GENERAL STUDY INFORMATION

Study Title

Include the study title below.

To reduce the burden of caregiving on health outcomes of women: Asian American family caregivers of persons living with Alzheimer's Disease

1 Review Type (Choose one)

Please choose which level of review best fits your research. This is an investigator's assessment of review and does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination of review conflict, the IRB's determination will be considered the official determination.

***Note**: Expedited review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by OHRP. If you would like help determining which type of review best fits your research study, please contact the IRB staff in the Office of Research Support & Compliance:*
https://research.utexas.edu/ors/human-subjects/get-help/

a ☐ **Full Board Review – Greater than Minimal Risk Research**

b ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypotheses

Please describe the research aims and hypotheses in the box below. To input text, click in the box below and start typing.
Note: Procedures will be explained in a separate section below.

The purpose of the proposed study is to preliminarily evaluate a technology-based information and coaching/support program, TACAD (**T**echnology-based Information and Coaching/Support Program for **A**sian American women who are family **c**aregivers of persons living with **A**lzheimer's **D**isease), in improving health outcomes of Asian American women who are family caregivers of persons living with Alzheimer's disease (AACA) and their care recipients. The **specific aims** of the study are to:

Aim 1. Qualitatively evaluate TACAD through an expert review and a usability test.

Aim 2. Quantitatively evaluate the preliminary efficacy of TACAD in improving health outcomes of AACA and their care recipients.

-***Hypothesis 1***. After controlling for background and health/disease factors, the intervention group (AACA who use TACAD and the Alzheimer's Association [AA] website) will show significantly greater improvements than the

active control group (AACA who use only the AA website) in their health outcomes (stress, physical and psychological symptoms, and quality of life) and their care recipients' health outcomes (activities of daily living, behavioral and psychological symptoms, mood status, and quality of life) from baseline (pre-test) to Time Points 1 (post 1 month) and 2 (post 3 months).

- ***Hypothesis 2***. After controlling for background and health/disease factors, the intervention group will show significantly greater improvements than the control group in caregiving experience (caregiving activity, coping, caregiving competence, and caregiving skills) from baseline to Time Points 1 and 2.
- ***Hypothesis 3***. After controlling for background and health/disease factors, the intervention group will show significantly greater improvements than the control group in theory-based variables (attitudes, self-efficacy, perceived barriers, and social influences related to caregiving of PLAD) from baseline to Time Points 1 and 2.

3 Study Background

Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

PLAD spend most of the course of their illness in the community and receive most of their care from informal (usually family) caregivers.[5] Currently, about 15 million adults, mainly women, annually provide 17.9 billion hours of family care for community-dwelling persons living with Alzheimer's and other illnesses.[1, 2] The situation is worse for **AACA**. Under-detection of cognitive impairment among Asian Americans remains prevalent,[1–3] and their cultural stigma produces suboptimal dementia management, placing them at a greater risk than Whites.[1–3] Although Asian Americans include highly diverse sub-groups, all Asian Americans across the sub-groups share many common characteristics, one of which is "filial piety," the belief that family members are in charge of caregiving roles.[3–6] Mainly due to this cultural belief, 42 percent of Asian Americans reportedly provide care to an older adult while 22 percent of the general population provides care to an older adult.[7]

The negative influences of caregiving on health outcomes of family caregivers are well documented.[8–10] The chronic stress of their role places them at greater risk for morbidity and mortality than non-caregiving peers.[8–10] The adverse effects on their psychological and physical well-being are extensive.[10–14] Furthermore, racial/ethnic minority women are more likely to suffer from caregiving burden compared with their counterparts, mainly due to their cultural attitudes related to AD and caregiving.[15–17] Furthermore, they rarely complain about their caregiving burden, delay seeking help, and seldom get support due to their cultural values, beliefs, and language barriers.[4–6,17] Subsequently, they have lower quality of life and fewer sources of information and support than Whites.[4–6,17] To reduce the burden of caregiving on health outcomes among family caregivers of PLAD and subsequently improve health outcomes of care recipients, many psychoeducation interventions were developed and used to provide information and support/coaching.[18] Indeed, a number of psychoeducation programs for caregivers have been developed and tested in relieving distress, increasing self-efficacy, managing caregiving challenges, and enabling caregivers to sustain care over longer periods of time.[19–22]

As mentioned above, however, **existing psychoeducational interventions** have rarely succeeded in achieving their goals among racial/ethnic minorities including Asian Americans because of several reasons.[18,23–25] Again, one major reason is the lack of consideration on caregivers' cultural attitudes related to AD and caregiving.[18,23–25] For instance, due to cultural hesitance to discuss dementia,[3,26–28] Asian Americans tend not to share their caregiving experience (e.g., heavy burden of caring, psychological and physical symptoms) until they get severe/serious problems that cannot be tolerated anymore. These women consequently shoulder the heavy burden of caregiving without adequate support although there exist some information and/or coaching/support available to them.[3,26–28] However, there is virtually no program that considers these women's cultural attitudes. Also, another major reason is: many caregivers cannot take part in existing programs because most require them to arrange care for the care recipients while they attend the programs.[29–35]

Technology-based programs could help overcome these two major drawbacks of existing programs by incorporating cultural tailoring and providing 24-hour access through the Internet without physical transportation. Also, in a meta-analysis of randomized clinical trials, Davies et al. found that technology-based programs were effective in producing changes in health outcomes**.**[36] Researchers also supported the effectiveness of technology-based interventions in approaching marginalized people with stigmatized conditions (e.g., racial/ethnic minorities).[37–40] These marginalized groups report greater interest in e-health than their more affluent counterparts.[41–46] Moreover, Internet use by Asians is greater than that of any other racial/ethnic groups; about 97% of Asian Americans have access to the Internet.[47,] In PSs, Asians preferred a technology-based program that would not require travel to a location outside of their home.[48–51] About 94% of Asian-American households own a cell phone (compared with 86% of total population).[52,53, 54] Both the literature[55, 56, 57] and PSs[48–51] support that older Asian American women preferred technology-based programs to traditional programs, and nationally recruiting/retaining Asian American women for a technology-based intervention is feasible.

Despite the reported strengths, few technology-based interventions are actually available for MWPLAD.[58] A meta-analysis of 12 interventions using information and communication technologies among informal caregivers of persons living with dementia[58] identified only two computer-based studies.[59,60] These two studies reported significant positive effects of the computer-based interventions that included educational modules and videos, decision support, and communication features.[59,60] Kajiyama[59] reported a significant positive effect on caregivers' stress (p=.017), and Brennan[60] indicated significant improvement in caregivers' decision-making confidence (p<.01). However, none of these programs specifically targets or offers features most appealing to AACA.

