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Learning to feel better and help better: a psycho-educative group program for informal caregivers of people with dementia living at home

Submission date
10/03/2021

Recruitment status
No longer recruiting

Registration date
17/05/2021

Overall study status
Completed

Last Edited
30/09/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The number of people with dementia is rising. Dementia limits the autonomy of the persons affected and their ability to manage their daily life. This means that people affected by dementia need help from other persons. This support is mainly given by informal caregivers, such as spouses or adult children. Caring for a person with dementia can be a challenging experience. Informal caregivers often feel unprepared and have no experience in performing care. They need to handle challenging symptoms of the person with dementia and an unpredictable course of the disease as well as provide continuous care. This can lead to chronic stress and a heavy burden, which can in turn lead to physical, psychological, emotional, social and financial problems for the informal caregivers. Poor health of the informal caregivers affects their ability to provide care and can lead them to institutionalize the person with dementia earlier than they would have wished. Therefore, informal caregivers of a person with dementia need support to manage and maintain the caring situation at home and to reduce the negative consequences for the person with dementia and themselves.
Studies show that psycho-educative interventions in which participants learn adequate coping strategies demonstrate the most promising results in improving the quality of life of informal caregivers. The program “Learning to feel better and help better” is such a psycho-educative intervention. The goal of the program is to support informal caregivers to better manage the daily stress of dementia caregiving. In the program, the caregivers learn to use and improve appropriate coping strategies as well as how to communicate effectively with a person with dementia and how to manage the difficult behaviours of the person affected.
The aim of this study is to evaluate the “Learning to feel better and help better” program. The study evaluates if the program is feasible and acceptable for informal caregivers and if it has a positive impact on their quality of life.

Who can participate?
Adults 18 years of age or older who regularly provide unpaid care and/or supervision to a close person with dementia or having substantial cognitive deficits and living in the community.

What does the study involve?
Participants are invited to join the study when they register to participate in the “Learning to feel better and help better” program. In the program the participants attend six weekly sessions and a follow-up session about 1 month after session 6. All participants willing to participate in the study have two (first and second phase of the trial) or three (third phase) interviews. The first interview is within 3 weeks before the start of the program. The second interview (only conducted in the third phase of the trial) is during the program (after week 5) and the third interview within 3 weeks after the end of the program. In all phases of the trial, participants are asked to fill in questionnaires about burden, psychological distress, self-efficacy, memory and behavioural problems of the person with dementia and the associated distress of the caregivers, during the interviews conducted before and after the intervention. In addition, in the third phase of the trial, participants are asked to answer open-ended questions about their relationship with the person with dementia at all three interview timepoints before, during and after the intervention. In the interview after the end of the program, in all phases of the trial, participants are also asked to evaluate the program with a questionnaire and open-ended questions.

What are the possible benefits and risks of participating?
The currently available scientific evidence suggests that this programme can help informal dementia caregivers to cope better with stressful daily life situations related to dementia caregiving and thereby help them maintain their caregiver role. Participation in the program provides informal dementia caregivers with the opportunity to share experiences with other caregivers in similar situations and to learn from each other. The program also provides information regarding dementia and strategies on how to manage the daily stress of dementia caregiving. Through their participation in the study, informal dementia caregivers help researchers to further improve and adapt the program to their needs.
Interview questions or listening to the experiences of other participants can provoke unpleasant emotions in the participants. Participants also need to invest time for the interviews before, during and after the intervention as well as for the participation in the seven intervention sessions. In addition, participants need to travel to the intervention site and eventually organise the care for the person with dementia during the intervention time.

Where is the study run from?
University of Applied Science and Arts Western Switzerland (Switzerland)

When is the study starting and how long is it expected to run for?
February 2014 to December 2024

Who is funding the study?
1. Leenaards Foundation (Switzerland)
2. Health Promotion Switzerland (Promotion Santé Suisse) (Switzerland)
3. The canton of Fribourg, Switzerland (Switzerland)
4. University of Applied Science and Arts Western Switzerland (Switzerland)

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Contact information

Type(s)

Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Protocol n°175/14

Study information

Scientific Title
Feasibility and effects of a psycho-educative group intervention for informal caregivers of people with dementia living at home: a pilot study

Study objectives
The aim of the study is to examine within a one group pre- and post-test design 1) the feasibility of implementing the program in two regions of French-speaking Switzerland, and 2) the effects of the program (see hypotheses below).

Regarding 1), the researchers will firstly collect quantitative evidence about feasibility (dropout and participation rates, acceptability of the diverse components of the intervention, participants' use of the trained strategies in daily life). They secondly collect qualitative evidence about the acceptability of the intervention from the point of view of informal dementia caregivers. They thirdly collect qualitative information about the experience of recruiters regarding barriers and facilitators for participation in the intervention.

Regarding 2), the researchers firstly test the hypotheses that five core outcomes will improve: they expect a decrease in a) the frequency of the memory and behavioural problems (MBP) of the person with dementia and b) the intensity of caregivers' MBP-related distress, as well as in c) the informal dementia caregivers' subjective burden and d) their psychological distress; they also expect an increase of e) the informal dementia caregivers' self-efficacy. The researchers secondly collect qualitative evidence about the impact of the intervention as perceived by the

informal dementia caregivers. They thirdly explore with a qualitative approach the changes in the quality of the relationship between the informal caregiver and the person with dementia during and after the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/08/2014 (original protocol) and 12/08/2020 (revised protocol), Ethics Review Board of the Canton of Vaud for Human Research (Commission cantonal d'éthique de la recherche sur l'être humain; Av. de Chailly 23, CH-1012 Lausanne; +41 (0)21 316 1836; scientifique.cer@vd.ch), ref: PB_2020-00064 (Protocol 175/14)

Study design
Multicentre interventional mixed-methods concurrent pre- and post-test trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Informal caregiving in the context of dementia

Interventions
All participants will participate in the program (non-randomised study). The program was originally developed by Louise Levesque, Francine Ducharme and their team in the 2000s based on the Lazarus and Folkman transactional theory of stress and coping. The program called “learning to feel better and help better” aims at improving the ability of informal dementia caregivers to cope with the stressful demands of caring for a person with dementia living at home. The content of the program focuses on 1) the appraisal of stressful situations, and 2) the coping strategies. Regarding appraisal, participants learn to break down a global situation into specific ones, identify more precisely what is stressful, and distinguish between situations or aspects of it which can be modified and those which cannot. Regarding coping strategies, participants are trained to choose an appropriate strategy depending on whether the situation can be modified or not, use problem solving for modifiable situations (seven-step procedure), use reframing for unmodifiable situations (look at things from another angle to reduce painful emotions), and seek for social support (identify precise support needs and best persons to address each of them). In addition, information is provided on how dementia may affect the communication and relational behaviour of the affected person, and how informal dementia caregivers may improve their communication skills and prevent tensions. The program uses a combination of 1) information provision, 2) group discussions, 3) work on personal stressful situations, and 4) exercises at home. In the first phase of the trial (feasibility study) the researchers applied the original program consisting of 15 weekly sessions of 2 hours each. In the second and third phase of the trial it was reduced to 6 weekly sessions of 3 hours each and a seventh follow up session (also 3 hours) 1 month after session 6, in order to facilitate participation. The intervention is designed for a group of 7 to 10 participants and led by specifically trained health professionals such as psychologists and nurses. In the first and second phases of the trial, five quantitative outcomes are assessed before and after participation in the intervention, and qualitative information about acceptability and impact is collected after

participation, within a face-to-face interview conducted by a person uninvolved in the intervention. In the third phase of the trial, additional information about relationship quality is collected before and after the intervention, as well as after session 5.

Intervention Type
Behavioural

Primary outcome(s)
Participant-reported outcomes:
1. Caregiver burden is measured using the Zarit Burden Interview within 3 weeks before the intervention starts and within 3 weeks after the intervention (pre- and post-intervention). The Zarit Burden Interview is a 22-items questionnaire. Responses are provided on a scale from 0 (never) to 4 (very often).
2. Memory and behavioral problems (MBP) and caregiver's MBP-related distress measured using the Revised MBP Checklist within 3 weeks before the intervention starts and within 3 weeks after the intervention (pre- and post-intervention). The Revised MBP Checklist questionnaire measures the frequency of 24 MBP in the preceding week between 0 (never) and 4 (daily), and the extent to which this problem disturbed or upset the informal dementia caregivers between 0 (not at all) and 4 (extremely).
3. Caregiver psychological distress is measured using the short version of the Ilfeld Psychiatric Symptoms Index within 3 weeks before the intervention starts and within 3 weeks after the intervention (pre- and post-intervention). The Ilfeld Psychiatric Symptoms Index asks participants to rate 14 symptoms related to depression, anxiety, anger and cognitive disturbance, on a 4-point scale from 1 (never) to 4 (very often).
4. Caregiver self-efficacy is measured using a visual analogue scale (VAS, as suggested by Bandura) within 3 weeks before the intervention starts and within 3 weeks after the intervention (pre- and post-intervention). The VAS ranges from 0 (no confidence at all in my ability to assume my caregiver role) to 10 (full confidence).

Outcomes regarding feasibility:
1. Dropout rate (percentage of informal dementia caregivers not completing the program) measured at the end of the program, calculated by the number of participants completing the program and participants not completing the program. Reasons for not completing the program are documented.
2. Participation rate (percentage of attended sessions) measured at the end of the program, calculated by the number of attended sessions of each participant and the total number of sessions. Reasons and time point of missing sessions are documented.
3. Acceptability of the four strategies taught in the program (communication, modifying unhelpful thoughts, problem-solving and support seeking) is measured within 3 weeks after the intervention using two items for each: 1) I found it difficult to understand, 2) I found it difficult to apply. The answers are given on a 5-point scale: 0 Not at all or very little, 1 A little, 2 Moderately, 3 Very, 4 Extremely.
4. Acceptability of six methods used (information provided in the didactic videos, information provided by the course leaders, information provided in the booklet, working on personal situations, group exchanges, and exercises at home) is measured within 3 weeks after the intervention using one item for each: I found it difficult to understand/do. The answers are given on a 5-point scale: 0 Not at all or very little, 1 A little, 2 Moderately, 3 Very, 4 Extremely.

Key secondary outcome(s))
Participant-reported outcomes:
1. Usefulness of the four strategies taught in the program (communication, modifying unhelpful

thoughts, problem solving and support seeking) is measured within 3 weeks after the intervention using three items for each: 1) I found it interesting, 2) I found it useful, and 3) It helped me in my daily life. The answers are given on a 5-point scale: 0 Not at all or very little, 1 A little, 2 Moderately, 3 Very, 4 Extremely.
2. Usefulness of the six methods used (information provided in the didactic videos, information provided by the course leaders, information provided in the booklet, working on personal situations, group exchanges, and exercises at home) is measured within 3 weeks after the intervention using two items for each: 1) I found it interesting, 2) I found it useful, and 3) It helped me in my daily life. The answers are given on a 5-point scale: 0 Not at all or very little, 1 A little, 2 Moderately, 3 Very, 4 Extremely.
3. Benefits of the program, negative aspects and the extent to which the program met participants' expectations are assessed with semi-structured qualitative one-to-one interviews within 3 weeks after the intervention
4. Relationship quality between the participants and the persons with dementia measured by conducting semi-structured qualitative one-to-one interviews within 3 weeks before intervention start, between session 5 and 6 of the intervention and within 3 weeks after the intervention

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Caregiver:
1. ≥18 years of age
2. Regularly providing unpaid care, assistance and/or supervision to a close person with dementia or showing substantial cognitive deficits
3. Lives in same household with the person with dementia or in a separated household
4. Sufficient French or German language skills

Person cared for:
5. Has a diagnosis of dementia or shows substantial cognitive deficits
6. Lives in her/his own home (community-dwelling)
7. Lives alone or with other persons

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Key exclusion criteria
Caregiver:
1. Volunteers who provide regular assistance to a person with dementia but had no prior bond to that person
2. Professional paid caregivers
3. Low caregiver burden (score below 10 on the Zarit Burden Interview)

Person cared for:
3. Living in a care institution
4. No memory and behavioral problems

Date of first enrolment
01/05/2014

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
Switzerland

Study participating centre
Haute école de santé Fribourg - School of Health Fribourg
Route des Arsenaux 16a
Fribourg
Switzerland
1700

Study participating centre
imad – institution de maintien à domicile
Avenue Cardinal-Mermillod 36
Carouge
Switzerland
1227

Study participating centre
Foyer de jour pour personnes avec démence La Valse du Temps
Route des Rangiers 7
Cornol
Switzerland
2952

Study participating centre
Association Neuchâteloise des Proches Aidants
Rue Louis-Favre 1
Neuchâtel
Switzerland
2000

Study participating centre
Hôpital du Valais - Pôle de Psychiatrie et Psychothérapie
Hôpital de Malévoz
Route de Morgins 10
Monthey
Switzerland
1870

Sponsor information

Organisation
University of Applied Sciences and Arts Northwestern Switzerland

ROR
https://ror.org/04mq2g308

Funder(s)

Funder type
Charity

Funder Name
Fondation Leenaards

Alternative Name(s)
Leenaards Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Funder Name
Imad - institution genevoise de maintien à domicile (Geneva home care institution)

Funder Name
Promotion Santé Suisse (Health Promotion Switzerland)

Funder Name
Canton of Fribourg, Switzerland

Funder Name
Association Fribourgeoise d'Aide et Soins à Domicile (Home Care Association Fribourg)

Funder Name
Association La Valse du Temps

Funder Name
Groupe Proches Aidants Jura (Informal carer group Jura)

Funder Name
Haute école de santé Fribourg (School of Health Sciences Fribourg)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the fact that the participants were asked for consent to the use of their data in this specific trial only.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/09/2018	19/03/2021	Yes	No

Results article			19/03/2021	Yes	No
Results article		27/02/2024	28/02/2024	Yes	No
Other publications	Qualitative study	28/09/2024	30/09/2024	Yes	No