

Group psychoeducational intervention program for family caregivers of people with dementia: a pilot randomized control trial in Chile

Submission date 22/09/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/04/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

It is widely documented that family caregivers experience a negative physical and psychosocial impact resulting from long-term care of a person with dementia, becoming potential social and health systems users. In Chile, it has been found that family caregivers present depressive, anxious symptoms, and intense burden. Worldwide, during the past 15 years, several psychoeducational interventions for family caregivers of people with dementia have been developed. Within the evidence-based interventions, the program "Cuidar Cuidándose" (Taking care of yourself for caring), developed in Spain, has been shown to be effective at reducing levels of depressive symptoms and dysfunctional thoughts about caregiving, as well as increasing pleasurable activities, by modifying caregiver's appraisal of people with dementia's behavioral and psychological symptoms. Considering this evidence, the main aim of this study is to evaluate the implementation and effectiveness of the psychoeducational program "Cuidar Cuidándose" in a group of Chilean family caregivers of patients with dementia.

Who can participate?

Relatives of people with dementia who directly care for the person with dementia at least three times a week, are not receiving financial compensation associated with caring, and do not have a physical or psychiatric disorder that prevents them from either attending the program sessions or answering the assessment questionnaires.

What does the study involve?

Participants randomly assigned to the intervention group take part in eight sessions of the "Cuidar Cuidándose" program carried out once a week plus one initial session about education on dementia. Each session lasts 1.5 to 2 hours. The rest of the participants have care as usual (mostly meaning no intervention).

What are the possible benefits and risks of participating?

Those who were part of the intervention group receive an evidence-based intervention (psychoeducational program) and established support networks for the future. Those assigned to the control group, after the follow-up assessment, receive a half-day workshop with the main

contents of the psychoeducational program. There is no potential risk in the study, however, some of the topics in the sessions could have been difficult for some participants. This situation was handled by the trained clinical psychologists who lead the intervention.

Where is the study run from?

Cities of Metropolitan and Valparaiso Regions (Chile)

When is the study starting and how long is it expected to run for?

October 2013 to October 2018

Who is funding the study?

National Agency for Research and Development (Chile)

Who is the main contact?

Dr Claudia Miranda-Castillo

claudia.miranda@micare.cl

Contact information

Type(s)

Scientific

Contact name

Dr Claudia Miranda-Castillo

ORCID ID

<https://orcid.org/0000-0002-0282-5845>

Contact details

República 217

Santiago

Chile

8320000

+56 (0)9 8768 7793

claudia.miranda@micare.cl

Type(s)

Public

Contact name

Ms Tamara Tapia Munoz

ORCID ID

<https://orcid.org/0000-0001-9248-1056>

Contact details

55W 125th St

New York

United States of America

10027
+56 (0)13473580764
thamara.tapia@sph.cuny.edu

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

FONDECYT 1141279- CHILE

Study information

Scientific Title

Implementation and evaluation of the effectiveness of an evidence-based psychoeducational program in a group of family caregivers of people with dementia

Study objectives

The results are expected to confirm one or more of the following hypotheses:

1. Family caregivers who receive the intervention will present a lower average of dysfunctional thoughts associated with caregiving compared to the control group.
2. Family caregivers who receive the intervention will present higher frequency of pleasant activities compared to the control group.
3. Family caregivers who receive the intervention will present a better quality of life compared to the control group.
4. Family caregivers who receive the intervention will present less depressive symptoms compared to the control group.
5. Family caregivers who receive the intervention will present fewer anxiety symptoms compared to the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Original: Approved 10/10/2013, University of Valparaíso Faculty of Medicine Bioethical Committee for Research (Hontaneda 2653, Valparaíso, Chile +56 (0)32 2507370; eticafacultadmedicina@uv.cl), ref: N°17/2013
2. Follow-up: Approved 25/10/2017, Pontificia Universidad Católica de Chile, Social Sciences Arts and Humanities Ethical Committee (Alameda 340, 4th Floor, Santiago, Chile +56 (0)2 23541047; eticadeinvestigacion@uc.cl) ref: FONDECYT 1141279

Study design

Multicenter pilot interventional evaluator-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Mental health and quality of life of family caregivers of people with dementia

Interventions

The participants are community-dwelling family caregivers of people with dementia. They are contacted through neurologist practices, poster advertisements, day centers, and primary care services in Santiago and Valparaíso. After the participant agrees to participate they are randomly allocated through software. The randomization is carried by a team member with no access to participants' identification or the measurement documents or dataset. Evaluators are blinded to the group allocation.

