

# **Intervention Development for Project TEACH (Tailored Education for Aging and Cognitive Health) for Dementia Prevention in Midlife Adults: Design and Protocol for Pilot Randomized Controlled Trial**

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# Intervention Development for Project TEACH (Tailored Education for Aging and Cognitive Health) for Dementia Prevention in Midlife Adults: Design and Protocol for Pilot Randomized Controlled Trial

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## Abstract

**Background:** Twelve modifiable risk factors account for 40% of dementia cases globally, yet population adherence to health behaviors associated with these factors is low. Midlife is a critical window for dementia prevention, as brain pathology often begins to accumulate years or decades before the onset of symptoms. Although multidomain behavioral interventions have been efficacious for reducing risk of cognitive decline, adherence is low. Intrapersonal factors, such as health beliefs, are known mediators of the relationship between knowledge and health behavior.

**Method/Design:** In keeping with Stage I of the NIH Stage Model for Behavioral Intervention Development, this study will use mixed methods to 1) develop an enhanced health education intervention, including an explanatory method for communicating information about dementia risk and personal health beliefs; and 2) conduct a pilot randomized controlled trial (N=20 per intervention arm) over 8 weeks to assess feasibility of delivering the enhanced intervention versus basic health education alone. Proximal outcomes (measured at baseline, 4 weeks, and 8 weeks) include perceived threat of Alzheimer's disease, dementia awareness, and self-efficacy.

**Conclusion:** Study findings will reveal the feasibility of delivering an 8-week multi-domain health education intervention for primary prevention of dementia in midlife and will provide preliminary evidence of mechanisms of change.

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## Original Manuscript

Intervention Development for Project TEACH (Tailored Education for Aging and Cognitive Health)  
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Trial

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## Abstract

**Background:** Twelve modifiable risk factors account for 40% of dementia cases globally, yet population adherence to health behaviors associated with these factors is low. Midlife is a critical window for dementia prevention, as brain pathology often begins to accumulate years or decades before the onset of symptoms. Although multidomain behavioral interventions have been efficacious for reducing risk of cognitive decline, adherence is low. Intrapersonal factors, such as health beliefs, are known mediators of the relationship between knowledge and health behavior.

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**Conclusion:** Study findings will reveal the feasibility of delivering an 8-week multi-domain health education intervention for primary prevention of dementia in midlife and will provide preliminary evidence of mechanisms of change.

**Keywords:** health behavior change, dementia prevention, Alzheimer's disease, multi-domain health intervention, protocol, intervention development

## 1. Introduction

### 1.1. Background and problem

By 2060, an estimated 13.8 million people in the United States will be living with Alzheimer's disease (AD), the most common form of dementia, with health care and long-term care costs exceeding \$1 trillion annually (Alzheimer's Association, 2023). While the U.S. Food and Drug Administration (FDA) has approved the first disease-modifying therapies for AD, these are currently only indicated for patients in the symptomatic phases of disease and remain costly. Primary prevention efforts are critical to achieving reductions in risk for dementia.

The 2020 report of the Lancet Commission on dementia prevention described 12 modifiable risk factors that account for 40% of dementia cases worldwide: depressed mood, diabetes, early life education, excessive alcohol consumption, hearing impairment, hypertension, obesity, physical inactivity, smoking, social isolation, toxin exposure (particularly air pollution), and traumatic brain injury (Livingston et al., 2020). Many of these factors confer particular risk in midlife, when cerebrovascular changes, AD neuropathology, and related pathologies begin to accumulate in the brain (Apátiga-Pérez et al., 2022). Thus, targeting prevention efforts to adults in midlife or early late life is likely to confer maximal benefit (Cadar, 2017).

Unfortunately, population adherence to health behaviors for dementia prevention is low among midlife adults. In 2014, only 28.4% of Americans aged 45 to 64 met federal guidelines for aerobic exercise, and 17.6% met guidelines for both aerobic and muscle-strengthening activity (U.S. Centers for Disease Control and Prevention, 2018a). Adherence to healthy diet recommendations is also poor, with only 23.5% of Americans eating the recommended 5 servings of fruits and vegetables daily and more than 70% exceeding dietary guidelines for sodium, saturated fat, and added sugars (U.S. Centers for Disease Control and Prevention, 2018b). Modification of these health behaviors through multi-domain lifestyle intervention may promote positive cognitive and brain health outcomes. For example, the Finnish Geriatric Intervention Study to Prevent Cognitive Impairment

and Disability (FINGER) was a multi-domain intervention that included physical activity, nutritional guidance, cognitive training, and management of vascular risk factors (Kivipelto et al., 2013). After two years of intervention, participants in the active treatment condition showed a 25% larger improvement on composite cognitive measures and lower risk of cognitive decline compared to the control condition (Rosenberg et al., 2018). This has led to large, multi-site replication studies in the United States (U.S. POINTER; Baker et al., 2023) and worldwide, though results from these trials are not yet available. Similarly, the Systematic Multi-Domain Alzheimer Risk Reduction Trial (SMARRT) trial demonstrated that individual health coaching and nurse visits modestly improved cognition and health indices associated with dementia risk in older adults at elevated risk for dementia compared to a health education control (Yaffe et al., 2024).

