ISRCTN13063260 https://doi.org/10.1186/ISRCTN13063260

Yoga-based mindfulness intervention for older adults with mild cognitive impairment

Submission date
26/04/2022

Recruitment status
No longer recruiting

Registration date
28/04/2022

Overall study status
Completed

Last Edited
17/04/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Research shows that mindfulness and yoga have been associated with a range of positive outcomes in older adults with mild cognitive impairment (MCI). This study aims to compare the effectiveness of a yoga-based mindfulness (YBM) intervention versus psycho-educational sessions (PES) in improving cognitive and physical functions and mental health outcomes for older adults with mild cognitive impairment (MCI). Mild cognitive impairment (MCI) is a condition in which someone has minor problems with cognition - their mental abilities such as memory or thinking.

Who can participate?
People aged 60 years and over with any type of MCI who attend Hospital Clinic, Universidad de Chile, Santiago

What does the study involve?
Participants will be randomly assigned to either the intervention or control group. Participants in the intervention group will receive a yoga-based mindfulness intervention (YBM) for an hour once weekly for a total of 8 weeks, The YBM intervention is implemented through videos that have been recorded according to the following exercises in each session. Mindful chair-based Hatha yoga will be used with an emphasis on proper Hatha yoga physical exercise or body awareness exercises. The program will include both formal and informal mindfulness practices consisting of techniques such as body scan, breath meditations and loving-kindness meditation as well as mental exercises and being mindful of daily interactions and activities of daily life functioning, and emotional management. Participants will be assessed before the intervention, the week following the last session of the intervention, and 3 and 6 months after the intervention is finished. Participants in the control group will receive a psychoeducational session through a text that will be delivered to them by WhatsApp.

What are the possible benefits and risks of participating?
The program is designed to improve cognitive function and functionality, decrease symptoms of depression and anxiety and promote wellbeing, which could have a positive effect on participants' mental health. There are no known risks of participating in this study.

Where is the study run from?
Universidad de Chile Clinical Hospital (Chile)

When is the study starting and how long is it expected to run for?
March 2019 to January 2024

Who is funding the study?
FONDECYT Comisión Nacional de Ciencia y Tecnología (Chile)

Who is the main contact?
Maryam Farhang
mfarhang@hcuch.cl

Contact information

Type(s)
Principal Investigator

Contact name
Dr Maryam Farhang

ORCID ID
https://orcid.org/0000-0001-6345-6329

Contact details
Facultad de Salud y Ciencias Sociales, Universidad de Las Americas (UDLA)
Manuel Montt N° 948, Providencia
Santiago de Chile
Santiago
Chile
7500000
+56 (0)987736931
mfarhang@udla.cl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FONDECYT 3190275

Study information

Scientific Title

The impact of a yoga-based mindfulness intervention versus psycho-educational session for older adults with mild cognitive impairment: a randomized control trial

Study objectives

H1. Older adults with mild cognitive impairment (MCI) in the yoga-based mindfulness (YBM) intervention will have a different change in their cognitive function – as measured through Moca assessment, before and after the intervention – than those in the PES intervention (with the same measures before and after).

H1.1. Older adults with MCI in the YBM intervention will have a different change in their physical function – as measured through the Barthel Index (BI) and The Lawton Instrumental Activities of Daily Living Scale (IADL), before and after the intervention – than those in the PES intervention (with the same measures before and after).

H1.2. Older adults with MCI in the YBM intervention will have a different change in their well-being – as measured through the Pemberton happiness index, before and after the intervention – than those in the PES intervention (with the same measures before and after).

H1.3. Older adults with MCI in the YBM intervention will have a will have lower anxiety and depression levels – as measured through the Geriatric Anxiety Inventory (GAI) and the Geriatric Depression Scale (GDS-5), before and after the intervention – than those in the PES intervention (with the same measures before and after).

H2. Cognitive function will have an effect on physical function in older people with MCI, mediated by psychological factors (depression, anxiety and well-being).

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 05/06/2019 and 01/04/2020, Ethical Committee of the Hospital Clínico, Universidad de Chile (Dra. Teresa Massardo Vega
Presidenta del Comité Ético Científico, Hospital Clínico de la Universidad de Chile, Santos Dumont 999, Independencia – RM, Santiago, Chile, 8380000; +56 (0)229789008; comiteetica@hcuch.cl), ref: ACTA DE APROBACION N0 029 and ACTA DE APROBACION N0 022
2. Approved 26/07/2021, Ethical Committee of the Universidad de Las Américas (Presidenta Comité Ético-Científico, Universidad de Las Américas; Avenida Manuel Montt N°948, Edificio E, piso 3, Providencia, 7500000, Santiago, Chile; +56 (0)2 2253 1517; mrobledano@udla.cl), ref: CEC_FE_2021009

Study design

Two-arm individually randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cognitive and physical functions and mental health outcomes of older adults with mild cognitive impairment (MCI)