TACAD that will be tested in the proposed study offers several **unique features** that were rarely used in existing programs. **First**, none incorporated racial/ethnic minorities' cultural attitudes in the design, and none used cultural tailoring. Yet, cultural tailoring is essential in providing effective information and coaching/support for Asian American caregivers. For example, Confucian cultural heritages prescribe Chinese women to live in harmonious social relations, subsequently inhibiting them from expressing potentially disruptive and distressing emotions and/or symptoms.[2,4–7] Thus, technology-based programs that do not consider this cultural attitude would not best serve this group. It is also well known that the programs culturally tailored to meet the specific needs of a subgroup would be much more effective than generic programs because tailored programs address only those factors known to be important to specific recipients.[61–64] TACAD has multiple components that are culturally tailored to AACA based on the findings from PSs and the criteria for rigor in cross-cultural research[65] (see Intervention). **Second**, the self-adaptation functionality included in TACAD allows further personalization of the intervention components using a machine-learning method (Genetic Algorithm; see the section on TACAD), which was never used in existing programs. Through this functionality, TACAD can deliver the most relevant and effective information and coaching/support to each participant while considering diversities among AACA. Because there exist diversities even among the two sub-ethnic groups of Asian Americans,[66] this personalization is necessary for AACA. Furthermore, this is consistent with the NIH's direction related to precision/personalized medicine/health.[67–69] **Third,** none of the programs incorporated both group and individual (real-time and personalized) coaching/support by culturally matched bilingual healthcare providers. There exist added benefits to protocols that include both group and individual coaching/support. Group coaching/support through non-face-to-face interactions work well for Asian Americans because of their collectivist culture.[70–72] Also, individual (real-time and personalized) coaching/support through non-face-to-face interactions would work well for those whose cultures still stigmatize dementia.[73–76] Furthermore, culturally matched bilingual interventionists can ensure efficacy in coaching/support, limit the potential for harmful communications, provide reliable and objective information/resources, and nurture a positive group culture in culturally appropriate and sensitive ways.[77–79] **Fourth,** peer-based social media services that allow individuals to generate public profiles, develop a list of users with whom to share connections, and interact with the users through Internet interactions and instant messaging are rarely used in existing programs.[80] Social media sites such as *Facebook* effectively communicate and encourage user participation around health topics.[81] While social media as a health tool is understudied, findings indicate its effectiveness in providing information and coaching/support to racial/ethnic minorities.[81–83] **Finally**, few existing programs incorporate VR technology in the intervention.[84–86] VR can be a more accessible, scalable, and appealing delivery method for this specific population since they would not need to travel. VR can be used to

create highly ecologically controlled simulations resembling the daily life contexts in which patients' daily instrumental activities usually take place. The immersive and engaging virtual environment promotes caregivers' actual understanding of PLAD' daily experience and provides a sense of control and multiple dimensions of empathy.[84–86] Actually, VR has been widely used to help family members learn more about the challenges their loved ones with dementia face, and to build empathy among family caregivers of PLAD.[87–90] Its effectiveness in increasing empathy has been reported in the literature,[87–90] and VR was reported to be an effective intervention to train caregivers of persons with dementia.[84–86] Originally, TACAD includes a VR component based on "A Walk Though Dementia"(a free Android & iOS Virtual Reality app giving an insight into life with dementia), which will be used to change AACA's attitudes related to AD and caregiving by increasing their empathy. However, the original VR that we planned to use was discontinued by the developer and only a 360 degree video clipping of the VR component is currently available. Thus, the VR component was replaced with the 360 degree video clipping of the VR. **In summary**, if TACAD, by incorporating all these components, proves to be effective, it can fill the gap in these programs and ultimately reduce health disparities in racial/ethnic minority caregivers of PLAD. This study will also accelerate the translation of the technology-based programs into various settings and populations and will be an important contribution to health and quality of life among racial/ethnic minority caregivers of PLAD.

4 Design and Methodology

Provide a brief description of the study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

The study includes two phases: (a) a usability test and an expert review (Phase 1) and (b) a pilot randomized clinical trial (Phase 2). Phase 1 has been completed at Emory, and only Phase 2 will be conducted at Univ. of Texas at Austin (UT Austin). For Phase 2, the data will be collected at three points: (a) pre-test; (b) post 1 month; and (c) post 3 months. The collected data will be analyzed after the data collection of all the participants is completed.

5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

The data will be randomly assigned with serial ID numbers. All tests will be assumed two-sided and an alpha level of .05 will be used. SAS 9.4 will be used for data processing and all statistical analyses. Missing data will be handled by multiple imputations of dependent values.[101–103] Analyses just of complete data will be conducted and comparisons of groups with and without missing data will be made. In addition, sensitivity analyses of complete data will be conducted and compared imputed data analysis. An **intent-to-treat** analysis will be employed. For **Hypotheses 1 to 3,** differences in continuous outcome measures over time will be examined using **linear mixed-effects modeling.**[104] In particular, we will fit mixed effects models to each continuous outcome measure.[105,106] We will use random intercepts as well as explore random slopes to represent subject level variability. Fixed-effects corresponding to group, time and group x time interaction will be included in the model. A significant group x time interaction will indicate substantial differences in the groups over time. Restricted maximum likelihood method will be used for estimation, and the most appropriate covariance structure will be examined.

Since Data and Safety Monitoring Boards (DSMBs) are required only for phase III clinical trials (NOT-OD-00-038.html), we do not include a DSMB for this intervention study. For the proposed intervention study, we have

the following data safety monitoring plan (DSMP). First, to manage and protect the data collected, only summary data will be openly accessible to funding agency or will appear in publications. Research participants will be informed that they are free to decline to answer any questions they do not wish to answer or to stop participating in the project at any time. When a participant withdraws from participation, the data that they have provided will be immediately removed. Also, the data will have no identifying information to link a subject to the data.

The participants' records will be handled as confidentially as possible. Only the research team will have access to the study records. As mentioned above, only a serial ID number assigned by the researcher will be attached to the data, and the data will be stored in a locked file cabinet in a research office. No identity information, including IP addresses, will be attached to any of the individual or group data. Therefore, research participants will not be identifiable directly or through the identifying information linked to subjects. No individual identities will be used in any reports or publications that will result from this study. Additionally, as explained above, the Web site will be developed and maintained such that it conforms to the HIPAA standards. Finally, data in the servers will be daily monitored by Dr. Chee to ensure its safety and security.

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Check each research procedure included in your study.
A full description of all study procedures should be provided in the Procedures (Details) section below.
Procedures denoted with "" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☐	Bio-specimens*	☐	Biometrics	☐	Registry or Repository*
☐	Focus Group	☐	Genetic Analysis	☐	Genomic Data Sharing
☐	International Research*	☒	Interview/Survey	☐	MRI
☐	Protected Health Information*	☐	Observation	☐	Radioactive Material/PET/Nuc. Med
☐	Record Review	☐	Sensors (Externally Placed)	☐	Sensors (Inserted)
☐	Audio (only) Recording	☐	Video Recording	☐	X-Ray/CT/DEXA

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.
A full description of all study interventions should be provided in the Procedures (Details) section below.

** Interventions denoted with "*" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☒ **Behavioral** ☐ **Device*** ☐ **Drug/Biologic***

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Check the box(es) below if you are implementing research procedures that require oversight from additional UT committees.