Despite promising results of single- and multi-domain intervention trials (Barnes et al., 2023; Gallardo-Gómez et al., 2022; Valls-Pedret et al., 2015), adherence to these interventions remains problematic even with intensive individualized coaching. For example, only 19% of participants adhered to all components of the FINGER intervention (defined as attending at least 66% of sessions within each component) (Coley et al., 2019). As expected, participants with higher adherence showed the greatest cognitive benefits of the intervention (Ngandu et al., 2022). Adherence is likely to be even lower for less intensive interventions and over longer follow-up intervals. Thus, although research has identified critical components of health behavior interventions for dementia prevention, new approaches are needed to sustain health behavior change over years to decades.

### *1.2. Theoretical approach*

There are numerous theoretical models that describe mechanisms of health behavior change. One of the oldest is the Health Belief Model (HBM) (Rosenstock, 1974), which states that personal health beliefs including perceived threat of disease, perceived benefits and barriers, and self-efficacy are mediators of health behavior change. These health beliefs, as well as cues to action, motivate health behavior change. The HBM has rarely been applied to dementia directly. In one recent study



surveying Chinese adults about knowledge of dementia prevention and current health behaviors (Li et al., 2022), perceived benefits, cues to action, and self-efficacy played a partial mediating role between knowledge and health behavior, supporting the utility of the HBM in the context of dementia prevention.

We propose a working model in which individual health beliefs are moderated by constructs identified by the Science of Behavior Change Research Network (Nielsen et al., 2018). Namely, one's degree of dementia risk, future time perspective, reward sensitivity, and executive control moderate health beliefs, which determine likelihood of making a health behavior change (Figure 1). By educating patients about the HBM and these personal health belief factors, we hypothesize that there will be increased engagement in behaviors known to prevent dementia. The goal of this study is to use this theoretical orientation to develop a novel, personalized educational program for primary prevention of ADRD in midlife adults: Tailored Education for Aging and Cognitive Health (Project TEACH).

### *1.3. Study objectives and design overview*

As an NIH Stage I behavioral intervention development study, the primary objectives are to establish feasibility and preliminary estimates of efficacy of the TEACH intervention. The objectives of this study are 1) to use qualitative methods to develop an enhanced health education intervention, including an explanatory method for communicating information about personal health beliefs; and 2) to conduct a pilot randomized controlled trial (RCT; N=20 per intervention arm) over 8 weeks to assess feasibility and preliminary efficacy of the enhanced health education intervention versus basic health education alone on AD risk perception, self-efficacy, and knowledge about dementia risk. To establish feasibility of measurement for future distal outcomes, we will collect pre- and post-treatment body weight, blood pressure measurement, HbA1C and lipid panel, and physical activity/sleep quality measured by a wearable activity monitor.

## **2. Design and Methods**

## 2.1. Study Setting and Recruitment

Project TEACH will take place at Rhode Island Hospital/Alpert Medical School of Brown University in Providence, RI. Participants will be recruited from the Rhode Island Alzheimer's Disease Prevention Registry and the greater Rhode Island community. All study procedures have been reviewed and approved by the Institutional Review Board at Rhode Island Hospital. All participants will be screened for inclusion and exclusion criteria by phone and eligible participants will provide written, informed consent before participating in assessment and intervention procedures. All study-related information will be stored securely at the study site and in password-protected databases. The RCT is registered at ClinicalTrials.gov, NCT05599425. Any modifications to the protocol that could impact the conduct of the study, potential benefit to the participant, or participant safety profile will be agreed upon by all study investigators and approved by the Rhode Island Hospital IRB prior to implementation. Administrative changes to the protocol, including minor corrections or clarifications, will be documented in a memorandum and in records of the protocol version.

## 2.2. Participants

Inclusion criteria were adapted from the U.S. POINTER study, a multi-domain lifestyle intervention clinical trial for AD (Baker et al., 2023). Inclusion criteria include: a) age 45-69 years; b) normal cognition (Minnesota Cognitive Acuity scale > 52; Tremont et al., 2011); c) proficiency in written and spoken English; and d) at least two of the following dementia risk factors: i) BMI > 24.9; ii) systolic blood pressure > 100 mmHg; iii) LDL cholesterol > 115 mg/dL; iv) HbA1C > 5.6%; v) at least one *APOE*  $\epsilon$ 4 allele; vi) first-degree relative with AD. Exclusion criteria include: a) history of serious mental illness (i.e., schizophrenia, bipolar disorder); b) history of major neurologic or neurodevelopmental disorder that affects cognitive performance (e.g., stroke, epilepsy, intellectual disability); c) current alcohol or drug use disorder based on self-report; and d) current enrollment in an AD prevention clinical trial.

### 2.3. Measures

Empirically validated measures were selected from the Science of Behavior Change Research Network to assess specific health belief constructs (Table 1). These measures were administered to a group of 177 adults aged 50+ to establish normative data to inform interpretation within our target population (Zakrzewski et al., in press). Modifiable dementia risk factors will be assessed using the Australian National University Alzheimer's Disease Risk Index (ANU-ADRI), a self-report inventory that assesses dementia risk across multiple domains and has been validated in middle-aged and older adult cohorts (Andrews et al., 2017; Anstey et al., 2014). All measures will be administered electronically via Redcap survey or computerized paradigm administered via e-Prime (v3.0, Psychology Software Tools, Pittsburgh, PA). Data will be deidentified. Data integrity will be enforced through range checks, consistency checks, and referential data rules.

