Alzheimer's Disease Cooperative Study
UC San Diego

HALT-AD Protocol and Analysis Plan

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"Healthy Actions and Lifestyles to Avoid Dementia or Hispanos y el ALTo a la Demencia Program" (HALT-AD)

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Protocol Title:	A Pilot Study for the Healthy Actions and Lifestyles to Avoid Dementia or Hispanos y el ALTo a la Demencia program (HALT-AD)
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Protocol Synopsis

Title	A Pilot Study for the Healthy Actions and Lifestyles to Avoid Dementia or Hispanos y el ALTo a la Demencia program (HALT-AD)
Background & Rationale	Alzheimer' disease and dementia are common, and feared. Recent scientific advances have underscored the significant population attributable risk of modifiable risk factors including those whose modification particularly when combined could delay or prevent dementia. However, there is an important gap in having this opportunity translated by individuals to make lifestyle changes and address their personal risk factors to preserve their brain health and preventing dementia. The preventive message does not fit the medical model well and the opportunity is not reaching the public or engaging it through public health programs that can intervene to bridge the gap. Healthy Actions and Lifestyles to Avoid Dementia or Hispanos y el ALTo a la Demencia program (HALT- AD) is a novel bilingual educational program that will focus on reducing risk factors with the ultimate goal of preventing dementia. It will be centered around a web-based interactive virtual online platform that will be developed to be dynamic, engaging, and interactive. HALT-AD will be complemented by remote facilitated support discussion groups which will focus on the content of the educational material and the invocation of change through participant engagement and compliance. Prior to launching the full HALT-AD program, it is essential that we conduct a preliminary pilot study to evaluate the program's first prototype including: the usability of- and engagement with- the online platform, users' acceptability of the learning content and facilitated support discussion groups. As well, effectiveness of the program in changing knowledge, self-efficacy, and dementia-related lifestyle risk measures will be assessed. This initial four-months pilot study will focus on at least three educational courses (such as: introduction to dementia and risk factors, sleep, diet, and social connectivity). The information generated from this study will help inform the development of the second program's prototype, expected to benefit from the initial pilot to become more user-friendly, effective and accessible to our target audience.
Study Design	This pilot study will be a longitudinal study of an inception cohort exposed to the HALT AD online educational program for a four month study. It will utilize pre- and post- intervention collection of quantitative and qualitative data to evaluate the program's first prototype.
Target Population	• Cognitively normal midlife and older-adult participants will be eligible to participate in this pilot study with the following inclusion criteria; Ages 50-85

	• Montreal Cognitive Assessment-Telephone/Blind version (T-MoCA) Score ≥18/22 • Sufficient proficiency in English or Spanish to undergo clinical assessment and participate in an online educational program. • Technical ability to participate in an online educational program (i.e. computer/tablet and internet access; ability to send and receive emails) • Sufficient vision and hearing to participate in online educational program (judgement of site investigator)
Number of Participants	A total of 20 participants will be enrolled at UCSD • 10 participants will complete the English version of HALT-AD • 10 participants will complete the Spanish version of HALT-AD We are aiming to recruit 50% women and to enroll a diverse participant sample across varied age ranges within both language groups.
Study Duration	Estimated duration of the entire pilot evaluation period is **approximately 4 months** (including participant enrollment, pilot study, focus groups and completion of data collection) • Individual HALT-AD participation: **3 Months** participation in online HALT-AD program
Study Goal and Aims	**Overall Goal:** To conduct a preliminary pilot study to evaluate the first prototype of HALT-AD. **Aims:** 1. To evaluate engagement with- the online platform 2. To evaluate preliminary evidence on the effectiveness of the program in changing a) knowledge, b) self-efficacy, and c) dementia-related lifestyle risk factors. 3. To determine users' acceptability of the program content 4. To determine users' acceptability and satisfaction with the facilitated support discussion groups 5. To evaluate the usability of the online platform
Outcome Measures	**Primary Outcome Measures:** 1. Users' engagement with- the HALT-AD online platform as measured by: • The total amount of time (in minutes) spent per user on all courses combined

	• The percentage of participants who completed all courses **Secondary Outcome Measures:** 1. Preliminary evidence on the effectiveness of the program in changing knowledge, self-efficacy, and dementia-related lifestyle risk factors will be evaluated by: • Change from baseline in knowledge on the HALT-AD knowledge assessment survey at 4 months • Change from baseline in self-efficacy on the New General Self-Efficacy Scale at 4 months • Change from baseline in lifestyle risk on the HALT-AD Lifestyle Risk Assessment Survey at 4 months **Exploratory Outcome Measures:** 1. Users' acceptability of the HALT-AD program content will be determined by: • HALT-AD Course Acceptability Survey • Focus group discussion 2. Users' acceptability and satisfaction with the facilitated support discussion groups will be determined by: • Facilitated support discussion group Acceptability Survey • Focus group discussion 3. The usability of the online platform will be evaluated by: • HALT-AD User Experience Survey • Net Promotor Score Survey
Statistical Plan	Descriptive statistics will be used for quantative data. Change scores will be computed where applicable. Change = (4 months score - baseline score). Continuous data will be presented with mean, standard deviations, median, minimum and maximum and 95% confidence intervals. Categorical data will be presented as proportions and percentages. Changes in continuous outcome measures between baseline and post-intervention will be analyzed by repeated measures t-test. Qualitative data generated from focus groups, logs, and open-ended survey questions will be thematically analyzed using inductive qualitative coding. **Sample Size and Power** Given that this pilot study is being conducted to contribute to the development of the HALT-AD program, we did not power to detect an

	intervention effect size over time. The sample size for the pilot was estimated based on prior experience in the development of similar programs.

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LIST OF ABBREVIATIONS:

AD	Alzheimer's Disease
ADRD	AD and related dementias
AE	Adverse event
BMI	Body Mass Index
CMS	Centers for Medicare and Medicaid Services
CRF	Case Report Form
HALT-AD	Healthy Actions and Lifestyles to Avoid Dementia
ICF	Informed Consent Form
NGSE	New General Self-Efficacy
NPS	Net Promoter Score Survey
T-MoCA	Montreal Cognitive Assessment-Telephone/Blind Version
UEQ	User Experience Questionnaire
ICMJE	International Committee of Medication Journal Editors

1.0 INTRODUCTION

1.1 Background

Alzheimer's disease (AD) is the single most feared disease associated with aging [1, 2], having a devastating social and economic impact on patients, families, and the community [3]. With its aging demographic, the growth of affected Americans is exponential with one person diagnosed every 67 seconds in the United States. The annual cost of AD to the US economy is over $260 million [4]. Over 84,000 individuals have AD in San Diego county alone [5], and 690,000 across California. There is a 35% increase projected within approximately the next decade [3]. Coinciding with these general trends for America's aging population, there are currently just over 4 million Hispanic Americans ages 65 and over in this group, which is projected to grow to almost 20 million by 2060 [6], with 3.6 million having AD [7]. Currently, close to half (45%) of all older Hispanic Americans are living in two states, California and Texas. Given that this population is disproportionately affected by social determinants leading to poor health outcomes placing them at increased risk of AD [8], the development of culturally informed preventive interventions that target modifiable risk factors to reduce dementia risk in Hispanics is paramount.

Progress in finding effective pharmaceutical treatments to modify or definitively treat AD and related dementias (ADRD) has been extremely disappointing [9]. Recent research underscores a population attributable risk of 28.2% associated with a range of modifiable risk factors across the lifespan [10], and encouraging results from studies combining multiple risk factors as a focus of their intervention [11]. In turn, efforts to successfully modify lifestyle and other health factors (e.g., vascular health, physical activity, diet, sleep etc.) addressing personalized risk could have an enormous long-term benefit in delaying or preventing dementia. While the medical sector and Centers for Medicare and Medicaid Services (CMS) are constantly innovating individual service delivery [12], insufficient attention has been given to systematically translating biomedical research on lifestyle changes to reduce dementia risk through information at the population level that can promote effective behavioral change. Indeed, this approach is our best current opportunity for dementia risk reduction.

1.2 Rationale

Healthy Actions and Lifestyles to Avoid Dementia or Hispanos y el ALTo a la Demencia program (HALT- AD) is a novel bilingual educational program that will focus on reducing risk factors with the ultimate goal of preventing dementia. It will be centered around a web-based interactive virtual online platform that will be developed to be dynamic, engaging, and interactive. Through interactive courses, the educational content of HALT-AD will provide guidance on modifiable lifestyle risk factors and the identification of treatable medical conditions including cerebrovascular health, sleep, sensory loss, social isolation, mood, diet, and physical activity.

Participants in HALT-AD will be provided with personalized risk profiles, will be encouraged to learn about their risk factors and how they can effectively modify them, and will be provided with feedback on their progress. They will participate in facilitated support discussion groups,

which will focus on the content of the educational material and the invocation of change through participant engagement and compliance.

