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Cost-effectiveness of an interactive home-based tele-exercise program for informal caregivers of patients with dementia in a rural environment: gender perspective

Submission date
28/04/2020

Recruitment status
No longer recruiting

Registration date
02/06/2020

Overall study status
Completed

Last Edited
21/05/2020

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Female family members, typically spouses or daughters, who are responsible for taking care of patients with dementia in the majority of cases, are currently a vulnerable population, who report several health-related quality of life difficulties in their daily life. The emerging evidence also suggests the use of internet-based interventions may be an appropriate resource to support informal caregivers, particularly those finding it difficult to leave their home or demanding flexibility due to caregiving-related responsibilities. Moreover, the long distances to regular services of provision with the opportunity to do physical exercise or to attend conventional facilities, such as a gym, when the caregiver lives in small and/or rural municipalities, do not help either caregiver get involved in regular physical exercises programs. The aim of this study is to evaluate the cost-effectiveness and the effects of a tailored internet-based physical exercise intervention for female family caregivers on their health-related quality of life. Several dimensions of health (physical and mental) will be evaluated: health-related fitness variables (balance, body composition, muscular strength, endurance, and flexibility); subjective burden, anxiety, depression, psychological symptoms and global health-related quality of life. The cost-utility of the intervention will be also evaluated.

Who can participate?
Female caregivers aged 40 or older living at home with a relative with dementia

What does the study involve?
Participants are randomly divided into two groups: the intervention/exercise group and the control group. The intervention program will be carried out by a Graduate in Sport Sciences personal trainer by videoconference. The exercise group will perform 3-weekly sessions of physical exercise with a duration of 60 minutes for 9 months. The control group will not receive any treatment during the 9 months of the intervention. Participants are assessed at the start of the study, 3 months after the intervention and at 12 months (follow-up).

What are the possible benefits and risks of participating?
Although it has been previously well documented that interventions that are based on physical exercises are beneficial for health (physical and psychological, as this exercise program is provided at caregivers' homes and is also adapted to the caregivers' needs (less time-consuming, they do not need to look for another caregiver while performing the session). However, the following potential adverse effects of the intervention have to be taken into account. First, physical harm or injuries. In this case, if the participant is severely injured, the personal trainer will recommend the caregiver to visit the doctor. If the caregiver is not able to continue the intervention because of the injury, she should withdraw the intervention. Second, caregivers may feel resentful while carrying out physical exercises. Finally, the session of physical exercise might be interrupted because of caregivers' behaviours.

Where is the study run from?
University of Extremadura (Spain)

When is the study starting and how long is it expected to run for?
January 2011 to December 2012

Who is funding the study?
Institute for the Elderly and Social Services, Ministry of Health and Social Policy (Spain)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
185/2010

Study information

Scientific Title
Cost-effectiveness of an interactive home-based tele-exercise program for informal caregivers of patients with dementia in a rural environment: gender perspective

Study objectives
An interactive physical exercise program for informal caregivers of patients with dementia in rural settings is 1) applicable, 2) effective at improving health-related quality of life and fitness, and 3) a cost-effective resource to complement the usual healthcare system

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2010, Biomedical Ethics Commission of the University of Extremadura (Comité de Bioética y Bioseguridad. Vicerrectorado de Investigación, Transferencia e Innovación, Edificio Rectorado, Av. Elvas, S/N, 06006 – Badajoz, Spain; +34 (0)924289305 Ext: 9305; vrinvestigacion@unex.es), ref: 7/2010

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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
Informal caregivers of people with dementia (Alzheimer's disease or vascular)

Interventions
A controlled longitudinal experimental design will be applied with randomisation in the home environment of the main caregivers of patients with dementia for 12 months. The intervention period will be 9 months but the effects will also be evaluated at 12 months (3 months post-treatment). The sample will be randomly divided into two groups: intervention or exercise group and the control group.

The intervention program will be carried out by a Graduate in Sport Sciences personal trainer by videoconference. The exercise group will perform 3-weekly sessions of physical exercise with a duration of 60 minutes for 9 months.

The control group will not receive any treatment during the 9 months of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline, at 3 months after the intervention and at 12 months (follow-up for cost-utility analysis):
1. Sociodemography and habits (physical activity, nutrition) measured using sociodemographic questionnaire, International Physical Activity Questionnaire and Mini-Nutritional Assessment
2. Cost-utility, use of the health system, and health-related quality of life measured using EQ-5D and SF-36 questionnaires
3. Caregiver burden measured using Zarit Burden Interview
4. Back pain measured using Rolando Morris questionnaire
5. Health-related fitness measured using functional fitness tests: Body Mass Index, Tinneti Balance, Time Up and Go, Functional Reach, Bi-handgrip strength, Curl-Up and Ito-Shirado Test, Stretching of the trunk, flexibility ROM Test, cardiovascular endurance by Canadian Step Test and balance by Biodex Balance Platform
6. Psychological symptoms measured using Global Depression Scale and Symptom Check-List 90 Revised
7. Adherence to the program measured using register of sessions

8. Health status of the patient with dementia measured using Global Deterioration Scale of Reisgberg, Barthel Index and EQ-5D-3L proxy

Secondary outcome measures
1. Adherence to physical exercise program measured using register of the number of sessions performed at 3 months after the intervention.
2. Health status of patients measured using the Global Deterioration Scale, Barthel Index and EQ-5D-3L at baseline, at 3 months after the intervention and at 12 months (follow-up for cost-utility analysis)

Overall study start date
30/01/2011

Completion date
20/12/2012

Eligibility

Key inclusion criteria
1. Female
2. Provision of at least 20 h of unpaid per week, in-person care per week to a relative living at home with dementia
age ≥40 years
3. No medical condition that would limit participation in moderate-intensity exercise program
4. No participation in any regular physical activity program (i.e., has engaged in less than two >20-min sessions of exercise per week during the previous 36 months)
5. No changes in medication for at least 6 months prior to study entry; and no plans to move from the place of residence within 12 months of study entry

Participant type(s)
Carer

Age group
Adult

Sex
Female

Target number of participants
52 (26 in the control group and 26 in the exercise group)

Total final enrolment
40

Key exclusion criteria
1. Caregiver aged below 40 years
2. Caregivers participating in another physical exercise-based intervention
3. Medical contraindication to practise physical exercise

Date of first enrolment

01/05/2011

Date of final enrolment
30/07/2011

Locations

Countries of recruitment
Spain

Sudan

Study participating centre
Federation of Associations of Family Caregivers of patients with Alzheimer Disease and other dementias in Extremadura
Avda. del Pilar, 74
Don Benito (Badajoz)
Sudan
06400

Sponsor information

Organisation
Institute for the Elderly and Social Services (Instituto de Mayores y Servicios Sociales)

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Sponsor type
Government

Website
https://www.imserso.es/imserso_01/index.htm

Funder(s)

Funder type

Government

Funder Name
Institute for the Elderly and Social Services (Instituto de Mayores y Servicios Sociales)

Results and Publications

Publication and dissemination plan
A study protocol will be published in a peer-reviewed journal after the ISRCTN is provided. Planned publication of the study results in a high-impact peer-reviewed journal within the next 3 months.

Intention to publish date
11/08/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other