## 3. Phase 1: Protocol Development

### 3.1. Objective.

The first phase of the study is to develop an enhanced health education intervention using qualitative methods. The intervention adapts an existing 24-session program (two sessions/week for 12 weeks) that was designed to educate participants about major modifiable risk factors for dementia. The basic intervention was originally designed for patients diagnosed with mild cognitive impairment (MCI) or mild dementia. It is designed to increase knowledge of AD risk factors but does not include tailored content about personal health beliefs that affect health behaviors (Tremont et al., 2022). We have adapted the basic intervention for a cognitively unimpaired population in middle age/early late life by aligning the content with the modifiable dementia risk factors included in the 2020 Lancet Commission report (Livingston et al., 2020) and ensuring recommendations are appropriate for the target age group rather than the older MCI/dementia patients for whom the intervention was originally designed.

The TEACH intervention will include the same didactic content as the basic health education

intervention. However, a major focus of the intervention will be discussion of their health belief profiles and how their behavioral tendencies affect engagement in and maintenance of specific health behaviors. Sessions will include discussion of perceived risk for AD, perceived benefits of behavior change to mitigate AD risk, troubleshooting barriers to action, making specific action plans, and implementing natural reward systems to bolster self-efficacy.

### 3.2. Focus Groups

#### 3.2.1. Structure of the focus groups

We will first conduct focus groups (4-5 groups of 6-8 participants) to develop content, educational strategies, and delivery methods for communicating about modifiable AD risk factors and the HBM and personal health beliefs. During each focus group, we will present images conveying AD risk factors and the HBM and individual health belief factors that affect willingness to engage in behavior change. We will present a hypothetical person's profile across the AD risk spectrum and health belief measures described above, rather than participants' personal health information.

We will use purposive sampling to include diverse participants based on sex, education, race/ethnicity. Each group will take place in a private location at Rhode Island Hospital. Sessions will be digitally recorded and professionally transcribed. A research assistant will be present in the group to take notes and record non-verbal communication and participant interactions that could be missed by using the audio recording only. We plan to have 4-5 groups of 6-8 participants, but additional groups will be added as needed to reach data saturation (i.e., when no new information emerges from the group discussion). The focus groups will last one hour and will follow a standard discussion guide, including probes to explore and seek clarification. The groups will be attended by two study investigators; one will serve as the facilitator who will provide an overview of the group discussion and present questions and follow-up probes.

#### 3.2.2. Qualitative analysis

Following each group, transcripts and field notes will be reviewed by two members of the research team who have experience with focus groups and qualitative data. They will review data independently. Focus groups will be analyzed using a framework matrix analysis (Gale et al., 2013; Rosen et al., 2023). In the framework matrix analysis of the focus group data, one rater will chart the data into a matrix by summarizing participant comments to each of the major focus group questions. Responses will be reviewed by the research team and major trends identified to determine clarity of messages, alternative ways of summarizing and displaying information, and preferences for explanatory images. This will be used to refine the explanatory framework for disclosing dementia risk and personalized health belief information. Images and language used to describe the health belief constructs will be developed from the thematic analysis of the focus groups. For example, we may visually present data in images or graphs that show the relative magnitude of personal health belief traits based on individuals' performance on the assessment measures.

### *3.3. Individual Qualitative Interviews*

#### *3.3.1. Structure of the qualitative interviews*

We will test the explanatory framework for communicating about personal health beliefs by conducting qualitative interviews with 10-12 individuals. Participants will complete the health belief assessments. Their personalized data will be scored and presented to them in a 30-minute individual session. A trained facilitator will complete a semi-structured interview with standardized questions and follow-up probes. This interview will use a phenomenographic approach, a well-accepted qualitative research method to study variations in how people learn and understand concepts in educational and healthcare settings (Stenfors-Hayes et al., 2013; Svensson, 1997). Phenomenography examines two components of learning: referential and structural (Marton & Pong, 2005). The referential aspect is the global meaning of the construct being conceptualized. The structural aspect is the specific combination of features (e.g., images, words or phrases) being deployed.

Questions will be constructed to allow participants to reflect on their experience and will

emphasize the relationship between the participant and the presented material (i.e., phenomenon). The interview will include questions about acceptability (e.g., “What is your reaction to your personalized health belief profile?”), appropriateness (e.g., “Explain your understanding of the presented information”), and applicability (“How does this information apply to you and your health?”).

### 3.3.2. *Qualitative analysis*

Interviews will be coded using applied thematic analysis (Guest et al., 2011). Interview transcripts will be coded by two team members and agreed-upon codes will be entered into NVivo software for analysis (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 12, 2020). Summaries of key codes will be written to generate themes about the understanding of health belief concepts and images and to identify overall preference for presentation of data about Alzheimer’s risk. Based on these analyses, intervention content will be modified to ensure participant understanding, generate relevant explanations, and simplify content as needed.

### 3.3.3. *Risks of disclosing personal health information*

There is potential for disclosure of AD risk factors and personal health beliefs to induce distress, though risk factor disclosure has previously been demonstrated to be safe and well-tolerated by most older adults (Chao et al., 2008; Green et al., 2009; Linnenbringer et al., 2010). To mitigate risk, personalized AD risk and health belief information will be presented by a licensed psychologist. Immediately following the health belief disclosure, participants will complete the Perceived Stress Scale (Cohen et al., 1994) and PHQ-9 (Kroenke et al., 2001). Participants will receive a follow-up phone call to re-administer these measures after two weeks.

