ISRCTN14411440 https://doi.org/10.1186/ISRCTN14411440

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

Registration date
10/03/2011

Overall study status
Completed

Last Edited
29/10/2013

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/09/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
An anticipated number of 200 caregivers were estimated to attain 85% power. The trial recruited 238 caregivers (115 randomised to the intervention arm, 123 randomised to the control arm).

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)

Sponsor details
Fundación Maria Josefa Recio - Instituto de Investigaciones Psiquiátricas
Egaña 10
Bilbao
Spain

E-48010
iip@fundacion-iip.org

Sponsor type
Government

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	results	01/01/2013		Yes	No