Elderly patients suspected of cognitive decline by family physicians; a cluster randomized controlled trial to improve the diagnostic and care process

Published: 26-07-2011
Last updated: 30-11-2024

To evaluate the feasibility and (cost) effectiveness of an intervention to improve the quality of dementia care and the wellbeing of home dwelling persons with dementia and their main informal caregiver.

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

Summary

ID

NL-OMON36676

Source
ToetsingOnline

Brief title
COMPAS-D

Condition

- Dementia and amnestic conditions

Synonym
possibly dementia, the most wellknown and prevalent form is Alzheimer's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: subsidie van ZonMW in het kader van het Nationaal Programma Ouderen en subsidie van de Stichting Stoffels

Intervention

Keyword: dementia, innovation, primary care, quality of care

Outcome measures

Primary outcome

Primary outcomes: quality of dementia care (set of 23 quality indicators)

Secondary outcome

Secondary outcomes: caregiver burden (SSCQ), patient behavioural symptoms (NPI), quality of life of patients (EQ5D and QoL-AD) and informal caregivers (EQ-5D), mental health problems of caregivers (GHQ 12). The incidence of new dementia diagnosis.

Economic outcomes: direct and indirect medical and societal costs.

Feasibility outcomes: level of implementation succes and failure factors of the intervention.

Study description

Background summary

In sight of the upcoming dementia epidemic it is of vital importance to optimize care for home dwelling dementia patients and their informal caregivers. At present, diagnosis and management of dementia in primary care is suboptimal. Previous studies suggest that the combination of training providers, deploying a care coordinator and structuring collaboration among care providing organisations could improve the quality of care for home dwelling dementia patients. Cost effectiveness was not yet assessed.

Study objective

To evaluate the feasibility and (cost) effectiveness of an intervention to

improve the quality of dementia care and the wellbeing of home dwelling persons with dementia and their main informal caregiver.

Study design

mixed methods: cluster RCT and qualitative analysis

Intervention

Intervention developed by expert opinion, literature review, focusgroups.
1) Family physicians classify cognitive function of all elderly patients, they are trained and supervised in collaborative diagnosis and management of dementia, collaborating with a trained practice nurse. 2) Practice nurses support patients and caregivers, do a structured assessment of care needs and make a care plan in consultation with the patient and informal caregiver if present and they coordinate care. 3) Collaboration among dementia care providers is structured within a region.

Study burden and risks

The interventions done within the context of the study are regarded to be of no risk to the patients and caregivers exposed to them. We aimed to minimise the burden placed on dementia patients and their caregivers by the half yearly interviews and questionnaire.

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

1. Patients are classified as possibly cognitively impaired or possibly having dementia based on FPs* general impression.
2. A primary informal caregiver can be identified. Definition primary informal caregiver: the person who has a central role in (and takes responsibility for) the care of an, independently living, disabled relative or partner.
3. The primary caregiver has sufficient mastery of the Dutch language.

Exclusion criteria

1. Patients are already diagnosed with dementia.
2. Patient or caregiver is terminally ill.
3. Permanent admission of the patient to a nursing home expected within 6 months.
4. The patient is not/no longer sufficiently capable of understanding spoken language or expressing him- or herself.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-10-2011
Enrollment:	312
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL34299.029.10