If any participant scores >13 on the PSS (indicating moderate distress) or >4 on the PHQ-9 (indicating possible depression), the Columbia Suicide Severity Rating Scale (C-SSRS; Posner et al., 2011) will be administered by a trained research assistant to assess suicidal ideation and intent. Should the participant endorse active suicidal ideation with a plan or intent to act, or endorse suicidal

behavior (e.g., a suicide/self-harm attempt or preparatory acts), the research assistant will immediately contact one of the study investigators (both licensed clinical psychologists) to conduct a more thorough risk assessment and make appropriate referrals for mental health treatment.

#### **4. Phase 2: Pilot Randomized Controlled Trial**

##### *4.1. Objective.*

The second phase of the study is to conduct a pilot parallel group, two-arm randomized controlled trial with 1:1 allocation to assess feasibility and preliminary efficacy of the TEACH intervention compared to basic health education alone.

##### *4.2. Approach*

###### *4.2.1. Procedures*

Forty participants will complete the baseline assessment of personal health belief factors described above (Table 1). Participants will be randomly assigned to the basic health education intervention or the TEACH intervention with a 1:1 allocation using a computer-generated randomization schedule. Due to the nature of the intervention, neither participants nor course instructors can be blinded to allocation. However, participants will be blind to study hypotheses and which intervention is considered active.

Each intervention will be conducted via a HIPAA-compliant video conference platform. The intervention will be delivered twice weekly for 8 weeks (see Table 2 for class topics). The intervention will begin within 2 weeks of baseline assessments. We will recruit at least 4 participants (3 in each treatment arm) into each group, with an intended group size of 6-8. Intervention content is designed to be modular, with each session focusing on a different modifiable AD risk factor.

Prior to beginning the intervention, participants will meet individually with the instructor for their assigned condition for a 30-minute introductory session. For participants in the basic health education treatment arm, this will include reviewing information about their personal health history and orienting them to what to expect from classes. For participants in the TEACH intervention arm,

this will include education about their personal dementia risk based on their health history and responses on the ANU-ADRI as well as their health belief factors using materials developed in Phase 1.

Attendance will be taken at each session, and participants will be given a schedule to track their progress and to record homework or home practice. Participants who miss a session will be contacted by email or telephone to review the missed session policy and to be encouraged to attend. Post-treatment assessments will be completed within 2 weeks of the last class and will include a measure of treatment credibility and expectancy for each arm of the trial (Devilly et al., 2000).

*4.2.2. Treatment fidelity and adherence.* Participants will be blind to which treatment arm they have been assigned. All intervention classes will be video recorded. These will be reviewed by a member of the study team for treatment adherence and protocol deviations using existing monitoring protocols from our prior study of the basic health education intervention (Tremont et al., 2022). Any protocol deviations will be directly addressed and remediated.

#### *4.3. Outcomes*

##### *4.3.1. Feasibility Benchmarks*

A primary goal of Phase 2 is to establish the feasibility of delivering the TEACH intervention. As part of the post-treatment assessment, participants will complete 7-point Likert scales assessing the understandability, satisfaction, and perceived relevance of course material. We have established the following feasibility benchmarks: 1) attendance; participants attend at least 75% of classes (12 of 16); 2) understandability; 80% of participants agree/strongly agree that material was understandable; 3) satisfaction; 80% of participants agree/strongly agree that the program was satisfying; 4) relevance; 80% of participants agree/strongly agree that the material was relevant to their personal situation.

##### *4.3.2. Proximal Outcome Measures*

The pilot RCT is designed to estimate preliminary efficacy of the intervention on proximal



outcome measures. These will be assessed at baseline, 4 weeks, and 8 weeks (study endpoint). Proximal outcome measures include: 1) the Perceived Threat of AD Scale (Roberts & Connell, 2000), a 7-item Likert-type scale assessing perceived likelihood, concern, and consequences of AD; 2) the Dementia Awareness Questionnaire (Heger et al., 2019), a measure of knowledge of modifiable AD risk factors; and the Generalized Self-Efficacy Questionnaire (Schwarzer & Jerusalem, 1995), which measures self-beliefs to cope with demanding situations. The 10-item PSS and PHQ-9 will also be administered at these timepoints to minimize risk of adverse events related to personal AD risk and health belief information disclosure. The procedures described above will be used to ensure the safety of participants who endorse clinically significant distress or depressive symptoms.

#### *4.3.3. Distal Outcome Measures*

This pilot RCT is powered to detect changes in proximal outcome measures. We will also administer the following measures pre- and post-treatment to establish feasibility of assessment: 1) weight measurement; 2) blood pressure measurement; 3) venipuncture for HbA1C and lipid panel (total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides); 4) 14-item Mediterranean Diet Assessment Tool (Martínez-González et al., 2012); 5) Community Healthy Activities Model Program for Seniors (CHAMPS) Activities Questionnaire for Older Adults (Stewart et al., 2001); and 6) 25-item Florida Cognitive Activities Scale (Schinka et al., 2005). Participants will also be provided a wearable activity monitor (Fitbit) to assess physical health (e.g., steps per day, heart rate variability) and sleep quality. All distal outcome measures will be considered preliminary and used to inform the design of a future, fully powered RCT.

#### *4.4. Power and Data Analysis*

We estimate attrition at 10% based on our previous study investigating the basic health education intervention. Power was derived based on three proximal outcome measures that are likely intercorrelated (assumed 0.5 correlation). Assuming 10% attrition, a sample size of 36 could detect a

medium effect ( $d = 0.5$ ) with a power of 0.80 and  $\alpha = .05$ .

