Developing and Testing the Enhancing Active Caregiver Training (EnACT) Intervention for Dementia Family Caregivers

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Protocol/Research Manual of Operations
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Study Aims

Aim 1: Develop and iteratively refine the EnACT intervention for ADRD caregivers.

This protocol is for Aims 2 and Aim 3 which is the clinical trial portion of the study:

Aim 2: Evaluate the feasibility and acceptability of the EnACT intervention.

Aim 3: Examine potential mechanisms of change over time and their subsequent impact on proximal and distal outcomes.

Study Design

This is a Stage 1b pilot study to test the feasibility and acceptability of the EnACT intervention. We will use a randomized waitlist control design. Participants will be randomly assigned to one of two groups. All participants will have a baseline measure (week 0), and a Pre timepoint (week 2). Group A will first participate in the intervention (three meetings offered every 2 weeks at Weeks 2, 4, and 6), followed by 8 weeks of follow-up. T1 will be a pretest gathered at enrollment. Group B will wait 8 weeks and then start the intervention at Weeks 8, 10, and 12, with a post-test at Week 14. Data will be gathered at six time points no less than 2 weeks apart over the course of the control, intervention, and follow up. A postintervention debriefing focus group will occur in Week 8 for Group A and Week 14 for Group B to gather feedback on the process and activities and any recommendations participants have for improving the intervention.

Sample Size

Sample Size/Power Analysis: We will recruit 30 dementia caregivers from the community. Participants enrolled will be randomly assigned to the group-based EnACT intervention (n = 15) and a waitlist control group (n = 15). As an NIH Stage 1b pilot study, the goal is to assess the plausibility of this work in order to guide the next stage of research. Thus, it should not be expected that the sample size will have outstanding power. Constrained longitudinal data analysis will be used on the data set (N = 30) to exploit randomization and integrated with the full longitudinal impact data to give greater power than more limited analyses. Simulations conducted in SAS and analyzed under the integrated model yield a respectable power of .70 against the null hypothesis when the hypothesized slope difference corresponds to a medium effect size of .5.

Sites

The intervention will take place at locations associated with our community partners' caregiver support groups, including senior centers, the Division of Aging & Adult Services, and offices of the Utah Chapter of the Alzheimer's Association. This includes online synchronous platforms such as Zoom.

Eligibility

Inclusion Criteria:

Persons providing primary, informal, support to family members with Alzheimer's disease or related dementia (ADRD). These individuals are 18 and older, and the ability to read and speak English.

Exclusion Criteria:

Formal caregivers, persons under the age of 18, and individuals who have English fluency ratings of *none* or *poor* will be excluded.

Recruitment

Potential participants who meet initial eligibility criteria (aged at least 18 years and an informal caregiver of a person with Alzheimer's disease or related dementias) will be identified through the Utah Caregiver Support Program and the Utah Alzheimer's Association. In addition, the TLC Research Study will be a referral source, providing referrals of previous research participants who agreed to be contacted about future research studies. Recruitment strategies include: 1) announcements and flyers shared via email, program newsletters, social media posts, libraries, pharmacies, and handed out at caregiver support groups, and 2) personal contact by program leadership and research staff, and 3) Opt-out letters sent to previous research studies who agreed to be contacted for future research. Interested individuals will be screened for eligibility based on inclusion/exclusion criteria by the student assistant or the primary investigator. Interested individuals will be invited to a pre-screening interview via phone or in person. This interview will be scheduled at a date and time and location that is convenient for the caregiver. Those who meet the final inclusion criteria will qualify for participation and be invited to take part in the study. The student assistant or the primary investigator will review the IRB-approved informed consent document, which will include a description of voluntary participation, study procedures, risks, and potential benefits. Those who consent will be enrolled in the study.

Enrollment

Randomization: After enrollment, 15 will be randomized to the intervention group and 15 will be randomized to the waitlist control group. Randomization will be done using randomized blocks of size 2, 4, and 6. The allocation table will be uploaded to REDCap for randomization by the study team. This will happen when groups of 10 are enrolled and repeated until 30 are enrolled. The allocation table will be made by a statistician and the people randomizing from REDCap will be blinded from the table.

