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Dementia care initiative in primary practice (German title: Initiative Demenzversorgung in der Allgemeinmedizin)

Submission date
28/08/2007

Recruitment status
No longer recruiting

Registration date
16/10/2007

Overall study status
Completed

Last Edited
01/02/2011

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.projekt-ida.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
IDA

Study objectives
The main research hypothesis is that for dementia patients still living at home a complex intervention consisting of a training of General Practitioners (GPs) in evidence based treatment, of the provision of caregiver support groups, and of actively approaching family counselling, can prolong time to nursing home placement in comparison to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics board of the Bavarian Chamber of Physicians (Bayerische Landesarztekammer) on the 30th May 2005 (ref: 05029).

Study design
Three armed cluster-randomised trial with recruitment by 220 GPs (clusters) and an intervention /follow-up period of two years. Observer blind assessment of secondary outcomes.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Mild to moderate dementia

Interventions
Control group: usual care (GPs receive only training in dementia diagnosis and in study procedures)

Intervention group 1: GPs receive additional training in evidence based dementia treatment, caregivers are offered participation in dementia caregiver support groups
Intervention group 2: as in intervention group 1 plus actively approaching family counselling

Training for the GPs had a duration of 0.5 days for the control group and 1 day for the two intervention groups. The caregiver support groups take place once a month. The contact frequency with the actively approaching family counselling is every 6 to 8 weeks. The total duration of follow-up is 2 years for all treatment arms.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time to nursing home placement (within two year intervention and follow-up period).

Secondary outcome measures
1. Subjective burden of informal caregivers (Burden Scale for Family Caregivers [BSFC])
2. Quality of life of the patients (EuroQol-5D measure [EQ5D])
3. Direct medical and non-medical costs (including informal care)
4. Cognitive functioning of the patients (MMSE)
5. Patients' ability to perform Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) (Barthel-Index, Nurses' Observation Scale for Geriatric patients [NOSGER] subscale IADL)

Secondary outcomes are measured at one and two years after study entry.

Overall study start date
25/06/2005

Completion date
31/12/2008

Eligibility

Key inclusion criteria
General practitioners:
1. Participating in a study specific training
2. Located in the study region of Middle Franconia

Patients:
1. Mild to moderate dementia (Mini-Mental State Examination [MMSE] between 10 and 23)
2. Member of the health insurance AOK
3. 65 years and older
4. Living at home
5. Having an informal caregiver who is willing to participate in study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
300 patients per study arm, 900 in total (as of the end of the study only 390 patients were recruited)

Key exclusion criteria
1. Patients having a terminal illness
2. Nursing home placement is already planned
3. Patients not able or willing to give informed consent

Date of first enrolment
25/06/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Germany

Study participating centre
Psychiatrische und Psychotherapeutische Klinik
Erlangen
Germany
91054

Sponsor information

Organisation
Federal Association of the Statutory Regional Health Insurance Fund (Allgemeine Ortskrankenkasse [AOK]) (Germany)

Sponsor details
Kortrijker Strasse 1
Bonn
Germany
53177

Sponsor type
Government

Website
http://www.aok.de/bundesweit/

ROR
https://ror.org/004cmqw89

Funder(s)

Funder type
Industry

Funder Name
The study is jointly and equally funded by:

Funder Name
The statutory health insurance AOK Bavaria (Germany)

Funder Name
The Federal Association of the AOK (Germany)

Funder Name
Pfizer Deutschland (Germany) - research-based pharmaceutical company

Funder Name
EISAI GmbH (Germany) - research-based pharmaceutical company

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?
Other publications	study design and baseline data report	01/05/2007		Yes	No
Protocol article	protocol	06/06/2009		Yes	No
Results article	results	18/11/2010		Yes	No