Pro-active care for the older people at risk for functional decline: Screening for vulnerability and effectiveness of a subsequent guided care plan in primary care

Published: 30-06-2009
Last updated: 04-05-2024

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

Summary

ID

NL-OMON33008

Source
ToetsingOnline

Brief title
Integrated Systematic Care for Older PEople (ISCOPE)

Condition

- Other condition

Synonym
older people with multiple problems, vulnerable elderly

Health condition

eerstelijns ouderengeneeskunde

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: care plan, frail elderly, general practice, pro active care

Outcome measures

Primary outcome

Difference in quality of life, functional status of the participants in the

intervention group versus the control group after 12 months.

Secondary outcome

Satisfaction of older persons, caretakers and caregivers with delivered care,

indicators for proactive, coherent care and costs per quality adjusted life

years (QALY).

Study description

Background summary

The number of older people with a combination of somatic, functional, mental or social problems is rising. The problems these older people are facing are not always known to care-providers. The general practitioner (GP) may sometimes suspect the presence of some of these problems, but usually only acts on demand. For vulnerable elders a screening/monitoring and proactive way of working is important, although this is not yet common in primary care.

Study objective

The aim of this project is to introduce a simple structural monitoring system to detect the deterioration in somatic, functional, mental or social health of individuals aged 75 years and over. Subsequently, a care plan will be made for

those older people with a combination of somatic, functional, mental and social problems.

Study design

Seventy general practices will be recruited from the region around Leiden. These 70 practices will be randomized 1 to 1 at practice level after all patients of 75 years have been selected form the Electronic Patient record (EPR).
The GPs and practice staff of the intervention group will then be trained in designing, executing and adjusting the care plan. In all 70 practices a short questionnaire with questions about somatic, functional, mental and social health is sent to all people of 75 years and older. The results of this questionnaire will be fed back to the GP's of the intervention group who will formulate a care plan, together with the particular older person, his/her caregiver and deliberated with other caretakers for older people with problems on 3 or 4 domains. For patients with problems in 1 or 2 domains the GP will initiate individual or programmatic interventions.

All older people with problems on 3 or 4 domains and a representative sample of the participants with problems on 0, 1 or 2 domains will be visited by a research nurse to administer a number of additional questionnaires, necessary for baseline measurements. After 12 and after 24 months those older people will be visited again. The results of these additional questionnaires will not be fed back to the GP.

Intervention

In the intervention group (35 practices), results of the screening questionnaire are sent back to the GP and are registered in the Electronic Patient Records (EPR) of the GP. The GP, in cooperation with practice staff (e.g. practice nurse, GP*s assistant), makes a care plan for all older people with problems in three or four of the four domains in the questionnaire after an exploratory interview with the patient and his/her caretakers. Depending on the seriousness of the problems and the kind of problems, the care plan will incorporate indicated diagnostic strategies, indicated interventions, medication review, referral to home care, contact with social work, treatment by paramedics or bringing together all caregivers involved in the care for the patient. GP and practice staff will be trained to implement this monitoring and pro-active way of working. The opinion and capabilities of the older person and his/her family and caretakers are included in this process.
For patients with problems in 1 or 2 domains the GP will initiate individual or programmatic interventions

Study burden and risks

Burden: It will take the participants a maximum of 15 minutes to fill in the screening questionnaire. All older people with problems in 3 or 4 of 4 domains and a representative sample of older people with problems in 0, 1 or 2 domains will be visited at home to administer additional questionnaires. This visit will take approximately one and a half hour. During this visit the research nurse administers questionnaires necessary for baseline of outcome measurement. In the intervention group, the GP may ask the older patient to pay him/her a visit at the practice or the GP visits the older patient at home to discuss a care plan tailored to the individual patient. In both intervention and control group, the screening questionnaire and outcome measurements will be repeated after 12 and after 24 months. After 6 months all participants receive the screening questionnaire and a questionnaire for the economic evaluation.

Risk: No additional risks are involved in this project compared to standard care. The interventions that will be used in the care plans or as programmatic intervention are commonly used or prescribed in General Practice. All standard care is according to current treatment guidelines.

Benefits: Early detection of vulnerability and offering integrated care is likely to be more effective and beneficial to prevent deterioration in functional abilities.

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

Inclusion criteria for screening: people aged 75 years and over enlisted in general practices.
Inclusion criteria for GP care plan in intervention practices: poor performance on >=3 out of 4 domains on screening questionnaire.

Exclusion criteria

Exclusion criteria for screening: terminal illness (life expectancy < 3 months),
Exclusion criteria for GP care plan: none.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2009
Enrollment:	10000
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	30-06-2009
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	NL27893.058.09