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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

Registration date
08/05/2022

Overall study status
Completed

Last Edited
22/04/2022

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
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
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
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
All

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
https://ror.org/02ap3w078

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?

Protocol file	22/04/2022	No	No