The Prevention and Reactivation Care Programme: a personalized, integrated intervention for prevention of functional decline after hospital stay.

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

Summary

ID

NL-OMON36510

Source
ToetsingOnline

Brief title
ZPH study

Condition

- Other condition
- Therapeutic and nontherapeutic effects (excl toxicity)
- Age related factors

Synonym
Frailty, Independence, Multimorbidity

Health condition

Ouderen Geneeskunde: Multimorbiditeit

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw;Nationaal Programma Ouderenzorg

Intervention

Keyword: Elderly, Functioning, Integrated care, Prevention

Outcome measures

Primary outcome

The effect evaluation will assess patient and caregiver outcomes (e.g. health related quality of life, physical functioning, cognitive functioning, social and emotional functioning, psychological functioning, objective and subjective burden of care), duration of hospital stay as well as (re-)admittance in hospital or nursing homes and mortality. Costs will be determined from a societal viewpoint for evaluation of cost effectiveness of the ZPH compared to current, usual care

Secondary outcome

Secundary study parameters for the effect evaluation are cognitive functioning and psychological/social functioning of the patient and patient self management.

Study description

Background summary

Elderly who are admitted in the hospital are at risk for hospital related functional loss. To prevent hospital related functional loss and promote a fast

recovery and return to independent living, the prevention and reactivation care program (Zorg voor Preventie en Herstel, ZPH) was developed.

Study objective

This health care evaluation study will compare the ZPH with other, usual forms of care given to frail elderly in the hospital. It will also evaluate the added value of a centre for prevention and recovery (Centrum voor Preventie en Herstel, CPH)

Study design

A research design in the form of an observational, prospective cohort study will be conducted in three hospitals (Vlietland, Ruwaard van Putten, Sint Franciscus Gasthuis). The effects of the CPH will be studied separately by means of a RCT, embedded in the ZPH hospital (Vlietland). The study will include an effect, process and cost evaluation using a mixed methods design of both quantitative and qualitative methods.

Intervention

Participants will receive care that is the standard at their hospital. In the Vlietland hospital this standard is the prevention and reactivation care program (ZPH). ZPH has been developed over many years and offers a package of interventions and treatment plans that are integral, multidisciplinary and goal-oriented (at physical, social, and mental domains of functional loss) as well as based on the needs of the individual patient. An extra element in the ZPH is the CPH for extra vulnerable elderly patients. CPH consists of a stay at the CPH centre and involves intensive and theme oriented reactivation treatments, specialized nursing home care, paramedical care (e.g. physiotherapy, dietetics, occupational therapy) and specialized mental health care (GGZ) (e.g. psychiatrist).

Study burden and risks

None

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

Aged 65 years and older
Admitted in one of the participating hospitals (expected stay >= 2 days)
At risk for loss of function (score > 2 on the ISAR and score 15 or lower on the Barthel index and/or score 3 or higher on the NPI);Inclusion criteria for stay in the CPH: positive score on a functional assessment list. Including delirium score, clinical determinants such as anemia and low BMI, and the burden for the informal carer

Exclusion criteria

Unable to answer questions or follow instructions (e.g. due to severe cognitive problems (MMSE score < 12) or being in coma) within 2 days of within 5 days after admission in the hospital
Terminal illness (life expectancy < 3 months)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2011
Enrollment:	2900
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL35205.078.10
Other	TC 2317