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The reduction of disability in community-dwelling frail elderly

Submission date 19/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/11/2009	**Overall study status** Completed	
Last Edited 09/01/2015	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMw 60-61900-98-213

Study information

Scientific Title
The reduction of disability in community-dwelling frail elderly: a randomised controlled trial

Study objectives
1. What is the effectiveness of a tailor-made, multi-component intervention in reducing disability and several secondary functional outcomes in frail elderly?
2. What is the impact of the intervention on the central informal caregiver with respect to perceived burden on health-related quality of life?
3. What is the impact of the intervention on health care utilisation, consumed goods and related costs?
4. Is the intervention performed according to the protocol, is the target group compliant with the intervention, and how is the content of the program valued by the target group and facilitators?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of Maastricht University/Academic Hospital Maastricht approval pending as of 20/10/2009 (ref: MEC 09-3-067)

Study design
Two-armed randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Disability prevention in frail elderly

Interventions
12 GP practices will be selected and randomly allocated to the intervention group or control group; data will be collected at 6, 12 and 24 months follow-up.

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 score of 6 and higher) a comprehensive multidimensional assessment (step 2) is conducted 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 whether additional assessments are needed, e.g. by a physiotherapist. After the assessment(s), 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, if possible) takes place to define a final 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).

During all phases of the intervention the use of self-management abilities will be stimulated. Self-management means that people take responsibility for their own health and well-being. A feeling of competence to change behaviour and a feeling of control over specific situations are important concepts within self-management; both are needed to change behaviour. Self-management supports people in maintaining their daily activities and social roles. Frail elderly learn to cope with changes that are due to diseases or disability by means of their rest-capacities and environmental resources, which is essential for daily functioning and quality of life. Self-activation and self-motivation are important features during all sessions. Therefore motivational interviewing techniques, such as client-centred counselling style, reflective listening and asking directive questions, are added. Motivational interviewing is a directive counselling-style in interventions to change behaviour. It has shown to be effective in both in-home and telephone-based interventions.

Older people in the control group are also identified as frail by means of the screening list (GFI score of 6 or higher). They receive care as usual; they can use and apply for all services as before.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The Groningen Activity and Restriction Scale (GARS) measures disability. The GARS will be assessed in a telephone interview at baseline and at 6, 12, and 24 months follow-up.

Secondary outcome measures
The following secondary outcomes will be assessed in a telephone interview at baseline, and at 6, 12, and 24 months follow-up:
1. Depression (Hospital Anxiety and Depression Scale)
2. Cognitive status (Telephone Interview Cognitive Status)
3. Fear of falling (Shorted Falls Efficacy Scale-International)
4. Participation (Maastricht Social Participation Profile, scale A)
5. Frequency of falls, assessed by the question: "How often do you have fallen during the past 6 months?"
6. Mortality, health care utilisation/consumed goods and related costs are registered during 24

months. The use of health care services relates to the frequency and duration of care from the following services: community health and social services, primary health care services and institutional care. Consumed goods are: helping aids, assistive devices and medication use.

As the proposed study will be embedded in the NPO, the MDS (Minimal Data Set) will be applied at baseline, 6, 12, and 24 months follow up by means of a postal questionnaire. The MDS provides global data on: age, gender, marital status, ethnicity, living arrangements, socio-economic status, level of education, health perception, multi-morbidity, 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 by the MDS.

Questions about social support interactions (Social Support List - Interaction version) and a question about feelings of loneliness (During the past 4 weeks, how often did you feel lonely?) are added.

Overall study start date
04/11/2009

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Frailty: score of 6 or higher on Groningen Frailty Scale (GFI)
2. Community-dwelling
3. Aged 70 years and over, either sex
4. Willingness to participate

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
420 participants

Key exclusion criteria
1. Those on a waiting list for admission to a nursing home
2. Cognitive impairments (Telephone Interview for Cognitive Status [TICS] less than 16)
3. Unable to communicate in Dutch
4. Confined to bed

Date of first enrolment
04/11/2009

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Universiteitssingel 40
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Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/08/2010		Yes	No
Results article	results	10/09/2013		Yes	No
Results article	cost-effectiveness results	01/05/2015		Yes	No