Prior to launching the full HALT-AD program, it is essential that we conduct a preliminary pilot study to evaluate the program's first prototype. At the end of the 3-month pilot program, evaluations will include: the usability of- and engagement with- the online platform and users' acceptability of the learning content and facilitated support discussion groups. As well as, evaluating preliminary evidence on the effectiveness of the program in changing knowledge, self-efficacy, and dementia-related lifestyle risk factors. The program will also be evaluated on metrics such as being user friendly, engaging, supportive and communicative, with the potential for scalability to state- and national-levels.

This initial four-months pilot study will focus on at least three educational courses (introduction to dementia and lifestyle risk factors, sleep and diet). It may also include a fourth educational course on social connectivity and lonliness. Completion of this initial pilot study will allow for a round of improvements informed by data from the program, on usability, as well as feedback from participants and citizen advisors. This will allow for an iterative process to build the program to its full content, with feedback to optimize the user experience and ensure the accessibility of the content. The information generated from this study will help inform the development of the second program's prototype, expected to benefit from the initial pilot to become more user-friendly, effective and accessible to our target audience.

2.0 STUDY DESIGN

This pilot study will be a longitudinal study of an inception cohort exposed to the HALT AD online educational program for a four-month study. It will utilize pre- and post- intervention collection of quantitative and qualitative data to evaluate the program's first prototype.

3.0 STUDY GOAL AND AIMS

3.1 Overall Goal

To conduct a preliminary pilot study to evaluate the first prototype of HALT-AD.

3.2 Aims

1. To evaluate engagement with- the online platform

2. To evaluate preliminary evidence on the effectiveness of the program in changing knowledge, self-efficacy, and dementia-related lifestyle risk factors

3. To determine users' acceptability of the program content

4. To determine users' acceptability and satisfaction with the facilitated support discussion groups

5. To evaluate the usability of the online platform

4.0 OUTCOME MEASURES

4.1 Primary Outcomes

4.1.1 Users' engagement with- the HALT-AD online platform as measured by:

- the total amount of time (in minutes) spent per user on all courses combined
- the percentage of participants who completed all courses

4.2 Secondary Outcomes

4.2.1 Preliminary evidence on the effectiveness of the program in changing knowledge, self-efficacy, and dementia-related lifestyle risk factors will be evaluated by:

- Change from baseline in knowledge on the HALT-AD knowledge assessment survey at 4 months
- Change from baseline in self-efficacy on the New General Self-Efficacy Scale (NGSE) at 4 months
- Change from baseline in lifestyle risk on the HALT-AD Lifestyle Risk Assessment Survey at 4 months

4.3 Exploratory Outcomes

4.3.1 Users' acceptability of the HALT-AD program content will be determined by:

- HALT-AD Course Acceptability Survey
- Focus group discussion

4.3.2 Users' acceptability and satisfaction with the facilitated support discussion groups will be determined by:

- Facilitated Discussion Group Acceptability Survey
- Focus group discussion

4.3.3 The usability of the online platform will be evaluated by:

- HALT-AD User Experience Survey
- Net Promotor Score Survey

5.0 ETHICS AND REGULATORY CONSIDERATIONS

5.1 Electronic Informed Consent

For the purposes of this study, the consent process will be completed remotely. A telephone call with the participant and a study coordinator will be scheduled in order to facilitate the informed consent discussion and to address any questions from the participant.

The electronic Informed Consent Form (ICF) will be maintained in REDCap. Participants will review the consent information and electronically sign the ICF directly within REDCap. The REDCap e-Consent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a 'hard-copy' PDF of the signed form. Participants will be able to download and keep a copy of the ICF for their records. The completed PDFs will be securely stored in REDCap's File Repository and will only be accessible to the program manager, study coordinators and Co-Principle Investigators (co-PIs). These files will be kept separate from other study data maintained in REDCap, which will be de-identified and coded by Participant ID only (see Figure 2 (page 23) for a description of how study will be entered and stored in REDCap)

It will be made clear to each potential participant that informed consent may be withdrawn at any time without needing to give a reason and that such withdrawal will not compromise the relationship between the participant and the Investigator nor the participant's future treatment.

The ICF will be provided in a language fully comprehensible to the prospective participants and ample opportunity must be given to inquire about the details of the study.

5.2 Potential Risks and Benefits Associated with this Study

5.2.1 Potential Risks

Risks associated with study participation are minimal and may include fatigue and/or frustration associated with cognitive screening at baseline and participating in an online educational program. Questionnaires on mood and lifestyle risk may increase negative affect. In order to mitigate these risks, participants will be reminded they can skip questions or take breaks. If a participant mentions negative emotions, the study coordinator will alert Dr.Sarah Banks, co-PI and clinical psychologist, who will attempt to contact the participant within 48 hours to suggest mental health resources.

There may be limits in protecting confidentiality during facilitated group discussions and focus groups. Participants will be reminded to keep group discussions confidential but this cannot be guaranteed.

5.2.2 Potential Benefits

Participants in this study may experience benefits from participating in a web-based educational program including increased knowledge and engagement regarding ways to promote their brain health, and possible positive reduction in their risk profiles, though such improvement cannot be predicted with any certainty. This study is expected to benefit the general community in the future by promoting public interest, literacy, and engagement in lifestyle interventions for brain health and dementia prevention through dissemination of HALT-AD to the broader public.

6.0 PARTICIPANT SELECTION

A total of 20 participants will be enrolled at UCSD with 50% (n=10) completing the English version of HALT-AD and 50% (n=10) completing the Spanish version. We are aiming to recruit

50% women and to enroll a diverse participant sample across varied age ranges within both language groups.

6.1 Inclusion Criteria

Participants must meet all of the following inclusion criteria to be eligible for enrollment:

1. Signed informed consent must be obtained and documented (from the participant).
2. Sufficient proficiency in English or Spanish to undergo clinical assessment and participate in an online educational program.
3. Ages 50-85
4. Montreal Cognitive Assessment-Telephone/Blind Version (T-MoCA) score $\geq$18/22
5. Technical ability to participate in an online educational program (i.e. ability to operate a computer/tablet and gain internet access; ability to send and receive emails)
6. Sufficient vision and hearing to participate in online educational program (judgement of site investigator)
7. Ability to sit comfortably for a period of at least 30 minutes

6.2 Exclusion Criteria

1. Participants who, in the opinion of the co-PIs, are not able to complete trial procedures or adhere to the schedule of study assessments will be excluded from study participation.
2. Individuals where English or Spanish is not sufficiently proficient for clinical assessment, and participation in a web-based educational program.
3. Participants who do not have sufficient vision and hearing to participate in an online educational program
4. Individuals who do not have the technical ability to participate in an online educational program. Technical ability is defined as ability to operate a computer/tablet and gain internet access; ability to send and receive emails)
5. Total Score on the T-MoCA <18
6. Individuals who have an advanced degree (e.g. Master's, MD, PhD) in an area related to brain health will not be eligible to participate.

7.0 STUDY PROCEDURES

7.1 Study Visits

The schedule of study visits and procedures to be performed at each visit are outlined below and summarized in the Schedule of Events table (Appendix 1). A detailed description of study procedures is located in Section 8.0. and a detailed description of study instruments is located in Section 9.0

7.1.1 Remote Study Visits

Pre-screening and screening visits will be conducted remotely over telephone. Participants will need access to a computer or mobile device in order to participate in HALT-AD and complete baseline and follow-up surveys on REDCap.

7.1.2 Pre-Screening Telephone Questionnaire (within a month prior to baseline)

Interested participants will be invited to complete a brief pre-screening questionnaire over telephone with a study team member to ascertain potential elegibility for the study. Participants will be asked to provide verbal assent prior to completing the questionnaire. Questions will include age, education, language fluency and access to technology needed to participate in the study. Total time to complete the pre-screening questionnaire is approximately 5-10 minutes.

7.1.3 Telephone Screening (within a month prior to baseline)

Following the pre-screening procedures described above, potentially eligible participants will be invited to complete the electronic informed consent process (see section 5.1). Once participants have electronically signed the ICF, the following procedures will be conducted remotely via telephone during the screening period (Estimated Time to Complete: up to 1 hour). Screening procedures may be completed over multiple days as long as all procedures are completed within 30 days prior to baseline. Procedures and instruments will be adapted for remote administration (see section 8.0 Study Procedure Descriptions and section 9.0 Study-Specific Instruments).

The following procedures will be conducted during the screening period (Estimated Time: 1.0-1.5 hours):

- Review of inclusion/exclusion criteria
- T-MoCA
- Hearing and Vision assessment
- Evaluation and confirmation of eligibility

Following completion of the screening assessments above, the co-PIs will be responsible for confirming participant eligibility to be enrolled in the study.