☐ **Energy introduced to the subject (electrical, magnetic, light)** ☐ **Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos** ☐ **Radiation exposure without direct clinical benefit**

☐ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus UT IBC approval is needed.

a ☐ **UT IBC has (or will have) oversight.**

Provide UT IBC Number:

b ☐ **Biological samples collected will not be stored at UT Austin and another agency has responsibility for biospecimen safety.**

10 Alternatives to Participation in This Study

Provide a description of alternatives to participation in this study, as applicable.

Since this is not a treatment study, the alternative is not to participate.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- *Description of all research procedures being performed and when they are performed, in sequential order.*
- *Describe/list all research measures/tests that will be used [**NOTE: upload copies of all measures, surveys, scripts, data collection forms, etc., in "Other Attachments" in UTRMS-IRB**].*
- *Secondary data or specimens that will be obtained, how they are collected, how are they used.*
- *Where research activities will take place and duration (include expected time commitment of participants).*
- *Study elements checked in #6 above should be described here.*

Note: if this is a multi-site or collaborative study include the following:

- *This is a "Multi-site Study that involves more than one site performing ALL aspects of the research procedures as outlined above." OR "This is a collaborative study that involves UT Austin researchers working with external researchers who are engaged in performing the following study activities (list activities)."*
- *For assistance with multi-site/collaborative research, download HRP-UT932 Request to Rely Assessment Form from the UTRMS-IRB Library and email irbreliance@austin.utexas.edu.*

The study includes two phases: (a) Phase 1 including an expert review and a usability test and (b) Phase 2 (a randomized control trial among 60 AACA). Only Phase 2 will be conducted at the Univ. of Texas at Austin.

Phase 1 (Aim 1)

For the expert review, the Cognitive Walkthrough method,[95] will be used with several topics related to the logistics and content of TACAD (including *the adequacy of cultural tailoring and specific unique needs of Asian Americans*). Please see the below for the details on TACAD. First, 5 self-identified *experts in family caregivers of PLAD who never participated in any previous studies of PIs* will be recruited through announcing the study at and outside Emory University, and asked to provide their evaluation on the TACAD within 2 weeks. Five experts are an adequate number for an expert review.[95] For a usability test, the first 10 AACA who agree to evaluate an early version of the TACAD, will be involved in a 1-month-long online forum. On the forum site, 1-2 topics related to specific areas for which the users' evaluation is needed will be posted each week. The topics include: (a) the overall structure, (b) preferences for color, designs, and menus, (c) preferences for content, (d) technical support and difficulties, (e) areas for additional content, (f) preferences for Internet resources, and (g) other issues (*the adequacy of cultural tailoring and specific unique needs of Asian Americans*). The messages will be analyzed using

a content analysis.[96] About 80-90% of usability problems could be identified by about 5-10 participants.[97] The findings from Phase 1 was incorporated into the refinement of TACAD.

Phase 1 was completed at Emory and TACAD was defined based on the findings. Thus, the data from the first phase will not be shared with UT research team.

Phase 2 (Aim 2)

All research activities in Phase 2 will be done virtually. The study website will be developed first. The study website is the Web-App of the intervention program. The website at Emory was originally developed and refined by the other PI, Dr. Wonshik Chee, and it is owned by Dr. Chee. As soon as the grant transfer is completed, the website will be housed at The Univ. of Texas at Austin. To access/use the program through the website, the participants will be provided with an account with ID and passwords, which they could change at their convenience. The data collected through the website will be just the data on the participants' activities in the website (e.g., how many times per week they log in and out, what components they used in the website, how many messages that they are posting) that will be used to determine the dose-response effect of the program later. The current website at Emory is: https://tacad.nursing.emory.edu Again, the website will be moved to UT- Austin once the grant transfer is completed, which requires this IRB approval.

When potential participants visit the website, they will review the "informed consent" and click "I agree to participate" if they agree. After checking them against the inclusion criteria, only those who meet the criteria will be automatically **randomized** into two groups within each sub-ethnic group using an automated random number generator through the website. The randomization will be done within each sub-ethnic group to have an adequate number of participants in each sub-ethnic group. The intervention group (Group 1) will use both TACAD and Alzheimer's Association (AA) website while the control group (Group 2) will use only AA website.
The women will be asked to fill out the baseline questionnaire. Then, they will be provided with IDs and passwords to log on the website. Both groups will have an electronic instruction sheet on when they need to come back and fill out questionnaires (see the below for the instruments) and/or use TACAD (see the below for more information on TACAD). Also, both groups will use the AA website (see the below for more information on the website) for **3 months**. Only the intervention group will use TACAD for **3 months**. Basically, they need to use TACAD and/or the AA website whenever they want to use; no requirement for reimbursement. They are recommended to visit the project website at least once a week and the intervention group is recommended to have weekly coaching/support sessions with the interventionists through chatting. At first time of use, the participants will have an informational session on the proper use of AA website and TACAD (with instructions on headsets) by phone and/or a webcam. During the intervention, the participants will provide their feedback on the research process as well as TACAD. Two weeks before the end of the 1st and the 3rd months, both groups will fill out the next set of the instruments; it usually takes about 30 minutes to complete each questionnaire. The questionnaires will be provided via **Qualtrics**. In addition, during the intervention period, the participants will be screened using the PHQ-9 only if the research team identifies severe depressive symptoms or suicidal ideation at any time point. We will make immediate recommendations for psychiatric referral for those with scores more than 10 on the PHQ-9 (the cut-point of moderate depressive symptoms; range=0~27) as the literature suggests[107–110]In such cases, participants will also be dismissed from the study.

TACAD. TACAD has four components in three languages (English, Mandarin Chinese, and Korean): (a) 2 sub-ethnic specific social media sites; (b) interactive online educational modules; (c) online resources; and (d) a 360 degree video clipping (a replacement of the VR component that was originally planned). The original VR that we planned to use was discontinued by the developer and only a 360 degree video clipping of the VR component is currently available. Thus, the VR component was replaced with the 360 degree video clipping of the VR. Two languages other than English were adopted because they are the primary languages of Chinese Americans or Korean Americans. The comparability of different language versions has been ensured through the standard-back

