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A nudge-based intervention to promote older persons' dementia prevention: the CULTIVAMENTE campaign

Submission date
21/06/2025

Recruitment status
No longer recruiting

Registration date
25/06/2025

Overall study status
Completed

Last Edited
25/06/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Nudge-based interventions have demonstrated efficacy in real-life clinical settings. Nonetheless, their effects on improving older adults at risk of dementia and healthcare providers' dementia prevention practices have not yet been tested.

Who can participate?
People aged 60 years or older with cognitive impairment but not dementia (at risk of dementia) in seven senior centers in Chile

What does the study involve?
Participants in the control centers (n = 4) received usual care (physical, social, and cognitive group activities led by healthcare providers, two times per week) and healthcare provider training about general aspects of dementia. Participants and healthcare providers in the intervention centers (n = 3) received the same usual care plus a nudge-based intervention encouraging Alzheimer's disease prevention and positive aging through posters, information brochures, and webpages. Main outcomes were a composite patients' dementia prevention behaviors score comprising six lifestyle risk factors, cognition (composite memory–executive functioning score and number of cases with mild-to-moderate cognitive impairment — MOCA <22 pts), and healthcare providers' practices. Intention-to-treat analyses using linear mixed models comparing treatment effects from baseline over follow-up were conducted.

What are the possible benefits and risks of participating?
Benefits include learning more about ways of preventing dementia. The intervention may help participants adopt healthier behaviors and improve cognitive outcomes. To ensure fairness and community benefit, all centers receive the full CULTIVAMENTE materials after the study, regardless of the allocated arm.

This study involved no procedures, medication, or direct behavioral manipulation. Participants were passively exposed to dementia prevention educational materials (e.g., posters, brochures, and a website) in their usual senior center setting. As such, there were no anticipated physical, psychological, or social risks to participants.

Where is the study run from?
Community Day Centers, Santiago, Chile

When is the study starting and how long is it expected to run for?
November 2022 to December 2024

Who is funding the study?
Whitney and Betty MacMillan Center for International and Area Studies, Yale, USA

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

Reducing dementia risk by identifying and promoting social determinants: a multi-site and multi-method study

Acronym
CULTIVAMENTE

Study objectives
We hypothesized that exposing healthcare providers and older adults at risk of dementia to a nudge-based campaign promoting positive aging and AD prevention will improve older adults' and healthcare providers' tendencies to engage in dementia prevention behaviors and dementia prevention practices, respectively.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/11/2022, Yale Human Research Protection Program, Institutional Review Boards (25 Science Park – 3rd Fl., 150 Munson St., New Haven, 06520-8327, United States of America; +1 203-785-4688; HRPP@yale.edu), ref: 2000033516

Study design
Pragmatic cluster-randomized trial with community senior centers

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Outcomes related to dementia risk reduction

Interventions
Once participants from all included centers were assessed for baseline information, senior centers were randomized to control or experimental groups using simple randomization with computer-generated random numbers.

Control group
Participants in the control centers received usual care, which consisted of two two-and-a-half-hour visits per week. Each visit consisted of diverse physical, cognitive, social, and community group activities directed by the centers' healthcare providers, in groups of 10 to 15 people per activity. As part of routine care, healthcare providers provided referrals to other social and

healthcare programs available in the municipality. The healthcare providers received a four-session (90 minutes per session) training on dementia (general aspects, early symptoms, risk factors, diagnosis, and management) led by a geriatrician as part of their usual training.

Experimental group
Participants and healthcare providers in the experimental centers, in addition to usual care and the same healthcare providers' training on dementia, were exposed to an AD prevention awareness campaign called CULTIVAMENTE (translation: cultivate mind), which refers to nurturing minds like plants. The CULTIVAMENTE campaign was designed by drawing on social cognitive theory and the stereotype embodiment theory. The campaign provided educational material/nudges using three different channels: posters, educational material (information brochures), and webpages (see supplementary material). The three formats promoted AD prevention with positively framed aging messages and images portraying active people who look like centers' attendees performing healthy and enjoyable activities for cognitive health.

To adequately reflect the theoretical principles and culturally adjust to the centers' participants' characteristics, the campaign was created following a design thinking approach, starting by conducting focus groups with older adults and healthcare providers in 10 other senior centers (older adults: 5-15 participants per group; healthcare providers: 3-7 participants per group) to understand conceptions about dementia prevention, reviewing existing literature on effective awareness and nudge campaigns, and creating multiple iterations of the campaign during its design based on feedback. The design thinking approach allowed the development of intervention materials that targeted the population characteristics maximizing message receptivity. For example, based on focus group results, 'AD' was selected over 'dementia' because it was found that the former was more related to cognitive health than the word 'dementia'.