All participants, regardless of adherence or attrition, will be included in the primary intent-to-treat analysis. Primary analyses will use generalized linear mixed models to compare pre- and post-treatment change in proximal outcome measures by treatment arm. We will use *t*-tests to assess group differences in feasibility benchmarks (attendance, understandability, satisfaction, relevance) by treatment arm. Secondary analyses will examine the relationship between treatment dose (defined as class attendance) and proximal outcome measures). Given that this is a Stage I pilot study, all inferential statistical results will be considered preliminary and used to assess feasibility of the TEACH intervention. Distal outcomes will not be formally analyzed but will be used to determine feasibility of assessment for future studies.

## 5. Discussion and Conclusions

Despite a robust body of evidence describing modifiable health behaviors that could reduce global dementia burden by 40% (Livingston et al., 2020), multi-domain behavioral interventions for primary prevention of dementia have been hampered by poor adherence (Coley et al., 2019; Ngandu et al., 2022). This study uses behavioral science to educate individuals about the intrapersonal factors that promote and maintain health behavior change (i.e., understanding *why* we behave the way we do in addition to educating people about *what* behaviors are optimal). We hypothesize that this personalized approach will result in higher treatment adherence and greater efficacy of a multi-domain health education intervention.

Very little research to date has used personalized intervention to promote health behavior change specifically for primary prevention of dementia. One of the challenges in dementia prevention is that individuals must maintain health-promoting behaviors like dietary changes and exercise for years to avert or delay an adverse outcome (dementia) that is perhaps decades away. Thus, effective interventions must focus on maintenance of health behavior change over the long term. One recently completed trial, the SMARRT intervention, used motivational interviewing to

assess participants' values and motivators to reduce Alzheimer's risk and help them adopt specific, achievable risk reduction steps (Yaffe et al., 2019; Yaffe et al., 2024). Participants in the active intervention showed greater improvements in cognition, dementia risk factors, and quality of life. However, the SMARRT trial enrolled participants aged 70 to 89, whereas our intervention is designed to target midlife adults aged 40-69. Additionally, the TEACH intervention adopts the Health Belief Model and will specifically educate people about intrapersonal processes that may promote health behavior.

This Stage I intervention development project aims to use a mixed-methods approach to refine a multi-domain behavioral health intervention for primary prevention of dementia in midlife and early late life (age 45-69). The first phase of the project will use qualitative methods, including focus groups and individual interviews, to develop the personalized health education intervention (TEACH; Tailored Education for Aging and Cognitive Health). This will include development of an explanatory method for communicating information about personal health beliefs that is perceived to be acceptable, appropriate, and applicable to participants. The second phase of the project includes a pilot RCT to examine the feasibility and preliminary efficacy of the TEACH intervention compared to basic health education on personal dementia risk perception, dementia knowledge, and self-efficacy. If successful, this study will contribute new knowledge about personalized health education for primary prevention of dementia and a framework for educating individuals about intrapersonal processes that may be barriers or facilitators of health behavior change. Results will be used to inform intervention development and design a fully-powered randomized controlled trial to determine efficacy of the TEACH intervention versus basic health education alone.

## 6. Funding

This project is funded by NIH R21AG075328 (MPI Korthauer and Davis). This funding source had no role in the design of the study and will not have any role during its executive, analyses, interpretation of the data, or decision to submit results for publication.

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## 8. Authors' Contributions

JDD and LEK conceived of the study and are primary grant holders. GT provided expertise with health education for dementia prevention. RKR provided expertise with qualitative methods. All authors assisted with study design and implementation. All authors approved the final manuscript.