translation process. The social media sites will be assisted, coached/moderated, and monitored by culturally matched bilingual RNs under the supervision by PIs. Coaching/support through social mediate sites (with chat functions) will focus on: (a) changing attitudes toward and beliefs about AD and caregiving, (b) building self-efficacy for caregiving, (c) minimizing information needs and uncertainty, and (d) enhancing social support through multiple ways. Within the project website, a social media site (like Facebook) is included. The site is developed by Dr. Wonshik Chee and owned by him. The participants' activities are daily monitored by the interventionists and Dr. Chee to prevent any possible harmful effects. The RNs will be trained by the PI. Her/his first 10 messages through social media sites and chat functions will be monitored/evaluated by the research team, and the team's feedback will be incorporated into her/his subsequent interactions. The social media site will be very similar to Facebook. All participants can post their messages (e.g., sharing their experience) and pictures and they can see others' postings. The participants will use their pseudonyms that they choose when they join the study, but their profile pictures will not be posted. All postings will be visible only at the project website. No identifiers will be used except pseudonyms. We also developed online educational modules while considering the women's cultural attitudes found in the literature: TACAD aims to correct misinformation on AD and caregiving by providing state-of-science evidence-based educational content and to provide examples of culturally appropriate caregiving strategies that can be easily adopted. *Culturally relevant content* (e.g., filial piety, respect for elderly, mind-body interactions, etc.) and *culturally tailored* educational materials and online resources from Asian scientific authorities are also incorporated. Again, 360 degree video clipping components based on "A Walk Through Dementia (WTD)" will be used to help caregivers learn more about the challenges their loved ones with dementia face, and to build empathy among the caregivers (subsequently changing their attitudes). WTD uses VR technology to give an idea of the challenges faced by people with dementia. Using 3 everyday scenarios (at the supermarket, on the road and at home), users are given insight into some of the symptoms that people with different forms of dementia including AD may experience. The original VR that we planned to use was discontinued by the developer and only 360 degree video clippings of the VR component is currently available. Thus, the VR component was replaced with the 360 degree video clippings of the VR. The 360 degree video clippings basically have the same content of the VR component without the 3-dimentionality, which could be just viewed through Youtube site without any device. They are:

A Walk Through Dementia - walking home (3 minutes 20 seconds)
https://www.youtube.com/watch?v=R-Rcbj_qR4g&ab_channel=AlzheimersResearchUK).

A Walk Through Dementia - at the supermarket (4 minutes 52 seconds)
https://www.youtube.com/watch?v=TaeNgo8bR2k&ab_channel=AlzheimersResearchUK

A Walk Through Dementia - at home (2 minutes 34 seconds)
https://www.youtube.com/watch?v=2EO7Dh3fM7Y&ab_channel=AlzheimersResearchUK

TACAD also has self-adaptation functionality based on Genetic Algorithm such that the program can deliver the most relevant and effective educational modules and online resources to each participant by using a machine learning method. Cultural tailoring was theoretically guided by the criteria for rigor in cross-cultural research.[65] Based on the criteria, TACAD incorporated specific components to: (a) respect cultural uniqueness; (b) understand cultural contexts; (c) use cultural examples; (d) have flexibility; (e) adopt multiple languages; (f) have culturally matched bilingual research team members; and (f) engage community consultants and research participants. Presentation styles were tailored to Asian culture. Through the process, both surface and in-depth cultural tailoring was done. TACAD used a free-form matrix information architecture[91] and included menus based on the four components. *Graphic User Interface controls,*[92] the *Ruby on Rails (ROR)*[93] *framework, and the Xen hypervisor*[94] *were used. Due to the use of ROR, different language versions could be easily added to the program, and cultural*

tailoring methods used in this program could been easily adopted to different sub-ethnic groups. All the usages of different components will be automatically recorded in the server, which will allow the evaluation of different components. For instance, the usages of individual educational modules will be recorded on the server, so the association of the usages of specific modules to outcome variables could be easily determined later. To assess contamination, we will gauge crosstalk by open-ended questions about it at T1&2. We will estimate its effects statistically by testing if intervention effects are weaker among those who crosstalk.

Alzheimer's Association (AA) Website. The AA website has information in various areas related to AD and caregiving (https://act.alz.org/site/Donation2?df_id=51079&51079.donation=form1&mfc_pref=T&utm_source=google&utm_medium=paidsearch&utm_campaign=giving_google&s_subsrc=giving_google&gad=1&gclid=CjwKCAjw8symBhAqEiwAaTA__CfaR61oNeY9mrdwZRbCKeviZPR7UdFVXpPJaAoSv8GavnyaFx0nxhoCH6EQAvD_BwE). For instance, the webpage on caregiving includes information on caregiving, care option, financial/legal planning, caregiver health, daily care, stages and behaviors, and safety. The content will be available in the three languages at the project website. The usages of the AA website and additional information searches (the participants will use them only through the project website) will be automatically recorded through the project server and later used for data analyses. Both groups will be asked to maintain their usual care. The interventionists will weekly remind the control group to use the AA website.

Instruments. The instruments to measure caregivers' health outcomes (primary outcomes; Hypothesis 1) include: (a) ***Multidimensional Caregiver Strain Index,[2] Perceived Stress Scale***,[3] Acculturation Stress Scale (ASS),[148] and Social Readjustment Rating Scale (SRRS) [149] (to measure stress); (b) the Women's Symptom Index[150] (to measure physical and psychological symptoms); and (c) EQ-5D-5L[151–154](to measure the quality of life). The instruments to measure care recipients' health outcomes (primary outcomes; Hypothesis 1) will include: (a) Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)[155,156](to measure the cognitive status of care recipients); (b) Lawton ADL/IADL Scale[157] (to measure PLAD's activities of daily life); (c) Revised Memory and Behavior Problem Checklist[158] (to measure behavioral and psychological symptoms of care recipients); (d) Neuropsychological Inventory Questionnaire[159] (to measure care recipients' mood status); and (e) Quality of Life Scale in Alzheimer's Disease[160] (to measure care recipients' quality of life). The instruments to measure *caregiving experience* (secondary outcomes; Hypothesis 2) will include: (a) ***Caregiver Activity Survey[1]*** *(to measure caregiving activity);* (b) Ways of Coping Scale[161] (to measure coping); (b) Pearlin Mastery, Loss, and Competence Scale[162] (to measure caregivers' mastery of caregiving competence); and (c) Caregiver Assessment of Behavioral Skill Scale (to measure caregiving skills).[163] The theory-based variables (attitudes, self-efficacy, perceived barriers, & social influences; Hypothesis 3) will be measured using the modified Questions on Attitudes, Subjective Norm, Perceived Behavioral Control, and Behavioral Intention (QASPB).[164] Covariates that will be considered in determining the effect of TACAD on outcome variables include caregivers' sociodemographic characteristics and caregiving history (e.g., socioeconomic status, PLAD information, length of caregiving, co-residence with recipient). The reliability and validity of all the instruments have been established among Asian Americans. Cronbach's alpha of the instruments ranged from .70 to .96 among Asian Americans. *Because no existing instruments have culture-specific measures, we will add open ended questions to all the measures to explore culture specific aspects that are missing in the specific measures.* The same questionnaire will be used at the three time points except the questions on sociodemographic characteristics and caregiving history (e.g., socioeconomic status, PLAD information, length of caregiving, co-residence with recipient). The questions on sociodemographic characteristics and caregiving history (e.g., socioeconomic status, PLAD information, length of caregiving, co-residence with recipient) will be asked only at the pre-test. This has been clarified on p. 10.

The final versions of all materials will be uploaded via Modification for IRB review prior to any implementation. All communication/reminder templates will be uploaded via Modification prior to administration.

