Title: Heart Health Buddies: Peer Support to Decrease CVD Risk
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Purpose. This intervention will use a hybrid reciprocal peer support and peer coach model to initiate and sustain healthy behavioral changes. Veterans who are at-risk for cardiovascular disease (CVD) will be enrolled in the study and paired with another Veteran to receive and provide social support around engaging in CVD risk reduction behaviors. Enrolled participants will be offered a series of group sessions focused on CVD risk reduction goal setting and action plan development. Between group sessions, peer partners will be asked to have weekly calls to discuss action plan challenges, explore options for problem solving, and provide encouragement and accountability for personal goals. Participants who do not engage in the group sessions or weekly phone calls, or who request additional help, will receive support from trained peer coaches. The goal of this pilot is to evaluate the proof of concept for this hybrid reciprocal peer support (RPS) and peer coach intervention to improve heart healthy behaviors among Veterans at risk for CVD. The aims are:

Aim 1: Examine the feasibility and acceptability of a 12-week hybrid peer coach-reciprocal peer support intervention for Veterans at risk for CVD

- Feasibility will be evaluated by ease of recruitment, measurement of enrollment and retention rates
- Acceptability will be assessed quantitatively by successful and attempted peer partner contacts as well as self-report of amount, frequency and modality of contacts, rates of participation in group sessions, and through post-intervention qualitative interviews with study participants and study staff

Aim 2: Explore gender differences in feasibility/acceptability of new hybrid peer support model

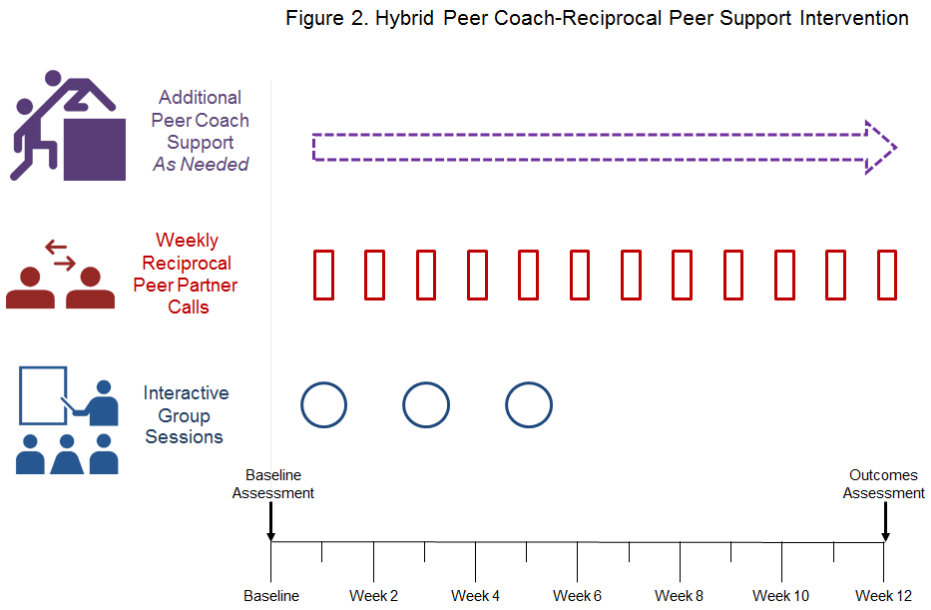
- Gender differences will be evaluated through qualitative comparison of participant reported experiences with intervention content as well as peer and group interactions by gender; and, quantitatively via exploration of differences in enrollment, retention, refusal reasons and frequency of peer contacts

Background and Significance. The majority of middle-aged Veterans have at least one risk factor for cardiovascular disease[1]; these risk factors and subsequent cardiovascular disease (CVD) lead to significant personal and financial burden for patients and the VA healthcare system[2]. Poor social support incurs additional risk of cardiac and all-cause mortality [3], while higher levels of social support lead to better health outcomes[4]. Unfortunately, many Veterans are socially isolated, and 61.8% of female and 47.6% of male middle-aged Veterans are unmarried [5]. While supplemental social support can come from multiple sources, one type that may be especially well-suited to the Veteran population is peer support. Peer support is an evidence-based

approach to augmenting social support and could be a valuable tool to promote Veteran engagement in CVD risk reduction behaviors. There are multiple approaches of using peer support to improve health. One example is *reciprocal peer support* which pairs individuals to both give and receive social support around a common health goal. A second is *peer coaching* which delivers unidirectional support from someone with advanced training and who has improved their health behaviors to an individual with the same disease state but who is currently struggling with behavior change. Both peer coach and reciprocal peer support models have been effective in promoting health outcomes [6,7]. The strength and benefit of these different models of peer support varies based on patients' motivation levels and their ability to proactively engage with peers.