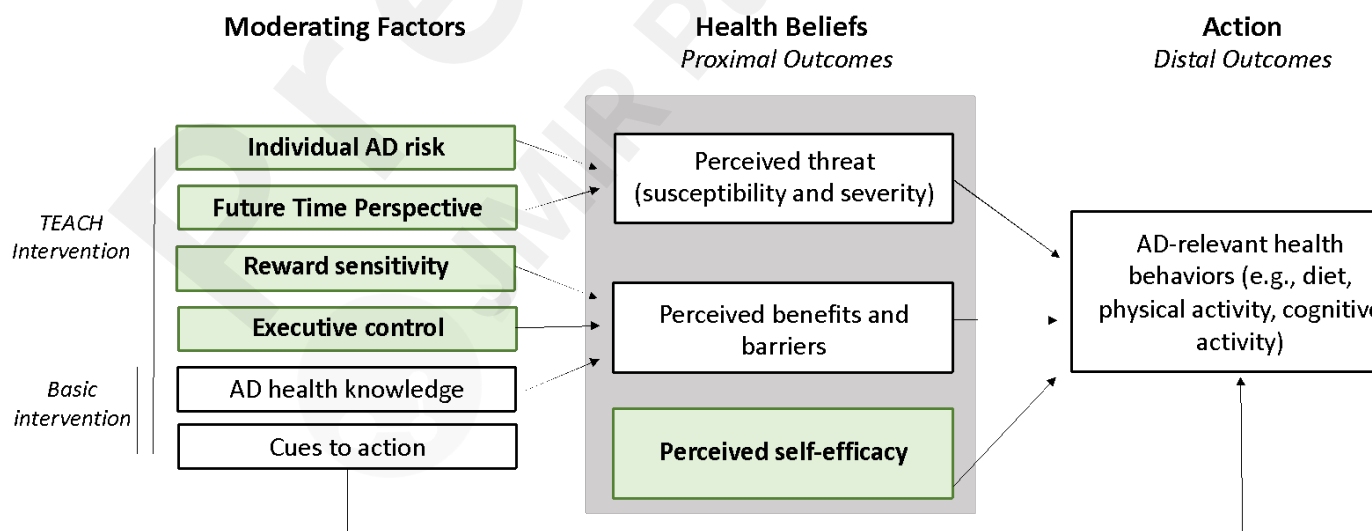
Table 1. Health belief assessment

Health Belief Domain		Measure		Citation		Method	Description	Time
Perceived susceptibility		Future Time		Carstensen &	10-item self-		Perception of the future as time-limited	5 min.
		Perspective Scale		Lang, 1996	report		AD risk assessment including	
		ANU Alzheimer's Disease Risk Index		Andrews et al., 2017	45-item self-report		demographics, medical history, physical activity, cognitive activity, social engagement, diet, toxic exposure	20 min.
Perceived benefits and barriers		Monetary Choice Task		Kirby et al., 1999	27-item self-report		Reward sensitivity/delay discounting; tendency to discount future rewards (i.e., preference for small rewards received sooner versus larger rewards received later)	5 min.
		Deferment of Gratification Scale		Ray & Naiman, 1986	12-item self-report		Reward sensitivity; ability to defer gratification versus pursue immediate rewards	5 min.
		Consideration of Future Consequences Scale		Strathman et al., 1994	12-item self-report		Reward sensitivity; tendency to guide behavior based on short- versus long-term consequences	5 min.

Self-efficacy	Parametric	Go-No	Langenecker et al., 2007	computer	Executive control; response inhibition	7 min.
	Go Task					
	Attentional Network		Fan et al., 2002	computer	Executive control; conflict monitoring	20 min.
	Test					
Self-efficacy	Generalized	Self-	Schwarzer & Jerusalem, 1995	10-item self-report	Belief in one's own abilities	5 min.
	Efficacy Scale					

Table 2. Intervention class topic list

Session	
n	Topic
1	Physical activity (aerobic)
2	Sleep
3	Nutrition
4	Substance use (alcohol, tobacco, cannabis)
5	Physical activity (resistance training, mind/body practice)
6	Cognitive activity
7	Diabetes
8	Social relationships
9	Hypertension
10	Stress management and positive thinking
11	Obesity
12	Depression, anxiety, and mental health
13	Traumatic brain injury
14	Medications and supplements (including medication side effects)
15	Hearing loss
16	Air pollution and toxin exposure



*Figure 1.* Theoretical model adapted from the Health Belief Model. Constructs shown in green reflect domains assessed via empirically-validated measures from the Science of Behavior Change Research Network.



## References

- Andrews, S. J., Eramudugolla, R., Velez, J. I., Cherbuin, N., Easta, S., & Anstey, K. J. (2017). Validating the role of the Australian National University Alzheimer's Disease Risk Index (ANU-ADRI) and a genetic risk score in progression to cognitive impairment in a population-based cohort of older adults followed for 12 years. *Alzheimers Res Ther*, 9(1), 16. <https://doi.org/10.1186/s13195-017-0240-3>
- Anstey, K. J., Cherbuin, N., Herath, P. M., Qiu, C., Kuller, L. H., Lopez, O. L., . . . Fratiglioni, L. (2014). A self-report risk index to predict occurrence of dementia in three independent cohorts of older adults: the ANU-ADRI. *PLoS One*, 9(1), e86141. <https://doi.org/10.1371/journal.pone.0086141>
- Association, A. s. (2016). Changing the trajectory of Alzheimer's disease: how a treatment by 2025 saves lives and dollars. In.
- Association, A. s. (2023). 2023 Alzheimer's disease facts and figures. *Alzheimers Dement*, 19(4), 1598-1695. <https://doi.org/10.1002/alz.13016>
- Baker, L. D., Snyder, H. M., Espeland, M. A., Whitmer, R. A., Kivipelto, M., Woolard, N., . . . Group, U. S. P. S. (2023). Study design and methods: U.S. study to protect brain health through lifestyle intervention to reduce risk (U.S. POINTER). *Alzheimers Dement*. <https://doi.org/10.1002/alz.13365>
- Barnard, A., Hollingum, C., & Hartfiel, B. (2006). Going on a journey: understanding palliative care nursing. *Int J Palliat Nurs*, 12(1), 6-12. <https://doi.org/10.12968/ijpn.2006.12.1.20389>
- Barnes, L. L., Dhana, K., Liu, X., Carey, V. J., Ventrelle, J., Johnson, K., . . . Stubbs, B. J. (2023). Trial of the MIND diet for prevention of cognitive decline in older persons. *New England Journal of Medicine*, 389(7), 602-611.