SUBJECT POPULATION

12 Protected Subject Populations

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐ Active Military Personnel	☐ Children/Minors	☐ Decisionally Impaired Adults
☐ Emancipated Minors	☐ Fetuses	☐ Individuals with Limited English Proficiency
☐ Neonates (Uncertain Viability)	☐ Neonates (Non-Viable)	☐ Prisoners
☐ Pregnant Women	☐ UT Staff/Employees	☐ UT Students

13 Research Participant Information

Describe the general characteristics of the subject populations or groups including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g., teachers and students), clearly outline characteristics for each group.***

Asian American women who are family caregivers of persons living with Alzheimer's Disease

b Minimum Age

Include the minimum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state the minimum age for each group.***

18 years old

c Maximum Age

Include the maximum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state maximum age for each group.***

d Inclusion Criteria

Participants will be included if, by self-report, they are Asian American women who identify as Chinese or Korean; are caregivers of PLAD; can read and write English, Mandarin Chinese or Korean; and have access to the Internet through computers or mobile devices. Participants must be providing assistance for the PLAD in the early-middle stage of illness (Clinical Dementia Rating of ≥ 1) for whom there is no plan for institutionalization in six months. Caregivers may or may not reside with their care recipient.

e Exclusion Criteria

Describe the specific criteria that will be used to decide who will be EXCLUDED from the research. Define technical terms in lay language, as applicable.

Those who used the AA website previously and/or participated in other studies related to AD will be excluded. Men are excluded because the intervention was designed for Asian American women who are family caregivers of persons living with Alzheimer's Disease.

14 Total Sample Size

Enter the total target sample size below.

60

15 Sample size rationale

Describe your sample size rational below.

To test Hypotheses 1 to 3 (Aim 2), with 80% power and a type I error rate equal to 0.00625 to account for 9 outcome measures modeled within two hypotheses, group sample sizes of 105 each will have enough power to detect a difference of 0.5 between group means overall in the follow-up period. However, considering the proposed study period, limited budget, and the inherent explorative nature of the study, we will include only 60 (30 per group) women; 30 will be adequate for a pilot intervention study.[100]

SCREENING AND RECRUITMENT

16 Identification and Screening

*Check the box below if this study involves a screening process **prior** to the informed consent process.*

☐ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**
1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 Identification and/or Screening Procedures

Describe the identification and/or screening procedures below.

When potential participants visit the project website after seeing the study announcements posted on online and offline communities/groups, they will be provided with the information sheet (consent form) and asked to give their consent by clicking the "I agree to participate" button. Then, when they agree, they will be verified against the inclusion and exclusion criteria (see the above) by server-side programs. When they meet the criteria, they will be asked about their sub-ethnicity. Then, the potential participants will be divided into Chinese and Korean, and randomized into two groups using an automated random number generator via the project website.

18 Recruitment Overview

Check box indicating all recruitment methods utilized for this research.

☒	**E-mail**	☒	**Flyer**
☒	**In-Person**	☐	**Letter**
☒	**Social Media**	☐	**Research Pool**
☐	**Telephone/Text**	☒	**Snowball Sampling**
☒	**Web-post**	☒	**Word of Mouth**

19 Describe the recruitment process, including where recruitment will take place.

Describe recruitment procedures in the box below. Describe all elements checked above to provide a complete understanding of the recruitment strategies/methods.
NOTE: Upload copies of all recruitment materials to UTRMS-IRB in the "Recruitment Materials" section.

The settings will be online and offline communities/groups for Asian Americans. About 97% of Asian Americans have access to the Internet and regularly use it.[47,] Thus, a technology-based intervention will likely have larger public health effect for this group than others. Both the literature[55, 56, 57] and PSs also support that nationally recruiting and retaining AACA through the Internet is feasible and highly effective. In a Google search, over 48 million online groups for Asian Americans were retrieved (with up to over 1,000 members). Yet, Asians are also well known about their hesitance to participate in a research study.[72] Thus, offline communities/groups for Asian Americans (e.g., clinics, churches) will also be targeted, which allows to recruit those who do not use online groups. Racial/ethnic minorities are more successfully recruited in churches and support/social groups with culturally specific memberships.[99] When offline communities/groups for Asian Americans were searched with Google, over 4 million sites were retrieved (with up to 30,298 members). Thus, we do not expect any difficulties in recruiting 60 participants through these settings (see Recruitment & Retention plan). The study will be announced through their sites, listservs, instant messaging, flyers, snowball sampling, and word of mouth after obtaining the permission to post the study announcements through online and offline communities/groups. In addition, Facebook groups related to Alzheimer's Disease will also be contacted for study announcements. We will also recruit from the Collaborative Approach for Asian Americans & Pacific Islanders Research & Education (CARE) Registry (UCSF IRB No.23-39121). The final recruitment materials will be updated and provided via Modification prior to administration.

In addition, the announcements for recruitment will be posted on the **feed** on the @utnursing_research Instagram. Please note that the research team will not post anything regarding the study on their personal account.

OBTAINING INFORMED CONSENT

20 Consent Overview

Check the box(es) for consenting procedures that will be used.

☐	**Obtaining Written Informed Consent/Parental Permission**	☒	**Requesting a Waiver of Documentation of Informed Consent**
☐	**Requesting a Waiver of Informed Consent**	☐	**Requesting an Alteration of the Required Elements of Informed Consent**
☐	**Obtaining Child Assent**	☐	**Obtain Consent Using a Short Form with a Witness**

21 Consent and Assent Processes

Provide a detailed description of consent/assent procedures in the box below. Include: who will obtain consent, where will consent be obtained, how is consent obtained, how consent/assent is documented, and when the

consent process will occur in such a manner that participants will have sufficient time for adequate consideration.

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp consent forms for approval.

When potential participants visit the project Web site, they will be asked to review the informed consent form that provides general information on the proposed project, including: (a) the purpose of the study, (b) staff on the study, (c) the data collection period, (d) potential physical and psychological risks involving inconvenience, confidentiality, and invasion of privacy, (e) their rights to withdraw, (f) how to maintain complete confidentiality (using IDs and passwords), (g) what they are being asked to contribute to the study, and (h) how their participation will be reimbursed. They will be asked to give their consent to participate by clicking I agree to participate. When the button is clicked, participants' profiles will be checked against the inclusion and exclusion criteria. Internet protocol addresses of the participants will also be monitored to detect multiple submissions by the same person. After getting the consent, the participants will be linked to the Qualtrics system to go through the screening process and fill out the pre-test questionnaire.

When participants give their consent to participate in the study, they will be informed that the data collected during the study will remain confidential unless a participant appears at risk for harming herself or others. The informed consent form will include checkboxes next to each risk statement in red font that participants must check to indicate that they have read it. Also, the informed consent form on the Web site will include e-mail addresses for the PI and research staff under the question "Do you have any questions?" Thus, participants will be able to send an e-mail directly to the PI and/or research staff with their questions. E-mail will be answered within 24 hours on weekdays and 48 hours on weekends. In addition, participants will be able to call the research office using the phone number provided on the informed consent form (next to the risk statements), which will also be responded to within 24 hours on weekdays and 48 hours on weekends. The risks involved in the proposed study will not be more than those usually faced in daily life.

