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Danish Alzheimer Intervention StudY

Submission date	Recruitment status	[_] Prospectively registered
16/08/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/09/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hukommelsesklinikken.dk

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
DAISY

Study objectives
That early social support, education, and counselling for patients with Alzheimers Disease (AD) is cost-effective and improves quality of life and reduces depressive symptoms in patients and caregivers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Research Board approved on February 27, 2004 (reference number: KF 02-005/04).

Study design
Multi-center, single-blind, controlled randomised trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dementia and Alzheimer's disease

Interventions
1. Individualised counselling meetings (fixed and open agendas):
1.1. two meetings with patient and carer (on initiation and towards the end of the intervention),
1.2. two meetings with patient,
1.3. two meetings with carer,
1.4. one meeting with patient, carer, and family network.

2. Teaching course for patients, approximately 12 participants, five scheduled sessions, including at each session:

2.1. information about key issues, supported by written information, fixed and open agenda,
2.2. support group activity.

3. Teaching course for carers (will take place simultaneously with course for patients, in a separate location), approximately 12 participants, five scheduled sessions, including at each session:
3.1 formalised teaching course (centralised program, local teachers),
3.2. support group activity.

4. Telephone counselling: follow-up phone call from project coordinator to patient/carer every two to four weeks.

5. Log-book to be kept by patient and carer (separate books), may be used at counselling visits to set the agenda. To be kept by patient/carer.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Patient:
1.1. depressive symptoms (Cornells depression scale)
1.2. proxy rated health related quality of life (Euro-QoL VAS)
1.3. MMSE

2. Caregiver:
2.1. depressive symptoms (Geriatric Depression Scale, GDS-30)
2.2. health related quality of life (Euro-QoL VAS)

Secondary outcome measures
1. Health related quality of life in patient (patient and proxy rated EuroQoL 5D and VAS, and Quality of life Alzheimers disease scale QOL-AD)
2. Health related quality of life in caregiver (EuroQoL 5D and VAS)
3. Behavioral symptoms: Neuropsychiatric Inventory Questionnaire (NPI-Q)
4. Activities of daily living (ADCS-ADL)
5. Insight scale
6. Resource utilisation in patient and carer (Resource Utilisation in Dementia, RUD)
7. Registry-based assessment of health care utilisation and key social and health related events during 12 months before inclusion and during follow-up time (minimum five years):
7.1. time to nursing home, placement and death
7.2. number of in-patient and out patient contacts in patient and carer
7.3. co-morbidity in patient and carer
8. Patient and carer satisfaction with intervention, public services and network questionnaire
9. Patient and carer knowledge and attitudes about key issues in dementia questionnaire

Overall study start date
01/03/2004

Completion date

21/08/2009

Eligibility

Key inclusion criteria
1. Progressing degenerative dementia (meeting international criteria for either probable AD, mixed AD/Vascular Dementia [VaD], or Dementia with Lewy Bodies [DLB])
2. Diagnosis established or confirmed by central specialist unit (memory clinic) in each center
3. Diagnosed within 12 months prior to inclusion
4. Aged above 50 years
5. Mild dementia: Mini-Mental State Examination (MMSE) score of more than 20
6. Primary caregiver (with close contact) who are willing to participate
7. Living at home
8. Sufficient language proficiency in Danish for adequate participation in counselling, interviews and tests
9. Informed consent from patient and caregiver

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
330

Key exclusion criteria
1. Severe somatic or psychiatric co-morbidity, including impaired hearing or vision, which will significantly impair cooperation to the program
2. Participation in other intervention studies at inclusion or during the study will not be allowed

Date of first enrolment
01/03/2004

Date of final enrolment
21/08/2009

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Neurology
Copenhagen

Denmark
2100

Sponsor information

Organisation
Memory Disorders Research Group (Denmark)

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Sponsor type
Research organisation

Website
http://www.hukommelsesklinikken.dk

ROR
https://ror.org/03mchdq19

Funder(s)

Funder type
Government

Funder Name
The National Board of Social Services

Funder Name
The Danish Ministry of Social Affairs

Funder Name

The Ministry of Health

Funder Name
The Danish Health Foundation

Funder Name
The Hospital Cooperation for Copenhagen

Funder Name
The Danish Alzheimer Foundation

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	25/11/2009		Yes	No
Other publications		22/12/2010		Yes	No
Results article	results	17/07/2012		Yes	No