Design. We propose a pilot study that will examine a 12-week intervention to evaluate proof of concept of a hybrid peer coach/reciprocal peer support intervention for Veterans (Figure 1). Using the ORBIT (Obesity Related Behavioral Intervention Trials) framework for intervention development[8], this phase II study will aim to assess acceptability and feasibility with specific attention to gender-differences and an assessment of factors contributing to successful peer engagement. Veterans who are at-risk for developing CVD will be invited to participate in a novel peer-support intervention that combines reciprocal peer support with additional peer coaching for less motivated participants and provides all participants with interactive, facilitated group sessions. The study will include up to 24 patients (or up to 12 peer-partner pairs) and up to 6 peer coaches per cohort. We will consider conducting a second cohort for this pilot depending on the results of the initial cohort. This study was presented to the Durham COIN's Veteran Research Engagement Panel (VetREP), a group of 11 Veterans who are dedicated to providing feedback, and input from this panel was incorporated into the design, including content for group sessions, peer partner matching criteria, approach to recruitment messaging, and intervention name.

Figure 1. Hybrid Reciprocal Peer Support/Peer Coach Intervention



Because participants who will be peer partners and peer coaches will both be considered study participants, we will list their eligibility criteria separately.

Peer support partner eligibility criteria will be determined by electronic data abstraction:
Inclusion Criteria

- Age 35-64 years
- Enrolled in a Durham VAHS primary care clinic (including the women's health clinic)
- At risk for CVD as defined by having at least one of the following:
  - Uncontrolled hypertension defined as at least one blood pressure >150/100 in the previous 12 months
  - Documented history of obesity defined as (BMI >30) in the previous 12 months
  - Uncontrolled non-insulin dependent diabetes mellitus (E11) defined as a hemoglobin A1c >8.0 in the last 12 months

Peer support partner Exclusion Criteria:

- Insulin-dependent diabetes
- Serious mental illness defined as schizophrenia, bipolar disorder, dementia, active psychosis psychiatric hospitalization within the last 12 months or current high-risk suicide flag in their CPRS medical record
- Active substance use as documented in CPRS or positive screening during telephone screening
- Limited Life expectancy (<6 months) or severely ill defined as enrolled in hospice or actively undergoing chemotherapy or radiation therapy for cancer
- Current pregnancy

Additional Peer support partner eligibility criteria will be determined by telephone screening:

- English as preferred language
- No significant hearing impairment that precludes participation in telephone calls
- Lives within 30 minutes of the Durham VAMC
- Agrees to attend regular visits per study protocol
- No contraindication to engage in at least moderate physical activity
- Lack of planned pregnancy within next 6 months
- Willing to use personal phone for peer and coach contact

Peer coach eligibility criteria will be determined by electronic data abstraction:
Peer coaches are intended to be patients with at least one CVD risk factor that was previously out of control and who have made a sustained behavior change related to increasing physical activity or diet. Coaches will be initially recruited through existing Durham VAMC program staff (e.g., nutritionists, MOVE! staff) who may be able to identify a potential coach based on the following *core* criteria. We will mail recruitment letters to potential coaches identified by staff. If we cannot recruit sufficient number of

coaches using this method, we will conduct an administrative data pull to identify potential coaches.

