ISRCTN32235611 https://doi.org/10.1186/ISRCTN32235611

Assessment of a psychosocial intervention to prevent depression and anxiety in elderly people who attend primary health care centers

Submission date
07/07/2018

Recruitment status
No longer recruiting

Registration date
25/07/2018

Overall study status
Completed

Last Edited
11/08/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
An effective way of decreasing depression and anxiety and promoting wellbeing in the elderly is using psychosocial interventions. However, there has been no evidence of this in Latin America. This study aims to assess a program in Chile that has been specifically designed to decrease symptoms of depression and anxiety and promote psychological wellbeing in self-reliant, elderly people who attend primary health care centres.

Who can participate?
Self-reliant 65-80 year olds who attend primary health care centres

What does the study involve?
Participants will be randomly assigned to either the intervention or control group.
Participants in the intervention group will take part in a 12 week program, consisting of 9 weekly 2 hour sessions, 2 phone calls and a week with no activities (week 11). Activities relate to the care of physical and mental health, including cognitive training, expansion of social support networks and behavioural strategies for the management and prevention of depression and anxiety symptoms. There will be training in relaxation, encouragement to develop activities that help participants to feel better and analysis of worries and loss experiences. Participants will be assessed before the intervention, and 18 and 36 weeks after the intervention on symptoms related to depression and anxiety, and psychological wellbeing.
Participants in the control group will receive passive education through a leaflet, and will receive the 12 week intervention program once the intervention group complete this program and their post-intervention activities.

What are the possible benefits and risks of participating?
The possible benefit of participating in this study is that the program is designed to 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?
The study will be run in 15 primary care centers in the province of Concepcion, Chile.

When is the study starting and how long is it expected to run for?
March 2017 to December 2019

Who is funding the study? (who will be paying the costs that the trial will incur during its lifecycle?)
FONDECYT Comisión Nacional de Ciencia y Tecnología (Chile)

Who is the main contact?
Sandra Saldivia
saldivi@udec.cl

Contact information

Type(s)
Public

Contact name
Mrs Sandra Saldivia

ORCID ID
https://orcid.org/0000-0002-7594-7069

Contact details
Facultad de Medicina, Dpto. de Psiquiatría, Universidad de Concepcion
Concepción
Chile
4030000
56-41-2204299
ssaldivi@udec.cl

Additional identifiers

Protocol serial number
FONDECYT 1171732

Study information

Scientific Title
Assessment of a psychosocial intervention to prevent depression and anxiety in elderly people who attend primary health care centers: A clinical randomized trial

Acronym
Vida Activa

Study objectives
In elderly people who attend primary health care centers and with no current mental health disorder, a brief group psychosocial intervention decreases depressive and anxious

symptomatology and increases subjective well-being, indicating promotional effects and possible preventive effects in regards to the development of depressive and anxious disorders and improve psychological well-being.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Ethics Committee of Health Services of Concepcion (Resolution from 04/03/2018, code CEC 17-09-53) and Talcahuano (Assessment Act 66 from 07/04/2017)., Chile.

Study design
Interventional multi-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Depression and anxiety

Interventions
Those who accept the invitation to participate in the study will receive the initial assessment and those who meet participant exclusion criteria will be identified. The initial assessment includes socio-demographics, mental health (depression and anxiety symptoms and depression and anxiety diagnosis according to DSM-IV criteria, and alcohol use) and subjective wellbeing. This will be carried out at the participants' homes by trained interviewers.
From this, those who meet the inclusion criteria will be used to generate the final list of participants, which will then be subject to block randomization by an external statistician with no connection to the participant assessment process. Each health care center in the study will be a block.
The intervention program is a twelve-week group program, consisting of two hour sessions once per week. The program includes activities that care for physical and mental health, including cognitive training, social support network and cognitive behavioural strategies that have been shown to be effective for therapeutic and preventative management of depression and anxiety symptoms. Specifically, these include training in relaxation, behavioral action, along with cognitive analysis and re-evaluation related to topics of worry and loss. The program is carried out by a psychologist and trained health worker, both of whom receive previous training and must pass a competence test. They will be both personally and distance-supervised on a weekly basis.
The control group will receive passive psycho-education using a leaflet.

Intervention Type
Behavioural

Primary outcome(s)
Depressive symptomatology will be assessed using the Patient Health Questionnaire (PHQ-9) (Baader et al., 2012; Kroenke, Spitzer, & Williams, 2001) before the intervention (pretest 3-4

weeks prior to the intervention), 18 weeks after the intervention (first post test) and 36 weeks after the intervention (second post test).

