Supporting Habit Formation to Attenuate Prefrailty in Elders (SHAPE) Pilot Study Protocol

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Countries of Recruitment	United States

1. The SHAPE Pilot Study

1.1 Objectives and Hypotheses

The main objective of the SHAPE pilot study is to determine the feasibility of using Habit Formation (HF) treatment to increase Physical Activity (PA) (reduction in daily in hours of sedentary time), and dietary among prefrail African Americans. This study will test two hypotheses:

> **Hypothesis 1**: *The SHAPE study will demonstrate good feasibility with high recruitment rate and successfully administrating all of measures among the target population.*
>
> **Hypothesis 2**: *Treatment group participants will demonstrate greater increases in primary outcomes (sedentary time and dietary quality) and secondary outcomes (prefrailty reduction, lower extremity strength, balance, and quality of life) at intervention completion.*

1.2 Background

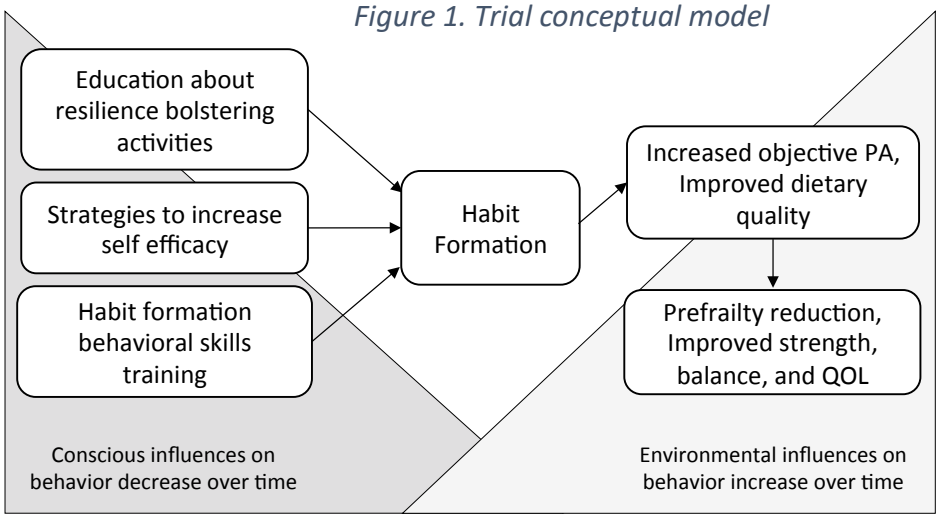
Frailty among older African Americans is common, detrimental and costly. Approximately 50% of older adults are pre-frail, [1-2] which makes them 2-3 times more likely to develop frailty within 3-7 years than non-frail elders.[2-5] Frailty, is defined as a decline in resilience across one or more domains of functioning that reduces an individual's ability to respond to or recover from stressors (e.g., illness or loss of a loved one).[6] In the context of frailty, acute social or health stressors can trigger a cascade of negative sequelae. Frail older adults are more likely to experience premature morbidity (as high as a 50% increase in relative risk), [4] mortality, and institutionalization.[1-2, 4, 7-8] African Americans have an especially high risk of becoming frail. African Americans are 2-4 times more likely to develop frailty than their European American counterparts, to do so at a younger ages, and to experience worse outcomes as a result.[1, 9-10] Moreover, correlates of frailty such as having less formal education and lower income,[12] living in lower quality neighborhoods,[12-15] higher rates of comorbid chronic diseases, obesity, and of disability are more prevalent in African American populations.[16-21]

Effective frailty reduction interventions delivered to older African Americans during the prefrailty stage could reduce or delay frailty and improve health outcomes among older African Americans. For prefrail older adults, the progression to frailty is neither inevitable nor irreversible. Pre-frail elders can regain non-frail resilience and are significantly more likely to do so than frail elderly.[5, 22-24] Moreover, pre-frailty represents an important, time-limited window of opportunity to intervene in the progression to frailty.[25] A recent study suggested that individual's spend approximately 7.4 years in the prefrail stage versus only 3.4 in the frail stage (before progressing to death or disability).[25] Interventions delivered during prefrailty may also require less intensive treatment than those delivered during frailty. Resilience-bolstering behaviors such as consuming adequate nutrition and increasing physical activity (PA) levels are currently the frontline non-pharmacological treatment for frailty reduction. Adequate nutrient intake (e.g., protein, vitamin D, fatty acids and minerals) protects against frailty by improving cell metabolism and anabolic signaling.[26] PA is considered frailty-protective through the effect that it has on attenuating sarcopenia,[26-27] stimulating muscle protein synthesis,[28-29] and

increasing muscle strength, and physical performanc.[26-27] Thus, intervening to increase physical activity and improve dietary quality among older adults during the prefrailty stage has the potential to reduce prefrailty and significantly improve both current and future health.