The reason for obtaining online consent (waiving the signed written consent) is multiple. **First**, we believe that it is unnecessary to meet with participants or to mail hard copies of the informed consent form for the sole purpose of obtaining signed written consent. **Second**, obtaining signed written consent from the participants across the nation raises a feasibility issue related to mailing and possible follow-up phone calls. **Third**, previous studies indicated that Asian Americans did not wish to sign a written consent for a historical reason: for instance, in Korea, data from surveys were once used to identify tax fraud, and some people's honest answers on the survey were used to assess an additional tax.[72] This Internet-based consent process has been used in all preliminary studies without any issues or concerns from participants or research staff members. The preliminary studies that compared the pen-and-pencil survey with the Internet survey questionnaire showed that the Internet-based consent process was similar to that of the pen-and-pencil survey in terms of its ability to explain the study and respond to questions from participants.[112] Interestingly, some participants in **preliminary studies** indicated that they preferred Internet communications to ask questions about the study because Internet communications are asynchronous (they could ask questions at any time) and e-mail is a written form of communication.

22 Electronic Consent

Check the box below if this study involves obtaining consent with an electronic signature. Be sure the section above is consistent.

NOTE: This box should NOT be checked participants are responding "yes" or clicking "I Agree" on a consent form. ***This section should only be completed if an electronic signature is being obtained.***

☐ **This study involves documenting informed consent/parental permission using an electronic signature.**

If true, specify method for obtaining e-consent below (e.g., DocuSign):

23 Consent and Translation

Check the box below to indicate that consent documents/scripts will be translated to a language other than English.

☒ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

If above is checked, complete the below information describing the translation process. Either A or B must be checked.

A ☐ **The consent documents will be translated by a certified translator.**

B ☒ **A non-certified translator will translate the consent documents.**

If selected, complete the next two items below. Section describing qualifications must be completed and backtranslation (ii) must be true.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

Bilingual graduate students at School of Public Health, Emory University, have already translated and got certified at Emory Univ. For each language, at least two bilingual graduate students were involved in the standard-back translation process.

ii ☒ **Another individual will confirm that the translation is accurate and appropriate**

26 Waiver of Documentation of Informed Consent

Only complete this section if a waiver of documentation of consent is requested (checked above in #21). To approve a waiver of documentation of consent, one of the following options must be appropriate and justified by the researcher.

*Please choose **one** waiver option and provide additional information as prompted.* ***Waiver option 2 is most common.***

A Waiver Option 1

Check the box below for each item (all required – #1-4) and provide protocol-specific information as to how the criteria below are met.

NOTE: This is the only applicable waiver of documentation option for greater than minimal risk research. If your study is greater than minimal risk and does not meet Option 1 criteria, you will need to obtain written consent.

1 ☐ The only record linking the subject and the research would be the consent document.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

2 ☐ The principal risk would be potential harm resulting from a breach of confidentiality.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

3 ☐ Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

4 ☐ Describe the mechanism for documenting that informed consent was obtained

Briefly explain how the researcher will document that consent was obtained from participants.

B Waiver Option 2

Check the box below for each item (all required – 1-3) and provide protocol-specific information as to how the criteria below are met.

1 ☒ The study is minimal risk.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

This is an online educational and behavioral change intervention study with minimal risk. The participants will participate in the study only through the project website using pseudonym and passwords.

2 ☒ Written consent would not be required outside the research context.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

The participants will participate in the study only through the project website using pseudonym and passwords. They will just need to click "I agree to participate" through the project website.

3 ☒ Describe the mechanism for documenting that informed consent was obtained

Briefly explain how the researcher will document that consent was obtained from participants. To input text, click in the light grey area below.

i The participants will participate in the study only through the project website using pseudonym and passwords. They will just need to click "I agree to participate" through the project website.

C Waiver Option 3

Check the box below for each item (all required – 1-4) and provide protocol-specific information as to how the criteria below are met.

1 ☐ The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm

i Describe the cultural group or community.

2 ☐ **The research presents no more than minimal risk of harm to subjects.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

3 ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

4 **Describe mechanism for documenting that informed consent was obtained**
To input text, click in the light grey area below

27 Waiver or Alteration of Informed Consent

Only complete this section if a waiver or alteration of consent is requested. *To approve a waiver or alteration of consent, all of the following criteria must be appropriate and justified by the researcher.* ***All boxes must be checked.***

SKIP THIS SECTION IF NOT REQUESTING A WAIVER/ALTERATION OF CONSENT

A ☐ **The research involves no more than minimal risk to the subjects.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

B ☐ **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

C ☐ **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining consent is required and not just impracticable to obtain consent).**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

D ☐ **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

28 Deception/Incomplete Disclosure and Debriefing

Only complete the sections below if requesting an alteration of informed consent for research that involves deception/incomplete disclosure.

Deception (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.

Incomplete disclosure means that the principal investigator withholds some information about the real purpose of the study or the nature of the research procedures.

See IRB Policies and Procedures Section 15 for a description of deception.

If this study does not involve deception/incomplete disclosure, skip this section.

A ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive the subject to the nature of the study).**

B ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

C **Describe the nature of deception/incomplete disclosure and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

D **Describe debriefing procedures.**

To input text, click in the light grey area below. ***NOTE: Upload the debriefing form to UTRMS-IRB in the "Consent Forms" section.***

BENEFITS

29 **Benefits to Society**

Describe the scientific and societal benefit(s) below.

The information that the participants provide will assist health care providers in developing and refining technology-based information and coaching/support programs for racial/ethnic minorities, which will ultimately benefit the society.

30 **Potential Direct Benefits to Participants**

Click on the applicable check box. A or B must be checked.

A ☒ **There is no anticipated direct benefit to participants.**

B ☐ **There are anticipated benefits to participants.**

i **If applicable, describe the potential direct benefits to participants.**

Describe potential direct benefits to participants below.

RISKS

31 Describe the risks associated with each activity in this research

To input text, click in the light grey area below. Note: Risks should also be outlined in the consent form(s).

This study poses minimal risks to participants, and the probability and magnitude of harm or discomfort anticipated in the proposed study are no greater, in and of themselves, than those ordinarily encountered in daily life. As in other traditional survey studies, participation in this study may be an inconvenience, and some of the questions may make research participants uncomfortable or upset. In addition, because internet communications are not 100% safe, and **despite our efforts to ensure safe and secure internet communications**, participation in online data collection may pose an added risk of the invasion of **privacy** and possible violations of **confidentiality**. Even with the most sophisticated technologies, there is always a possibility of hacking by outsiders.

32 Describe how each risk is mitigated/minimized.

To input text, click in the light grey area below. Note: Risks mitigation should be outlined in the consent form(s), as applicable.

Data collected through email and the Internet will remain confidential unless a participant appears at risk of harm. All the activities will be automatically recorded on the servers. All the online interactions will be daily monitored by the engineering PI, Dr. Chee, and by RN interventionists with consultation of a MD (Dr. Mao). During implementation, all research team members will meet weekly to monitor the research process, monitor the daily online records of the program usages and data collection progress, monitor participant adherence, and address any issues that arise, and consult as necessary with consultants.