After randomization, all the campaign materials (posters, information brochures, and webpages) were made available to healthcare providers in the experimental centers to be used at their convenience. To maintain a minimally invasive intervention and ensure high transferability to real-life clinical practice, there was no training for the use of any campaign material; strategies proposed by the research team were the poster installation and healthcare providers use of webpage material. Posters were located in strategic places of the senior centers' facilities (activity room, lunchroom, healthcare providers' offices, and main hallways). The information brochures for patients described facts about AD prevention and advice on activities (physical activity, diet) for preventing AD. The webpage for all users (www.cultivamente.cl) describes evidence-based recommended activities for AD prevention. Finally, a webpage exclusive to healthcare providers featured six ~40-minute training videos about dementia prevention based on the WHO Guidelines for Risk Reduction of Cognitive Decline and Dementia, and the Lancet Commission 2024 consensus.

Intervention Type
Behavioural

Primary outcome measure
The following primary outcome measures were assessed at baseline and 6 months (23 - 25 weeks) follow-up:
1. Cognitive healthy behaviors were measured with a previously validated composite measure comprised of an average of six z-scores of lifestyle factors related to dementia risk: physical activity, social activity, diet, cardiovascular care, smoking, and alcohol intake
2. Healthcare providers' practices toward dementia prevention was measured using interviews in

which older adult participants were asked if a healthcare provider has talked with them about ways to prevent AD or dementia (Yes, No/I don’t know) and if a healthcare provider have referred them to at least one of six different dementia risk factor management recommendations in the last six months (hypertension, weight or diet, cholesterol, hearing loss, depression, sleeping problems, or memory complaints management)
3. Memory was measured using the Memory Impairment Screen (MIS) scale that measures delayed free- and cued-recall
4. Executive functioning was measured using an alternative trail-making test, visuoconstruction skills (cube and clock drawing tests), verbal fluency (number of words in a minute), and abstraction (word-pairing)
5. The number of cases with mild-to-moderate cognitive impairment measured using the Montreal Cognitive Assessment (MoCA <22 pts)

Secondary outcome measures
Dementia prevention beliefs measured using 10 items, five-point Liker scale (higher score reflecting more positive beliefs), if they knew ways to prevent AD or dementia (Yes, No/I don’t know), and if they had asked a healthcare provider about ways to prevent AD or dementia (Yes, No) at baseline and 6 months (23 - 25 weeks) follow-up

Overall study start date
01/11/2022

Completion date
10/12/2024

Eligibility

Key inclusion criteria
1. 60 years or older
2.Mild dependency in activities of daily living (ADL)
3. Cognitive impairment (Montreal Cognitive Assessment -MoCA-20 score < 26 points or diagnosis of mild cognitive impairment)
4. At least one month of attending the center

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
60 Years

Sex
Both

Target number of participants
180

Total final enrolment

211

Key exclusion criteria
1. Dementia diagnosis
2. Diagnosis of a terminal disease or severe psychiatric disorder
3. Sensory or speech impairment that could limit participation in a survey
4. Willingness to participate in the study

Date of first enrolment
01/04/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Chile

Study participating centre
Centros Diurnos Comunitarios
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Sponsor information

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Funder(s)

Funder type
Research organisation

Funder Name
Whitney and Betty MacMillan Center for International and Area Studies

Alternative Name(s)
Yale MacMillan Center, MacMillan Center for International and Area Studies, Whitney and Betty MacMillan Center for International and Area Studies at Yale, MacMillan Center

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
• The name of the repository: Dropbox (https://www.dropbox.com/scl/fo/7mjtnf90dxsl259041m9q/ABjlZBI71DHtU4VPdnb4MY4?rlkey=ntev7dprvojvsrhvyhd8cg1ta&st=0d1w978f&dl=0)
• The type of data stored: Participants' sociodemographics and outcome information at baseline and follow-up (6 months) in CSV file format.
• Timing for availability: Data will be stored for a minimum of 5 years in accordance with institutional and ethical guidelines.
• Whether consent from participants was required and obtained: Informed consent was obtained from all participants at baseline, prior to the start of the intervention, during in-person visits at the senior center facilities. Participants were informed about the study objectives, the voluntary nature of participation, data confidentiality, and their right to withdraw at any time.
• Comments on data anonymization: After participants provided informed consent to participate in the study, a unique random ID was generated for each individual at the beginning of the survey. This ID was used to store and manage all study-related data. No personal identifiers such as full name, address, or other information that could allow participant identification were

collected or stored alongside the data. This ensured that all information remained anonymized and confidential throughout the study.
• Any ethical or legal restrictions: There are no ethical or legal restrictions. The study was approved by the Yale University IRB and conducted in accordance with ethical guidelines for minimal-risk behavioral research.
• Any additional comments: No additional comments

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		16/10/2023	25/06/2025	No	No