- Cadar, D. (2017). A life course approach to dementia prevention. *Journal of Aging and Geriatric Medicine*, 1(2).
- Carstensen, L. L., & Lang, F. R. (1996). Future time perspective scale. *Psychology and Aging*.
- Chao, S., Roberts, J. S., Marteau, T. M., Silliman, R., Cupples, L. A., & Green, R. C. (2008). Health behavior changes after genetic risk assessment for Alzheimer disease: The REVEAL Study. *Alzheimer Dis Assoc Disord*, 22(1), 94-97. <https://doi.org/10.1097/WAD.0b013e31815a9dcc>
- Cohen, S., Kamarck, T., & Mermelstein, R. (1994). Perceived stress scale. *Measuring stress: A guide for health and social scientists*, 10(2), 1-2.
- Coley, N., Ngandu, T., Lehtisalo, J., Soininen, H., Vellas, B., Richard, E., . . . HATICE, F. I. N. G., and MAPT/DSA groups. (2019). Adherence to multidomain interventions for dementia prevention: Data from the FINGER and MAPT trials. *Alzheimers Dement*, 15(6), 729-741. <https://doi.org/10.1016/j.jalz.2019.03.005>
- Fan, J., McCandliss, B. D., Sommer, T., Raz, A., & Posner, M. I. (2002). Testing the efficiency and independence of attentional networks. *J Cogn Neurosci*, 14(3), 340-347. <https://doi.org/10.1162/089892902317361886>
- Gallardo-Gómez, D., del Pozo-Cruz, J., Noetel, M., Álvarez-Barbosa, F., Alfonso-Rosa, R. M., & del Pozo Cruz, B. (2022). Optimal dose and type of exercise to improve cognitive function in older adults: A systematic review and bayesian model-based network meta-analysis of RCTs. *Ageing research reviews*, 76, 101591.
- Green, R. C., Roberts, J. S., Cupples, L. A., Relkin, N. R., Whitehouse, P. J., Brown, T., . . . Group, R. S. (2009). Disclosure of APOE genotype for risk of Alzheimer's disease. *N Engl J Med*, 361(3), 245-254. <https://doi.org/10.1056/NEJMoa0809578>
- Heger, I., Deckers, K., van Boxtel, M., de Vugt, M., Hajema, K., Verhey, F., & Köhler, S. (2019). Dementia awareness and risk perception in middle-aged and older individuals: baseline results of the MijnBreincoach survey on the association between lifestyle and brain

- health. *BMC Public Health*, 19(1), 678. <https://doi.org/10.1186/s12889-019-7010-z>
- Jones, C. J., Smith, H., & Llewellyn, C. (2014). Evaluating the effectiveness of health belief model interventions in improving adherence: a systematic review. *Health Psychol Rev*, 8(3), 253-269. <https://doi.org/10.1080/17437199.2013.802623>
- Kirby, K. N., Petry, N. M., & Bickel, W. K. (1999). Monetary Choice Questionnaire. *Journal of Experimental Psychology: General*.
- Kivipelto, M., Solomon, A., Ahtiluoto, S., Ngandu, T., Lehtisalo, J., Antikainen, R., . . . Soininen, H. (2013). The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER): study design and progress. *Alzheimers Dement*, 9(6), 657-665. <https://doi.org/10.1016/j.jalz.2012.09.012>
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine*, 16(9), 606-613.
- Langenecker, S. A., Zubieta, J.-K., Young, E. A., Akil, H., & Nielson, K. A. (2007). A task to manipulate attentional load, set-shifting, and inhibitory control: Convergent validity and test-retest reliability of the Parametric Go/No-Go Test. *Journal of clinical and experimental neuropsychology*, 29(8), 842-853.
- Li, H., Zhang, J., Wang, L., Yang, T., & Yang, Y. (2022). A health promoting-lifestyle prediction model for dementia prevention among chinese adults: based on the health belief model. *BMC Public Health*, 22(1), 2450. <https://doi.org/10.1186/s12889-022-14828-9>
- Linnenbringer, E., Roberts, J. S., Hiraki, S., Cupples, L. A., & Green, R. C. (2010). "I know what you told me, but this is what I think:" perceived risk of Alzheimer disease among individuals who accurately recall their genetics-based risk estimate. *Genet Med*, 12(4), 219-227. <https://doi.org/10.1097/GIM.0b013e3181cef9e1>
- Livingston, G., Huntley, J., Sommerlad, A., Ames, D., Ballard, C., Banerjee, S., . . . Mukadam, N. (2020). Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. *Lancet*, 396(10248), 413-446. <https://doi.org/10.1016/S0140->

[6736\(20\)30367-6](#)

- Marton, F., & Pong, W. Y. (2005). On the unit of description in phenomenography. *Higher education research & development*, 24(4), 335-348.
- Martínez-González, M. A., García-Arellano, A., Toledo, E., Salas-Salvadó, J., Buil-Cosiales, P., Corella, D., . . . Investigators, P. S. (2012). A 14-item Mediterranean diet assessment tool and obesity indexes among high-risk subjects: the PREDIMED trial. *PLoS One*, 7(8), e43134. <https://doi.org/10.1371/journal.pone.0043134>
- Ngandu, T., Lehtisalo, J., Korkki, S., Solomon, A., Coley, N., Antikainen, R., . . . Kivipelto, M. (2022). The effect of adherence on cognition in a multidomain lifestyle intervention (FINGER). *Alzheimers Dement*, 18(7), 1325-1334. <https://doi.org/10.1002/alz.12492>
- Nielsen, L., Riddle, M., King, J. W., Aklin, W. M., Chen, W., Clark, D., . . . Team, N. S. o. B. C. I. (2018). The NIH Science of Behavior Change Program: Transforming the science through a focus on mechanisms of change. *Behav Res Ther*, 101, 3-11. <https://doi.org/10.1016/j.brat.2017.07.002>
- Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., . . . Shen, S. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American journal of psychiatry*, 168(12), 1266-1277.
- Prevention, C. f. D. C. a. (2018a). National Health Interview Survey. In.
- Prevention, C. f. D. C. a. (2018b). Nutrition, Physical Activity, and Obesity. In.
- Ray, J. J., & Najman, J. M. (1986). The generalizability of deferment of gratification. *The journal of social psychology*, 126(1), 117-119.
- Roberts, J. S., & Connell, C. M. (2000). Illness representations among first-degree relatives of people with Alzheimer disease. *Alzheimer Dis Assoc Disord*, 14(3), 129-136, Discussion 127-128. <https://doi.org/10.1097/00002093-200007000-00003>
- Rosenberg, A., Ngandu, T., Rusanen, M., Antikainen, R., Bäckman, L., Havulinna, S., . . .

- Kivipelto, M. (2018). Multidomain lifestyle intervention benefits a large elderly population at risk for cognitive decline and dementia regardless of baseline characteristics: The FINGER trial. *Alzheimers Dement*, 14(3), 263-270. <https://doi.org/10.1016/j.jalz.2017.09.006>
- Rosenstock, I. M. (1974). The health belief model and preventive health behavior. *Health education monographs*, 2(4), 354-386.
- Schinka, J. A., McBride, A., Vanderploeg, R. D., Tennyson, K., Borenstein, A. R., & Mortimer, J. A. (2005). Florida Cognitive Activities Scale: initial development and validation. *J Int Neuropsychol Soc*, 11(1), 108-116. <https://doi.org/10.1017/S1355617705050125>
- Schwarzer, R., & Jerusalem, M. (1995). Generalized self-efficacy scale. J. Weinman, S. Wright, & M. Johnston, *Measures in health psychology: A user's portfolio. Causal and control beliefs*, 35, 37.
- Stenfors-Hayes, T., Hult, H., & Dahlgren, M. A. (2013). A phenomenographic approach to research in medical education. *Med Educ*, 47(3), 261-270. <https://doi.org/10.1111/medu.12101>
- Stewart, A. L., Mills, K. M., King, A. C., Haskell, W. L., Gillis, D., & Ritter, P. L. (2001). CHAMPS physical activity questionnaire for older adults: outcomes for interventions. *Med Sci Sports Exerc*, 33(7), 1126-1141. <https://doi.org/10.1097/00005768-200107000-00010>
- Strathman, A., Gleicher, F., Boninger, D. S., & Edwards, C. S. (1994). The consideration of future consequences: Weighing immediate and distant outcomes of behavior. *Journal of personality and social psychology*, 66(4), 742.
- Svensson, L. (1997). Theoretical foundations of phenomenography. *Higher education research & development*, 16(2), 159-171.
- Valls-Pedret, C., Sala-Vila, A., Serra-Mir, M., Corella, D., De la Torre, R., Martínez-González, M. Á., . . . Salas-Salvadó, J. (2015). Mediterranean diet and age-related cognitive decline: a randomized clinical trial. *JAMA internal medicine*, 175(7), 1094-1103.

- Apátiga-Pérez, R., Soto-Rojas, L. O., Campa-Córdoba, B. B., Luna-Viramontes, N. I., Cuevas, E., Villanueva-Fierro, I., . . . Luna-Muñoz, J. (2022). Neurovascular dysfunction and vascular amyloid accumulation as early events in Alzheimer's disease. *Metab Brain Dis*, 37(1), 39-50. <https://doi.org/10.1007/s11011-021-00814-4>
- Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*, 13, 117. <https://doi.org/10.1186/1471-2288-13-117>
- Guest, G., MacQueen, K. M., & Namey, E. E. (2011). *Applied thematic analysis*. sage publications.
- Rosen, R. K., Gainey, M., Nasrin, S., Garbern, S. C., Lantini, R., Elshabassi, N., . . . Nelson, E. J. (2023). Use of Framework Matrix and Thematic Coding Methods in Qualitative Analysis for mHealth: The FluidCalc app. *International Journal of Qualitative Methods*, 22, 16094069231184123.
- Tremont, G., Davis, J., Ott, B. R., Uebelacker, L., Kenney, L., Gillette, T., . . . Sanborn, V. (2022). Feasibility of a Yoga Intervention for Individuals with Mild Cognitive Impairment: A Randomized Controlled Trial. *J Integr Complement Med*, 28(3), 250-260. <https://doi.org/10.1089/jicm.2021.0204>
- Yaffe, K., Barnes, D. E., Rosenberg, D., Dublin, S., Kaup, A. R., Ludman, E. J., . . . Larson, E. B. (2019). Systematic Multi-Domain Alzheimer's Risk Reduction Trial (SMARRT): Study Protocol. *J Alzheimers Dis*, 70(s1), S207-S220. <https://doi.org/10.3233/JAD-180634>
- Yaffe, K., Vittinghoff, E., Dublin, S., Peltz, C. B., Fleckenstein, L. E., Rosenberg, D. E., . . .

Larson, E. B. (2024). Effect of Personalized Risk-Reduction Strategies on Cognition and Dementia Risk Profile Among Older Adults: The SMARRT Randomized Clinical Trial. *JAMA Intern Med*, 184(1), 54-62. <https://doi.org/10.1001/jamainternmed.2023.6279>

Zakrzewski, J.J., Gemelli, Z., Davis, J.D., Korthauer, L.E. (in press). Understanding health beliefs and health behaviors in older adults at risk for AD. *Journal of Alzheimer's Disease*.

## Supplementary Files



## Multimedia Appendixes

NIH summary statement.

URL: <http://asset.jmir.pub/assets/60b367fa4022c738b3114f3a41d59264.pdf>