All e-mail communication between participants and the research team will be kept confidential by saving e-mails on a firewall-protected computer that will be accessible only to research team members using passwords and will be kept in a locked research lab. Also, at the completion of the study, the saved e-mails will be permanently destroyed to ensure confidentiality. In addition, as described below, e-mail addresses will be used only for reminders and participation reimbursement, and will be kept separate from other participant data. Furthermore, their email addresses will be accessed only by the research team, and the participants can communicate with other participants only through the social media sites (no email address will be disclosed to other participants).

We have **multiple strategies** to check and monitor any **potential health risks** including depressive symptoms or suicidal ideation. First, when the participants select “yes” to the question on other diagnosed diseases at pre-test, they will be asked to specify the diseases on the questionnaire. Although the proposed study mainly depends on self-reports and we do not include clinicians’ evaluation of each participant, the detailed screening questions will definitely check for specific symptoms that may indicate any medical conditions that may place participants at risk. Then, before participating in the study, participants will be asked if they have a regular source

of healthcare so that the research team can refer them if an adverse event is identified during the data collection process. If participants do not have a regular source of healthcare, then the researcher will provide a list of nearby clinics or healthcare centers so they can go to for emergency healthcare, if needed. During the data collection process, online records of the intervention process will be monitored daily by the engineering PI, Dr. Chee, to ensure data safety and security. Also, the records will be monitored daily by the interventionists who are RNs in consultation with a MD (Dr. Mao) and a NP (Dr. Brewster), and any potential and actual medical risks and adverse reactions (e.g., severe depressive symptoms or suicidal ideation, etc.) will be identified. For effective communication during emergency situations, the research team will establish emergency communication channels before starting the study. In addition, during the intervention period, the participants will be screened using the PHQ-9 only if the research team identifies severe depressive symptoms or suicidal ideation. We will make immediate recommendations for psychiatric referral for those with scores more than 10 on the PHQ-9 (the cut-point of moderate depressive symptoms; range=0~27) as the literature suggests[107–110]In such cases, participants will also be dismissed from the study. Participants in both intervention and control groups will be encouraged to seek mental health help if and when necessary. Also, we will provide the participants with local mental health referrals and contact information for the National Suicide Prevention Lifeline (NSPI; 1-800-273-8255) or the crisis text line. If a participant is in imminent danger to self or others (at any time during the study), a proper authority (local police or dial 911) will be notified to ensure the individual's safety. Also, a participant's family may be notified with the participant's permission. Family members will be offered the fact sheet developed by the National Institute of Mental Health (NIMH),[111] and RN interventionists will help them learn about the signs and symptoms, risk factors, and warning signs of suicide.

All communication/reminder templates will be uploaded via Modification prior to administration.

33 Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.
One of the following must be checked (A, B, or C).

A ☐ **In the investigator's opinion, this study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

PLEASE NOTE: The IRB may determine minimal risk studies do require data safety monitoring under certain circumstances (e.g., if there is a known risk with an expected frequency).

B ☒ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan to monitor for safety (Data Safety Monitoring Plan (DSMP)).**

Complete Data Safety Monitoring Details

C ☐ **This study has a Data Safety Monitoring Board (DSMB).**

*Complete Data Safety Monitoring Details section below **or** upload this study's Data Safety Monitoring Board's charter that contains the information below.*

34 Data Safety Monitoring (Details)

Complete this section if the study has a Data Safety Monitoring Plan. ***SKIP this section there is not a DSMP/DSMB.***

If the study has a DSMB, ensure all items below are addressed in the charter (and charted uploaded to UTRMS-IRB) or provide additional information below, as needed.

A How is safety information collected?

To input text, click in the light grey area below.

All the activities for the intervention and for the retention strategies will be automatically recorded in the servers. All the online interactions will be monitored daily by the engineering PI, Dr. Chee and by RN interventionists with consultation from a medical doctor (Dr. Mao). During the intervention process, the research team will meet weekly to monitor the research process, the daily online record of program uses, data collection progress, and participant adherence; to address any issues that arise; and to consult as necessary with consultants.

B When will safety data collection start (for each participant or for the whole study, as applicable)?

To input text, click in the light *grey area below.*

From the point that each participant is enrolled with the project website.

C How frequently will safety data be collected?

To input text, click in the light grey area below.

All the activities for the intervention and for the retention strategies will be automatically recorded in the servers (24 hours for 7 days per week).

D Who will review the data for safety?

To input text, click in the light grey area below.

All the online interactions will be monitored daily by the engineering PI, Dr. Chee and by RN interventionists with consultation from a medical doctor and a nurse practitioner. Dr. Jun Mao (medical doctor) and Dr. Glenna Brewster (nurse practitioner) are consultants of the study. Only the interventionists will interact with the participants, and they will get consultation and advice from these two doctors.

E How frequently will data be monitored for safety concerns?

To input text, click in the light grey area below.

All the online interactions will be monitored **daily** by the engineering PI, Dr. Chee and by RN interventionists with consultation from a medical doctor.

F What data will be reviewed?

To input text, click in the light grey area below.

The research process, the daily online record of program uses, data collection progress, and participant adherence.

G State the frequency or periodicity of the review of cumulative data.

To input text, click in the light grey area below.

Through weekly research team meetings.

H State any conditions that would trigger an immediate suspension of the research.

To input text, click in the light grey area below.

Nonspecific for this study. The study will follow the NIH policies and regulations.

35 Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to next section. Include this information in your consent form.*

A List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).

To input text, click in the light grey area below.

While the participants fill out the questionnaire, several random questions that they have already answered will be repeated to check consistency for the purpose of **identity and authenticity verification**. When inconsistency is detected, the participant will not be allowed to continue her participation in the study. This mechanism has been used in the former studies of the PIs without a problem.

The participants have the right to leave a study at any time without penalty. If they want to withdraw, they need to send an email notification or a text message indicating their withdrawal to the research team. Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise

entitled. New findings developed during the course of the research that may affect the subject's willingness to continue to participate will be provided to the subject.

B **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

Those who withdraw will be encouraged to seek mental health help if and when necessary, but no further actions from the research team after they withdraw.

36 **Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

To input text, click in the light grey area below.

None specific for this study. The study will follow the NIH policies and regulations.

REQUIRED DISCLOSURES

37 **Required Consent Disclosures**

Identify each element below that may require additional information to be disclosed in the consent form. Click on the check box (or double click and type an "X" if using Google Docs).

A ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**

Add appropriate disclosure in consent form(s).

B ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

Add appropriate disclosure in consent form(s). See Title IX and Research Guidance for information and download the Title IX Reporting Form on the Special Topics page.

C ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

Add appropriate language to consent form(s).

i **Articulate methods for addressing and reporting incidental findings, if applicable.**

Ensure appropriate information is in consent form(s), as applicable.

PRIVACY AND CONFIDENTIALITY

38 Privacy

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants. Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.
To input text, click in the light grey area below.