Core Inclusion Criteria for coaches

- Age 35-64 years
- Enrolled in a Durham VAHS primary care clinic (including the women's health clinic)
- At least one of the following:
    - Hypertension
    - Hyperlipidemia
    - Current or prior obesity demonstrated by current BMI <30 with previous BMI >30 within last 24 months
    - Non-insulin dependent diabetes
- Sustained improvement in physical activity or dietary change within the previous 3-6 months

Data Pull Inclusion Criteria

- Age 35-64 years
- Enrolled in a Durham VAHS primary care clinic (including the women's health clinic)
- At least one of the following:
    - Hypertension with most recent BP <140/90, but with at least one BP >150/100 in prior 24 months
    - Prior obesity demonstrated by current BMI <30 with previous BMI >30 within last 24 months
    - Non-insulin dependent diabetes with hemoglobin a1c <8.0 with value >8.0 within the last 24 months

Peer coach exclusion criteria

- Insulin-dependent diabetes
- Serious mental illness defined as schizophrenia, bipolar disorder, dementia, active psychosis, psychiatric hospitalization within the last 12 months or current high-risk suicide flag in their CPRS medical record
- Active substance use as documented in CPRS or positive screening during telephone screening
- Limited Life expectancy (<6 months) defined as enrolled in hospice
- Contraindication to engage in at least moderate physical activity
- Current pregnancy or planned pregnancy in next 6 months

Additional Peer coach eligibility criteria will be determined by telephone screening:

- Sustained improvement in physical activity or dietary change within the previous 3-6 months
- English as preferred language
- No significant hearing impairment that precludes participation in telephone calls

- Lives within 30 minutes of the Durham VAMC
- No contraindication to engage in at least moderate physical activity
- Agrees to attend regular visits per study protocol
- Lack of planned pregnancy within next 6 months
- Willing to use personal phone for peer contact

Eligible patients will receive a recruitment letter from study staff at the Durham VAMC. Participants will have a least a week after recruitment letters are mailed to call in and opt-out of study participation. Potential participants will also be recruited via provider referrals or by calling study staff in response to advertisements. Study staff will call patients to further ascertain eligibility, describe the study and schedule an in-person baseline assessment.

Baseline visit: Veterans meeting eligibility criteria and who express interest in participating in the study will be scheduled for an in-person visit with a study staff member. Participants will sign a written consent and HIPAA. After completing the consent process, participants will complete self-report measures (see Table 1 below). This visit will be scheduled at a time acceptable to the Veteran and participants will be compensated $50 for this visit.

Table 1. Outcome measurements

Measure		
	Baseline	Week 12
Primary Outcomes		
Feasibility: Enrollment/Retention rates; amount peer contact	X	X
Acceptability: Qualitative interviews and peer process evaluation		X
Secondary Outcomes		
Patient Activation Measure (PAM)	X	X
International Physical Activity Questionnaire, short form	X	X
Starting the Conversation (Diet)	X	X
Health Specific Social Support instrument	X	X
Self-report heart health support	X	X
Physical parameters (height, weight, blood pressure)	X	X
Physical tests (Six-minute walk test, arm curl test)	X	X
FitBit output		X
Descriptive measures		
Demographics including smoking status, medical risk factors	X	
Military sexual trauma (MST)	X	
PSQ 8	X	X
PTSD PC-PTSD-5	X	X

Baseline visit content: The Veteran will complete surveys and baseline measurements including height, weight, blood pressure, arm curls, six minute walk, fasting blood draw, and an assessment to obtain information for peer matching (not peer coaches). Patient will also receive an activity monitor at the baseline visit. Participants will be compensated up to $120;$ 50 for completion of the baseline visit, $50 for the 12-week post-assessment, incentive of $20 for completing 10-12 weekly phone calls with their peer support, or $10 for completing 4-9 weekly phone calls with peer support. This will be measured by self-report through paper logs that participants will submit and/or through SMS/text messaging updates. The participants will be instructed not to include identifying information in texts.

Reciprocal peer pair matching: Prior peer support research supports the importance of giving and receiving peer support from someone of similar background and life experience (i.e., health condition). Peer pairs will be matched on primary behavior goal (either physical activity or diet) and gender. If possible given the small size of this study, peer pairs will also be matched on additional characteristics such as military era. However, we suspect that matching on this many variables will prove difficult due to the

small sample size. In the event that we have trouble matching an enrolled participant or a participant withdraws from the study, we may consider relaxing our criteria or matching more than two peers together, or have a coach work with a single participant directly.

