

Cost-utility and effectiveness on health-related quality of life and fitness of a home-based exercise in the caregivers of patients with Alzheimer's disease

Submission date 18/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/07/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/11/2021	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9/05

Study information

Scientific Title

Cost-utility and effectiveness on health-related quality of life and fitness of a home-based exercise in the caregivers of patients with Alzheimer's disease

Acronym

EADCA/09/05

Study objectives

1. Home-based exercise is effective in enhancing health-related quality of life, fitness and mental health in informal caregivers
2. Home-based exercise is cost-effective in informal caregivers
3. There are differences in this effectiveness between men and women caregivers

As of 29/07/09 this record has been updated. Updates can be found in the relevant fields with the above update date. Please note that the previously listed source of funding Spanish Federation of Rare Diseases (Federación Española de Enfermedades Raras) (FEDER) was incorrect. Please also note that the end date of the trial was extended from 31/12/2007 to 31/12/2008.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Bioethical Committee of the University of Extremadura on 12/06/2005, reference number 9/05

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Informal caregivers of Alzheimer's disease patients

Interventions

Current information as of 29/07/09:

9 month home-based exercise two days per week.

The control group will not receive any intervention (only the interview and measurements). In fact, we will exclude volunteers who are following other therapies to avoid disturbances or covariables.

Information at time of registration:

One-year home-based exercise two days per week.

The control group will not receive any intervention (only the interview and measurements). In fact, we will exclude volunteers who are following other therapies to avoid disturbances or covariables.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Stress of caregivers as assessed by the Zarit Burden interview
2. Health-related quality of life and its utilities to cost-effectiveness
3. Fitness
4. Psychological aspects (symptom checklist-90-R [SCL-90], interviews, and dimensions of health-related quality of life)

Secondary outcome measures

1. Back pain (Roland Morris index)
2. Perceived health (visual analogue scale [VAS])

Overall study start date

01/07/2006

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Non-professional caregivers who have been taking care of an Alzheimer's patient for more than 20 hours per week for more than six months and are expecting to continue for 12 months more

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100 caregivers (70 women and 30 men). Final number 61 women (31 intervention group) and 13 men (6 intervention group) (added 29/07/09)

Total final enrolment

48

Key exclusion criteria

1. Contraindications to physical exercise
2. Other physical therapies
3. Drugs affecting measures

Date of first enrolment

01/07/2006

Date of final enrolment

31/12/2008

Locations**Countries of recruitment**

Spain

Study participating centre

Faculty of Sports Sciences

Caceres

Spain

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Sponsor information**Organisation**

University of Extremadura (Spain)

Sponsor details

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Sponsor type

University/education

Website

<http://www.unex.es>

ROR

<https://ror.org/0174shg90>

Funder(s)

Funder type

Government

Funder Name

Research Plan of the Health Department of Junta de Extremadura European Social Funds - (2PR04B008)

Funder Name

Sanitary Research Funds (Carlos III Institut)

Funder Name

European Funds for Development (FEDER) (European Union) (PI051601) (as of 29/07/09)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2009		Yes	No
Results article		07/09/2020	03/11/2021	Yes	No