7.1.4 Baseline/ HALT-AD Program Launch (+/- 30 days)

Participants who are confirmed to be eligible to participate and enrolled in the study, will then complete the following baseline assessments. These may be completed on the same day as the screening visit, as long as they are conducted following the screening assessments and confirmation of eligibility (total estimated time approximately 30 min):

- Documentation of demographics, medical history (including past medical procedures and family history), medications
- Self-Report Height, Weight
- Body Mass Index (BMI) calculation (based on self-report current height and weight)
- Knowledge Assessment Survey

Following completion of the above baseline assessments, participants will be enrolled in the HALT-AD online program and will be provided with instructions for logging into and beginning their participation in the program (see section 7.2 for a complete description of HALT-AD).

Participants will also complete the following baseline assessments directly within the online HALT-AD program (total estimated time approximately 30 min-1.0 hour):

- New General Self-Efficacy Scale (NGSE)
- Lifestyle Risk Assessment
- Goal setting

Throughout the participants' participation in the 3-Month HALT-AD program, a study coordinator will maintain contact with the participant by telephone or email to check-in with participants, provide reminders about upcoming HALT-AD program elements and be available to answer any questions that may arise. E-mails will be sent from a secure UCSD health e-mail account.

7.1.5 Month 4/ End of HALT-AD Program

Following completion of the 3-Month HALT-AD program, participants will complete the following assessments remotely via the REDcap survey tool (total estimated time approximately 1.0 hour):

- HALT-AD User Experience Survey
- Net Promoter Score Survey
- HALT-AD Course Acceptability Survey
- Facilitated Discussion Group Acceptability Survey
- Knowledge Assessment Survey

Participants will also complete the following end of study assessments directly within the online HALT-AD program (total estimated time approximately 30 min-1.0 hour):

- New General Self-Efficacy Scale (NGSE)
- Lifestyle Risk Assessment
- Review of Goals

7.1.6 Post-Pilot Focus Groups

Following completion of the 3-month HALT-AD program, participants may be invited to participate in an end of study remote focus group(s) to further evaluate user-experience and satisfaction with HALT-AD. This will allow the study team to address in more detail the components that have been surveyed in the questionnaires on usability and acceptability: (e.g. level of difficulty and interest in the content, strengths and weaknesses, confidence in the content, applicability and impact in everyday life, clarifications, quality of design, animation and visual effects, effort needed, motivation for behavioral change). Participant feedback and responses will be used to make any necessary changes to the web-based HALT-AD program prior to launch of the full program. Total time to participate in the focus group is approximately 2 hours (1 hour to discuss web-based platform and 1 hour to discuss facilitated discussion groups).

Focus groups will be conducted remotely over video-call in smaller groups of approximately 5-10 other participants. Participants will need access to a computer, tablet or mobile device capable of making video-calls. The focus group discussions will be audio-recorded for transcription. All identifiable information will be removed from the transcripts and replaced by unique coded Participant ID number. Recordings will be destroyed once the focus group discussion has been transcribed.

7.2 HALT-AD PROGRAM DESCRIPTION

7.2.1 Overview

HALT-AD is a novel bilingual program that will focus on preventing dementia. The program will include an easily accessed interactive, online web-based program that will direct participants to engage in different evidence-based content, to learn and become motivated to change their personalized profile of modifiable risk factors. It will include up to date information and evidence for lifestyle risk factor modification that can be addressed to promote brain health and reduce dementia risk. HALT-AD will include learning courses that will be aligned with those modifiable risk factors with significant population attributable risk of dementia.

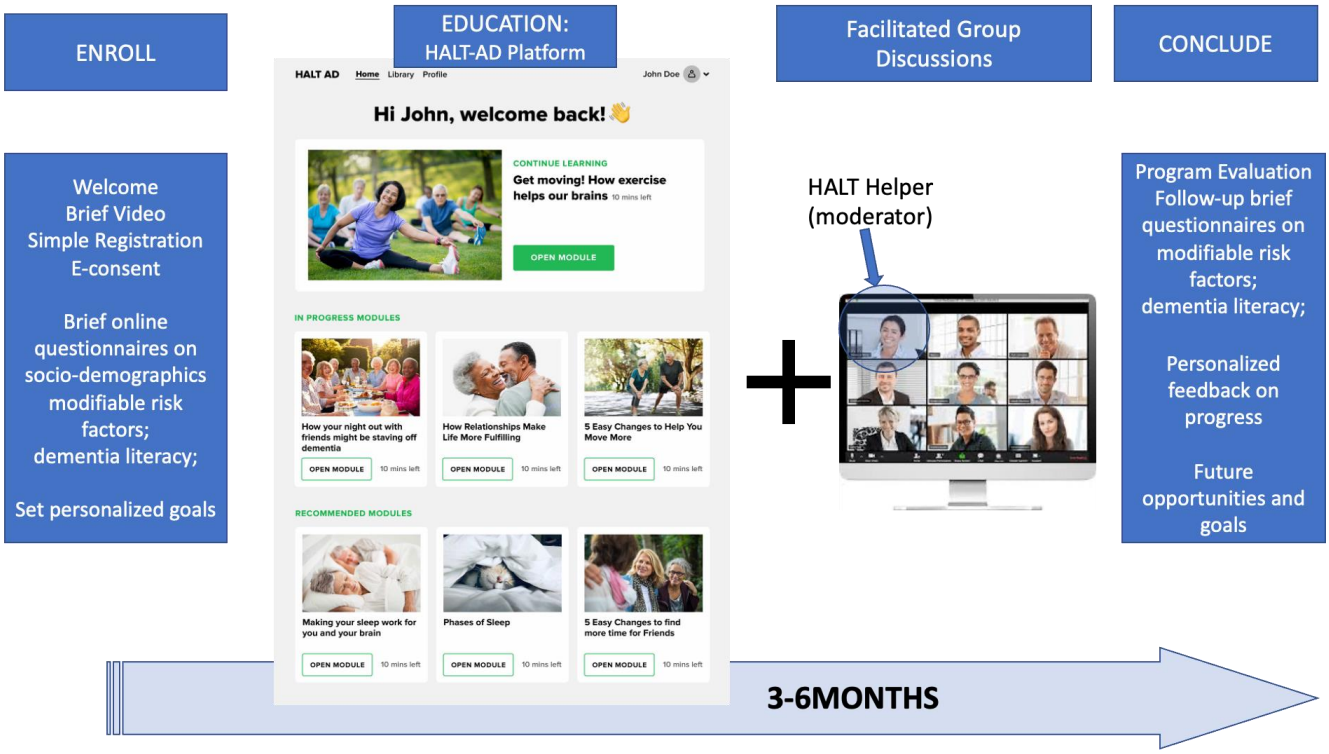
HALT-AD is a bilingual bicultural program with options to participate in English or Spanish. The program is developed as a collaborative effort by UCSD investigators with recognized expertise in the program's content areas, along with significant input from older-adult Citizen Advisors and Promotores (community health workers), ensuring cultural relevance and assisting in feedback within its iterative development.

For this initial pilot study, HALT-AD will focus on up to four initial learning courses:

- Introductory Course
- Diet
- Sleep or Physical Activity
- Social Connectivity and Loneliness

Once the full program is developed, additional learning courses will include, vascular factors (hypertension, diabetes, obesity and cerebrovascular health), physical activity (exercise), mood (depression and stress), mindfulness, sensory (vision and hearing) and cognitive training. Topic matters will also include advice on how to navigate the healthcare system as well as courses myths and popular misconceptions regarding brain health, and how risk profiles may differ in men and women.

Figure 1. HALT-AD Program Description



7.2.2 Program Registration

Participants will receive instructions on how to register and participate in the program at the baseline study visit. As outlined in Figure 1 at enrollment, participants will join a welcome page that will explain the program, followed by registration and creation of a personal password. Their registration will include demographic and lifestyle questions.

7.2.3 Program Elements

Participants will be provided access to HALT-AD where they will participate for approximately 1-2 hours a month for 3 months, from home, with their own devices and at their own time. Information within the courses will contain scientific evidence, explanation of principles and mechanisms that underlie positive effects, specific recommendations (e.g. a healthy recipe to make at home), suggestions to improve behavior in everyday life and typical barriers and tips to circumvent them. Participants will also be able to revisit course material as often as they would like. Additional program elements will also include interactive activities, quizzes and a resource library.

7.2.3.1 Personalized Profiles

Participants will be asked to complete a brief online lifestyle risk assessment at the beginning and end of their participation in the program. Questions will be related to the content in the program courses (e.g. sleep, diet, and mindfulness/compassion). A personalized profile will be developed for each participant based on their responses to the lifestyle risk assessment. A visual

aide (e.g. sliding scale) will be used on the program dashboard to show the participant their risk level in each lifestyle domain.

7.2.3.2 Goal Setting

Participants will also be asked to set goals based on their risk profile and to re-visit and update their goals at the end of the 3 month program.