Peer coaches: Before interaction with reciprocal peer pairs, coaches will undergo approximately 3-5 hours of **formal motivational interviewing-based communication training** by study team members including key skills such as active listening, non-directive support, eliciting change-talk, promoting incremental change, and patient confidentiality [3,11]. Peer coaches will reflect on their experience improving their own CVD risk factor control and consider how they can work with other Veterans to achieve similar success [11]. Peer coach training will be reinforced at monthly peer coach "check-in" meetings for debriefing and problem solving[12]. Coaches can also contact study team members if any urgent issues or concerns arise. Coaches will receive up to $370 in incentive payments for participation in study activities: $50 for completing the baseline, $75 for the initial training, up to $75 for attending and leading activities at the 3 group sessions ($25 per group), $50 for the 12-week follow-up and $10 per month per participant coached by phone up to a maximum of $40 per month (120 total). Coach to participants calls will be verified by self-report through submitted paper call logs and/or SMS/text reporting. They will be paid at 3 time points.

Initial Peer contact: Participants who complete the baseline assessment will be scheduled to attend the first group session (see Table 3). During this session, participants will be introduced to both their peer partner and peer coaches. This initial session will include an overview of key CVD facts, action planning, a brief (<1 hour) training session on being an effective peer partner (e.g. instruction on key MI communication skills), and relationship building activities for peer partners. Participants will set an initial action plan step towards their behavioral goal. At the end of this session, peer pairs will agree upon a time for their next contact which will take place via telephone. Depending on the timing of recruitment and the first group session, peer coaches may reach out to individual reciprocal peer participants by phone while awaiting the first group session to keep them engaged.

Structured group sessions: As noted through prior work, peer support interventions are most successful when paired with a structured behavior change or self-management

program. Behavioral change techniques [13,14] to be deployed through group sessions and peer interactions are noted in Table 2. Over the three-month pilot study period, there will be three group sessions led by peer coaches and a study interventionist at approximately week 1, week 3 and week 5. Each session will include brief instruction and practice of an accessible physical activity (i.e. stretching, yoga), a small amount of didactic content, and time for peer partners to problem solve action plans and provide in-person encouragement and support. Physical activity exercises and didactic content will be led by a study interventionist; peer activities will be led by coaches. Participants will be asked to complete brief assessments of the quantity and quality of their interactions with peer partners since the previous group session. Content for listed domains will be adapted from existing and previously developed resources (e.g. MOVE!'s Telephone lifestyle coaching workbook). Participants will be provided with personalized participation certificates at group 3.

	Timing	Content	Behavioral Change Technique
Group session #1	Week 1	Brief physical activity (PA) practice CVD risk basics Effective Peer Partner training Action Planning/Goal Setting 'Relationship-building' activities	• Review health consequences • Goal setting • Prompt barrier identification • Encourage self-monitoring • Instruction on performing behavior (PA) • Social support
Group session #2	Week 3	Brief PA practice Heart Healthy Eating Physical Activity (PA) Strategies Action Plan/Goal Setting	
Group Session #3	Week 5	Brief PA practice Blood pressure/Cholesterol Goals Action Plan/Goal Setting	
Reciprocal Peer phone calls	Weekly for 12 weeks	Weekly Action Plan Debriefing Trouble shooting Bidirectional support	• General encouragement • Social comparison • Problem solving • Social support
Peer coach contact	As Needed	Action Plan Debriefing Trouble shooting Unidirectional support	• Model desired behavior change • Social comparison • Encourage self-monitoring • Problem solving

<u>Reciprocal Peer Pair contacts:</u> Peer partners will be encouraged to have at least one contact every week for 12 weeks; this frequency of calls is supported by previous work in peer support and will allow them to work together on their weekly action steps [7,15]. Peer partners may have more frequent contact if they choose. Based on prior studies, we anticipate that the average length of each call will be approximately 10-20 minutes. In addition, peer partners will be encouraged to send text messages to each other or the coaches. We will recruit patients who are willing to use their own personal phone for peer and coach contact. During weekly calls, peer partners will discuss progress on their action plans and support each other with problem solving. Peer coaches will reach out to each peer partner after week 1 to check in about how the first call went and offer suggestions and assist with problem solving if communication concerns are raised. Peer buddies will be asked to send an SMS/text message to the study team phone after each call with their partner to assist with verification that a call has taken place. If no message has been received for a buddy pair for one week, then a SMS/text message will be sent to the pair reminding them to attempt a call. If no message has been received from a buddy pair for two weeks, then a peer coach will call them individually to check-in and assist with any problem solving as needed.

