Integrated Systematic Care for Older PEople.

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A slow and unpredictable deterioration of the capabilities of the older patient can lead to a vulnerable situation, often unnoticed by the caregiver. As a consequence, care is delayed and acute problems will arise that will need an immediate...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24755

Bron
NTR

Verkorte titel
ISCOPE

Aandoening

ENGLISH:
frailty, older people with multiple problems

DUTCH:
kwetsbare ouderen, ouderen met meerdere problemen

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Department of Public Health and Primary Care
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in quality of life, functional status of the participants in the intervention group versus the control group after 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

RATIONALE:

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.

OBJECTIVE:

The aim of this project is to assess the value/efficacy/cost-benefit of a simple structural monitoring system to detect the deterioration in somatic, functional, mental or social health of individuals aged 75 years and over followed by the execution of a care plan for those people with a combination of somatic, functional, mental and social problems.

STUDY DESIGN:

Randomisation: This study employs a randomised design. Seventy general practices (clusters) will be randomized in a 1:1 ratio to the experimental monitoring system or usual care.

MONITORING AND SCREENING PHASE:

From all 70 general practices a short screening questionnaire with questions about somatic, functional, mental and social health will be sent to all people of 75 years and older. Older persons who do not return the screening questionnaire will be contacted through the GP and

will be offered help with the questionnaire.

INTERVENTION:

In the intervention group (35 practices), results of the screening questionnaire will be sent back to the GP and registered in the Electronic Patient Records (EPR). The GP, in cooperation with practice staff (e.g. practice nurse, GP's assistant), will make a care plan for older people with problems in three or four of the four domains in the screening questionnaire, involving preferences and capabilities of the patient and his/her caretakers. This care plan will incorporate treatment goals and actions to be taken, such as indicated diagnostic strategies and interventions, medication review, referral to home care or social work or consultation with other caregivers involved. For patients with problems in 1 or 2 domains the GP will initiate individual or programmatic interventions. GP and practice staff will be trained to implement this monitoring and pro-active way of working. In the control group (usual care, 35 practices), the GPs will not receive feedback information from the screening questionnaire, patients will be provided usual care.

MAIN STUDY PARAMETERS AND ENDPOINTS:

The primary outcome of the study is the difference in functional status of the participants in the intervention group versus the usual care group after 12 months measured with the ADL (Acivities of Daily Living) items of the Groningen Activities Restriction scale.
Other outcomes are quality of life of participants, percentage of unplanned admission in nursing homes or hospitals, percentage home visits during evenings, nights and weekends and outcomes related to quality of care such as satisfaction of participants, caretakers and caregivers with delivered care and indicators for proactive, coherent care. Outcomes will be measured by means of an interview with structured questionnaires.

ECONOMIC EVALUATION:

The economic evaluation will compare incremental societal costs (screening, intervention, other health care consumption, (in) formal home care) to the difference in functional status (primary outcome measure) and in quality of life (cost-effectiveness analysis). For cost-utility analysis (costs per quality adjusted life years [QALY]), a Visual Analogue Scale for perceived health status and the EQ-5D+c (EQ-5D extended with a cognitive dimension) will be added. Both the cost-effectiveness analysis and cost-utility analysis will use a one-year time horizon, without discounting.

NATURE AND EXTENT OF THE BURDEN AND RISKS ASSOCIATED WITH PARTICIPATION,

BENEFIT AND GROUP RELATEDNESS:

It will take the participants a maximum of 15 minutes to fill in the screening questionnaire. Older persons not returning the screening questionnaire will be contacted by telephone through the GP and offered help to fill in the questionnaire. A representative sample of older people will be visited at home to administer additional questionnaires (home visit of 60-90 minutes).
In the intervention group, the GP may ask the older patient with multiple problems 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 usual care practices, the screening questionnaire and outcome measurements will be repeated after 12 and 24 months. After 6 months all participants receive the screening questionnaire and two questionnaires for the economic evaluation.

RISK OF PARTICIPATION:

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.

Doel van het onderzoek

A slow and unpredictable deterioration of the capabilities of the older patient can lead to a vulnerable situation, often unnoticed by the caregiver. As a consequence, care is delayed and acute problems will arise that will need an immediate solution. The actions taken in these situations, such as hospital or nursing home admissions, are not always beneficial for the older patients. The provided care is expensive and of less quality, and the older patient and the caregiver are often dissatisfied with the provided care. These urgent solutions will probably not be necessary when vulnerable situations are detected in time and adequate help is being organized. Further deterioration is then likely to be prevented.

Onderzoeksopzet

1. Start 1-9-2009;

2. M1-12 execution of the intervention;

3. Baseline measurements;

4. M13-24 outcome measurements and evaluation.

Onderzoeksproduct en/of interventie

The GP's formulate a care action plan for frail elderly.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for screening:

1. People aged 75 years and over;

2. Enlisted in general practices.

Inclusion criteria for GP care plan in intervention practices:

1. Poor performance on >3 out of 4 domains on screening questionnaire.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Exclusion criteria for screening:

1. Terminal illness (life expectancy < 3 months).

Exclusion criteria for GP care plan: None.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	10000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1836
NTR-old	NTR1946
Ander register	ZON-MW : 60-61900-98-126
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A