7.3 Facilitated discussion group

Participants will also participate in moderated remote discussion groups that will focus on learning and promotion of behavioral change. Discussion groups will occur approximately every 3 weeks and will be moderated by a social worker (ASW or LCSW) called HALT Helper Sessions will be filled on a rolling basis, with a variety of meeting times available to accommodate other commitments such as caregiving. Before each discussion group, the HALT Helper will review what the group is (and is not) and it will be made clear to participants that this is not group therapy but rather a facilitated discussion to focus on content that is being addressed in HALT-AD and to promote healthy lifestyle changes. Participants will also be reminded of the importance to maintain confidentiality during the group sessions and the limits to privacy/confidentiality due to the group setting at the beginning of each session.

7.4 HALT-AD Activity Data

The following data will be automatically collected through the HALT-AD program in order to evaluate user activity and engagement with the program:

Program Level Reporting	
Course Started %	How many users started the course
Course Complete %	How many users completed the course
Course Passed %	How many users passed the course
Minutes per learner	Average time spent per learner on a module
Average Score	Average Score per learner in a course
Participant Level Reporting	
Course Started %	How many courses were started by the learner
Course Complete %	How many courses were completed by the learner
Course Passed %	How many courses were passed by the learner
Minutes per Course	Average time spent per course

No identifiable information will be included in the study data set. All study data from HALT-AD will be de-identified and linked to the unique Participant ID prior to being included in the study database.

7.5 Compensation

Participants will be compensated $100 in the form of a gift card for their time and effort. Compensation will be provided at the end of the study or upon early withdrawal. Early withdrawal after completion of Baseline will not impact the amount of compensation provided.

8.0 STUDY PROCEDURE DESCRIPTIONS

8.1 Sociodemographics

Sociodemographic data (sex, age, handedness, languages, marital/partner status, living circumstances, education, employment history) will be captured.

8.2 Medical/Surgical/Family History

Relevant medical and surgical history will be captured as well as relevant medical history of first-degree relatives. A list of current medications will also be documented.

8.3 Height/Weight/BMI

Participants will be asked to self-report current height and weight during the baseline visit. Responses will be used to calculate BMI using the NIH BMI Metric Calculator (https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi-m.htm).

8.4 Hearing and Vision Assessment

Vision and hearing ability will be assessed by questions on perceived visual and auditory ability and an inventory of aids used. Participants must have relatively sufficient vision (with corrective lenses or other aids) so that they can identify symbols, stimuli and text presented on a computer screen in front of them. Participants must also have sufficient hearing (corrected with hearing aids or other voice amplification devices) to be able to follow spoken instructions and information that is presented only verbally.

9.0 STUDY-SPECIFIC INSTRUMENTS

9.1 Cognitive Measures

9.1.1 Montreal Cognitive Assessment-Telephone/Blind Version (T-MoCA)

The T-MoCA is a 5-10-minute test that has been validated for remote administration by telephone and provides a global assessment of cognition, covering domains of memory, language, attention and executive functioning [13]. The T-MoCA has been modified from the original MoCA to remove items requiring paper and pencil administration and visual stimuli. The total possible score is 22 with a cutoff score of greater or equal to 18 to indicate normal cognitive functioning.

9.2 Questionnaires

9.2.1 Knowledge Assessment Survey

Brief questionnaire that will be developed as the HALT-AD program content is finalized to assess general knowledge of dementia including risk factors, brain health and prevention. Participants' knowledge will be assessed pre and post participation in HALT-AD.

9.2.2 The New General Self-Efficacy Scale

Self-Efficacy is a concept that refers to one's global confidence in their ability to cope with demanding or novel situations. The New General Self-Efficacy scale is an 8-item 5-point likert scale (strongly disagree (1) to strongly agree (5)) which measure one's perceived competence in dealing with a range of stressful or challenging situations [14]. The scale will be completed online within HALT-AD.

9.2.3 Lifestyle Risk Assessment

Questionnaire to be developed by course leads to assess dementia risk based on HALT-AD Pilot Courses (e.g. Sleep, Diet, Physical Activity, Mindfulness/Compassion). Risk scores for each domain will be calculated.

9.2.4 HALT-AD User Experience Survey

Questionnaire adapated for HALT-AD based on questions from the User Experience Questionnaire (UEQ) available at https://ueqtryitout.ueq-research.org/. Participants will be asked to decide as spontaneously as possible which conflicting terms (e.g. annoying vs. enjoyable) better describes the HALT-AD program.

9.2.5 Net Promoter Score (NPS) Survey

The Net Promoter Score (NPS) Survey is a metric used in customer experience programs to measure the loyalty of customers to a product (What is Net Promoter Score? (Updated 2020) | Qualtrics AU). NPS scores are measured with a single question survey "How likely is it that you would recommend [Organisation X/Product Y/Service Z] to a friend or colleague?" and reported with a number from -100 to +100, a higher score is desirable.

9.2.6 HALT-AD Course Acceptability Survey

Questionnaire developed by the HALT-AD team to evaluate overall acceptability and satisfaction with the course content for the HALT-AD program. There are a total of 15 items including both multiple choice and open-ended questions (see Appendix 2).

9.2.7 HALT-AD Facilitated discussion group Acceptability Survey

Questionnaire to be developed in collaboration with the group facilitator. Questions will assess overall satisfaction and utility of the the monthly facilitated discussion groups.

10.0 EARLY DISCONTINUATION PROCEDURES

Participants are free to withdraw from study participation at any time, for any reason, and without prejudice.

Study Discontinuation for an individual participant may occur in the following circumstances:

1. Withdrawal of informed consent by the participant.

2. Adverse event or other significant medical condition which, in the opinion of the Investigator, render it necessary to remove the individual from study participation.

3. Any other occurrence that, in the Investigator's opinion, makes continued participation contrary to the participant's best interests.

If co-PIs discover sufficient reasonable cause for the premature termination of the study, the terminating party will provide written notification to the participant documenting the reason for study termination.

11.0 ADVERSE EVENTS

An adverse event (AE) is any untoward medical occurrence in a participant that occurs from the time of the baseline visit and up to 30 days after study participation has ended. For the purposes of reporting on the this study, an AE is defined as any unfavourable or unintended sign, symptom, or disease **associated with study participation** that is both non-serious and either temporally or causally related to study procedures. Pre-existing conditions, which increase in frequency or severity or worsen in nature during, or as a consequence of, a study procedure, may also be considered an AE if it meets the definition of being both non-serious and related to a study procedure. Adverse events that occur prior to the baseline visit will be documented as medical history.

An AE **does not** include:

- Medical or surgical procedures (e.g., surgery, endoscopy, tooth extraction, transfusion). The condition that leads to the procedure is the AE.
- Situations where an untoward medical occurrence has not occurred (e.g., hospitalization for elective surgery, social and/or convenience admissions).
- Worsening of symptoms associated with an associated co-morbid condition and not related to a study procedure.

11.1 Evaluation and Reporting of Adverse Events

All AEs (i.e., a new event or an exacerbation of a pre-existing condition) that occur from the baseline visit to the end of the pilot study and are related to the study procedures will be recorded as an AE in the study database. Adverse events that occur prior to the baseline visit will be documented as medical history. The Investigator will follow all AEs until the AE

resolves, or until the Investigator determines the event is chronic or clinically stable. If an AE remains unresolved at the conclusion of the study, the Investigator will make a clinical assessment to determine whether continued follow-up of the AE is warranted.

11.2 Assessment of Adverse Events

All AEs will be promptly documented on the Adverse Event CRF and assessed by the Investigator. Details of the event will include the dates of onset and resolution, severity, relationship to study procedures, seriousness, whether the event caused the participant to withdraw from the study, and outcome.

Severity: Severity will be graded and recorded according to the table below.

Severity	Definition
Mild	Awareness of event but easily tolerated
Moderate	Discomfort enough to cause interference with usual activity
Severe	Inability to carry out usual activity, incapacitating, requires medical intervention

Relationship: The relationship of the AE to study procedures will be determined by the Investigator, and assessed using the following definitions:

Relatedness	Description
Not Related	There is no evidence of a causal relationship and a causal relationship cannot be reasonably attributed to the study procedures. The event is clearly due to extraneous causes.
Unlikely Related	A poor temporal relationship exists between the event onset and study procedures. The event could easily be explained by the participant's clinical state, intercurrent illness, or concomitant therapies.
Possibly Related	A relationship cannot be ruled out with certainty and the event may be related. There is some evidence to suggest a causal relationship but the influence of other factors may have contributed to the event, such as the participant's clinical condition or concomitant treatment.
Probably Related	The event is likely related to study participation. There is evidence to suggest a causal relationship, such as reasonable temporal sequence from procedure. The influence of other factors is unlikely.
Definitely Related	The event is clearly related to study participation. There is clear evidence to suggest a causal relationship. The influence of other factors can be ruled out.

These criteria, in addition to good clinical judgment, should be used as a guide for determining the causal assessment.

12.0 STATISTICAL CONSIDERATIONS

12.1 Analysis Plan

Descriptive statistics will be provided for each timepoint on HALT-AD measures and change scores will be computed where applicable. Change = (4 months score - baseline score). Continuous data will be presented with mean, standard deviations, median, minimum and maximum and 95% confidence intervals. Categorical data will be presented as proportions and percentages. We will examine the proportion of participants reaching a defined threshold on usability measures. Changes in continuous outcome measures between baseline and post-intervention will be analyzed by repeated measures t-test.

