Opti-Med: Optimisation of a medication review programme for elderly in general practice.

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

Samenvatting

ID

NL-OMON29548

Bron
Nationaal Trial Register

Verkorte titel
Opti-Med

Aandoening

Elderly of 65 years and older with geriatric giant problems

Dutch:
Ouderen van 65 jaar of ouder met geriatrische reuzen problematiek

Ondersteuning

Primaire sponsor: VU Medical Center and NIVEL
Overige ondersteuning: ZonMW Priority Medicines

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Quality of Life as assessed with EQ5D and SF12 by the patient and with the EQ5D by proxies.

2. The presence of geriatric giants on a scale from 1-10.

Toelichting onderzoek

Achtergrond van het onderzoek

The objective of the Opti-Med study is to establish the cost-effectiveness of a structured medication review and monitoring of the medication used by patients aged 65 and over who present with a new ‘geriatric giant’ problem in general practice.
‘Geriatric giants’ are mobility and stability problems, incontinence and cognitive problems. About 25% of the patients of 65 years or older consult their GP in a year with a new problem that is related to a geriatric giant. In elderly patients these geriatric problems often co-occur with existing chronic diseases and changes in pharmacokinetics and -dynamics. These are all risk factors for suboptimal pharmacotherapy and medication-related problems.
In 2013, a study on an innovative medication review method will start in 20 general practices of the Academic Network of General Practitioner (ANH-Vumc) of the VU medical Centre in Amsterdam, The Netherlands.

In this cluster-randomized controlled study a centrally organised approach of a structured medication review program in 500 patients with geriatric complaints will be investigated. Primary outcome measures are changes in the presented geriatric giant (on a scale 1-10), health related quality of life by self-assessment with Euroqol (EQ-5D) and SF-12, and Euroqol from a proxy perspective by an informal care giver as well as a health care professional. Secondary outcome measures include medication satisfaction, number of drug related problems (DRPs), medication adherence and health care costs.
In addition, the success and failure factors for this new form of medication review will be investigated in a process analysis study.

Eligible patients will be identified retrospectively every eight weeks on the basis of a newly recorded ICPC coded diagnosis in their electronic medical record that could indicate a geriatric giant and will fill in a questionnaire to confirm their eligibility. Exclusion criteria include an ICPC diagnosis of dementia in the electronic medical file or the inability to fill in the questionnaires in combination with an MMSE examination score of 18 or less indicating serious cognitive impairment.

The medication review will follow Dutch guidelines for review of medicines for polypharmacy patients as much as possible. The unique element of this intervention is that the medication review is carried out by a centrally coordinated expert team, consisting of an independent GP and pharmacist, assisted by a ICT application.

This study is a collaboration between the EMGO+ Institute for Health and Care Research at VU University Medical Center Department of general practice & elderly care medicine and NIVEL (Netherlands Institute for Health Services Research)

Doel van het onderzoek

Several questions with respect to the routine use of medication reviews are not yet answered which hamper their large scale implementation. The Opti-Med study addresses these three problems.
1. A lack of evidence about the effectiveness of medication reviews in primary care in terms of improving health status;
2. Which patients benefit most of medication reviews and
3. Which method is most feasible in daily care in terms of workload.

In this study we will test the hypothesis that a structured review by a general practitioner and pharmacist, of all medication taken by elderly patients who present with a new geriatric problem in general practice will have a beneficial effect on patients' quality of life and will be cost-effective.

Onderzoeksopzet

Inclusion

Baseline T=0

Intervention (for intervention group)

3 months T=1

6 months T=2 = endline

Onderzoeksproduct en/of interventie

Intervention group

An external expert team consisting of an assistant, a general practitioner and a pharmacist will carry out the medication review of every participating patient in the intervention practices in cooperation with the practice nurse of each individual GP practice.
related problems (DRPs) experienced by the The patients' medication will be structurally

reviewed with the Dutch STRIP method and come to an medication advice.

The GP will have a consultation with the patient in which both the medication advice and the patient's perspective that has previously been assessed by a questionnaire is discussed and definitive changes in the medication will be implemented.

Control group

Usual GP care

Contactpersonen

Publiek

Van der Boechorstraat 7, room D550

Floor Willeboordse
Amsterdam 1081 BT
The Netherlands
+31-(0)20-4445584

Wetenschappelijk

Van der Boechorstraat 7, room D550

Floor Willeboordse
Amsterdam 1081 BT
The Netherlands
+31-(0)20-4445584

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

One or more of the following new geriatric giants:

1. Actual mobility problem;

2. Two falls or more in the last 6 months;

3. One fall in the last 6 months and a score on the visual analogue scale for Fear of Falling (VAS-FOF) of 5 or more;

4. Dizziness;

5. Urinary incontinence;

6. Problems with cognition.

The geriatric giants identification is a two-step approach:
1. Identification by ICPC codes in GP registration system. Every 8 weeks patients who consulted the GP with a relevant diagnosis in this time period and did not present the problem to the GP during the previous 12 months will be invited to participate.
2. Self-report by patients of the presence of at least one geriatric giant (5 or more on a scale of 1-10)

Additionally they have to indicate that they are willing to participate in the trial by signing an informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- All patients with a diagnosis of dementia in the medical record.

- Patients with an MMSE score of 18 or less. An MMSE interview is only carried out when patients indicated they needed help to fill in the inclusion questionnaire.

- A terminal illness leading to an expected death within six months.

- Not willing or unable to participate in studies trials according to GPs.

- Received a systematic medication review according to polypharmacy Dutch guidelines in the last 6 months

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-11-2013
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2013
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	NL4048

Register	ID
NTR-old	NTR4264
Ander register	ZonMW : 40-41600-98-11018
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A