

# Danish Alzheimer Intervention Study

<b>Submission date</b> 16/08/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/09/2012	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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/carers 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/carers.

### **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

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)

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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)

**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

### 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?
<a href="#">Results article</a>	results	25/11/2009		Yes	No
<a href="#">Results article</a>	results	17/07/2012		Yes	No
<a href="#">Other publications</a>		22/12/2010		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes