Case-finding of mild cognitive impairment and dementia and subsequent collaborative care: Design of a cluster RCT.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25985

Bron
Nationaal Trial Register

Verkorte titel
COMPAS D

Aandoening

Mild Cognitive Impairment (MCI), Dementia, Cognitive impairment, Frailty

Lichte cognitieve stoornissen, dementie, kwetsbaarheid

Ondersteuning

Primaire sponsor: VU UNiversity Medical Center, EMGO Institute for Health and Care Research
Overige ondersteuning: ZonMW, Stichting Stoffels

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary comparison between intervention and control PCPs is the number of incident MCI and dementia diagnoses after 12 months, in individuals already suspected of developing cognitive problems by their FP.
This is operationalized as follows:
All FPs are asked to again classify the cognitive status of individuals enrolled in the RCT, 1 year after the start of the intervention. This time, we ask them to categorise them as either:
1. No MCI or dementia;
2. MCI;
3. Dementia syndrome.
FPs are asked to indicate whether they explicitly disclosed the diagnosis to the individual with cognitive impairment and his or her informal caregiver.
In addition to this, we will check the medical records, including medical correspondence, for specialist and FP dementia diagnoses. We chose to make FPs classification after 1 year leading as we assume that, particularly in the control group, documentation of the cognitive status in the medical records is limited. Thus, when an individual is classified as having dementia we will regard it an incident case even when it is not documented as such is the medical records. If an individual is classified as not having dementia but the medical records suggest there may be dementia we will check again with the FP.

Validation of FP MCI and dementia diagnosis:
FPs MCI and dementia diagnosis will be compared to a reference standard diagnosis of cognitive status The reference standard used is the CAMCOG, the cognitive assessment part of the Cambridge Examination for Mental Disorders for the Elderly. We use the complete CAMCOG and the memory section of the CAMCOG to distinguish: 1) normal cognitive function for age, 2) MCI and 3) dementia. It will be administered to all participants at baseline and at 1 year follow-up. We chose the CAMCOG because it is relatively brief and easy to administer but still has good psychometric properties and because it allows distinguishing normal ageing, MCI and dementia[Schmand 2000].

Toelichting onderzoek

Achtergrond van het onderzoek

In the primary care setting, dementia is often diagnosed relatively late in the disease process and care for individuals with cognitive impairment is often guided by demand, rather then being proactive. There are indications that casefinding and proactive collaborative care are

beneficial to both patient and informal caregiver in terms of clarifying the cause of changed behaviour and cognition and by enabling planning of care and access to services. We hypothesize that active case finding in individuals in whom FPs suspect cognitive impairment increases incident MCI and dementia diagnoses. In addition, we explore the validity of these diagnoses and the effects of casefinding and collaborative care on the mental health of individuals with MCI or dementia and their informal carers.

Methods and design:

Design Cluster Randomised Controlled Trial.
Participants 162 individuals ≥ 65 years, in 15 primary care practices, in whom FPs suspect cognitive impairment, but without a dementia diagnosis.

Intervention:

Case finding and collaborative care. Two trained practice nurses (PNs) invite all patients with suspected cognitive impairment for a brief functional and cognitive screening. If the cognitive tests underpin the suspicion of cognitive impairment, individuals are referred to their FP for further evaluation. If MCI or dementia are diagnosed the team of FP and PN provide information and support. Furthermore, a comprehensive geriatric assessment takes place to identify other relevant geriatric problems that need to be addressed.

Control FPs provide care and diagnosis as usual.

Main study parameters After 12 months both groups are compared on: 1) Incident MCI and dementia diagnoses and 2) patient and caregiver quality of life (QoL-AD; EQ5D) and mental health (MH5; GHQ 12) and caregiver competence to care (SSCQ).

The first results are expected medio 2013.

Doel van het onderzoek

We hypothesize that active case finding in individuals in whom FPs suspect cognitive impairment increases incident MCI and dementia diagnoses. In addition we explore the validity of these diagnoses and the effects of collaborative care on the mental health of individuals diagnosed with MCI or dementia and their informal carers.

Onderzoeksopzet

T0 = baseline, T1 = 6 mnths, T2 = 12 mnths.

Onderzoeksproduct en/of interventie

The intervention in this study was developed by our project team comprising several FPs and in close collaboration with three FPs participating in the study. It is aimed at individuals classified as having 'possible cognitive impairment or dementia' by their FP and contains the following elements:

Training of FPs and practice nurses:

In order to improve recognition, diagnosis and management of MCI and dementia in primary care, FPs and PNs will undergo a training adapted from the training provided by Perry et al. in their study on case finding of dementia in primary care(Perry et al. 2008). The training focuses on collaboration between FPs and practice nurses in diagnosing and managing dementia. FPs will consider barriers to dementia diagnosis and will learn how to diagnose dementia according to current guidelines (particularly the dementia guideline of the Dutch College of General Practitioners)(2003b). Additionally, differential diagnosis and pharmacological treatment of behavioural problems are addressed.

Practice nurses are trained to administer cognitive tests, to interpret the results and to formulate a hypothesis about the cognitive status of the individual tested. In addition, practice nurses are trained to administer the Resident Assessment Instrument (RAI), a standardised instrument for broad functional assessment of elderly patients and their informal caregiver. They learn to make a care plan based on the RAI results and evaluate it periodically.

Case finding of MCI and dementia:

1. Cognitive classification of all individuals aged 65 or older.
FPs in both conditions are asked to estimate the cognitive function of all individuals aged 65 or older in their practices;

2. Screening and diagnosis in individuals classified 'possible cognitive impairment or dementia' In the intervention practices two PNs are deployed who will perform the additional tests. They will focus exclusively on individuals with suspected cognitive impairment. They offer a brief screen of cognition (Mini Mental State Examination[MMSE] and Visual Association Test[VAT]), mood (Prime-MD), sensory functions and need for home care to all study participants. Individuals with an MMSE score > 1 SD below the average MMSE of healthy individuals of comparable age and education and/or a VAT score ≤ 4 are referred to the FP for further evaluation according to the dementia guideline of the Dutch College of General Practitioners(Kempen, Brilman, & Ormel 1995;Lindeboom et al. 2002). Figure 2 provides an overview of the intervention.

If the cognitive tests indicate cognitive performance is worse than normal for age and education, individuals are seen by their FP. The FP evaluates whether dementia, or if the criteria for dementia are not met, MCI is present. If dementia or MCI are diagnosed, the team of FP and PN provide information and support for the individual with cognitive impairment and, if present, for the informal caregiver. Subsequently they will offer a RAI assessment. Based on the results of this assessment they prioritise problems and prepare a care plan in consultation with the individual with MCI or dementia, the informal caregiver and the FP.

Additionally, the PNs will gain expert knowledge on dementia services in the region and establish close collaboration with secondary care providers. to the team of FP and PN will make agreements on collaboration with these providers based on the outlines for this in the National Collaboration Agreement for primary dementia care. These include for example agreements on information exchange, prescription of drugs, consultation and referral, crisis situations, (crisis-) admission.
The practice nurses will serve patients of several PCPs. Patient contacts will take place according to a predefined schedule. FPs remain responsible for all medical care, including crisis management during the study.

Control FPs provide care and diagnosis as usual.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Individuals > 65 years in whom family physicians suspect cognitive impairment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patient with FP or specialist diagnosis 'probable dementia';

2. Patient or informal caregiver terminally ill;

3. Permanent admission to a nursing home expected within 6 months;

4. Not sufficiently capable of understanding spoken language or expressing him- or herself.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2012
Aantal proefpersonen:	162
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-04-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3237
NTR-old	NTR3389
Ander register	METC VUMC : 2010/297
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A