Furthermore, the continuous measures collected directly from the program will be analyzed to evaluate program use during the 3-month period. User engagement as measured by the average total amount of time (in minutes) spent on all courses combined and the percentage of participants who completed all courses, overall and by age, gender and educational level will be tracked.

The post-pilot interviews/focus groups will collect more detailed feedback on the experience with the program and these will be guided by the results obtained on the usability and functionality questionnaires. Qualitative analyses (content analysis) will be used for responses to open-ended questions (e.g. suggestions for improvements of the web platform) obtained during focus groups. Answers to open-ended questions will be first transcribed verbatim in Word, then the text will be imported into MAXQDA. Thematic analysis will be conducted in MAXQDA to identify common themes arising from the focus group discussions. Themes will be defined and described in a Table format. Saturation will be reached and analysis will be considered complete when no new themes are identified.

12.2 Sample Size and Power

Given that this pilot study is being conducted to contribute to the development of the HALT-AD program, we did not power to detect an intervention effect size over time. The sample size for the pilot was estimated based on prior experience in the development of similar programs.

13.0 RECORDING AND COLLECTION OF DATA

13.1 Case Report Form

The co-PIs and study team will be trained on elecontric case report form (eCRF) completion. The investigator is responsible for all entries in the eCRF for completeness, accuracy and clarity. The investigator or designee should complete the eCRF as soon as possible after the information is

collected. The investigator is responsible to endorse all the information recorded in the eCRF and will provide formal approval of the final submitted data.

All electronic data captured on the eCRF will be de-identified and coded by unique Participant ID. Electronic files will either be stored within REDCap or in study files on the password protected UCSD Health File server (see Figure 2 and Figure 3 below for descriptions of the data flow in REDCap and UCSD Health File Server) . All study files will only be accessible to study co-PIs and team members.

The program manager for this study will be responsible for storing all participant identifying information (name, contact, e-mail address) and to maintain the master file that links the participant to their unique Participant ID on a secure password-protected UCSD Health File server. This master file will be kept separate from all other de-identified study data generated in this study.

Figure 2. REDCap Data Flow

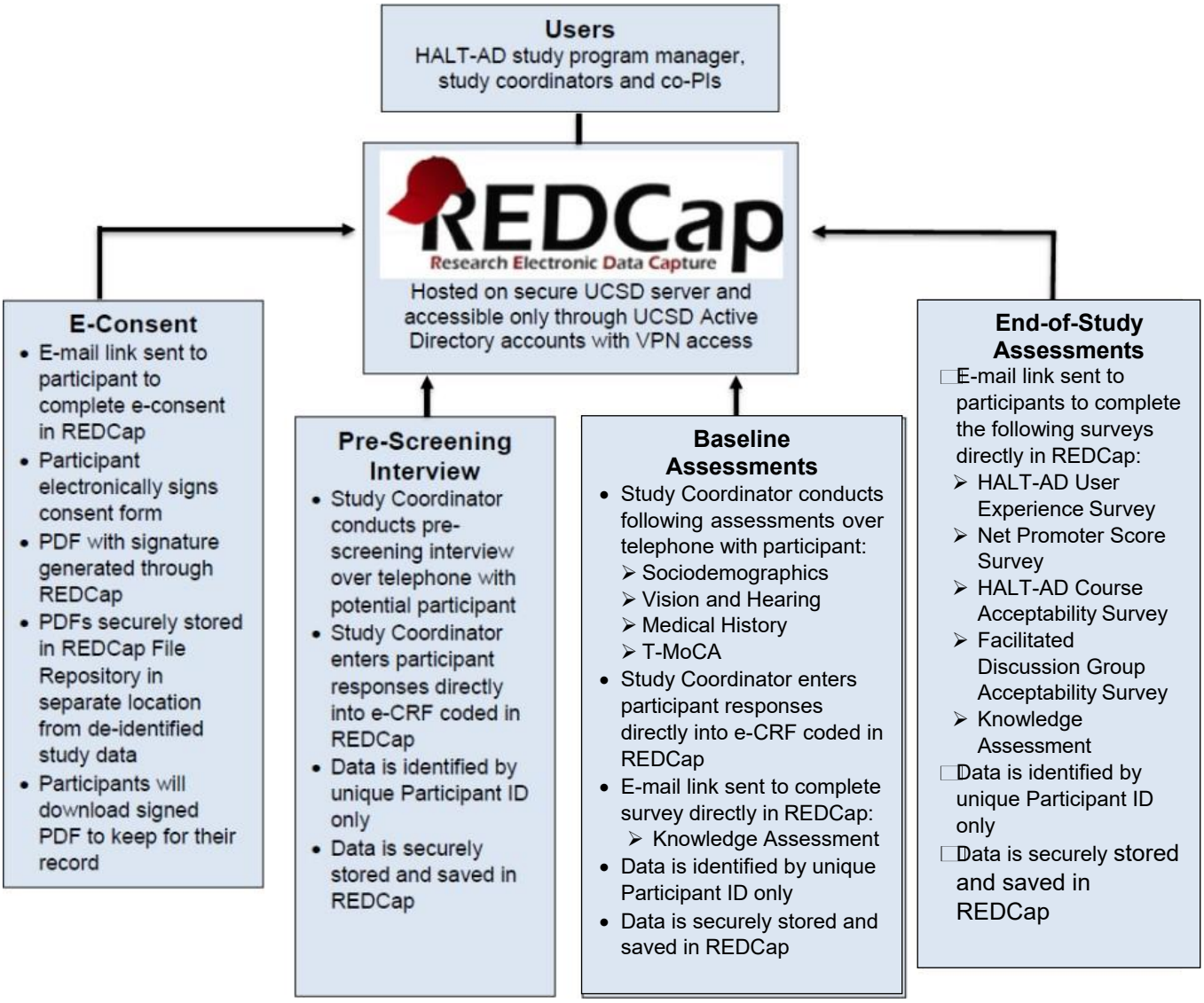
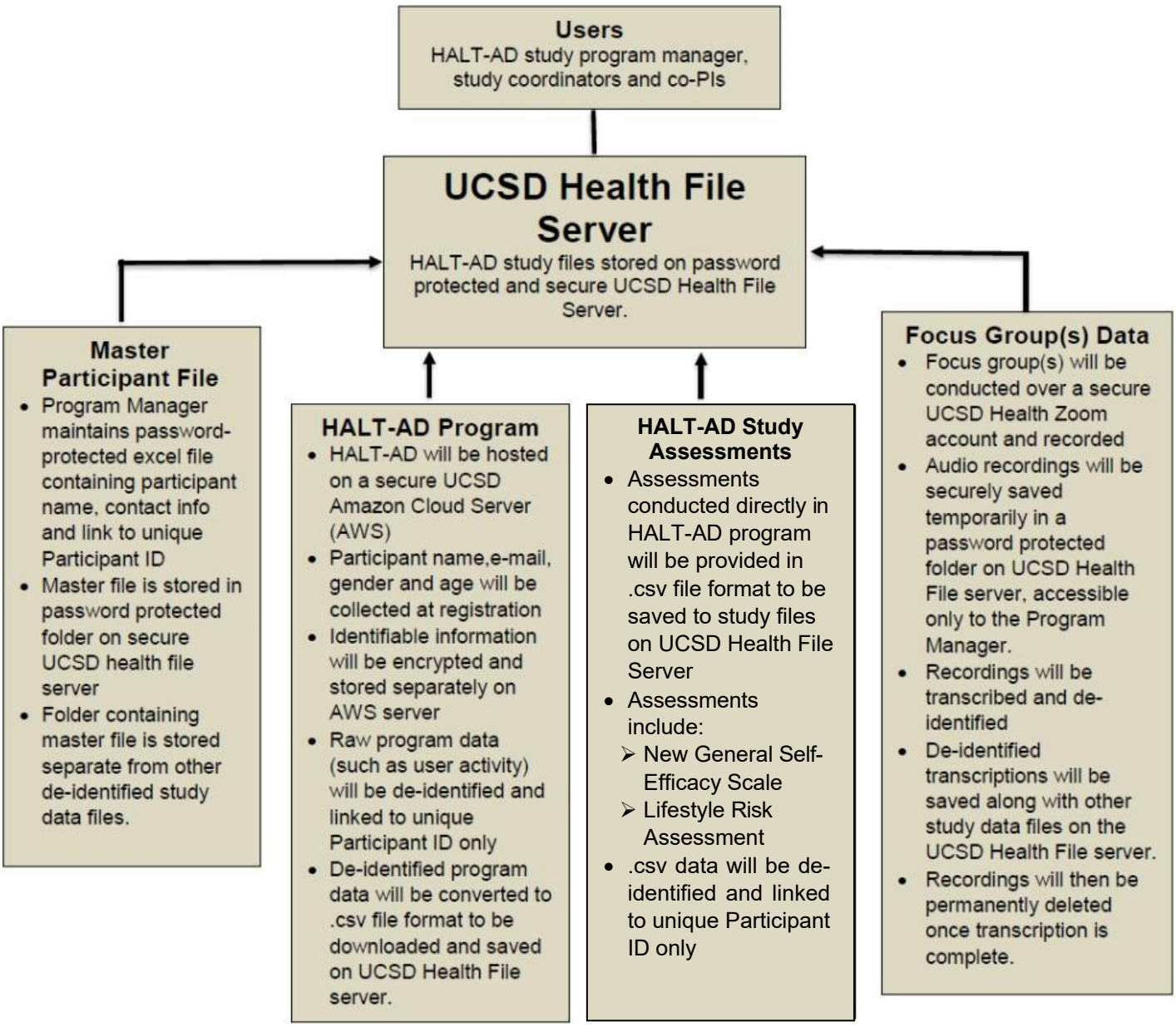