A novel, evidence-based habit formation program is used the SHAPE study to improve dietary quality and decrease total sedentary time (ST) could reverse prefrailty or delay its progression among older adults. The habit formation program consists of 12 treatment sessions over 12 weeks. In each session, an occupational therapist will deliver educational content, and use HF techniques and behavioral skills to facilitate frailty protective behaviors. The conceptial treatment model approach to improve dietary quality and reduced ST among frail older adults (**Error! Not a valid bookmark self-reference.**). HF approaches are effective across a range of behaviors, easy to implement, satisfactory to participants, tailorable to the individuals' unique context, and correlated with key health outcomes.[54, 63-65]

Figure 1. Trial conceptual model



1.3 Study design

The SHAPE pilot study is a two-armed, single blinded, randomized control trial study (Figure 2). Community dwelling prefrail African Americans ages 55 and older is the target population to account for accelerated aging among African Americans.[66] The sampling frame are Afiracan American adults who register in the Healthier Black Elders Center's Participant Resource Pool (PRP). The screening, consent, and enrollment procedures will follow a strict IRB-approved protocol over 16 weeks. Eighty prefrail African Anericans will be randomized to the treatment or control group.

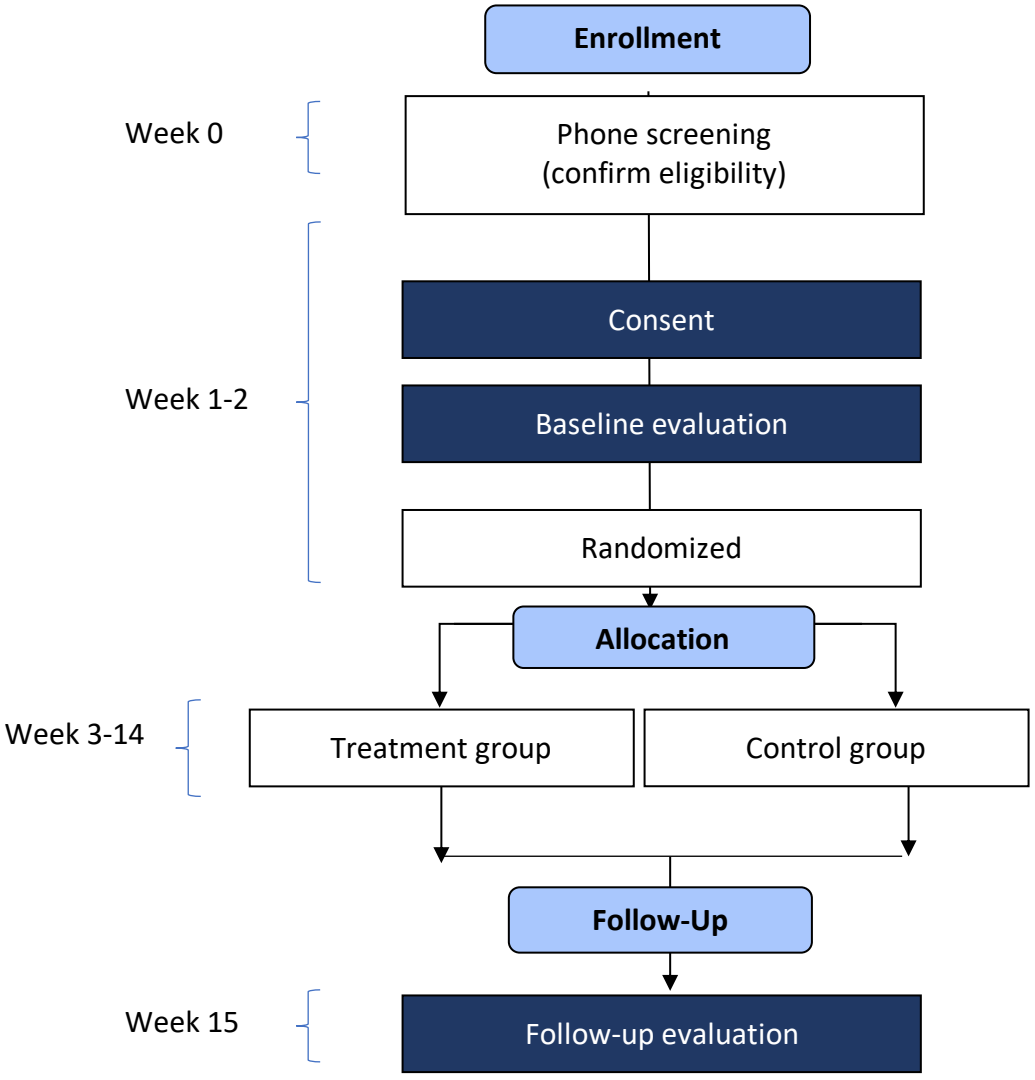
1.3.1 Participants eligibility

The inclusion criteria of participants includes: (a) English-speaking, (b) community dwelling, (c) members of PRP registry, (d) prefrail (evaluated by the Fried's Frailty Criteria Index), (e) self-identify as African Americans, (f) aged 55 and older. The exclusion criteria include: (a) diagnosed psychiatric disorders, (b) moderate