Time Commitment

Participants will participate across 14 weeks. Those in Intervention first (Group A) will participate in three caregiver meetings held every two weeks across six weeks. This will be followed by data collection check-ins over 8 weeks. The second group (Group B) will begin with 8 weeks of data collection check-ins, followed by three caregiver meetings over 6 weeks. Each meeting will be scheduled every two weeks and last 60 minutes. Survey check-ins will be repeated six times

and will include completion of a survey via phone or internet. Two weeks after the final intervention meeting, participants will be invited to meet together to discuss thoughts about the caregiver training activities.

Frequency and duration of intervention. EnACT will be offered three times to each person. It will occur every two weeks for a total of three 60-minute sessions. Each participant will be invited to complete one take-home written exercise after session 1 and session 2, which will involve journaling about topics related to the session.

Study assessments for caregivers will include (total time = 95 minutes):
Baseline survey: 20 minutes
Time 2 survey: 15 minutes
Time 3 survey: 15 minutes
Time 4 survey: 15 minutes
Time 5 survey: 15 minutes
Time 6 survey: 15 minutes

Additional time commitments will include:
Study Eligibility Interview: 15 minutes
Final debrief focus group: 60-90 minutes

Reimbursement

Caregivers will receive $25.00 for each caregiver meeting that they attend, $10 for the completion of three surveys gathered outside of meetings, and $50 to attend the final focus group meeting. It is possible to receive $155.00 total in compensation. Payment will be distributed at the end of the study either through direct deposit or check. You will only be paid for each visit or survey that you complete. If you discontinue early from the study, you will receive a partial amount based on how many meetings and surveys you complete.

Assessment Schedule

Survey data will be gathered at six time points no less than two weeks apart over the course of control, intervention, and follow up.

Focus group data will be gathered during the debrief meeting two weeks after intervention meetings are complete.

Feasibility and Acceptability data will be gathered throughout. Satisfaction surveys will be gathered at the end of each intervention session as part of the session.

Baseline Assessment (T1): Demographics, Imagined Interactions, Capacity to Adapt, Caregiver Capacity to Appraise Demands, Perceived Stress, Caregiver Well-being

Survey Assessment (Week 2 (T2), Week 5 (T3), Week 8 (T4), Week 11 (T5), Week 14 (T6):
Imagined Interactions, Capacity to Adapt, Caregiver Capacity to Appraise Demands, Perceived Stress, Caregiver Well-being

Measures

Feasibility: number screened and enrolled, retention rates, levels of engagement, intervention delivery, assessment-protocol duration, and completion rates

Acceptability: satisfaction with intervention, audio/video documentation of intervention meetings, post-intervention focus groups

Focus Groups: questions on suggestions for improvement, preference compared to other programs they've experienced, barriers to or benefits of use.

Demographics: age, education, gender identity/sexual orientation, race/ethnicity, employment, salary, caregiving experience, frequency of theatre attendance, care–recipient relationship, caregiver support, time as caregiver, type of caregiver, sex and age of care partner, participation in caregiver training or support, type of caregiver training/support, frequency of caregiver training/support, activity/hobbies and frequency of participation.

Imagined Interactions: *Survey of Imagined Interactions* (7-point Likert scale questions) measures outcomes of imagining interactions, including four subscales: *Specificity* (5 items), *Discrepancy* (7 items), *Proactivity* (3 items)

Capacity to Adapt: *Resilience Scale* (7-point Likert scale questions) measures one's ability to adapt, specific to constructs of meaning, self-confidence, perseverance, serenity, and loneliness (25 items)

Caregiver Capacity to Appraise Demands: *Revised Caregiving Appraisal Scale* (RCAS; 5-point Likert scale questions) asks ADRD caregivers to assess the following five subscales: *Burden* (9 items), *Satisfaction* (6 items), *Mastery* (4 items), *Demand* (3 items), *Impact* (3 items)

Perceived Stress: *Perceived Stress Scale* (5-point Likert scale questions) measures self-reported stress (10 items)

Caregiver Well-being: *Modified Caregiver Burden Inventory* (CBI; 5-point Likert scale questions) 24 items comprising five subscales: *Time*, *Physical*, *Social*, *Emotional*, *Developmental*. *Positive Aspects of Caregiving Scale* (PAC; 5-point Likert scale questions) measures the perceptions of the benefits of caregiving (9 items.)

