Effectiveness and costs of post-diagnosis treatment in dementia coordinated by multidisciplinary memory clinics in comparison to treatment coordinated by general practitioners.

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OBJECTIVES: To determine, given a societal perspective, MMCs' effectiveness and costs in post-diagnosis care for dementia-patients to improve or stabilize patient's health related quality of life and performances in daily living and to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON30964

Source
ToetsingOnline

Brief title
AD-Euro Study

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer's disease, Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZONMW programma Doelmatigheid

Intervention

Keyword: Cost-benefit analysis, Dementia, Disease management, Multidisciplinary memory clinic

Outcome measures

Primary outcome

PRIMARY OUTCOME MEASURES: Patients: Health-related quality of life as measured

with a dementia specific HrQoL-instrument (i.e. QoL-AD) and functional

performance in daily living as measured by the IDDD (Instrumental activities of

Daily living in Dementia Diagnosis); Informal caregivers: caregiver burden as

measured with the Sense of Competence Questionnaire (SoCQ).

Costs will be assessed from a societal perspective, using the Resource

Utilization in Dementia-questionnaire (RUD), which has been used in several

other economic evaluations in AD treatment.

See page 14-15 from the protocol for a detailed description

Secondary outcome

SECONDARY OUTCOME MEASURES:

PATIENTS:

1. Behavioural disturbances will be measured using the NeuroPsychiatric

Inventory (NPI; Cummings, 1994).

2. Cognition will be measured with the MMSE (Folstein et al, 1975). This is a

brief, widely used test of cognitive function, with good reliability and validity. Another cognition oriented secondary outcome variable is the Alzheimer*s Disease Assessment Scale - Cognition (ADAS-Cog; Rosen et al, 1984); this is a more sensitive scale measuring cognitive function and including more items that assess short-term memory. It is frequently used in drug trials as the principal cognitive measure, allowing the effects of this intervention to be compared with antidementia drug trials.

3. Depression. The Cornell Scale for Depression in Dementia (Alexopoulos et al, 1988) rates depression in five broad categories (mood-related signs, behavioural disturbance, physical signs, biological functions and ideational disturbance) using information from interviews with staff and participants. Good reliability and validity have been demonstrated.

4.Weight, which is easy to measure, and is a valid and reliable global measure of mental and physical well-being.

CAREGIVERS:

1.Mood and anxiety will be measured using the Hospital and Anxiety Depression Scale (HADS, Spinhoven, 1997), which is translated and validated in Dutch.

2. Satisfaction with care will be measured as we also did in an earlier study on MMCs (vHout, 2001).

3. Quality of life will also be rated for caregivers looking at their own quality of life with the Caregiver-Qol, derived from the QOL-AD (Selwood, 2005).

Study description

Background summary

BACKGROUND: In The Netherlands a rapidly increasing number of multidisciplinary memory clinics (MMC) currently diagnose 25% of the patients with dementia. Following the diagnostic work-up, MMCs are increasingly involved in post-diagnosis treatment and co-ordination of care, which probably is very important for patients and caregivers, but also very time consuming and expensive. This study will focus on the important question whether this complex post-diagnosis treatment and care co-ordination, evaluated both on effectiveness and costs, should be carried out by MMCs (intervention) or by General Practitioners (GPs) (control) as pivot of delivery of health care for these patients

Study objective

OBJECTIVES: To determine, given a societal perspective, MMCs' effectiveness and costs in post-diagnosis care for dementia-patients to improve or stabilize patient's health related quality of life and performances in daily living and to improve informal caregiver's perceived burden of care.

The objective of the MTAannex study will be to study the course and reliability of quality of life measures in dementia in relation to quality of life measures registered from caregivers in order to provide an advice on how to best apply quality of life measures in dementia in future projects.

Study design

STUDY DESIGN: Controlled, randomized study on effectiveness and costs, in which 228 patients are randomised over intervention and control condition.

Intervention

INTERVENTION: Multidisciplinary Memory Clinics (MMCs) will deliver 12 months of post-diagnosis treatment and care, which consists of:
1. Initiating, targeting and monitoring acethylcholinesterase inhibitors (AChI), as regular symptomatic drug treatment in case of Alzheimer*s disease (AD).
2. Other drug interventions in patients with other types of dementia and/or psychiatric or somatic co-morbidity.
3. Initiating psychosocial interventions and care-coordination.

CONTROL: In the control group the patients with dementia will be referred back to the GP after diagnosis has been made, with advices on drug treatment, and on

psychosocial interventions and care-planning. GPs will co-ordinate this care, but can also refer to a range of other services as they currently do in regular practice except the MMCs.

Study burden and risks

The burden related to the measurement scales is low: these are all known, 'non-intrusive' questionaires, which altogether ask 2 hours from patient and caregiver per measurement point.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria:
1.The patients fulfil DSM-IV TR criteria for dementia with a Clinical Dementia Rating of 1 or 2 (CDR, Hughes, 1982), and MiniMental State Examination (MMSE) score between 10 and 26.
2. All patients are diagnosed as having dementia in one of the participating 7 MMCs.
3. Each patient has a caregiver who is in touch with the patient at least once a week.
4. Patients and carers gave informed consent for participation in the study.
5. All patients are living independently at the start of the study (not in a nursing home, but they may reside in or next to a home for the aged).
6. Each patient has a specific target for post-diagnosis care as formulated by the MMCs (for example: drug treatment with cholinesterase inhibitors in probabale AD; or specific co-morbidity such as paranaoid delusions which asks for drug treatment, care-coordination and/or psychosocial treatment)

Exclusion criteria

Exclusion criteria
1. Severe behavioural disturbances, such as severe depression and aggression to such an extend that participation in this trial is impossible (as judged by the responsible MMC-specialist).
2. Physical co-morbidity requiring a clear priority for another more somatically oriented therapy.
3. Lack of care/support, which probably will cause insufficient compliance to the intervention and the research protocol.
4. Severe problems in vision and/or hearing that make the collection of research data impossible.
5. Uncomplicated dementia patients, with no wish for symptomatic drug treatment, in whom MMcs have no specific advices or treatment targets, except for the diagnostic disclosure.
6. Expression of unwillingness to participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2007
Enrollment:	228
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL16603.091.07