

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

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## 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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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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(s)**

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, Tinetti 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 Reisberg, Barthel Index and EQ-5D-3L proxy

## **Key secondary outcome(s)**

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)

## **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  $\geq$ 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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

Female

## 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)

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

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

## **Results and Publications**

### **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