The intervention is the psycho-educational program "Cuidar Cuidándose" (Caring taking care of yourself). The program has shown to be effective in reducing levels of depressive symptoms and dysfunctional thoughts about caregiving, as well as increasing pleasurable activities and modifying the caregiver's appreciation of the problematic behaviors of the person with dementia (Márquez-González, Losada, Izal, Pérez-Rojo & Montorio, 2007; Losada, Márquez-González & Romero-Moreno, 2011). This program is part of evidence-based interventions for family caregivers of people with dementia previously mentioned in systematic reviews in the area (Gallagher-Thompson et al, 2012; Olazarán et al, 2010). The program consists of eight sessions, once a week. Each session lasts for approximately 1.5 hours to 2 hours and includes a maximum of eight caregivers. Each group session is led by a trained psychologist with knowledge of the cognitive-behavioral model.

The control group receives treatment as usual.

Intervention Type

Behavioural

Primary outcome measure

All primary outcomes were assessed at baseline and at the end of the intervention:

1. Dysfunctional thoughts about caregiving measured using the Dysfunctional Thoughts Questionnaire
2. Frequency of pleasant activities measured using the Questionnaire of Satisfaction with Free time
3. Quality of life measured using the EuroQoL- 5 Dimensions (EQ-5D)

Secondary outcome measures

All secondary outcomes were assessed at baseline and at the end of the intervention:

For the family caregiver:

1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale
2. Level of burden experienced by family caregivers measured using the Caregiver Burden Scale

For the person with dementia:

1. Severity of dementia measured using the Clinical Dementia Rating (CDR)
2. Quality of life measured using the Quality of Life Scale in Alzheimer's Disease (QoL-AD)
3. Functionality measured using the Technology-Activities of Daily Living Questionnaire (T-ADLQ)
4. Behavioural and psychological symptoms measured using the Neuropsychiatric Inventory (NPI-Q)

Overall study start date

10/10/2013

Completion date

02/10/2018

Eligibility

Key inclusion criteria

1. Being a relative of the person with dementia
2. Directly caring for the person with dementia at least three times a week
3. Not receiving financial compensation associated with care

Participant type(s)

Carer

Age group

Adult

Sex

Both

Target number of participants

156

Total final enrolment

73

Key exclusion criteria

Caregivers with a severe physical or psychiatric problem that might prevent them from attending the sessions of the psychoeducational program and/or responding to the battery of instruments

Date of first enrolment

27/07/2015

Date of final enrolment

16/02/2018

Locations

Countries of recruitment

Chile

Study participating centre**Chilean Alzheimer Corporation**

Desiderio Lemus 0143, Recoleta

Santiago

Chile

8420000

Study participating centre**Andrea Slachevsky - Neurologist private practice**

Av. Vitacura, 5951

Santiago

Chile

7630000

Study participating centre**MIDAP- Chile**

Avda. Vicuña Mackenna 4860, Macul

Santiago

Chile

7810000

Study participating centre**Centro de Salud Familiar Nueva Aurora (primary care center)**

Variante Agua Santa P/ 5, Nueva Aurora

Viña del Mar

Chile

2520000

Study participating centre**University of Valparaiso**

School of Psychology

Hontaneda 2653

Valparaiso

Chile
2340000

Sponsor information

Organisation

National Agency for Research and Development

Sponsor details

Moneda 1375
Santiago
Chile
8320000
+56 (0)2 2365 4486
rcarvajal@anid.cl

Sponsor type

Government

Website

<https://www.conicyt.cl/fondecyt/>

ROR

<https://ror.org/02ap3w078>

Organisation

Millennium Institute for Research in Depression and Personality

Sponsor details

Vicuña Mackenna 4860
Santiago
Chile
7820436
+56 (0)2 23542438
susana.maldonado@midap.org

Sponsor type

Research organisation

Website

<http://midap.org/?lang=en>

ROR

<https://ror.org/012pnb193>

Funder(s)

Funder type

Government

Funder Name

Agencia Nacional de Investigación y Desarrollo

Alternative Name(s)

Agencia Nacional de Investigación y Desarrollo de Chile, National Agency for Research and Development, Government of Chile, Chilean National Agency for Research and Development, ANID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Chile

Results and Publications

Publication and dissemination plan

A report with the main findings will be submitted to a Q1 or Q2 journal.

Intention to publish date

01/09/2022

Individual participant data (IPD) sharing plan

The anonymized dataset generated during and/or analyzed during the current study are/will be available upon request from Dr Claudia Miranda (claudia.miranda@unab.cl; clmirandac@gmail.com). The data will be provided in a dataset with Stata format (.DTA). The data was recorded in cross-sectional disposition (wide) with baseline and follow-up in separate columns. The data will become available after the main publication, for 2 years, via email, by formal request to the principal investigator. It will require the principal investigator to be involved in monitoring analyses and manuscripts resulting from these data. Informed consent was obtained for each one of the participants and it stated that the principal investigator could use the data for research purposes with no identification of the participants. The data contain sociodemographic characteristics of the caregivers, type and time since their relatives' diagnosis, as well as baseline and follow-up data of the principal and secondary variables.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			22/04/2022	No	No