Alzheimer's Disease Cooperative Study
UC San Diego

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

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University of California, San Diego
Consent to Act as a Research Subject

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

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?
Dr. Howard Feldman and Dr. Sarah Banks, are conducting a research study to find out more about the usability of a bilingual web-based educational program that is designed to help midlife and older adults learn how to prevent dementia through lifestyle changes. You have been asked to participate in this study because you are an adult between 50-85 years old and have the technical ability to participate in an online education program. Participants must have access to their own tablet or computer in order to participate. There will be approximately 20 participants in this study.

Why is this study being done?
The purpose of this study is to gather information about the usability of an online educational program called Healthy Actions and Lifestyles to Avoid Dementia or Hispanos y el ALTo a la Demencia program (HALT- AD). Prior studies have shown that programs that focus on promoting brain health and managing lifestyle risks (such as poor diet, obesity, physical inactivity, sleep issues, loneliness) may help in preventing or lowering the risk of dementia. To address this, we have developed the HALT-AD program. HALT-AD is an educational program designed to teach you about dementia and lifestyle changes that can help preserve brain health and lower dementia risk. 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 will help us learn how well the program is working and to make changes before the larger study begins.

What will happen to you in this study and which procedures are standard of care and which are experimental?
If you agree to be in this study, the following will happen to you:

Study Visit 1 (Confirm your eligibility for the study)
You will complete an initial **study visit by phone-call** with a study team member in order to determine if you are eligible to participate in this pilot study. This will include:

- Taking a test of memory and thinking
- Answering questions about your vision and hearing
- Confirm your eligibility for the study

Study Visit 2 (Answer Questions about yourself)

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If it is determined that you are eligible to participate, you will be enrolled in the study and will complete the following activities. These may be completed on the same day as your initial study visit by phone-call or they may be completed at a later time:

- Answer questions about yourself (such as your birth month and year, gender, education, employment history and living circumstances)
- Answer questions about your medical and family history
- Self-report your height and weight

Participate in the online HALT-AD program for 3 months

Following completion of your study visit 1 and 2 activities, you will register and begin your participation in the 3-month HALT-AD online program. During your participation in the program, you will complete the following activities:

- Register online
- At the beginning and end of the program, you will answer questions about yourself (e.g. questions about your daily lifestyle, your mood, and your general knowledge of brain health)
- Spend about 1-2 hours per month participating in the online educational program. The program may include topics such as sleep, diet, physical activity, and social connectivity/loneliness. The program is newly developed and considered experimental.
- Based on your personalized profile, set lifestyle goals for yourself and review the goals
- A study coordinator may periodically contact you by telephone or email to provide you with additional instructions or reminders. You may also contact a study coordinator by telephone or email if any questions arise or if you need assistance.

Participate in **online facilitated group discussions by video call** every 3 weeks for 3 months:

- Engage in HALT-AD related conversations with other study participants and a social worker called a HALT Helper. 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
- The group discussions will focus on learning and promotion of behavioral change

End-of-Study Activities

Once you have completed your 3-month participation in the HALT-AD program, you will be asked to do the following activities in order for us to gather some more information on how well the program works and whether any changes are needed.

Complete **online questionnaires** at the end of the study:

- You will receive an email inviting you to complete questionnaires through a web-based system called REDCap

- The questionnaires will ask about your experience and satisfaction with the HALT-AD program and facilitated group discussions

Participate in **online focus group(s) by video call** at the end of the study**:**

- You will be invited to participate in one to two focus groups
- During the focus group(s) you will engage in online discussions with a study team member and a group of other study participants
- You will answer questions about your experience and satisfaction with the HALT-AD program and facilitated group discussions
- This will be an open-ended discussion that will allow us to evaluate the pilot program and make any necessary changes before the larger study begins
- Total time to participate in focus group(s) is approximately 2 hours (1 hour to discuss web-based platform and 1 hour to discuss facilitated discussion groups)
- The online focus group(s) will be audio recorded to help the study team transcribe participants' feedback

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

Your participation in this study will last approximately 4 months and all activities will be done online or over the phone.

The approximate time commitment involved in this study is as follows:

- Initial study visit by phone call: 1-1.5 hours
- Answering questions about yourself and medical history: 30 minutes
- HALT-AD program: 1 -2 hours per month for three months
- Facilitated group discussion by video call: 1 hour every three weeks (4 hours total)
- Online questionnaires at the end of the study: 1 hour
- Focus group(s) by video call: 2 hours at the end of the study

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

1. A potential for the loss of confidentiality. Research records will be kept confidential to the extent allowed by law. Any information gathered in this study that can identify you will be held in confidence by UCSD. The HALT-AD website will be hosted on the secure UCSD Health server. All data from the program will be de-identified (all identifying information removed) and linked to a unique Participant ID prior to being included in the study database. 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. Electronic files will

be securely stored on password protected computers and accessible only to the study team. Research records may be reviewed by the UCSD Institutional Review Board.

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. Audio recordings will be destroyed once the focus group discussion has been transcribed. All identifiable information will be removed from the transcripts and replaced by unique coded Participant ID number.

2. Fatigue and/or frustration associated with cognitive testing and participating in an online educational program. Questionnaires on mood and lifestyle risk may increase negative emotions. Participants may skip questions or take breaks if needed. If a participant mentions negative emotions, the study coordinator will alert Dr. Sarah Banks, a clinical psychologist, who will attempt to contact the participant within 48 hours to suggest mental health resources.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

Because this is a research study, there may also be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternative to participation in this study is not to participate.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you from participating in this study. 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 may benefit the general community in the future by promoting public interest, literacy, and engagement in lifestyle interventions for brain health and dementia prevention through providing the web-based educational program to the broader public.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw or refuse to answer specific questions in an interview or on a questionnaire at any time

without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you will be required to contact the study team. You may withdraw by letting the study team know in writing, that you are no longer interested in participating or by contacting the study team by phone.

1) Please send the letter to: Dr. Howard Feldman and Dr. Sarah Banks, UC San Diego, 9500 Gilman Drive, La Jolla, CA 92093-0949.
2) You may contact Dr. Howard Feldman, Dr. Sarah Banks, and the study team at: 858-246-1333.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
The PI may remove you from the study without your consent if the PI feels it is in your best interest or the best interest of the study. You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

Will you be compensated for participating in this study?
In compensation for your time, you will receive $100 for participating in this research. Compensation will be provided by gift card at the end of the study or upon your early withdrawal from the study. Early withdrawal after completion Visit 2 will not impact the amount of compensation you receive.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

Who can you call if you have questions?
Dr. Howard Feldman, Dr. Sarah Banks, Dr. Sara Moukarzel, and/or a study coordinator have explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Howard Feldman or Dr. Sarah Banks at 858-246-1333.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

After the study is finished:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. The website will only include a summary of the results when they become available. You may access this website at any time.

Your Signature and Consent

You have received a copy of this consent document.

You agree to participate.

You agree this form and any later updates to this form and notices provided in connection with this study may be provided to you in an electronic version. You agree that you are able to electronically receive, review, and save a printed or electronic copy of this form containing your signature. We and you agree to electronically sign this form. We and you agree that our actions to electronically sign this form document your informed consent. We and you agree that our electronic signatures have the same meaning and effect as handwritten signatures. You understand that you can request a paper form if you would prefer to use a paper consent form

_____ _____

Subject's signature Date