Partners will be provided with sample questions and prompts to initiate and guide discussion on action plans and problem solving. However, they will not be scripted as to promote authentic communication and enhance the perceived value of peer communication; thus, tangential topics or patient concerns may be covered. All participants will be instructed not to give medical advice and that they should not act on any advice given to stop or start a new therapy without discussing with their provider. Participants will have contact information for study staff in case a participant would like to request a new partner and the 24-hour VA crisis line number if he or she is having urgent concerns about a partner's well-being. It is expected that incompatibility of peer dyads requiring cessation of peer contact will be rare based on previous reciprocal peer support trials [6,16]. If a peer pair is recognized as incompatible, those peers will be accommodated on a case-by-case basis including potentially having them join another peer partner team or being supported directly by a peer coach.

Peer coach contacts: Peer coaches will have up to three types of interactions with the reciprocal peer pairs: 1) leading activities and discussions at group sessions, 2) a beginning and mid-study phone call to individual peer partners to check-in on peer partner experiences and provide guidance and interaction support, and 3) ongoing phone support as needed. As needed coach phone support will be triggered by: 1) lack of participant engagement in calls to partner or attending group sessions (for example, if there are no phone calls between a pair of reciprocal peer support partners in first 10-14 days), or 2) if requested. Coaches will have sample scripts to reference during phone support calls and a manualized guide for group session activities. All group sessions will be monitored for fidelity by the PI using a checklist for key features of the planned session. Coaches will then receive supportive feedback on their approach and pointers on needed adjustments. They will also have opportunity to role play during at least group monthly sessions with all peer coaches to practice and hone their communication and non-directive support skills. The amount of time each coach will spend providing support will be 10 hours over 12 weeks at a minimum for group session participation and initial calls with peer pairs. Additional time with ad hoc support for individuals as needed is unknown and will be determined during the course of the pilot, but is expected not exceed an additional 12 hours. Peer coaches will be asked to keep a log of the time spent working with peers during the course of the study.

Peer contact monitoring: We will ask participants to send an SMS/text message to the study coordinators study phone after each call with their peer buddy (and for coaches after calls with a peer buddy participant). If we have not heard from a buddy pair after one week, we will send SMS reminder. All text messages will be sent from a study specific phone number used only for texting and calling participants. Receiving SMS/text message verification of buddy pair communication and coach to buddy communication will help us to identify an efficient, validated method of communication verification for future use in future studies. Other monitoring approaches may include: a) self-report of the number and approximate length of recent calls during each group session; b) a brief, post-intervention survey that will include specific questions about frequency and duration of peer communication; c) informal participant feedback about peer contact process, improvements needed to peer orientation and need for specific

support materials. Participants will receive the portion of their incentive that is based on the number of calls completed depending on the number of calls that they have reported.

Outcome Measures: Outcome measures will be assessed during a post-intervention visit at 12 weeks with all peer coaches and reciprocal peer partners. Participants who complete the post-intervention evaluation at week 12 will receive a $50 incentive. Heart health buddies are paid $50 after the baseline and after the 12-week follow-up visit.

Feasibility will be evaluated by assessing recruitment rates overall and by different approaches (i.e., #patients sent letters, #consented, #consented in response to flyers, #consented by provider referral), retention rates (#participants completing week 12 post-intervention assessment, # completing baseline assessment), drop-out rates, and reasons for refusal. We will also track frequency and amount of completed peer partner and peer coach calls using self-report via SMS/text message and on paper logs as well as attendance at group sessions.

