

Training of the ability to live independently 75+.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20024

Source

Nationaal Trial Register

Health condition

Frail elderly, living at home, problems with physical functioning as well as problems of somatic, psychological and/or social nature.

Kwetsare thuiswonende ouderen van 75 jaar en ouder die naast problemen in het functionele domein ook problemen hebben in het somatische, psychische en/of sociale domein.

Sponsors and support

Primary sponsor: TNO Kwaliteit van Leven (TNO Quaylit of Life)
Leiden

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The ability to live independently and participation, as measured with the Physical Performance Test and the questionnaire User-Participation.

Secondary outcome

1. Perceived health state;
2. Quality of life;
3. Restraints in important daily activities;
4. Psychological and social functioning;
5. Level of physical activity;
6. Fall incidents;
7. Use of care;
8. Treatment satisfaction;
9. Perceived effect;
10. Mobility.

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.

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.

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. The study populations consists of persons of 75 years and older living at home who have problems with physical functioning as well as problems of somatic, psychological and/or social nature.

Study objective

The aim of this study is to determine the (cost)effectiveness of a home-based functional training programme as compared to regular 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.

The home-based intensive functional training programme 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 design

T0: Baseline measurement before randomization and start of therapy.

T1: 4 months after T0 (after finishing therapy).

T2: 8 months after T0.

T3: 12 months after T0.

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 the home situation. The intensity and repetitions of the exercises are progressively increased over time and performed in progressively more challenging ways such as double tasking. To achieve a long-term effect, the physiotherapist will guide the participant during the training programme in regular and safe physical activity and thus stimulate the participant to more physical activity at home and in the neighbourhood.

In addition, caretakers can be called in for guidance in the home situation to stimulate the participant to perform daily activities and to stay active. This prevents caretakers take needlessly daily activities off the participant's hands.

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 physiotherapist who has not been educated in the functional training programme.

Contacts

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Eligibility criteria

Inclusion criteria

1. 75 years or older;
2. Living independently;
3. 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;
4. Understanding questions and instructions.

Exclusion criteria

1. Terminal illness (life expectancy less than 3 months);
2. Planned surgery within 3 months;
3. Physiotherapy or exercise therapy at the moment of inclusion;
4. 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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-07-2010
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion	
Date:	06-07-2010
Application type:	First submission

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
NTR-new	NL2280
NTR-old	NTR2407
Other	ZonMW : 311060302
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A