Data Collection and Management

Data collection forms and standardized data collection procedures will be developed for the project. These procedures will include a data codebook for all instruments and a procedures manual that will outline the timeline for data collection and specific procedures for data entry and error checking. All participants will be assigned a unique identifier, and all data entered into the study database will only utilize this identifier. A list of the subject names and the associated codes will be stored in a locked cabinet. These methods will provide accurate recording and storage of data, participant confidentiality, and timely data analysis. The current project will use Research Electronic Data Capture (REDCap), which is a secure web application for building and managing online databases. REDCap provides functionality and features to rapidly develop the project database. The database and data entry forms are intuitive, easy to use tools for collecting data, and include data validation. The longitudinal module will be used so that the same data may be captured on multiple assessments.

Data collection will include (1) focus groups (digital recordings and transcriptions), (2) observations (field notes, research journaling), (3) surveys using paper, pencil, online, or via phone, (4) digital video documentation of intervention testing. We have developed data collection protocols to ensure maximum compliance and protection for all data collected.

Data from surveys will be manually entered directly into REDCap, an encrypted online data capture and storage system. REDCap (Research Electronic Data Capture) is a HIPAA-compliant system hosted at the University of Utah Center for Clinical and Translational Science (CCTS). REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Participant questionnaires are delivered in person, de-identified, and entered manually by research staff into REDCap, where it is securely stored and protected. Manually entering data into REDCap reduces incorrect data entry, as the system is built to limit the type of data entered for each question, and allows for checking entry by multiple members of the research team. This enhances security and protects confidentiality of data. Focus groups will be audio recorded, and intervention testing will be video recorded. Audio recordings will be transcribed by a professional transcriptionist and de-identified. Video and audio recordings and transcriptions will be uploaded to a secure shared file on the U of U protected electronic environment. Recordings on digital devices will be deleted once they are backed up to protected servers. These digital recordings are used to examine intervention feasibility. Field notes and journaling from observations will be typed into a password protected and encrypted computer, de-identified, and saved to the UofU protected electronic environment.

Statistical Management & Analysis

The primary goal is to assess feasibility and acceptability of the EnACT intervention within the context of a randomized study, as well as the study protocol. Based on research best-practices guidance from NIH and noted experts, pilot studies—due to their smaller sample sizes and the frequent design adjustments necessary to maximize recruitment, retention, and quality assessment of outcomes—cannot definitively test hypotheses, nor can they provide reliable effect-size estimates. Nevertheless, this pilot will assess whether a subsequent full-scale RCT (NIH Stage III) modeled after this pilot is logistically feasible and acceptable.

Analysis

Descriptive statistics will be used to describe screening, recruitment, enrollment, retention, completion rates, and satisfaction survey results. Qualitative data will be analyzed based on each construct of feasibility and acceptability. NVivo software will be used to organize qualitative data analysis and document an audit trail. Digital audio recordings will be professionally transcribed. Video and written documentation will be directly imported and analyzed in the software. Data will first be coded using these constructs as a priori codes. Then within each code, pattern coding will be used to group data to facilitate descriptions of the screening, recruitment, and enrollment process. In addition, we will use qualitative data to describe reasons for attrition, engagement, satisfaction with the intervention, and intervention delivery. The PI and RA will meet weekly to analyze data, and monthly with the larger team to resolve conflicts in coding and to group patterns into major themes. The use of both quantitative measures and qualitative observations will allow for a rich, in-depth description of both feasibility and acceptability of this intervention.

Feasibility of Outcome Measures

Seven instruments (demographics, *The Survey of Imagined Interactions, Resilience Scale*, *The Revised Caregiving Appraisal Scale, Perceived Stress Scale*, *Modified Caregiver Burden Inventory*, and *Positive Aspects of Caregiving Scale*) will be used to assess potential outcomes associated with the theoretical framework for this study. Participants in Stage-1b will take the demographic questionnaire at time one and the other instruments at all 6 timepoints. We will gather data on the duration of these tests, proportion completed, and the burden associated with these measures at each timepoint. This will include documenting retention rates, timepoint completion rates, length of intervention meetings, the amount of time to complete measures, and field notes regarding reactions to taking the battery.