Figure 3. UCSD Health File Server Data Flow



13.1.1 HALT-AD Website Server

The HALT-AD website will be hosted on the UCSD Amazon Cloud server. Participants will be asked to provide their e-mail address and name to register for HALT-AD. This information will be encrypted and kept on the server in a separate location from the program data. Raw program data will linked to unique Participant ID and provided in excel format to be stored with other study data on asecure password-protected UCSD Health File Server (see Figure 2 for a description of the data flow for the HALT-AD program)

13.1.3 REDCap Surveys

Data and questionnaires that are not collected directly within the online HALT-AD website, will be securely collected and stored in REDCap. All study data from REDCap will be de-identified and coded by unique Participant ID only (see Figure 1 for a description of the study data that will be stored within REDCap).

13.1.4 Focus Groups Recordings and Transcription

Audio-Recordings from the focus group(s) will be transcribed. All identifiable information will be removed from the transcriptions and names will be replaced by unique Participant IDs. Audio-recordings will be permanently deleted once transcription is complete. The de-identified transcriptions will be stored with other study data on a secure password-protected UCSD Health file server (see Figure 2 UCSD Health File Server Data Flow).

13.2 Study Files and Participant Source Documents

Participant confidentiality is strictly held in trust by the study investigators and research staff. Authorized representatives may inspect all documents and records required to be maintained by the Investigator. The study site will permit access to such records. Any data, forms, reports, and other records that leave the site will be identified only by a participant identification number to maintain confidentiality.

The co-PIs must maintain adequate and accurate records to enable the conduct of the study to be fully documented and the study data to be subsequently verified. These documents include Investigators' Study Files, original participant source documents generated at the study site, or completed source document worksheets. The term "original" means the first recording of the data.

The co-PIs will ensure theinvestigator files are maintained, including essential documents such as the study protocol and its amendments, informed consents, staff curriculum vitae, correspondence, and other appropriate documents.

13.3 Rater Training

Study staff will be trained on the assessments and study specific cognitive, functional and behavioral measures that are described in Sections 8.0 and 9.0. study database.

13.4 Incidental Findings

In the event that an incidental finding is identified as being medically significant, the program manager will link the participant code to the participant identity and the finding will be passed on to the co-PIs within 24 hours. The co-PIs will be responsible for determining the significance of the finding, arranging appropriate follow-up and informing the primary care physician (if provided).

14.0 PUBLICATIONS POLICY AND SHARING OF DATA

The results of this study will be disclosed or published only in combined form based upon the statistical analysis performed by the study Investigators. No identifiable personal information will be included in any publication or presentation. Authorship of publications resulting from this

study should accurately reflect the academic contribution of individuals to the design and implementation of the trial, analysis of the data and preparation of the manuscript. All funding partners will be acknowledged. All publications that arise from the use of study data will give acknowledgement, attribution, or co-authorship as appropriate in accordance with the International Committee of Medication Journal Editors (ICMJE) standards.

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16.0 APPENDICES

APPENDIX 1: Schedule of Events

UCSD HALT-AD PILOT STUDY SCHEDULE OF EVENTS						
PROCEDURES	**SCREENING**	**BASELINE**	**MONTH 1**	**MONTH 2**	**MONTH 3**	**MONTH 4**
Remote Study Procedures (on Zoom or REDCap)						
ELECTRONIC INFORMED CONSENT (E-CONSENT)	X					
INCLUSION/EXCLUSION CRITERIA EVALUATED	X					
SOCIODEMOGRAPHICS		X				
MEDICAL/SURGICAL/FAMILY HISTORY		X				
WEIGHT, HEIGHT (participant estimates) and BMI		X				
HEARING AND VISION ASSESSMENT	X					
MONTREAL COGNITIVE ASSESSMENT (MoCA)	X					
HALT-AD USER EXPERIENCE SURVEY						X
NET PROMOTER SCORE SURVEY						X
HALT-AD COURSE ACCEPTABILITY SURVEY						X
KNOWLEDGE ASSESSMENT SURVEY		X				X
FACILITATED DISCUSSION GROUP ACCEPTABILITY SURVEY						X
FOCUS GROUPS						X
HALT-AD Online Assessments						
NEW GENERAL SELF-EFFICACY SCALE (NGSE)		X				X
LIFESTYLE RISK ASSESSMENT (Diet, Sleep, Mindfulness)		X				X
GOAL SETTING AND REVIEW		X				X
FACILITATED DISCUSSION GROUPS[1]			X*	X*	X*	

[1] *Facilitated Discussion Groups will occur approximately every three weeks in between Months 1-3. They will occur prior to the start of each new content module.

16.1 APPENDIX 2: Survey Instruments

16.1.1 Knowledge Assessment Survey

Below are some statements about brain health and dementia prevention. Please read each statement carefully and choose whether you think the statement is True or False.

1. If I am healthy, my brain should not age at all over time.
2. As I age, I will most certainly have dementia.
3. People from Hispanic or African American backgrounds have a higher risk of developing Alzheimer's Disease.
4. Being physically inactive and being obese are two examples of factors that can increase our chances of developing Alzheimer's Disease.
5. Hanna may avoid dementia by making healthier lifestyle changes such as getting better sleep, eating a healthier diet, and being more physically active.
6. There are many reasons why older adults may feel lonely. Reasons include losing family members, facing difficulties in moving around, and well as feeling empty and sad.
7. Everyone experiences loneliness the same way. It is not personal, and it does not differ across people.
8. People that are lonely have an increase in abnormal proteins in their brain. The accumulation of abnormal proteins in the brain occurs during the development of Alzheimer's Disease.
9. If you are feeling lonely, there is nothing you can do to overcome your loneliness.
10. Sometimes, when we are very lonely, making personal initiatives such as joining a volunteering social group does not always work. That's totally OK.
11. An average adult should be getting 7-9 hours of sleep a day. Getting 4-6 hours of sleep a night on a weekly basis does not significantly affect brain function, since it is only a few hours less than the recommended amount.
12. When we haven't sleep for 24 hours, our cognitive abilities decrease to a point that is like when someone is legally drunk.
13. Lack of sleep can affect our health in a variety of ways, including increasing our risk of developing a stroke, weakening our immune defenses, and contributing weight gain.
14. Developing new habits and routines like going outdoors, practicing mindfulness, cultivating social relationships, creating a daily routine, reducing caffeine intake at night, and seeking help when needed are all lifestyle changes that can improve sleep.
15. Because sleep issues are so personal, there are no treatments.

16. A combination of exercises, including aerobic, non-aerobic, endurance, and more, are all extremely helpful in keeping our mind resilient and can potentially protect our brains from changes that happen with aging.

17. Physical activity and exercise are only helpful for those younger than 65.

18. Pain, dizziness, shortness of breath, tightness in the chest while exercising are healthy symptoms that are a result of being physically active.

19. Measuring our heart rate and comparing it to our target heart rate is the only way we can check to see if we are exercising at a moderate-intensity level.

20. Setting SMART goals and using a common habit as a habit trigger for physical exercise are two easy ways to help us maintain a physically active lifestyle in the long-term.