or severe cognitive impairment (verified using the validated 6CIT and operationalized as score of ≥ 10),[68-69] the use of prescription drugs that could affect cognition and functioning (e.g., neuroleptics), (c) individuals with typical daily pain ratings of ≥ 7/10, (d) plan to change residences during the study period; (b) rely on a wheelchair for home or community mobility; (e) are actively receiving home care services, occupational, or

physical therapy; (f) are on dialysis or who have an end stage disease (e.g., stage IV heart failure); (g) are enrolled in a health promotion program focused on PA and diet; and (h) those who have a baseline dietary quality score of ≥ 85/100 as their diet would already be very close to ideal (average score for U.S. population = 59).

Figure 2. Overview of the SHAPE pilot study.

Raters will conduct the activities in the navy boxes.



1.3.2 Phone screening

The study coordinator calls potential participants from the participant resource pool (PRP) registry to screen for exclusion criteria (a)-(g). If potential participants passed the phone screening, the coordinator will schedule consent/baseline evaluation visit and assign 1-2 raters for the visit.

1.3.3 Consent visit

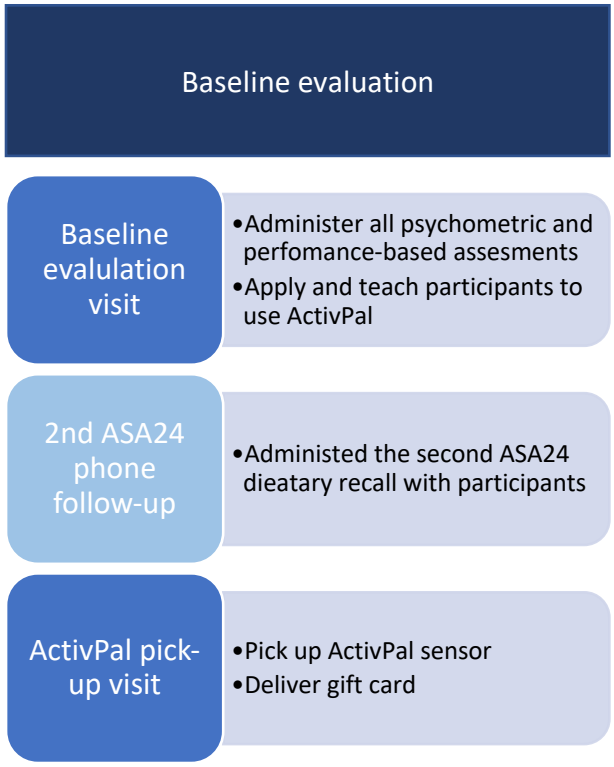
Consenting visits will take place at participants' home. Raters should call potential participants 1 day ahead of time to confirm if they are still available. During the visit, raters will explain and help participants understand the SHAPE study procedure. All components of the consent form should be clearly delivered (see 2.3 consenting procedure). Consent forms must be attained before any data collection activities started. Both potential participants and the raters will sign two copies of consent forms, one for the potential participants to keep and one for the lab.