Interventions
Participants within the outpatient clinic at Clinical Hospital-Universidad de Chile will be allocated to the intervention or the comparator with a 1:1 ratio based on random computer-generated numbers, using simple random sampling. Participants assigned to the experimental group will receive the Yoga-based mindfulness intervention (YBM) for 1 hour once weekly for a total of 8 weeks. The YBM intervention will be based on video (that has been recorded by facilitators who have knowledge about yoga and mindfulness and who will be blinded to the identifiable data) according to the following characteristics. Information about yoga and mindfulness will be delivered to seniors through specific exercises in each session. Mindful chair-based Hatha yoga will be used with an emphasis on proper Hatha yoga physical exercise or body awareness exercises (Patel, Newstead, Ferrer, 2012) and mindfulness. If participants find themselves unable to do a particular posture, they should be free to skip it and engage with their body with the attitude of kindness and acceptance, and after the completion of each posture the participants will be asked to be aware of which groups of muscles will be contracting, stretching and will be used to keep their body steady and balanced. The mindfulness component will be based on the MBSR guideline developed by Kabat-Zinn (1990) which has been adapted from the mindfulness protocol developed by Wong (2016) for older people with MCI. The program will include both formal and informal mindfulness practices. Participants will be encouraged to practice formal mindfulness meditation techniques by using techniques such as body scan, breath meditations and loving-kindness meditation to observe and maintain attention on an object of meditation without judgment and reactivity even when one becomes distracted by drifting thoughts or uncomfortable emotions. Informal mindfulness practice involves extending such attentiveness and awareness to engaging daily experiences such as mindful walking and eating. The informal practice will also include mental exercises such as reading, puzzles and language as well as being mindful of daily interactions and other ADLs. The control group will receive a passive psycho-education with general information about wellness, self-care in health and promotion of exercise that will be delivered via text through the WhatsApp application each week.

Intervention Type
Other

Primary outcome measure
Cognitive function assessed using a Spanish version of Montreal Cognitive Assessment (MoCAS1- 2) via live video call at baseline and post-intervention, 3 and 6 months follow up.

Secondary outcome measures
Assessed using the telephone-based survey before random assignment (pre-test), the week following the last session of the intervention (post-test), and then at 3- and 6-months follow-up:
1. Physical function assessed using:
1.1. The Barthel Index (BI) to measure performance in activities of daily living (ADL)

1.2. The Lawton Instrumental Activities of Daily Living Scale (IADL) to assess the independent living skills of an individual and measures functional ability as well as declines and improvements over time
2. Psychological well-being assessed using the Pemberton happiness index
3. Anxiety assessed using the Geriatric Anxiety Inventory (GAI)
4. Depression assessed using the Geriatric Depression Scale (GDS-5)

Overall study start date
15/03/2019

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. Aged 60 years and above
2. People who have MCI diagnosed by three criteria:
2.1. By a neurologist and/or psychiatrist, and/or geriatrician, and/or the neuropsychologist. through evaluation by saying that they had memory problems confirmed by an informant (in case if they have a formal or informal caregiver or simply, their partner), (but without problems in their activities of daily living)
2.2. Score < 21 at the Montreal Cognitive Assessment (MoCA <21)
2.3. Without dementia according to the criteria of the Clinical Dementia Rating Scale (CDR) a score of 0.5

Participant type(s)
Patient

Age group
Senior

Lower age limit
60 Years

Sex
Both

Target number of participants
44

Total final enrolment
38

Key exclusion criteria
1. People who did yoga and/or mindfulness within the last 6 months
2. The presence of a psychiatric clinical diagnosis; or neurological/cerebrovascular condition.
3. Presence of a disabling physical illness or/and presence of a disability that limits and/or

impede communication such as major impairments in eyesight, and/or hearing or upper limb motor movements; and/or other health problem that would interfere with regular yoga and mindfulness practice

Date of first enrolment
13/09/2021

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Chile

Study participating centre
Hospital clinico Universidad de Chile
Av Santos Dumont 999, Independencia, Región Metropolitana
Santiago
Chile
60.910.000-1

Sponsor information

Organisation
Universidad de las Américas

Sponsor details
Manuel Montt N° 948, Providencia
Santiago de Chile
Santiago
Chile
7500000
+56 (0)22531000 [6376]
hcanon@udla.cl

Sponsor type
University/education

Website
https://www.udlacdmx.mx/

ROR
https://ror.org/02j003371

Organisation
Hospital Clínico de la Universidad de Chile

Sponsor details
Av Santos Dumont 999, Independencia, Región Metropolitana
Legal Representative of Hospital Clinico Universidad de Chile:
Dra. María Graciela Rojas Castillo
Santiago
Chile
8380000
+56 (0)229788517
mgrojas@hcuch.cl

Sponsor type
Hospital/treatment centre

Website
http://www.redclinica.cl/

ROR
https://ror.org/02xtpdq88

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

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

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are/will be available upon request from Maryam Farhang (mfarhang@hcuch.cl). The database will be available in Stata database format. The data will be available after the study is completed. Data will be available only for private reanalyses. There will be no way to identify the participants of the program from the data used

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/11/2022	28/11/2022	Yes	No