Acceptability will be assessed through post-intervention interviews. The conversation will be recorded via a VA-approved device (USB Sparky recorder). Peer partners will be called on the phone. Coach feedback will be collected at either the final coach check-in group, or over the phone. The recording will be kept on a VA computer behind a VA firewall. For all participants, we will ask about perceived value of group sessions, training experience, facilitators and barriers to peer interactions, and general feedback about improving the intervention. Reciprocal peer participants will also be questioned about their perceptions of the peer matching process and receipt of support from peer coaches. Peer coaches will be asked about the value of the monthly coach meetings and their experience supporting reciprocal peer pairs and individual participants. Experience with peer interaction will be assessed using an established 17-item peer process measure[17] that includes questions on availability of peer, assistance in daily management, support provided and linkage to care, and a measure that assesses to what extent support received was directive vs non-directive[18]. Social support will be evaluated by Health specific social support scale, which is a 12-item scale used in other interventional research. Physical activity will be measured using the International Physical Activity Questionnaire, short form[20] which assesses PA during the previous 7 days and is summarized in a continuous measure of MET-min per week. It will also be assessed at baseline and 12 weeks with a 6-minute walk and arm curl test, and recording steps and active minutes from an activity monitor at group sessions and the 12 week study visit. Diet will be assessed using *Starting the Conversation*[21] which is an 8-item measure designed for health behavior promotion with summary scores ranging from 0 (more healthy diet) to 16 (less healthy diet). Physical parameters such as weight, height, serum lipids and blood pressure will also be measured. Venipuncture will take place at a Durham VAMC clinical lab to obtain lab values, with blood samples staying within the Durham VAMC environment. Specimens will not be retained.

Analyses: Aim 1: Examine the feasibility and acceptability of a 12-week hybrid peer coach/reciprocal PS intervention for Veterans at risk for CVD:

Quantitative measures We will calculate the outcome retention rate. For self-report we will calculate mean and distribution of the number and duration of peer phone contacts (both reciprocal peer pairs and peer coach calls) and compare to planned call frequency. We will also ask participants about any behavior changes made during the intervention and compare change from baseline in a diet and exercise assessment. We will also examine changes from baseline in patient-centered measures (e.g. physical parameters, social support) to assess variability of outcome measures to ensure appropriate responsiveness needed for use in an IIR. We will not interpret p values or determine an effect size as this is not appropriate for a pilot[22].

Qualitative measures: Post-intervention interviews will be audio-recorded and analyzed using a rapid analysis approach based on key features of peer support [23] (e.g. support of daily management) and *data-derived* codes. Participant responses will be organized by pre-planned constructs (e.g., barriers and facilitators to peer partner interactions) and suggestions for improving the intervention. The qualitative interview will take place by calling the participant from a VA phone or in-person focus group for the coaches, and recorded on a VA-approved recording device (Sparky USB recorder). The recordings will be kept on a VA computer behind the VA firewall. Team members will listen to the recorded interviews and take detailed notes according to the pre-planned constructs. This process will be completed for approximately five interview recordings. After the initial review and coding, the preliminary findings will be discussed as a team. Additional review by other team members will take place as needed. Once any differences have been resolved, then the rest will be coded independently by Dr. Goldstein. Interview results will inform further intervention tailoring. For example, we may learn that peers would prefer more frequent opportunity to meet with their partner early in the intervention or that peers want additional access to peer coaches.

Aim 2: Assess gender differences in feasibility and acceptability of 12-week hybrid peer coach/reciprocal peer support intervention: We plan to target 50% recruitment of women Veterans to allow for stratification of feasibility and acceptability assessments by gender. We will seek evidence of large differences in recruitment, retention, or rates of peer call completion that might suggest lower engagement in intervention activities. Additionally, we will stratify interview analysis by gender to explore qualitative findings that may vary by gender. Such differences, if identified, would inform the need for gender-specific tailoring of the intervention activities. For example, if female participants attend group sessions at notably lower rates than male participants and qualitative interviews identify that women do not feel comfortable participating in peer activities with men, then we will consider a gender-specific peer intervention for CVD risk reduction in the future.

Sample size: As noted, we plan to recruit sufficient participants to support two cohorts of reciprocal peer pairs and group sessions, with a target enrollment of up to 24 Veterans plus up to 6 Veteran peer coaches. This will allow adequate opportunity to evaluate feasibility and acceptability for our pilot protocol and sufficient input from participants to inform intervention tailoring and improvement for a larger RCT while being responsive with the practical limitations of the shortened time period for this pilot. A larger sample is not needed as we are trying to be powered to perform inferential statistics.

