Pilot behavioral changes in homes for the elderly.

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Primary objectives:This is a pilot study. The main objective is to investigate the feasibility of the study. This feasibility will be tested by estimating: 1. the percentage of inclusion, 2. the incidence of behavioural changes for which the GP is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON36880

Source
ToetsingOnline

Brief title
Pilot behavioral changes in homes for the elderly.

Condition

- Cognitive and attention disorders and disturbances

Synonym
behavioural changes, cognitive disturbances

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aged, delirium, dementia, depression

Outcome measures

Primary outcome

This is a pilot study. The main objective is to investigate the feasibility of the study. This feasibility will be tested by estimating: 1. the percentage of inclusion, 2. the incidence of behavioural changes for which the GP is consulted. The incidence behavioural changes found will be influenced by the cooperation of the geriatric nurses and the GP*s.

Secondary outcome

Secondary objective is to investigate the prevalence of behavioral changes at baseline and the prevalence and incidence of symptoms of delirium, depression and dementia associated with these behavioral changes

gnoses made by the own GP related to these behavioural changes

Study description

Background summary

Little is known about the prevalence of behavioural problems in homes for the elderly. Little is known about the prevalence of delirium, depression and dementia in relation to behavioural changes. For the feasibility of future studies about extensive diagnostic methods and prognosis in these cases, more information about prevalence and incidence is needed. The hypothesis is that the prevalence and incidence found in this study will be higher than prevalence found by the GP in usual care.

Study objective

Primary objectives:
This is a pilot study. The main objective is to investigate the feasibility of

the study. This feasibility will be tested by estimating: 1. the percentage of inclusion, 2. the incidence of behavioural changes for which the GP is consulted. The incidence behavioural changes found will be influenced by the cooperation of the geriatric nurses and the GP*s.

Secondary objective is to investigate the prevalence of behavioral changes at baseline and the prevalence and incidence of symptoms of delirium, depression and dementia associated with these behavioral changes.

Study design

About eighty inhabitants of one home for the elder in the city of Groningen will be asked to participate in this study. At baseline all inhabitants who signed an informed consent will be tested with a MMSE (mini mental state examination), a GDS-8 or a CSDD (Geriatrc depression scale, Cornell scale of depression in dementia) and a CAM (confusion assessment method).
During the 3 following moths all inhabitants who show a new behavioural change for which the geriatric nurse decides to ask the GP for a house-visit, will be reported to the investigators. After that the investigators will fill in an NPI-Q (Neuro-psychiatric inventory- questionnaire) asking the geriatric nurse about the behavioural changes they observed. The inhabitant will be tested again using the MMSE, GDS or CSDD and CAM. The results of this testing will not be reported to the GP. The GP will perform 'care as usual'.
After three months the investigator will check with the participating GP's for their diagnoses in the patients that showed behavioural changes.

Study burden and risks

The nature of the burden for participants in this study is a one-time visit of an investigator for baseline testing. For some participants, who show behavioural changes during the following three months, there will be a second visit for testing. During these visits participants are asked to conduct a MMSE and to answer 8 yes/no questions about depressive symptoms (GDS-8). This will take about 30-45 minutes of their time. The other tests are observational tests that are filled in after the interview with help of observations of the geriatric nurses. This will be no burden to the participant. Taking this test and answering those 8 questions can in some cases cause a little tiredness or maybe a slight feeling of disturbance with the participant.
The participant will receive care as usual from his or her own GP. I think that this investigation is no risk for the participants. The investigations are quite similar to the tests the own GP will sometimes perform during usual care.

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 in baseline-measurements:
living in a home for the eldery: 'Bernlef'
registered with one of three GP's attached to this home for the elder
signed informed consent
65+
inclusion in second stage of study:
home-visit is requested because of behaviuoral changes

Exclusion criteria

no informed consent signed by the person living in the home for the elder nor signed by his of her closest relative
Unable to perform a MMSE due to severe somatic ilness.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL40859.042.12