Descriptive statistics—including frequency counts, percent distribution, range, mean, median, and standard deviation— were calculated for all variables and timepoints. Descriptive statistics will be reported for the full sample (n = 30), and then for the immediate (n=15) and wait-list (n=15) groups. We will conduct independent samples statistics (chi-square, Fisher's exact test, Student's t test, and Mann–Whitney tests), as appropriate, to statistically compare immediate to wait-list groups for baseline equivalency. We will use generalized linear categorical dose-response models where the effect of intervention over time on the main and secondary outcomes are estimated. Specifically, the regression controls for baseline measures and defines and estimates two separate parameters: D1, natural change at week 8 and D2 the additional impact of the intervention at week 8. The null hypothesis of natural benefit in the waitlist at 8 weeks (D1) is defined as D1 = 0. The null hypothesis of no additional benefit of the intervention is D2=0 for week 8 (intervention) and week 14 (end of intervention phase in waitlist control). The overall intervention change is defined as the linear combination of D1+D2. Importantly, this

framework allows the change in outcomes in the waitlist control during their active intervention phase to contribute to the estimate of D2 which is advantageous for the current smaller sample size. All alphas will be set at 0.05 but the focus will be to examine the direction and magnitude for promising trends to be validated in a future fully powered study. Estimation is done with maximum likelihood and we will report 95% lower and upper confidence intervals.

Handling of Missing Data

Using maximum likelihood estimation, we will use all available data for analysis. This allows us to reduce bias in the estimation. The maximum likelihood estimates given the observed data points are the values most likely to have generated the complete ensemble of observed sample data under the assumed model. Missing data patterns will be examined and imputation if assumption of missing at random is not rejected may be considered in the presence of significant amount of missing data.

Ethical Issues

Ethical Considerations

Oversight for this study will be done through the University of Utah Institutional Review Board (IRB), which will be designated as the single IRB. Participation in this study involves no more than minimal risk. There is the possibility that some research activities may be fatiguing or produce unpleasant feelings. There is a risk of loss of confidentiality, however, all participant data will be coded in a confidential manner that will protect the identity of the participant. Protections will be put in place, including training for all personnel involved in the study, completing Collaborative Institutional Training Initiative (CITI) certifications in humans subjects protections and practice in accordance with Good Clinical Practice guidelines.

Potential Risks and Benefits for Participants

Potential benefits exceed the minimal risks associated with this study.

Potential Risks: Participants may become fatigued participating in focus groups, completing surveys, or participating in the intervention. Some questions in the focus groups, intervention, and surveys may prompt caregivers to report on negative caregiving experiences. This may evoke negative, unpleasant feelings, or emotional responses such as crying or sadness. There is a risk of loss of confidentiality, identification of personal identities, or information.

Potential Benefits: The information obtained and the process of developing and testing the intervention may lead participants to feel more prepared for ADRD caregiving. The knowledge gained from this study may benefit other caregivers in the future. The proposed research will advance knowledge about preparing ADRD caregivers for the experience. The results may increase knowledge about the mechanisms involved in enhancing active caregiver training and its subsequent impact on proximal and distal outcomes associated with the caregiver stress process and caregiver wellbeing. The benefits exceed the minimal risk associated with this study.

Adverse Event and Serious Adverse Event Collection and Reporting

All study staff will be trained to observe participants for any **Adverse Event**, defined as an untoward event or potentially abnormal symptom, reaction, or outcome, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research. Examples of potential adverse events, listed in a general order or seriousness, might include:

- increased stress, fatigue, or sadness
- inability to cope
- hospitalization due to emotional factors
- suicide attempts
- death
- any type of reported or suspected abuse (participant as victim or abuser)

Some events may be classified as **Unanticipated Problems** (UP), defined as any incident, experience, or outcome that meets all of the following criteria: 1) unexpected, in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the study population; 2) related or possibly related to participation in the research procedures; 3) suggests that the research places participants or

others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The vast majority of adverse events occurring in human subjects are not unanticipated problems, but a small proportion of adverse events are unanticipated problems. Unanticipated problems include other incidents, experiences, and outcomes that are not adverse events.

