Central Utrecht Elderly Care Project

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The aim of the project is to evaluate the best method of supported care in general practice that leads to greater self-sufficiency, higher retention of functions and thus improved quality of life, less use of care facilities and a lower burden of...

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

Summary

ID

NL-OMON34794

Source
ToetsingOnline

Brief title
Om U project

Condition

- Other condition

Synonym
frailty, multimorbidity

Health condition

chronische ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw subsidie in het kader van het Nationaal Programma Ouderenzorg

Intervention

Keyword: elderly, frailty, multimorbidity

Outcome measures

Primary outcome

The primary outcome parameter is change in daily functioning. Daily functioning (ADL) is measured with the Katz 15 questionnaire which is embedded in the Minimal Data Set questionnaire.

Secondary outcome

Secondary outcome parameters are:

1. Quality of life (RAND-36, EQ5D, both embedded in the Minimal Data Set)

2. Care use (number of referrals, admittances, prescriptions, diagnoses and visits) expressed in:

a) number of *elective* interventions in secondary care (planned admittances);

b) number of *emergency* admittances in secondary care, nursing homes and older people homes homes;

c) number of contacts with the general practitioner*s surgeries, outside the regular hours;

d) number of contacts with the healthcare assistant, the general practitioner, the general practice assistant and GNPC;

e) medication use, dysfunctional and functional polypharmacy;

f) consultation with other primary carers (AMW (General Social Work), physiotherapy, homecare);

3. Mortality

4. Cost-effectiveness analysis (CEA)

For the CEA, the ratio of differences in the main outcome measure - (I)ADL - between the three groups and differences in costs will be analyzed.

5. Patient satisfaction

Patient satisfaction will be measured in the Minimal Data Set.

6. Comparison of frailty index courses between groups, with particular attention to the proportion of patients with polypharmacy, multimorbidity and a care gap of > 3 years. Secondly, focus on the correlation of frailty index scores with daily functioning and quality of life as reported in the Minimal Data Set.

7. Time spent on informal caring and burden of this care for the informal carer; health status and quality of life of informal carer.

The secundary outcome parameters are partly measured with the extraction of routine care data by UPRIM, and partly with data acquired in the Minimal Data Set questionnaires (the MDS for the participants as well as for the informal carers).

Study description

Background summary

With the increase of older people in society it can also be expected that the number of older people with increased frailty will rise. The precise definition of the term *frailty* is still being discussed in the international arena. This project uses the following definition: *a loss of resources in various functional domains that leads to decreased reserve capacity to deal with stress.* (source: National Elderly Care Programme (Nationaal Programma

Ouderenzorg) 2008-2011, Steverink N, Slaets J.P.J, Schuurmans H, van Lis M, Gerontologist 2001).
Older people with multi-morbidity interviewed in the Utrecht region experience problems with a lack of *overview* by their primary care givers and a lack of care coordination. This was discovered during research carried out last year by the Utrecht Patients* Support Group (CliëntenBelang Utrecht). 'What I need is someone who knows what*s going on and can see things from my side.* This heartfelt cry was made by an older person with multimorbidity in the Utrecht region. Older people in the region wish to be kept informed and need someone who can help them to make well-considered decisions with regard to their health. Health care professionals do not coordinate care sufficiently, nor do they keep each other adequately informed. The Central Utrecht Elderly Care Project (Om U) aims to provide the answer to older peoples* need for more coordination of care and integrated care.

Study objective

The aim of the project is to evaluate the best method of supported care in general practice that leads to greater self-sufficiency, higher retention of functions and thus improved quality of life, less use of care facilities and a lower burden of care for older people. This will be brought about by adequately monitored adaptations to the existing care structure.

Study design

A cluster randomized, controlled, single blind intervention study in the general practice. A three-armed study design is used to compare the effects of two interventions with the usual care group during a 12 months follow-up period.

Intervention

1. Periodic (quarterly) Risk Identification of frailty and Monitoring of care to older people (UPRIM) in electronic medical records of the general practice.
2. UPRIM plus the introduction of a specially trained Geriatric Nurse Primary Care (GNPC), who maintains contact with the patient and their caregivers, develops and monitors an individual care plan and coordinates the care provided by all involved parties. Patients will also be visited by the GNPC at their homes.

Study burden and risks

Patients will be asked to fill in a questionnaire three times a year. Filling in these questionnaires will take about 20-30 minutes each time. Besides that, patients in the intervention group of UPRIM and the GNPC will have one or more

home visits of the GNPC, depending on the level of care required.

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

Potentially frail older people; patients of 60 years and older in general practice setting with one or more of the following three criteria:
- multimorbidity (defined as a frailty index score of 0.20 or higher, for eleborate details see chapter 5 of the protocol), AND/OR
- polypharmacy (5 or more different drugs in actual chronic use), AND/OR
- care gap (more than three years no contact with the general practice, except for the yearly influenzae vaccination)

Exclusion criteria

- terminally ill patients
- patients living in an elderly care home or nursing home
- patients on a waiting list for an elderly care home or nursing home

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2010
Enrollment:	5000
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-04-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-05-2011

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL30071.041.10