1.3.4 Baseline evaluation

Ideally, once potential participants consented, raters will immediately start the baseline evaluation. However, if the potential participant need time to think about joining the study or are unwilling to do the baseline evaluation immediately after consent, raters should reschedule another time for baseline evaluation visit (figure 2).

At baseline evaluation visit, the raters will collect potential participants' sociodemographic characteristics and anthropometrics. A series of psychometric and performance-based measurers will also be conducted for eligibly confirmation and primary/secondary outcomes (table 2; see 1.4.2 for procedure of measurement administration). Most of the measures will be conducted in the baseline evaluation visit, except for ActivPal activity-tracking device (measures sedentary time) and Automated Self-Administered 24-hour (ASA24) dietary recall (measures dietary quality).

Figure 3. Breakdown of baseline evaluation by tasks



Sedentary time is measured by Community Healthy Activities Model Program for Seniors (CHAMPS) and the ActivPal activity-tracking device. At baseline evaluation visit, the rater will teach potential participants to use the ActivPal activity-tracking device. The potential participant will wear the ActivPal sensor for **seven consecutive days** to collect baseline activity data. At the end of the tracking period, the rater will schedule **an**

ActivPal pick-up visit to retrieve the tracker from the participant.
To evaluate potential participants' dietary quality, the rater will administer two ASA24 dietary recalls in two non-consecutive days. The ASA24 is a web-based tool that enables multiple, automatically coded, self-administered 24-hour recalls for multiple meals. At baseline evaluation visit, raters will log in to the ASA24 system respondent website to go collect recalls of meals dietary from the previous day. **A 2nd ASA24 phone follow-up will be scheduled** two days after the baseline evaluation will be conducted to collect another day of participants'' dietary intake.

After completing consent/baseline evaluation visit, all files and tools should be returned to the Fritz lab in the same day. If raters need to return the tools overnight, please remember not to leave the tools in raters' car, some tools need to be in certain temperature.

1.3.5 Randomization and Blinding

After consent/baselinve evaluation visit. The study coordinator will check participants' eligibility. Randomization was carried out by a coordinator not involved in data collection or analysis activities. Data collectors were blinded to arm assignment.

Participants will be allocated using a 1:1 ratio via adapted randomization sequences generated *a priori* by the study statistician, Dr. Hu, using an online tool (https://www.sealedenvelope.com/simple-randomiser/v1/lists) to form a randomization table with a variable block size (2,4, or 8). Randomization sequence concealment will be achieved by query of the REDCap (Research Electronic Data Capture) system.

1.3.6 Recruitment

Participants are recruited through PRP list from the Healthier Black Elders Center (HBEC). A preidentified list was screened by the center coordinator. Raters cold call people on the list to invite potential participants to join our study.

1.3.7 Intervention period

The treatment group will receive habit formation intervention for 12 weeks. The HF intervention is delivered by an experienced geriatric occupational therapist. The 12-week long, intervention is delivered to each participant during 12 face-to-face, home based sessions (each lasting ~60 minutes). An initial session (week 2) focuses on welcoming the participant to the program, and delivering educational content about prefrailty, frailty protective behaviors, and the concept of HF. In preparation for the sessions covering ST reduction and MVPA the next session (week 3) focuses on pain, its management, and the relationship between pain and activity (described below). Weeks 3-11 include weekly HF sessions focused on ST reduction, MVPA and dietary behaviors (see Table 2 for session content). A closing session occurs in week 12 to review program progress and create maintenance plans.

The control group will receive 12 weeks of newsletters focused on general healthy aging topics. Within 4 days of mailing the newsletter, the coordinator will call the participant, verify receipt of the newsletter, and ask them if they have any questions about the materials. Phone

call will last ~15 minutes. Control condition participants receive no further intervention.

1.3.8 Follow-up data collection

When the 12-week intervention period is over, the coordinator will assign raters for follow-up evaluation. Most of the measures will be re-administered.