Collection: Study staff will monitor any potential adverse event or unanticipated problem through every phone call with participants and study staff, during live sessions with study participants, or as expressed by participants on each questionnaire or other data collection instrument. This type of general monitoring of participant safety and well-being will be conducted on an ongoing and continual basis, during each interaction between study participant and study staff.

If there is evidence that an adverse event may have potentially occurred during the study period (i.e., from consent through the end of the study), study staff will immediately (within 24 hours) complete an adverse event reporting form on paper, where they describe the event and classify it based on the following grading and attribution criteria:

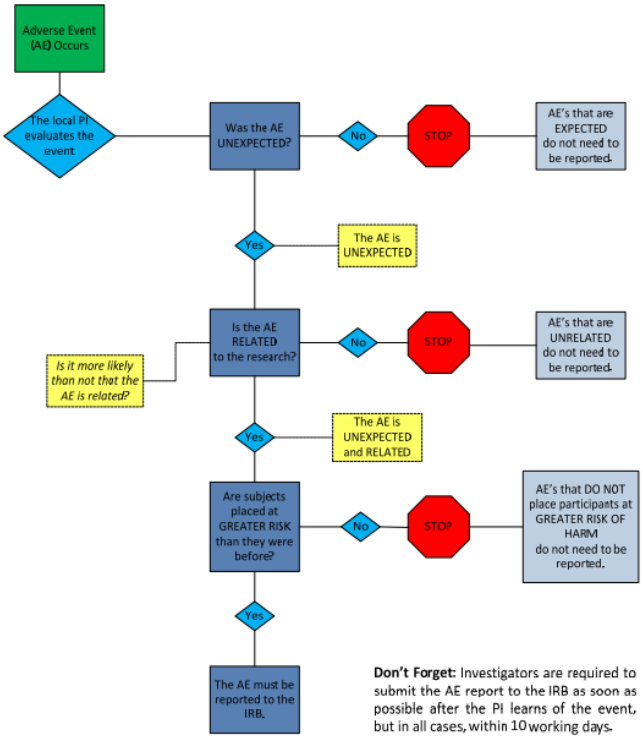
Severity	How severe was the event? ***Mild*****:** symptoms are easily tolerated and only minor irritant to participant; do not require therapy, medical evaluation, or legal intervention. ***Moderate***: symptoms cause low level of inconvenience to participant; improved through simple therapeutic measures. ***Severe***: symptoms are incapacitating and significant interruption to participants normal daily activities; require treatment or intervention by medical, therapeutic, or legal professional Note: While this severity scale is useful in determining seriousness of an event, it does not automatically distinguish between an adverse event (AE) and a serious adverse event (SAE). See below for SAE definition.
Expectedness	Was the event expected to occur or was it unexpected, meaning was it not anticipated based on current knowledge of the intervention protocol or potential risks outlined in the consent form or study protocol? ***Unexpected*** or ***Expected*****.**
Relatedness	Was the event related to the study intervention and/or participation in the study? ***Definitely Related*****:** event is clearly related to participation in the study (i.e., use of intervention or completion of data collection questionnaires). This can be confirmed by a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state. ***Possibly Related***: event follows a reasonable temporal sequence from administration of the study intervention or follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors. ***Not Related***: The adverse event is clearly not related to participation in the study - i.e. another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event.

Based on the classification criteria above and the context of the particular participant and event, the reporting study staff with consultation from the PI as needed will determine whether the event should be classified as a **Serious Adverse Event** (SAE). The AE reporting form will contain a column to indicate whether the event is considered a SERIOUS adverse event. SAEs are defined as a subset of the AEs and represent the most severe events that pose a significant hazard for the participant; they are defined as events that result in death, are life threatening, require or prolong hospitalization, or cause persistent and significant disability or incapacity.

Reporting: In accordance with NIH and institutional guidelines, the PI will collect all AE reporting forms from study staff as they are submitted, and discuss them with the internal "data & safety monitoring" committee (see section 3) during monthly meetings. After, the PI will prepare a summary report for the NIA Program Officer, to be submitted quarterly.

