Effect of functional training on the ability to live independently and participation of frail elderly of 75 years and older

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33205

Source
ToetsingOnline

Brief title
Training of the ability to live independently 75+

Condition

- Other condition

Synonym
frail, multimorbidity

Health condition

eerstelijns ouderen geneeskunde: multimorbiditeit

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: ZonMW;Nationaal Programma Ouderenzorg

Intervention

Keyword: ability to live independently, elderly, frail, physiotherapy

Outcome measures

Primary outcome

The primary outcome measure is the ability to live independently and participation, as measured with the Physical Performance Test and the questionnaire Impact on Participation and Autonomy.

Secondary outcome

Secondary outcome measures are: perceived health state, quality of life, restraints in important daily activities, psychological and social functioning, level of physical activity, fall incidents, fear of falls, use of care, treatment satisfaction, perceived effect, mobility, and cardiovascular fitness.

Study description

Background summary

The functional training programme, in contrast to traditional exercise programmes, focuses on training of those daily activities which are problematic for the elderly. We expect that particularly in frail older people with multiple problems in daily functioning, functional training can improve their ability to live independently, especially when it will be delivered individually and in the older persons* homes.

Study objective

The aim of this study is to measure the (cost)effectiveness of a functional training programme delivered in the older persons* homes as compared to

traditional physical therapy with regard to the ability to live independently and participation of frail elderly of 75 years and older with problems in physical functioning.

Study design

The study consists of two parts: a screening study and an intervention study. By means of a short screening questionnaire (via general practitioner) frail elderly will be traced. A research staff member of the LUMC will visit the frail elderly at home to check whether the older person meet the inclusion criteria of the intervention study *Physiotherapy 75+*. Their general practitioner will check whether physiotherapy is safe and give them a referral for physiotherapy. This is the start of the intervention study. A research staff member of TNO will visit these elderly at home for a baseline measurement (questionnaires and physical tests) and will ask informed consent to participate in the study. Subsequently, the elderly will be randomized to the functional training programme (n=75) or regular physical therapy (n=75). Follow-up measurements will take place 3, 6 and 12 months later.
First, a pilot study will be conducted to the feasibility of the training and the measurements.

Intervention

The elderly in the functional training programme will be referred to a physiotherapist who has been specially educated to deliver the functional training programme in the older person*s home. In the functional training programme (maximum of 18 sessions) the daily activities experienced as troublesome by the participant are trained in a stepwise manner in the home situation. In addition, caretakers or home care workers can be called in for guidance in the home situation to stimulate the elderly to perform daily activities themselves and to stay active. To achieve a long-term effect, the physiotherapist will guide the older person during the training programme in regular and safe physical activity and thus stimulate him or her to more physical activity at home and in the neighbourhood. The elderly in the control group will receive regular physical therapy (usually consisting of muscle exercises, balance exercises and walking exercises) (maximum of 18 sessions) from a physiotherapists who has not been educated in the functional training programme.

Study burden and risks

Burden
It will take the participants a maximum of 15 minutes to fill in the screening questionnaire. The visit of the research staff member of the LUMC will take approximately 1 hour. The research staff member of TNO will visit the participant 4 times to fill in a questionnaire and to perform some physical

tests (approximately 1.5 hour per visit). The physical therapy intervention consists of a maximum of 18 sessions of a half hour.

Risks
Physiotherapists are used to treat (frail) elderly in a safe manner. The training programme will be tuned to the capacities of the individual. As a result the risk of participation to the study is not larger than the risk of physical tiredness. Literature shows that high age and frailty are no contraindications for participation in a training programme. In the former study on the effectiveness of the functional training programme in fairly healthy elderly living at home no serious side effects or injuries were reported. Before inclusion in the study, the general practitioner will check whether the older person has a contraindication for physical therapy.

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

- 75 years or older
- living independently
- problems in physical functioning (restraints in daily activities)
- and, in addition, problems in at least one of the following domains: somatic, mental and social functioning
- understanding questions and instructions

Exclusion criteria

- terminal illness (life expectancy less than 3 months)
- planned surgery within 3 months
- physiotherapy or exercise therapy at the moment of inclusion or in the three months preceding inclusion
- contra-indication for physical exertion (assessed by general practitioner)

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:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL28893.058.09