Table 1 Overview of measurements and testing time

Evaluation time point (week)	Variable	Measure
Screening		
Phone screening (w0)	Eligibility	1. Phone screening eligibility form
	Frailly status	2. Paulson Lichtenberg Frailty Index (PLFI)
	Cognitive impairment	3. The Six Item Cognitive Impairment Test (6CIT)
Primary outcome*		
Baseline (w1), follow-up (w15)	Sedentary time	4. Community Healthy Activities Model Program for Seniors (CHAMPS)
Baseline evaluation (w1-2), follow-up (w15)	Sedentary time	5. ActivPal kcal expenditure
Baseline (w1, 2nd phone follow-up), follow-up (w15, 2nd phone follow-up)	Dietary quality	6. Automated Self-Administered 24-hour (ASA24) dietary recall
Secondary outcome		
Baseline (w1), follow-up (w15)	Frailty status	7. The Fried's Frailty Criteria • Grip strength with dynamometer • 15 ft walking test
	Lower extremity muscle strength	8. Short Physical Performance Battery (SPPB) • 3-meter walking test
	Balance	
	Quality of life	9. The World Health Organization Quality of Life- BREF (WHOQOL-BREF)
Habit formation (Treatment group only)	Habit formation	10. The self-reported habit index subscale
Demographics and other mediators		
Baseline (w1)	Comorbidities	11. Comorbidity Checklist
	Sociodemographic	12. Sociodemographic Form
Baseline (w1), follow-up (w15)	Participants anthropologies	13. Participants anthropologies forms • Weight • Height • Waist circumference
	Depressive symptoms	14. Geriatric Depression Short form (GDS)
Treatment session 1,3,5,7,9 (w 3, 5,7,9,11)	Habit formation	15. Self-report habit index (SRHI)

Note. *Both primary outcomes will be used for screening potential participants' eligibility.

2. Data analysis plan

2.1 Data analysis

Feasibility outcomes such as recruitment, retention, and attendance data were presented by descriptive statistics. Differences in baseline characteristics between the two groups were tested by independent t tests or chi-square/Fisher's exact tests. For the primary and secondary outcomes , effect sizes were be represented by Cohen's D, where 0.2 indicates small, 0.5 as moderate, and 0.8 as large effects. As for mechanisms of behavior change, pre and post habit formation effect sizes are estimated by Cohen's D. All statistical analyses were conducted by IBM SPSS software, version 26.0 (SPSS Inc., Chicago, IL).

2.2 Sample size estimation

We did not use power analysis to estimate study sample size for determine efficacy. We aim to recruit 15 participants in per group suggested for feasibility pilot study.

2.3 Assessments

Primary outcomes (measured at week 0 and 1 week post intervention). Sedentary Time (ST) was measured via the ActivPal wireless activity tracker. ActivPal is a validated tool with a commercialized program to generate mean minutes of total ST (min/day), sum of 30-minute bouts ST, and sum of 60-minunite bouts ST, as well as the number of 30-min bout ST and 60-munites bout ST per day. Participants wore the ActivPal device on their thigh for seven days during their waking hours. Dietary Quality was measured using the Healthy Eating Index (HEI) and operationalized as the total HEI score generated from the National Cancer Institute's ASA 24®.

Secondary outcomes (measured at week 0 and 1 week post intervention). Pre-frailty status was measured using the current gold standard, the Cardiovascular Health Study frailty criteria as composite index consisting of the following components: (a) self-reported weight maintenance; (b) walking speed (the mean time of two trials for the time taken to walk 15 ft. reported in seconds); (c) grip strength, (mean score of grip strength reported in Lbs. of three trials on the dominant hand using a calibrated Jaymar dynamometer); (d) exhaustion, measured as a response of "All of the time" or "Most of the time" to the following two questions reported on a 4 point Likert scale, "I felt that everything I did was an effort in the last week," and "I could not get going in the last week"; and (e) total Kcals of energy expended over a 7 day period, measured via Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire. Change of all PA and MVPA duration (minutes/week) measured by CHAMPS. We also used Activpal to estimate the cumulated MVPA duration. We cumulated MVAP minutes by selecting activity intensity greater than 3 METs. Physical Function was measured via the Short Physical Performance Battery (SPPB) subtests for lower extremity strength and balance. Depressive symptoms were measured using the Geriatric Depression Scale (Kieffer & Reese, 2002). Participant anthropometry such as weight circumference (inch) was measured by a girthometer, height (cm) by a stadiometer, and weight (pound) by medical scales. Body mass index (BMI) was also calculated based on participant anthropometry. Quality of life was measured using the 26-item validated WHOQOL-BREF. Occupational performance was

measured by the Canadian Occupational Performance Measure (COPM), but only among treatment group participants. Habit Formation was measured using the validated, 4-item, Self-Report Behavioral Automaticity Index (SRBAI). The SRBAI measures perceptions of behavioral automaticity for an identified behavior. To track habit formation during the intervention, the SRBAI was administered to treatment condition participants every 2 weeks from sessions 3-11 to assess changes in automaticity for their self-selected habits.