In the event that an AE is considered *serious*, *unanticipated*, and *related* to the intervention, the PI will report it to the NIA Program Officer and the internal "data and safety monitoring" committee (see section 3) within 48 hours of knowledge of the event. All deaths require expedited reporting, typically within 24 hours of the study's knowledge of the death. Any expedited report will be followed by a detailed, written SAE report as soon as possible (typically within 48 hours and following the SAE reporting template from IRB). A summary of all SAEs will be maintained by the study's internal "data and safety monitoring" committee and reported to the NIA Program Officer quarterly.

In the event of an unanticipated problem (UP), the PI will report the nature of the problem within 48 hours to NIA Program Officer and forward it to OHRP using ohrp@osophs.dhhs.gov within two weeks of the event. The study's internal "data and safety monitoring" committee (see section 3) will call a meeting within 48 hours of learning about the UP to discuss a corrective plan and measures to prevent reoccurrence. They will update study protocols, retrain staff, or communicate with study participants, as needed, to prevent reoccurrence.



All adverse events, will be reported to University of Utah IRB according to the flow chart. University of Utah requires that only AEs that are unexpected and related to study procedures be reported to the IRB. This reporting is to be done as soon as possible and within 10 working days after learning about the event.

Protection Against Study Risks

All study staff will receive training and certification for human subjects research, including "good clinical practice," through the Collaborative Institutional Training Initiative (CITI). All study staff will receive extensive training and be required to follow study protocols related to informed

consent and general protection of privacy and confidentiality, which have been created according to the guidelines and regulations associated with the conduct of human subjects research. Project staff will follow-up on all suspected adverse events with the help of available mental health and social service resources and in accordance with all applicable laws governing participant safety.

Informed Consent Process: Consent will be obtained at a location of the participant's choosing. This may be at a community-based location, such as a library, senior center, or location of a caregiver support group sponsored by our community partners (Alzheimer's Association and the Utah Caregiver Support Program). Or it may be at the potential participant's residence if they have a difficult time traveling and consent for us to meet at that location. Techniques for recruitment will include presentations to community partners, caregiver support groups, and adult day centers. We will incorporate a process that includes sharing flyers and social-media postings with community contacts via UCSP and the Utah Alzheimer's Association.

During the recruitment process, if an individual is interested, they will be asked to let investigators know either in person (at recruitment meetings) or via email and phone numbers provided in recruitment materials. Interested individuals will be screened for eligibility based on inclusion/exclusion criteria by the student assistant or the primary investigator. Interested individuals will be invited to a pre-screening interview via phone or in person. This interview will be scheduled at a date and time and location that is convenient for the caregiver.

Those who meet the final inclusion criteria will qualify for participation and be invited to take part in the study. The student assistant or the primary investigator will review the IRB-approved informed consent document, which will include a description of voluntary participation, study procedures, risks, and potential benefits. Those who consent will be enrolled in the study.

There is no required time between informing participants and actually obtaining consent, but there may be time between pre-screening for inclusion criteria and the obtaining informed consent. Participants will also be informed, upon review of the informed consent document, that they can wait, think about it, before signing and providing official consent. Participants will also be informed that consent is an ongoing process and will be allowed to withdraw at any time.

Measures to minimize coercion include scheduling meetings at times and locations of the potential participants' choosing. In addition, participants will be informed that they can ask questions at any time and take time to assess the informed consent document before signing. Before meeting to review the informed consent documents, participants can choose to receive a digital version of the form in preparation for the meeting. All potential participants and all those who agree to participate, will be given copies of informed consent documents.

Provisions will be made to allow adequate time to exchange information and questions between the investigator and participant. Participants will first be screened for eligibility in person or via telephone. At that time, participants will be given the opportunity to schedule a meeting to discuss informed consent. Participants will also be asked if they would like a digital copy of the informed consent to prepare for the meeting. During the initial screening, potential participants will be invited to ask questions. They will be invited to review informed consent documents in advance of the meeting and to note any questions they may have in preparation. At the informed consent meeting, potential participants will be notified that they can ask questions at any time throughout the process of research and that we will check-in with them throughout to see if they have any questions or concerns.