All the procedures will happen at the project server and website. The participants will use pseudonym during their participation in the intervention components through the project website; research staff members or other participants will not be able to identify them. Also, the participants will join the study independently through the project website, so non-participants will not know that they join the study.

To manage and protect the data collected, only summary data will be openly accessible to funding agencies or will appear in publications. Research participants will be informed that they are free to decline to answer any questions they do not wish to answer or to stop participating in the project at any time. When a participant withdraws, the data that they have provided will be removed immediately. Also, the data will have no identifying information to link a subject to it. The collected data will be recorded in a database using postgreSQL. The database backup will be performed daily and will be encrypted. Again, data in the servers will be daily monitored by the engineering PI, Dr. Chee, to ensure its safety and security.

39 Confidentiality and Data Security Plan

Provide general information below regarding confidentiality and data security plan. Provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.
Include the following, as applicable:

- *If identifiers will be coded to protect confidentiality describe how and where identifiers are stored.*
- *Describe where and how data is stored and maintained.*
- *Include details regarding storage of consent forms, if applicable.*

To input text, click in the light grey area below.

For safe and secure data collection via the Internet, the project Web site will conform to the HIPAA standards. The servers for the project website will be hosted on a HIPAA certified resource provided by UT Austin. Data are backed up according to UT Austin Information Systems Security protocols and procedures and conform to NIH research data retention guidelines. A detailed disaster recovery plan is in place and regularly reviewed by the University of Texas IT office.

The participants' records will be handled as confidentially as possible. Only the research team will have access to the study records. The data will be de-identified. Only a serial ID number assigned by the research team will

be attached to the data. Therefore, research participants will not be identifiable directly or through the identifying information linked to subjects. No individual identities will be used in any reports or publications that will result from this study.

All e-mail communication between participants and the research team will be kept confidential. Email addresses will be separately stored from the deidentified data. At the completion of the study, the saved e-mails will be permanently destroyed to ensure confidentiality. E-mail addresses will be used only for reminders and participation reimbursement and will be kept separate from other participant data.

40 Research Data/Records Destruction Details

Confirm general research data/information (including consent forms, as applicable) destruction timeline. ***One of the following must be checked.***

☐ **Research Data/Records will be retained for 3 years after study completion per UT record retention policy.**

☒ **Research Data/Records will be retained for longer than 3 years and retention information is provided below.**

Describe data retention timeline below. To input text, click in the light grey area below.

Deidentified data will be retained at the UT Qualtrics system for secondary analyses of the data and for data sharing requirements by NIH for 10 years after the completion of the study. All the data will be stored at the UT Qualtrics system. The data with the identifiers will be eliminated when the study is completed.

41 Confirm identifiable data destruction details

One of the following must be checked.

☒ **Identifiable data will be destroyed.**

If checked, ensure the below section describes identifiable data destruction plan and timeline.

The only identifiable data will be the participants' email addresses, which will be destroyed after the completion of the study (will be kept only for the participant reimbursement and accounting purposes, which will not be linked to the data). The electronic consent will be stored on the project server that will be linked only to a serial number attached to the data (no link to ID information).

☐ **Identifiable data will not be destroyed.**

If checked, explain below the rationale for retaining identifiable data indefinitely.

42 Data Access

Click on the check box (or double click and type an "X" if using Google Docs) for each group of individuals that will have access to study data.
If you plan on creating a repository, complete the repository form as well (download from Library in UTRMS-IRB).

☒ Study Team Members	☒ External Collaborators	☐ Data coordinating center
☒ Sponsor	☒ Future Sharing with other researchers	

☐ **Others**

Describe below. To input text, click in the light grey area below.

43 Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data.

To input text, click in the light grey area below. Ensure that data sharing and future use is addressed in the consent form(s).

The final data that will be available through the proposed study will be de-identified and the associated codebook that defines the data will be available for sharing with other researchers. The data will be available for secondary analyses especially by those who wish to investigate the efficacy of the technology-based program in various variables other than our major outcome variables. The availability of the data will be announced on the project website of the proposed study. Any researcher who wishes to use the data must request permission to conduct secondary analyses of the data from the PIs of the proposed study by e-mail or regular mail and provide the PIs with a 1-page long abstract (single-spaced) of the proposed analysis and her/his CV. The decision on data sharing will be made by the research team, including the PIs, co-investigators, and consultants, after they review the abstract and CV. When the research team decides to share the data with the researcher, the data in SPSS format, abstract, and original findings of the proposed study will be provided to the researcher. The researcher will be requested to: (a) agree that she/he will provide the findings from her/his analyses to the PIs at the completion of the analyses, (b) acknowledge the original study and the NIH in her/his future publications, and (c) not use the findings from the data for any commercial purposes. This agreement will be made in a written form. The data will have no identifying information to link a subject to her/his data. The data will be provided to the researcher as a password-protected zipped file that needs to be downloaded from a HIPAA certified cloud resource provided by UT Austin.

44 Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.
If a Certificate of Confidentiality is not applicable for this study, skip this section.

A ☒ **NIH has issued a Certificate of Confidentiality for this study.**

Ensure CoC language is included in the consent form(s).

B ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

Ensure appropriate CoC language is included in consent form(s). Apply for a CoC for non-NIH funded research here: NIH Certificate of Confidentiality System. Once CoC is granted by NIH, you must update the consent form language and ensure a copy of the CoC approval (only for non-NIH funded research) is uploaded to UTRMS-IRB.

COMPENSATION AND COSTS

45 Compensation

Click on the check box (or double click and type an "X" if using Google Docs). A or B must be checked.

A ☒ **Subjects receive compensation.**

i ☒ **Confirm: Amount of compensation and its form is reasonable for this population for the activities requested of them.**

ii Total Amount of Compensation

Include the total amount of compensation below.

Each participant will receive $50 gift certificates upon completion of pre-test (T0), T1 (post 1 month), and T2 (post 3-months). The amount was determined based on Preliminary Studies while considering the internet and smartphone fees that may occur due to the participation.

iii Type of Compensation

☐ **Cash** ☐ **Check** ☒ **Gift Card**

☐ **Course Credit** ☐ **ClinCard** ☐ **Tango Card**

☐ **Other**

Describe other form of compensation below.

iv **Proration Schedule**

Describe the proration schedule for multi-visit/session studies. Skip if not applicable.

The participants will be paid for the questionnaires completed each time point. But, they will NOT be paid by their participation in the intervention. For instance, if they withdraw after completing the pre-test, they will get a gift certificate of $50. If they withdraw after completing the post 1-month test, then they will get two gift certificate of $50 (one for pre-test and the other for post 3-month test).

B ☐ **Subjects will not receive compensation.**

46 Costs

A or B must be checked.

A ☒ **Participants will have no costs associated with this study**

B ☐ **Participants will have the following costs associated with this study.**

- ☐ **Standard of care procedures contributing to study data**
- ☐ **Research procedures not associated with standard of care**
- ☐ **Administration of drugs / devices**
- ☐ **Study drugs or devices**
- ☐ **Transportation and parking**

i **Describe all costs below.**

To input text, click in the light grey area below.

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