3. Potential Benefits, Risks and Alternatives

3.1 Benefits

There will be considerable benefits to the participants enrolled in the proposed study. All participants will receive information about how to reduce cardiovascular disease risk, and how to increase physical activity or improve your diet. In addition, participants in the active treatment group will receive free health coaching, while participants in the attention control group will have a trained research assistant deliver health related education.

3.2 Risks

Potential risks of research participation-physical, psychological, financial and legal risks among others-are considered minimal. In-home evaluations and assessments of barriers may result in fatigue or aggravation. In addition, some questions may touch on emotionally-sensitive issues that could cause anxiety or other forms of emotional stress. The performance-based testing involves observation of everyday activities, which may result in fatigue or embarrassment.

Participants will be told that their involvement in this research study is voluntary and that they may choose not to participate or withdraw their consent at any time. Withdrawal from the study will not at any time affect the commitment of the clinician to administer care, and there will be no penalty or loss of benefits to which participants are otherwise entitled. Participants who undergo the study visits will be given the option to reschedule the visit or take a break at any time during the study if necessary. There is little legal risk to participating in this research. All research-related information will be kept confidential and accessible only to authorized members of the research team.

3.3 Minimization of Risks

We are a HIPPA covered entity and comply with all HIPPA regulations. To protect against and minimize potential risks, participants will be carefully screened and evaluated for eligibility by research coordinator.

To avoid or minimize symptoms of fatigue, agitation, or emotional distress due to testing, participants will be instructed to notify the rater or interventionist if they experience any discomfort. They will also be periodically questioned about their tolerance for the tests/intervention. Testing and interviews will be terminated if participants develop fatigue, agitation, or emotional distress.

An ID number will be assigned to each participant. All data collected from a participant will be labeled with the ID number. All participant electronic and hard-copy data will be kept under double-lock protection. All hard copy forms that contain personal identifiers (e.g., name, address, phone numbers) will be stored in a separate locked file drawer under double-lock protection. No publication or presentation of the study data will uniquely identify or provide sufficient information to uniquely identify participants.

Risks during the home visit will be minimized by having licensed and trained interventionists available to monitor safety during intervention.

To guard against unauthorized data access, all shared-use computer systems at the lab are protected with passwords, which are changed at 4-month intervals. Only individuals with a particular "need to know" status are given access, and system privileges are carefully restricted. All personal computers to be used in the Administrative Unit are located within a secure area, and the system is locked when not in use. SPSS software packages will be used for data management and analysis. Datasets generated from these programs will not contain any HIPPA data.

Data will be entered into a REDCap database. REDCap servers are securely housed in an onsite, limited-access data center managed by the Wayne State University IT. All data are stored on a private, firewall protected network. All users are given individual user IDs and passwords, and their access is restricted on a role-specific basis. REDCap was developed specifically around Health Insurance Portability and Accountability Act security guidelines and is implemented and maintained according to Washington University guidelines. Study data will be collected via tablet in the field and managed using REDCap electronic data-capture tools hosted at Washington University. REDCap is a secure, Web-based application designed to support data capture for research studies.

3.4 Adverse events

- What is an adverse event?

  An adverse event is any reaction, side effect or untoward event that occurs during the course of the study. Adverse events are categorized as serious (see below) or non-serious, as related or not related to the study intervention, and as expected or unexpected. For the purpose of the present trial, clinically insignificant events will be excluded from any type of AE documentation. These include colds, flu, cuts, scrapes, coughs, headaches, stomach complaints, general fatigue and mild symptoms. Behavioral AEs that will be tracked in this trial include increases in emotional distress and problems managing everyday activities (functional changes).

  Serious adverse events (SAEs) are defined as deaths, life-threatening events, permanently or substantially disabling events, congenital anomalies, events requiring an initial hospitalization or prolonging a current hospitalization, or events that require intervention to prevent permanent impairment or damage. SAEs in this trial could include inpatient hospitalization for cardiovascular or other cardio-metabolic disease related problems.
- In the visit, if there is an SAE that is emergent, call 911.
- Document AE in rater's log in Redcap.
- Notify Study coordinator immediately if there is an AE or SAE.

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