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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/09/2020		[X] Protocol		
Registration date	Overall study status Completed Condition category Mental and Behavioural Disorders	Statistical analysis plan		
08/05/2022		☐ Results		
Last Edited		Individual participant data		
22/04/2022		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 Cuidandose" 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

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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 Valparaiso. 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(s)

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)

Key secondary outcome(s))

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

ΔII

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

ROR

Organisation

Millennium Institute for Research in Depression and Personality

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, Agencia Nacional de Investigación y Desarrollo de Chile (ANID), ANID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Chile

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			22/04/2022	No	No