Data Management: Data collection will occur using VA-approved software, which are REDCap, Epi Info,and/or Excel, and Atlas Ti. Recording of the post-intervention interview will be over the phone and recorded on a Sparky device. A study tracking database will be created for this study in conjunction with the Center's software development team using Microsoft.NET and/or excel spreadsheets. Outcome measures will be entered into database using REDcap, which is a VA Intranet Web application approved by VA and run by VA VIReC. The REDcap software is web-based but participants will be interviewed either in person or over the phone and data will be entered by study staff on VA computers behind the VA's firewall. The data are housed on a VA Informatics & Computing Infrastructure (VINCI) Server. All study data will be stored on a secure VA server. The tracking and survey databases for this study will be developed in conjunction the Durham COIN biostatistics unit (directed by Dr. Olsen, mentor) and the software development core. Call attempts, call lengths and number of texts will be collected by self-report. Study participants will be encouraged to wear a pedometer/activity meter for the duration of the study. We will provide a non blue-tooth enabled pedometer/activity meter type device to the participants. We will ask them to bring their pedometer to each group meeting, and the final assessment, so that steps or daily activity data from the past 21-30 days can be manually collected from the device by a staff member during the group meeting/assessment.

Safety Monitoring Plan. This is a minimal risk study so the potential for serious adverse events related to the study is low. We will document reported adverse events or problems on a standardized case report form detailing the event, when it occurred, any pertinent diagnostic workup, any treatment, and whether and when the symptom or problem resolved. Study staff will report any adverse event or unanticipated problem to the PI immediately. We will review any such events and determine the likelihood they were due to the study. Statistical tests are not planned for analyzing the safety data during the conduct of the study. There are no conditions that trigger an immediate suspension of the research. The PI will report any serious, unexpected, and study-related adverse event or unanticipated problem to the local IRB according to the institution's requirements. The IRB will review all adverse events during continuing review, which will likely occur annually. All adverse events will be reported in the annual report to the VAMC IRB.

There are few potential risks associated with any of the measures or data to be collected. Participants do not have to answer any question that they do not wish to answer, as will be explained during the consent process. There are also small risks of injury or heart problems due to increased participation in physical activity. The threat of this potential problem will be reduced by screening for contraindications to physical activity participation and by providing proper instruction regarding methods for engaging in physical activity safely, as well as contraindications for continuing physical activity. Because the main physical activity to be stressed is low impact (e.g. yoga, walking), we do not anticipate that the health risks will be over and above the risks normally associated with daily activities.

Privacy, Confidentiality, and Information Security

1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

The Personal Health Information that will be obtained, used, and/or shared for this study includes:

Identifier(s)	Source(s) of Health Information
☒ Names	☒ Medical history & physical exam information
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: address	☒ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: birthdate, treatment dates	☒ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe: blood draw to measure hemoglobin A1c and Fasting lipid levels
☒ Telephone numbers	☒ Progress notes
☐ Fax numbers	☒ Diagnostic / Laboratory test results
☐ Electronic mail addresses	☒ Operative reports
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☒ Medical record numbers	☐ Discharge summaries
☐ Health plan beneficiary numbers	☒ Survey / Questionnaire responses
☐ Account numbers	☐ Billing records
☐ Certificate and/or license numbers	☐ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☐ Sickle cell anemia information
☐ Device identifiers and serial numbers	☐ Alcoholism or alcohol use information
☐ Web Universal Resource Locators (URLs)	☐ Drug abuse information
☐ Internet Protocol (IP) address numbers	☐ Mental health (not psychotherapy) notes
☐ Biometric identifiers, including finger & voice prints	☐ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☒ Any other unique identifying number, linked study ID, characteristic, or code, describe: Study ID	☐ Other, describe:

2. Data and/or Specimen Acquisition:

Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes: Surveys, in-person sessions and telephone interviews.

☒ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.): We will review medical chart data to check if participants meet inclusion criteria. We will also perform a data pull of potentially eligible participants using VINCI, using approved VA procedures. Potentially eligible participant data will be pulled and transferred to a secure Durham VAMC server. As the potential study pool may be large but the study number is small, the data pull will pull small batches of names and IDs to review and screen, before additional names are pulled until enrollment is complete.
☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: .
Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.