Key secondary outcome(s))
The following will be assessed before the intervention (pretest 3-4 weeks prior to the intervention), 18 weeks after the intervention (first post test) and 36 weeks after the intervention (second post test):
1. Anxiety symptomatology will be assessed with the anxiety subscale of the Symptom Check List (SCL-90-R) (Derogatis & Cleary, 1977; Gempp & Avendaño, 2008)
2. Depressive disorder will be assessed using Module E of the Composite International Diagnostic Interview (CIDI 2.1) (WHO, 1997)
3. Anxiety disorder (panic disorder and generalized anxiety disorder) will be assessed using the anxious disorders section of the Mini-International Neuropsychiatry Interview (MINI) (Sheehan, Lecrubier, Sheehan, Amorim, Janavs et al., 1999, Ferrando, Franco- Alfonso, Soto, Bobes García, Soto et al., 2000).
4. Psychological wellbeing will be assessed using the Pemberton Happiness Index (Hervás & Vázquez, 2013)

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. Aged 65-80 years
2. Self-reliant
3. Health center user

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
538

Key exclusion criteria
1. Diagnosis of common psychiatric disorder (e.g. depressive or anxiety disorder)
2. Diagnosis of severe mental disorder
3. Physical disability
4. Disability that limits and/or prevents communication

Date of first enrolment

01/08/2018

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Chile

Study participating centre
Centro de Salud Familiar San Vicente
Brasil 360, Talcahuano
Talcahuano
Chile
4260000

Study participating centre
Centro de Salud Familiar Leocán Portus
Manuel Barros Borgoña 2645, Las Salinas. Talcahuano
Talcahuano
Chile
4260000

Study participating centre
Centro de Salud Familiar Los Cerros
El Galgo S/N, Lobos Viejos. Thno.
Talcahuano
Chile
4260000

Study participating centre
Centro de Salud Familiar Paulina Avendaño
Carlos Dittborn 4100, Talcahuano
Talcahuano
Chile
4260000

Study participating centre
Centro de Salud Familiar Talcahuano Sur
Postdam 632, Hualpén

Hualpen
Chile
4600000

Study participating centre
Centro de Salud Familiar Hualpencillo
Bulgaria 2845, Hualpén
Hualpen
Chile
4600000

Study participating centre
Centro de Salud Familiar La Floresta
Bremen 3851, Pob. España, Hualpén
Hualpen
Chile
4600000

Study participating centre
Centro de Salud Familiar La Leonera
Manuel Rodriguez S/N, Chiguayante
Chiguayante
Chile
4100000

Study participating centre
Centro de Salud Familiar Chiguayante
Chiguay esquina La Marina, Chiguayante
Chiguayante
Chile
4100000

Study participating centre
Centro de Salud Familiar Pinares
La Marina 1295, Chiguayante
Chiguayante
Chile
4100000

Study participating centre
Centro de Salud Familiar Juan Soto Fernández (ex Costanera)
Avda. Zañartu 850 Pob. Pedro del Río Zañartu
Concepción
Chile
4030000

Study participating centre
Centro de Salud Familiar Lorenzo Arenas
Carlos Oliver Nº 50, Lorenzo Arenas, Concepción
Concepción
Chile
4030000

Study participating centre
Centro de Salud Familiar O'Higgins
Salas 538
Concepción
Chile
4030000

Study participating centre
Centro de Salud Familiar Santa Sabina
Pedro Mariño 1948 Barrio Norte
Concepción
Chile
4030000

Study participating centre
Centro de Salud Familiar Tucapel
Juan de Dios Rivera 1060
Concepción
Chile
4030000

Sponsor information

Organisation
University of Concepcion

ROR
https://ror.org/0460jpj73

Funder(s)

Funder type
Not defined

Funder Name
Consejo Nacional de Ciencia y Tecnología Chile FONDECYT 1171732

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated and/or analysed during the current study are/will be available upon request from Sandra Saldivia (ssaldivi@udec.cl). The raw data will be available in SPSS database format. Processed data will be available in R. The data will be available after the study is completed in December 2019. Data will be available only for private reanalyses to be used in an interested research and for two months. 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?
Results article	Examining the profiles of mental health symptoms and well-being at baseline	28/04/2025	11/08/2025	Yes	No
Protocol article	protocol	29/08/2019	30/08/2019	Yes	No
Basic results		10/08/2020	21/08/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes