

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

Submission date 28/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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 Landesärztekammer) 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