Protection Against Risks: All possible precautions will be taken to protect the safety, privacy, and confidentiality of all persons contacted to be in the project and for those who consent to participate.

Project staff will be trained to continually monitor for negative emotional responses either during their contact with the participants or as indicated on any of their submitted questionnaires. If a participant is discovered to be experiencing distress or an adverse event, the PI will address the specific issues, answer questions, and if necessary, assist the participant in formally withdrawing from the study if desired. If needed, participants will be referred (or to preserve confidentiality, will be provided information so that they can refer themselves) to sources of professional help within the community. In the event that the study staff have identified a serious adverse event (SAE), the participant will be administratively withdrawn from the study; their participation in the study will be automatically and immediately discontinued.

To protect participant privacy and confidentiality,

- All participants will be identified in study files and monitoring reports by identification numbers, not names or other identifying characteristics.
- All study-related information and data will be password-protected with access limited to CITI-certified research staff only. Study data will be de-identified.
- All communication (verbal or written) among project staff regarding any participant will use ID numbers only. Email communications will contain "PHI" in the subject line, which automatically encrypts the message until retrieved on a secure server.
- Unattended workstations will be locked and only able to be unlocked with a password.
- Once all of the study data are gathered, entered and cleaned for errors, the personally identifying information (name, phone and address) will be deleted and any hard copies destroyed.

Interim Analysis

Planned analyses are distinct for Aims 1, 2 and 3. Aim 1 has a unique sample, design, and planned analysis, while Aims 2 and 3 share a sample, design and planned analysis. All three aims of the study are important parts of stage 1 intervention development activities. Aim 1 provides data for Stage 1A (intervention development and refinement) and Aims 2 and 3 provide data for Stage 1B (feasibility and pilot testing). As described in the previous section, we have developed study protocols to ensure participant safety for each aim of the study. Although we will conduct the analyses for each aim as that aim is completed, we do not have any rules, based on those interim analyses, for stopping the study overall.

Data Safety and Monitoring

This project represents stage-1 development activities for a behavioral intervention. As such, it does not constitute an NIH-defined phase III clinical trial. Nor does the study design involve multiple field sites. Lastly, the EnACT intervention and the planned design is considered minimal risk. **Thus, this study does NOT require a data and safety monitoring board.**

Ultimately, the PI, will monitor participant accrual and retention and audit data quality, particularly examining levels of missing data. The PI is ultimately responsible for maintaining the integrity and quality of all study data under the guidance of primary mentor. Data audit reports will be reviewed quarterly to monitor progress and quickly identify and address potential problems. To assist in data and safety monitoring, a "data and safety monitoring" committee will meet to review progress. Safety reports will be submitted to this committee twice a year, and include a detailed analysis of study progress, data and safety issues.

As a general principle, this committee is responsible for developing all protocols that ensure confidentiality and safety of study participants, and then monitoring that those protocols are being practiced by all study staff at all times. Particular responsibilities of this committee include:

- To provide initial and ongoing training to all study staff related to participant safety and data security*
- To review quarterly-generated accrual reports to ensure that sample targets are being met for each Aim of the project
- To review any adverse events that have been reported by study staff to the PI. At monthly meetings with co-mentors, the PI will discuss these events and how we might address similar issues of participant safety in the future with updated protocols or PI/staff training. In the event of serious adverse events, the PI will inform this committee via email of the nature of the event (within 24 hours of receiving the report) and the actions taken to report it to both IRB and NIA. When discussing adverse events, participants will be referred to by ID number, rather than name, unless the identity is needed to be known by the members of this committee in order to provide support and intervention, as needed, to the participant.
- To review analyses to ensure accuracy and replicability of data and data analyses**

*We will use the Research Electronic Data Capture (REDCap) program to securely manage screening, enrollment, and retention data, as well as to generate weekly reports to monitor study progress.

** The PI and mentoring team are committed to using an “open science framework” to ensure best practices in project management, team transparency and accountability, and an ability to share resources with other researchers, as needed, and at the conclusion of the project.