbers Addresses, including zip code Dates associated with care Date of birth Internet Protocol (IP) address numbers/URLs Voice recording age gender depressive symptoms disordered eating behaviors quality of life diagnoses height weight health service use Patient ICN

b) Please Answer:

Y **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**

Y **Do you certify that the research could not practically be conducted with out the waiver?**

Y **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**

Y **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) **Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

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All data will be stored on secure servers or in a locked file cabinet in a locked office. Only staff with a need to access the information will have access to study data. Participant information will be coded.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

We will destroy data according to VA policies.

15. 2 Waiver of Authorization for Recruitment

waiver of authorization for recruitment

a) Describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.

This waiver of authorization is requested for access to PHI prior to screening, after screening (but before enrollment in the study) We plan to collect the following PHI: Names Social Security numbers Telephone numbers Addresses, including zip code Dates associated with care Date of birth Internet Protocol (IP) address numbers/URLs Voice recording age gender depressive symptoms disordered eating behaviors quality of life diagnoses height weight health service use

b) Please Answer:

Y **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**

Y **Do you certify that the research could not practically be conducted with out the waiver?**

Y **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**

Y **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) Please describe an adequate plan to protect any identifiers from improper use and disclosure.

All data will be stored on secure VA servers or in a locked file cabinet in a locked office. Only staff with a need to access the information will have access to study data. Participant information will be coded.

d) Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

We will destroy data according to VA policies.

16. Attachments

Attachment Name	Attached Date	Attached By	Submitted Date
PHQ	11/06/2018	breland	
VR-12	11/06/2018	breland	
Disordered Eating Screen	11/07/2018	breland	
B-IPQ	11/07/2018	breland	
Screen shots of online tool	11/07/2018	breland	

Breland CDA 15-257	11/15/2018	ahorwege	
Lcat3.0	05/19/2019	breland	
P4 screener	05/19/2019	breland	
Control v4	02/19/2020	breland	
EMBER v4	02/19/2020	breland	
Payment Form	02/28/2020	breland	
Baseline Questionnaire	06/30/2021	breland	
Follow-Up Questionnaires	06/30/2021	breland	
Lost to follow-up letter	06/30/2021	breland	
Digital Participant Letter	06/30/2021	breland	
Paper Participant Letter	06/30/2021	breland	
Phone Scriptv1	06/30/2021	breland	
10-day call guide	06/30/2021	breland	
EMBER Opt Out Letter	06/30/2021	breland	
EMBER VARQ	06/30/2021	breland	
Breland IIR 19-422	07/01/2021	breland	

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all Stanford research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the IRB for review prior to the implementation of such change. Any complications in participants or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. Inasmuch as the Institutional Review Board (IRB) includes faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of

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any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

https://stanfordmedicine.box.com/shared/static/qbsi8u8h47qsotxhdpuzz50xlrqa0sgo.pdf Report promptly any new information, complaints, possibly serious and/or continuing noncompliance, or unanticipated problems involving risks to participants or others.

All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data)

APPROVAL LETTER/NOTICE NOTE: List all items (verbatim) that you want to be included in your approval letter (e.g., Amendment date, Investigator's Brochure version, consent form(s) version(s), advertisement name, etc.) in the box below.

Y By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.