16.1.2 New General Self-Efficacy Scale

1. I will be able to achieve most of the goals that I have set for myself.

2. When facing difficult tasks, I am certain that I will accomplish them.

3. In general, I think that I can obtain outcomes that are important to me.

4. I believe I can succeed at most any endeavor to which I set my mind.

5. I will be able to successfully overcome many challenges.

6. I am confident that I can perform effectively on many different tasks.

7. Compared to other people, I can do most tasks very well.

8. Even when things are tough, I can perform quite well.

16.1.1 HALT-AD User Experience Survey

Decide as spontaneously as possible which of the following conflicting terms better describes the HALT-AD web platform (website). There is no "right" or "wrong" answer. Only your personal opinion counts!

annoying	O O O O O O O	enjoyable
not understandable	O O O O O O O	understandable
creative	O O O O O O O	dull
easy to learn	O O O O O O O	difficult to learn
valuable	O O O O O O O	inferior
boring	O O O O O O O	exciting
not interesting	O O O O O O O	interesting

unpredicatble	O O O O O O O	predicatble
fast	O O O O O O O	slow
inventive	O O O O O O O	conventional
obstructive	O O O O O O O	supportive
good	O O O O O O O	bad
complicated	O O O O O O O	easy
unlikable	O O O O O O O	pleasing
usual	O O O O O O O	leading edge
unpleasant	O O O O O O O	pleasant
secure	O O O O O O O	not secure
motivating	O O O O O O O	demotivating
meets expectations	O O O O O O O	does not meet expectations
inefficient	O O O O O O O	efficient
clear	O O O O O O O	confusing
impractical	O O O O O O O	practical
organized	O O O O O O O	cluttered
attractive	O O O O O O O	unattractive
friendly	O O O O O O O	unfriendly
conservative	O O O O O O O	innovative

16.1.1 Net Promoter Score (NPS) Survey

"How likely is it that you would recommend HALT-AD to a friend or colleague?"

16.1.2 HALT-AD Course Acceptability Survey

1) Overall, was it **easy** to understand the information presented in the courses?
   Not at all easy
   Slightly easy
   Moderately easy
   Very easy *(skip to question 3)*
   Extremely easy *(skip to question 3)*

2) What changes can we make for information to become more understandable?
   _____

3) Rate the overall **amount of information** presented in the courses:
   Too little
   About right
   Too much

4) Generally, was the information presented in the courses **boring?**

Not at all boring (skip to question 6)
Slightly boring
Moderately boring
Very boring
Extremely boring

5) What changes can we make for information to become less boring?

_____

6) Generally, was the information presented to you in the courses **helpful**?

Not at all helpful
Slightly helpful
Moderately helpful
Very helpful
Extremely helpful

7) Generally, did you find the **activities** in the courses to be **interesting**?

Not at all interesting
Slightly interesting
Moderately interesting
Very interesting *(skip to question 9)*
Extremely interesting *(skip to question 9)*

8) How can we change the activities to make them more interesting?

_____

9) Generally, did you find the **activities** in the courses to be **helpful**?

Not at all helpful *(skip to question 11)*
Slightly helpful *(skip to question 11)*
Moderately helpful *(skip to question 11)*
Very helpful
Extremely helpful

10) In what ways were the activities helpful? *(skip to question 12)*

_____

11) How can we change the activities to make them more helpful?

_____

12) Generally, were the **quiz questions clear**?

Not at all clear
Slightly clear
Moderately clear
Very clear
Extremely clear

13) Overall, was the information in the courses **new** to you?

Not at all new
Slightly new
Moderately new
Very new
Extremely new

14) Overall, did you find the information in the courses to be **uplifting**?

not at all uplifting
Slightly uplifting
Moderately uplifting
Very uplifting
extremely uplifting

15) How likely are you to recommend these courses to a family member, friend or colleague?
extremely unlikely
Unlikely
Likely
Extremely likely

16.1.3 HALT-AD Facilitated discussion group Acceptability Survey

Questionnaire to be developed in collaboration with the group facilitator. Questions will assess overall satisfaction and utility of the the monthly facilitated discussion groups.

16.1.4 HALT-AD Lifestyle Risk Assessment

Questionnaire developed by course leads to assess dementia risk based on HALT-AD Pilot Courses (e.g. Sleep, Diet, Physical Activity, Mindfulness/Compassion). Risk scores for each domain will be calculated.

16.2 APPENDIX 3: Screening Questions

16.2.1 PRE-SCREENING TELEPHONE INTERVIEW

Thank you for your interest in the Healthy Actions and Lifestyles to Avoid Dementia or Hispanos y el ALTo a la Demencia program (HALT- AD) study. My name is [**name**], and I am [**role/title**] at the [**site name**]. Are you able to understand me well in English, or should I give you the following information in Spanish?

Is this a good time to talk? *(If Yes, proceed with verbal consent language below. If No, confirm with participant when would be a good time to call back)*

The HALT-AD study is designed to determine if a new online educational program and discussion groups, available in English and in Spanish, can help midlife and older adults learn how to prevent dementia through lifestyle changes. Before we offer the HALT-AD program to a large group, we are conducting an initial pilot study to help us assess the usability of the program. Your participation in this pilot study would help us learn how well the program is working and to make changes before the larger study begins.

In order to see if you are eligible to participate in this study, I would like to ask you some questions about your background. This is completely voluntary and you can stop at any time. If you give me your verbal permission, I will write down your responses and enter them into the study data base. This will allow us to see what recruitment methods work well and to potentially make changes in the future. No information that can identify you will be included in the study database. Your contact information will be securely stored at the study site and will be kept separate from your responses to this questionnaire. If you are not eligible for this study, we will delete your contact information unless you give us permission to keep it to re-contact you if eligibility for this study changes or to see if you are interested in participating in a future study *(see section B below for optional permission to re-contact ineligible participants)*.

Now, would you like to see if you are eligible to participate? q Yes q No

Do you give me your permission to continue with the questions and permission to also write the responses down?q Yes q No

[*YES, continue below Section A; NO, continue below Section B*]

Section A:

1. First, can you please tell me how you heard about this study (*select all that apply*)?
   - ☐ Flyer
   - ☐ Social Media
   - ☐ Word of mouth (please specify):
     - ☐ Family member
     - ☐ Friend
     - ☐ Neighbor
     - ☐ Other (please specify): _____
   - ☐ Other (please specify): _____

2. What is your age? _____

3. Have you been diagnosed with dementia or Alzheimer's disease? q Yes q No

4. Do you have access to a computer or tablet that connects to the internet? q Yes q No

5. Do you understand the basic functions of the computer or tablet and can you navigate to different web pages on the internet? q Yes q No

6. Do you have the ability to send and receive emails? q Yes q No

7. Do you have an advanced educational degree in an area related to brain health? q Yes q No

8. What is your primary language? _____

9. Participants are able to complete the online educational program in either English or Spanish. In which language would you prefer to participate? _____

10. a) On a scale from 0 to 10, please select your level of proficiency in speaking [**language participant indicates on Question 7**]:

- None (0)
- Very low (1)
- Low (2)
- Fair (3)
- Slightly less than adequate (4)
- Adequate (5)
- Slightly more than adequate (6)
- Good (7)
- Very good (8)
- Excellent (9)
- Perfect (10)

b) On a scale from 0 to 10, please select your level of proficiency in understanding spoken language in [**language participant indicates on Question 7**]:

- None (0)
- Very low (1)
- Low (2)
- Fair (3)
- Slightly less than adequate (4)
- Adequate (5)
- Slightly more than adequate (6)
- Good (7)
- Very good (8)
- Excellent (9)
- Perfect (10)

*≥ 7 out of 10 is considered proficient

If potential participant does not pass this pre-screen or target recruitment per language, gender, or age group is currently full, proceed to B below.

If potential participant does pass this pre-screen, proceed with providing information on next steps: inviting potential participant to receive electronic informed consent form for their review and scheduling a telephone call to discuss the ICF and answer any questions they may have.

Section B:
If potential participant does not meet eligibility criteria **[say]**

Unfortunately, you are not eligible for this specific study.

Would you be willing to be contacted in the future if eligibility for this pilot study changes or to participate in a future study? q Yes q No

If participant cannot be enrolled because recruitment in target group (language, gender, age range) is full **[say]**

Unfortunately, recruitment in this pilot study based on your eligibility *[specify reason i.e. language group, gender, age range]* is currently full.

Would you be willing to be contacted to participate in a future study? q Yes q No

Thank you so much for your time today. We appreciate you.

16.2.2 HEARING AND VISION

Hearing

1. How would you describe your hearing (with a hearing aid if you use one)?
   - £ Excellent
   - £ Very good
   - £ Good
   - £ Fair
   - £ Poor

2. Do you have sufficient hearing (corrected with hearing aids or other voice amplification devices) to be able to follow spoken instructions and information that is presented only verbally?
   - £ Yes
   - £ No
   - £ Don't know

3. Do you find it difficult to follow a conversation if there is background noise, such as TV, radio or children playing, even if using a hearing aid or assistive device as usual?
   - £ Yes
   - £ No
   - £ Don't know

4. Do you use a hearing aid or specialized equipment, or services for persons who are deaf or hard of hearing, for example, a volume control telephone or TV decoder?
   - £ Yes
   - £ No
   - £ Don't know

5. If **YES**, Which of the following equipment do you use to hear better? (check all that apply)
   - £ Hearing aid
   - £ Computer to communicate (e.g., email or chat services)
   - £ Volume control telephone
   - £ TTY or TTD
   - £ Message relay service
   - £ Other phone-related devices (e.g., flashers)
   - £ Closed caption TV or decoder
   - £ Amplifiers (e.g., FM, acoustic, infrared)
   - £ Visual or vibrating alarm
   - £ Cochlear implant

£ Another aid (please specify): _____

6. If your hearing loss began before middle age, is it likely to have been
   Present from early childhood
   Due to noise exposure at work
   Due to a disease or medical condition?

