

# Efficacy of a psychoeducative intervention program to prevent or reduce the burden associated with caring for dementia patients

**Submission date**

18/02/2011

**Recruitment status**

No longer recruiting

Prospectively registered

Protocol

**Registration date**

10/03/2011

**Overall study status**

Completed

Statistical analysis plan

Results

**Last Edited**

29/10/2013

**Condition category**

Nervous System Diseases

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

**Protocol serial number**

PI08/90812

## Study information

**Scientific Title**

Efficacy of a psychoeducative intervention program to prevent or reduce the burden associated with caring for dementia patients: a two arm single blind, multicentre, randomised controlled trial

**Acronym**

EDUCA-II

**Study objectives**

1. The caregivers allocated to the psychoeducative intervention program will present less burden at endpoint (4 months) than the caregivers allocated to the control condition.
2. The caregivers allocated to the psychoeducative intervention program will present better mental health at endpoint (4 months) than the caregivers allocated to the control condition.
3. The caregivers allocated to the psychoeducative intervention program will present better quality of life at endpoint (4 months) than the caregivers allocated to the control condition.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Ethical and Scientific Research Committee of Navarra, Spain, approved on August 5th 2008.

**Study design**

Two arm single blind multicentre randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Burden associated to dementia caregiving

**Interventions**

Control group: Caregivers allocated to this group received the usual support from the day center or memory clinic where the patients had a multifaceted /multiprofessional care which aimed at reducing the rate of cognitive decline (cognitive stimulation groups) and improve or maintain as long as possible daily abilities (occupational therapy). The caregiver received periodical interviews and information about the situation and clinical course of the patient.

Intervention group: Caregivers allocated to this group were exposed to the same usual care the control group received plus a psychoeducative intervention program. This intervention was administered in 7 group sessions of 90 minutes each and the sessions were administered 2 weeks apart. The caregiver received standardised information about the clinical course of dementia and training on different cognitive and behavioural skills to increase her care abilities, communicative skills and relaxation.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Change since baseline to endpoint in the caregiver burden as assessed by the Zarit Burden Interview

**Key secondary outcome(s)**

1. Change since baseline to endpoint in the caregiver mental health as assessed by the General Health Questionnaire, 28 items
2. Change since baseline to endpoint in the caregiver quality of life as assessed by the SF-12

**Completion date**

30/09/2010

**Eligibility**

**Key inclusion criteria**

1. Males or females with age more than or equal to 18 years, giving care to a familiar person with a diagnosis of dementia according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV)-TR criteria
2. The caregiver was not professionally paid for caregiving
3. The familiar diagnosed of dementia was receiving appropriate care as outpatient in a day center or memory clinic
4. The caregiver spend a minimum of 4 hours/day to care for the patient with dementia
5. The patient cared for had at least two instrumental activities impaired (a score of 0 in the Lawton & Brody scale) or one activity of daily life impaired (Katz index codes A or D)
6. Signed informed consent to participate in the trial

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Caregivers without time to attend the psychoeducative intervention training
2. Caregivers receiving currently or recently (last year), any standardised psychoeducative intervention similar to the one administered in the trial

**Date of first enrolment**

01/09/2009

**Date of final enrolment**

30/09/2010

# Locations

## Countries of recruitment

Portugal

Spain

## Study participating centre

Egaña 10

Bilbao

Spain

E-48010

# Sponsor information

## Organisation

Maria Josefa Recio Foundation - Institute of Psychiatric Research (Spain)

# Funder(s)

## Funder type

Government

## Funder Name

Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain) (ref:PI08/90812)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2013		Yes	No