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

Submission date	Recruitment status	Prospectively registered		
18/02/2011	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/03/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
29/10/2013	Nervous System Diseases			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Manuel Martín-Carrasco

#### Contact details

Egaña 10 Bilbao Spain E-48010 iip@fundacion-iip.org

# 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 Committe 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 profesionally 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?

Results article 01/01/2013 Yes No

Participant information sheet 11/11/2025 No Yes