Vision

1. How would you characterize your eyesight (using glasses or corrective lens if you use them)?
   Excellent
   Very Good
   Good, Fair
   Poor
   Non-existent (non-existent = blind)

2. Do you have relatively sufficient vision (with corrective lenses or other aides) so that you can identify symbols, stimuli and text presented on a computer screen in front of you?
   Yes
   No
   Don't know

3. Do you wear glasses?
   Yes
      Near (Reading)
      Distance
   No
   Don't know

4. Besides glasses or contact lenses, do you use any aids or specialized equipment for persons who are blind or visually impaired, for example, magnifiers or Braille reading materials?
   Yes
   No
   Don't know

5. If **YES,** Which of the following aids do you use? (Please choose all that apply)
   Magnifiers
   Braille reading materials
   Larger print reading materials
   Talking books
   Recording equipment or portable note-takers
   Closed circuit devices (e.g., CCTVs)

A computer with Braille, large print, or speech access
A white cane
A guide dog
Another aid (please specify): _____

16.3 APPENDIX 4: Baseline Assessments

16.3.1 SOCIODEMOGRAPHIC INFORMATION

BIRTH; SEX; GENDER IDENTITY

1. What is your date of birth?_____/ _____
   MM YYYY
2. People living in the United States come from many different cultural and racial backgrounds. Which racial category do you identify with? (Choose all that apply):
   - ☐ American Indian or Alaskan
   - ☐ Native Asian
   - ☐ Native Hawaiian or other Pacific Islander
   - ☐ Black or African American
   - ☐ White
   - ☐ Latin American
   - ☐ More than one race
   - ☐ Unknown or prefer not to answer
3. Which ethnic category do you identify with?
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino
   - ☐ Unknown or prefer not to answer
4. What sex was originally listed on your birth certificate?
   - ☐ Female
   - ☐ Male
5. Do you think of yourself as:
   - ☐ Female
   - ☐ Male
   - ☐ Transgender woman/trans woman/male-to-female (MTF)
   - ☐ Transgender man/trans man/female-to-male (FTM)
   - ☐ Genderqueer/gender nonconforming neither exclusively male nor female
   - ☐ Additional gender category (or other; please specify): _____
   - ☐ Decline to answer

HANDEDNESS

1. What is your hand preference? (Hand used predominantly, not necessarily

hand you write with exclusively)

- ☐ Left
- ☐ Right
- ☐ Ambidextrous

MARITAL / PARTNER STATUS

1. What is your current marital/partner status? (Choose the one that describes you now)
   - ☐ Single
   - ☐ Married
   - ☐ Domestic partnership
   - ☐ Separated
   - ☐ Divorced
   - ☐ Widowed

CURRENT LIVING CIRCUMSTANCES

1. Please describe your living environment:
   - ☐ House or apartment/condominium that you own
   - ☐ Apartment/condominium or house that you rent
   - ☐ Retirement home (autonomous living)
   - ☐ Residence for semi-autonomous individuals
   - ☐ Nursing home or long-term care (assisted living)
   - ☐ Other, please specify: _____

2. Please describe your living environment:
   - ☐ Urban
   - ☐ Suburban
   - ☐ Rural

3. With whom do you live? (Please check all that apply)
   - ☐ I live alone
   - ☐ Spouse/significant other
   - ☐ Children/grandchildren
   - ☐ Other members of the family
   - ☐ Friend(s)
   - ☐ Other (specify): _____

EDUCATION

2. What is the highest grade or level of school you completed or the highest degree obtained? (Choose one)

- ☐ Never attended school
- ☐ Some primary/grade school; specify number of years completed: _____
- ☐ Completed primary/grade school
- ☐ Some high school; specify number of years completed: _____
- ☐ Completed high school. Graduated? YES £ NO £
- ☐ GED
- ☐ Apprenticeship; specify number of years completed: _____
- ☐ Technical school or community college; specify number of years completed: _____ Graduated? YES £ NO £
- ☐ Some university; specify number of years completed: _____
- ☐ Undergraduate degree at university; please specify degree/specialty (e.g. B.A., B.Sc., B.Eng., LL.B., B.Ed., etc.): _____
- ☐ Some graduate (post-undergraduate) school; specify number of years completed: _____
- ☐ Graduate degree at university; please specify degree/specialty (e.g., M.A., M.Sc., Ph.D., LL.M., other graduate degree): _____

EMPLOYMENT HISTORY

1. What is your current employment status? (Choose one)
   - ☐ Paid employment
   - ☐ Retired
   - ☐ Voluntary/unpaid work
   - ☐ Unemployed

16.3.2 MEDICAL HISTORY

Past Medical History
1. History of type II diabetes? _____ Yes _____ No _____ Unknown
2. Currently being treated for type II diabetes? _____ Yes _____ No _____ Unknown
3. Currently being treated for high blood pressure? _____ Yes _____ No _____ Unknown
4. Past head trauma? _____ Yes _____ No _____ Unknown **4a. If Yes, what was the date of the most recent head trauma?** _____ MM/DD/YYYY
5. Is there a history of strokes? _____ Yes _____ No _____ Unknown **5a. If there is a history of strokes, when did the last stroke occur?** _____ MM/DD/YYYY
6.Have you experienced any episodes of fainting or blackouts? _____ Yes _____ No **6a. If Yes, when was the lasttime you fainted or had a blackout?** _____

7 History of any type of seizure?
_____ Yes
_____ No
_____ Unknown/Uncertain

7a. If Yes, when was the last known seizure?

_____
MM/DD/YYYY

8. History of epilepsy (recurrent seizures)?
_____ Yes
_____ No
_____ Unknown

8a. If Yes, when was the last epileptic event?

_____
MM/DD/YYYY

9. History of malignant cancers?
_____ Yes
_____ No
_____ Unknown

9a. If Yes, in remission?
_____ Yes
_____ No
_____ Unknown

9b. If Yes, what was the date of remission?

_____
MM/DD/YYYY

10. Current diagnosis of a mental health or behavioral disorder?
_____ Yes
_____ No
_____ Unknown

10a. If Yes, please specify: _____

10b. If Yes, are medications currently being taken to treat this disorder?
_____ Yes
_____ No

_____ Unknown

11. Drug or alcohol dependency or a history of drug or alcohol abuse?
_____ Yes
_____ No
_____ Unknown

12. Currently have a diagnosis of obstructive sleep apnea?
_____ Yes
_____ No
_____ Unknown

12a. If yes, who made the diagnosis:
_____ Primary care physician
_____ Neurologist
_____ Psychiatrist
_____ Sleep Center
_____Other

12b. If Yes, please indicate one of the following in regards to participant treatment?
_____ Yes, treatment prescribed and compliant
_____ Yes, treatment prescribed and not fully compliant
_____ No
_____ Unknown

13. Please indicate all the surgical procedures that you have undergone, as well as your age and whether a general anesthetic was administered.

Type of surgery	Age	General anesthetic?		
		Yes	No	Unknown
£ Cataract surgery				
Heart surgery:				
£ Coronary bypass surgery				
£ Pacemaker surgery				
£ Coronary stent insertion				
£ Angioplasty				
£ Bariatric surgery				
£ Gastrectomy				
£ Bowel surgery (e.g. for adhesions, cancer, resection)				

☐ Urology surgery (e.g. bladder, kidney)						
☐ Hip replacement						
☐ Knee replacement						
☐ Other(s):						

Family History

14. Please indicate which of your blood relatives have/had a history of any of the following conditions.

Condition	Family history		Relative(s) affected	Age of Onset (if known)	Number of relatives affected	
	Yes	No			1st °	2nd °
A. Neurological disorders						
Memory problems without a diagnosis of dementia	£	£				
Alzheimer's dementia	£	£				
Frontotemporal dementia	£	£				
Other dementia (specify):	£	£				
Parkinson's disease	£	£				
Epilepsy or seizures	£	£				
Stroke	£	£				
Multiple sclerosis	£	£				
Amyotrophic lateral sclerosis (ALS)	£	£				
B. Mental health disorders						
Depression	£	£				
Bipolar disorder	£	£				
Other mood disorder	£	£				
Anxiety disorder	£	£				
Schizophrenia	£	£				
Suicide or suicide attempt	£	£				
C. Other disorders						
Diabetes mellitus	£	£				
Cancer	£	£				
Heart disease	£	£				
Hypertension	£	£				

	Other:	£ £				

16.3.3 CURRENT MEDICATIONS

Instructions: The participant should have on hand all their current medications and supplements (herbal, vitamins) or a list of current medications from the pharmacy (plus an accounting of supplements if not prescribed by a physician). With this information, fill out the table below. Be sure to include injected medications/supplements.

Medication Name	Indication	Start Date (YYYY)

(**Interviewer Note:** If more space is needed than provided on this page, print more pages and paginate accordingly.) Total number of current medications (incl. supplements and vitamins)