3. Level of Data:
The following level(s) of data will be acquired/maintained for this study (*check all that apply*):
☒ Identified (e.g., names, addresses or other identifiers included)
☒ Coded (direct and/or all identifiers removed, but study code/ID included)
☐ De-Identified (all HIPAA 18 and study ID/code removed):
- ☐ Verified Statistically
  OR
- ☐ Verified by Absence or Removal of HIPAA 18 and study ID

☐ Limited Data Set
☐ Other: Describe:

4. Location of Data and/or Specimens, and Data Retention Plan:
A. Data will be stored electronically in \\vhadurhsrdfile1\$projects. If a tracking database is developed for the study, at \\vhadurhsrdfile1\$research\Distributed Apps\HSRDTrackingApp. Data that will be stored electronically include patient demographics, survey data and data from in-person sessions. The data will be stored on a secure VAserver (Durham VAMC building 1, room FG104) and backed up on a regular schedule.
☒ Data will also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).
B. Data Retention Plan
☒ Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently,

destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager.
☐ Other data retention plan, describe:

5. **Data Access and Data Recipients:** Only members of our VAMC research team will have access to identifiers and coded data. Study staff at other VA sites will access the data stored on a Durham VA server through a link provided to them. They will have access to a study folder that is behind the VA firewall.

All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team. A partial off-site waiver has been obtained to conduct study group meetings at an off-site location (Duke Sara W. Stedman Nutrition and Metabolism Center). No data will be stored there. A limited amount of phi (sign in sheets, retrieval of participants' paper call logs or self-questionnaires) will be transported to and from this site. Study staff will secure the data by placing in secure containers during transport.

6. **Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:**

I. ☐ Data and/or specimens will <u>not</u> be transported or transmitted outside of Durham VAMC environment.

II. ☐ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center.

III.

a. ☒ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

b. ☒ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:
NOTICE!!! Access to these records is limited to: AUTHORIZED PERSONS ONLY. Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

☐ Data and/or specimens will be transmitted to other VA sites using the following method(s):
☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).
☐ Data are coded or contain identifiers and thus will be sent
☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).
☐ Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.
☐ Other, describe:

IV. ☒ Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.
☐ Data are coded or contain identifiers and thus will be sent via <chose method of transfer such as FIPS 140-2 encrypted CD or FIPS 140-2 encrypted hard drive/flash drive> using VA—approved carrier with tracking.
☐ Data are coded or identified and will be sent via the Safe Access File Exchange (SAFE) at https://safe.amrdec.army.mil/safe/. SAFE is a secure method of exchanging files <2GB to and from individuals with a valid .gov, .mil, .com, or .edu email address. <insert information including collaborator name.>
☐ Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF) <insert information including sponsor name and URL and the encryption the site uses.>
☒ Other, describe: paper sign in forms as well as collection of phone logs will be physically secured and transported by study staff.

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:

☐ Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

V. ☐ We will communicate with veterans enrolled as participants in this research study through MyHealtheVet .

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant's name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

C. ☒ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials. <Please contact the facility privacy or security officer to obtain a copy of the form.>

The memo referenced above is required to be fully signed for each study team member BEFORE any data can be transported by that individual.

D. ☒ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:

NOTICE!!!
Access to these records is limited to: AUTHORIZED PERSONS ONLY. Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

7. Risk Mitigation Strategies:

☐ Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.

☐ Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.

☒ Direct identifiers will be maintained separately from data and or specimens by using a code to "identify" subjects. In a separate database (i.e., a "linking" or "cross-walk" database) this code will be linked to identifying subject information.

☐ Other, specify:

8. Suspected Loss of VA Information:

Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

9. Reporting of Results:

☒ Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published. Research results will be conveyed to the subject and and/or health care provider by request.

☐ Other results reporting plan, describe:

10. Future Use of Data:

☐ Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.

- ☐ Future Use of data is optional (i.e., not required by the research subject).
- ☐ Future Use of data is required for participation in the study.

☒ No future use of data is currently planned.

11. Use of Mail Merge Technology

☒ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly "matched". If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

12. Use of Non-Standard Software

☒ I do NOT intend to use any new specialized software (i.e. Software that's not already approved OR installed) in this study.

☐ I intend to use specialized software that has not already been installed and it has been approved for use by the VA Technical Reference Model (TRM) Group.
(Note: All new software must be approved by TRM before it can be installed on VA systems.)

☐ I intend to use previously installed software on my VA computer.

<Provide the name of the software and a description of how it will be used.>

13. Use of Cloud Computing Services

☒ Cloud computing services will NOT be used in this study.

☐ Cloud computing services WILL be used in this study as described below and have been approved nationally by the VA Chief Information Officer (CIO). (Note: ONLY cloud computing services that have been approved nationally may be used.)

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