The reduction of disability in community-dwelling frail elderly: a randomized controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34653

Source
ToetsingOnline

Brief title
The reduction of disability in community-dwelling frail elderly

Condition

- Other condition

Synonym
disability, frailty, impairment, vulnerability

Health condition

frailty, disability

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw/Nationaal Programma Ouderenzorg

Intervention

Keyword: disability, elderly, frailty, prevention

Outcome measures

Primary outcome

The primary outcome measure is the Groningen Activity and Restriction Scale (GARS). The GARS is a reliable and valid measure for assessing disability in the domains of ADL, IADL and mobility in an elderly population.

Secondary outcome

As the proposed study will be embedded in the NPO, the MDS (Minimal Data Set) will be applied. The MDS provides global data on: age, gender, marital status, ethnicity, living arrangements, socio-economic status, level of education, health perception, multimorbidity, daily functioning in ADL, mental well-being, cognitive functioning, social functioning and quality of life. Data about the impact of the intervention on informal caregivers (perceived burden and health-related quality of life) will also be provided. Additional outcomes (secondary outcomes) are anxiety, depression, cognitive status, social support, hours which are spend on activities, feelings of loneliness, frequency of falls and fear of falling. Mortality, health care utilization/consumed goods and related costs will be also registered.

Study description

Background summary

Depending on the definition of frailty up to 40% of the Dutch elderly population is frail and an increase in the number of frail elderly is expected. Frail elderly are more vulnerable for adverse health outcomes such as acute and chronic diseases, and disability. Disability is a relevant health problem, because it is associated with a loss of independency in carrying out essential tasks and roles needed for self-care and independent living. Participation in meaningful activities that is related to one*s quality of life is limited. In addition, disability is associated with a higher risk for mortality, hospitalization, long-term care and related costs. The number of disabled older people is expected to triple until 2050. Therefore, an intervention for delaying or preventing disability is highly relevant in community-dwelling frail elderly. However, evidence about effective interventions is limited.

Study objective

We propose a randomized controlled study to investigate the effectiveness of the intervention. Secondly, a comprehensive process evaluation will be conducted to validate the effectiveness of the intervention and to facilitate future implementation. We will study the content of the program, the performance according to protocol and the compliance with the intervention. Thirdly, data on health care utilization and consumed goods are collected to determine the cost-effectiveness of the intervention.

Study design

In the study 420 community-dwelling frail elderly (70 years or older) and their informal caregivers will be included through a screening of 70+ elderly in twelve GP practices in the region of the Westelijke Mijnstreek. Based on a randomization on practice level, six practices (=210 participants) receive the new intervention as part of the NPO transition project (intervention group) and six practices (=210 participants) receive care as usual (control group). Assuming that 80% of frail elderly has a central informal caregiver, who will also be included in the study, 340 informal cargivers will be added resulting in a total sample size of 760. Data for the effectiveness evaluation will be measured at 6, 12 and 24 months follow-up. Therefore a combination of telephone interviews, postal questionnaires and registries from health insurance, general practitioners and hospitals will be used.

Intervention

The focus of the intervention is on disability prevention. It is a tailor-made

and multidisciplinary intervention that consists of six steps. After an initial postal screening (step 1) of frail older people (GFI * 5) a comprehensive multidimensional assessment (step 2) will be done by a practice nurse in collaboration with the general practitioner (GP). The assessment phase focuses on the identification of existing limitations in daily life and on risk factors for future limitations (e.g. polypharmacy, mobility, falls, lack of social and productive activities, cognitive impairments). Practice nurse and GP determine if additional assessment is needed for example by means of the GP, physiotherapist or other specialist from the first and second echelon. After the assessment, the practice nurse and GP formulate an interim action plan (step 3). In case of complex problems clients can be discussed in a multidisciplinary team (practice nurse, GP, physiotherapist and occupational therapist). Consequently, a meeting between the practice nurse and the client (and informal caregiver) takes place to define a definitive action plan, including goals, strategies and actions (step 4). The action plan can be related to a toolbox of interventions, which will be executed by the multidisciplinary team (step 5). During executing and after finishing the components of the toolbox, the practice nurse and the client evaluate the achievement of goals, the implementation of strategies into daily life and the need for support in the following period (step 6).

Study burden and risks

Intervention participants (n=210) receive in the beginning two home visits by a practice nurse (2x 60 minutes). Consequently, participants receive a tailor-made intervention which is related to a toolbox of interventions. Interventions participants can follow several parts of the toolbox. Each part takes round about 5-10 hours. The burden of receiving the intervention can vary a lot among participants, depending on the tailor-made nature of the intervention. A total length of 4-6 months can be expected.
For research purposes all participants (intervention and control group, n=420) have to fill in a short screeningslist at the start. For the effect evaluation a postal questionnaire (ca. 30 minutes) has to be filled in at 4 moments in time and participants will be called four times for a telephone interview (35 min). Postal questionnaires and telephone interviews will be spread over a period of two years. At the end of the intervention, intervention participants will be asked to fill in a short questionnaire for the process evaluation (ca. 10 minutes). In addition several participants will be visited for a short interview (30 min).
Central informal caregivers (n=340) have to fill in a short questionnaire (ca. 30 minutes) at 4 moments in time spread over a period of two years.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- community-dwelling
- age: 70 years and over
- frailty: moderate to severely frail (a GFI score of at least 5)

Exclusion criteria

- those on a waiting list for admission to a nursing home
- cognitive impairments (TICS < 16)
- unable to communicate in Dutch
- confined to bed

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2010
Enrollment:	760
Type:	Actual

Ethics review

Approved WMO Date:	02-12-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	29-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	21-01-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	16-03-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-04-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ISRCTN	ISRCTN31954692
CCMO	NL30037.068.09