Drug use Reconsidered in the Elderly using goal Attainment scales during Medication Review - The DREAMeR-study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27932

Source
NTR

Brief title
DREAMeR

Health condition

Medication review, Elderly, Polypharmacy, Drug-Related Problems (DRPs), Goal Attainment Scales

Medicatiebeoordeling, Ouderen, Polyfarmacie, Farmacotherapie gerelateerde problemen (FTP's), Goal Attainment Scales

Sponsors and support

Primary sponsor: SIR Institute for Pharmacy Practice and Policy
Source(s) of monetary or material Support: - Nederlandse Service Apotheek Beheer BV - Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP)

Intervention

Outcome measures

Primary outcome

1. Health-related quality of life (EQ-5D-5L)

2. Number of hindering complaints per patient

Secondary outcome

1. Health care utilization (used for calculating direct medical costs and non-medical costs)

2. The number of drug changes per patient

3. The number and type of ceased drugs after 3 and 6 months

4. The number and type of added drugs after 3 and 6 months

5. The number and type of goals at baseline

6. Scores on the Goal Attainment Scales (GAS) measured after 3 and 6 months

7. The number and type of drug-related problems (DRPs) per patient

8. Implementation rate of the recommendations associated with the DRPs

Study description

Background summary

The objective of the DREAMeR study is to investigate whether a clinical medication review, focused on the perceived hindering complaints and personal wishes of the patients regarding their medication, improves health-related quality of life and reduce hindering complaints of older persons aged 70 years or older using 7 or more drugs. Besides that we aim to establish the cost-effectiveness of a clinical medication review.

In this randomized controlled intervention study the effects of clinical medication reviews in 750 patients aged 70 years or older and using 7 or more chronic medicines, will be investigated. Primary outcome measures are: health related quality of life measured by self-assessment with Euroqol (EQ-5D-5L) and the number of hindering complaints measured after 3 and 6 months. Secondary outcome measures include health care utilization (used for calculating direct medical costs and non-medical costs), number and type of drug changes per patient and scores on the Goal Attainment Scales (GAS) measured after 3 and 6 months, number and type of goals at baseline and number and type of drug-related problems (DRPs)

per and implementation rates of the recommendations associated with the DRPs. Pharmacists will select patients aged 70 years or older using 7 or more medicines and invite them for a medication review. Exclusion criteria include: patients where the GP is not the primary caregiver, life expectancy shorter than 6 months, hospital admission < 1 month before the start of the trial and persons who already received a medication review in the past 12 months.

The medication review will follow Dutch guidelines for medication review including the STRIP-method (implicit method of medication review). The unique element of this intervention is that the medication review will pay specific attention to the patients complaints, wishes and self-defined goals related to their medication. Besides that specific attention will be paid to the follow-up and evaluation step of the medication review process.

In 2016 this study will start in about 25-30 community pharmacies located throughout the Netherlands of the franchise formula Service Apotheek. These pharmacists collaborate with their associated general practitioners.

This study is a collaboration between the SIR Institute for Pharmacy Practice and Policy, Utrecht University, Leiden University Medical Centre and Nederlandse Service Apotheek Beheer BV.

Study objective

Clinical medication reviews are increasingly performed. Studies have shown effects of medication reviews on process- and intermediate outcomes, like Drug Related Problems, medication changes and surrogate parameters such as LDL or HbA1c. Moreover, studies suggest that medication reviews can improve pain management or reduce falls. However little effect has been shown on major clinical outcomes, like morbidity, mortality, hospital admissions or quality of life. In particular, quality of life is related to the individual needs of patients in relation to their health and daily problems. The wish to use less medication is common among the elderly with polypharmacy. In this context, more and more research is performed on the topic: "deprescribing" in the elderly. These studies indicate that it is possible to discontinue (preventive) medication in the elderly if the benefits of a drug (e.g. long-term effect) no longer outweigh the disadvantages (e.g. experienced adverse events).

This study, focuses on the elderly with polypharmacy who experience health problems which are possibly related to the use of medication. We hypothesize that a medication review focused on the patient's wishes related to their medication and a well performed follow-up and evaluation will have a beneficial effect on patients' quality of life and will reduce the hindering complaints.

Study design

Inclusion

Baseline T=0

Intervention (for intervention group)

3 months T=1

6 months T=2 = endline

Intervention

Intervention group

Patients in the intervention group will directly receive a clinical medication review at the start of the study.
The medication review will be performed according to the STRIP method (implicit method).

The pharmacist will interview the patient about their medicines. Any experienced health problems that may be related to the medication will be discussed. Specific questions will be asked about practical problems, adherence and positive and negative experiences of the patient with the drugs. In consultation with the patient personal goals will be formulated (Goal Attainment Scales). These goals will concentrate on improving everyday health and personal comfort for the patient. The patient may also mention the occurrence of adverse health effects, such as preventing a new cardiovascular or cerebrovascular event or gastrointestinal bleeding. Subsequently a structural analysis will be performed and drug-related problems (DRPs) will be identified. These DRPs will be prioritized related to the defined goals and, if possible, recommendation(s) will be formulated. Complete discontinuation of medication ("deprescribing") shall, where possible be explicitly addressed.

After that the pharmacist will have a consultation with the general practitioner to establish a pharmaceutical care plan which includes recommendations for drug changes or extra (laboratory) monitoring. It also includes which actions will be carried out when and by whom. This treatment plan will then be discussed with the patient and interventions will be gradually implemented. Two follow-up moments will be planned in 3 months, where the interventions and goals will be evaluated by the pharmacist or the GP and adjusted if necessary.

Control group (waiting list)

Patients in the waiting list group will receive usual care and will be provided with a clinical medication review after 6 months.

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Eligibility criteria

Inclusion criteria

Home-dwelling patients aged 70 years or older, using 7 or more chronic medicines

Exclusion criteria

Persons receiving repeat prescriptions solely from a specialist. (the GP is not the primary caregiver).

Persons with a life expectancy shorter than 6 months. Persons who had a hospital admission < 1 month before the start of the trial.

Persons who already received a medication review in the past 12 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2016
Enrollment:	750
Type:	Actual

Ethics review

Positive opinion

Date:	23-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44034
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5607
NTR-old	NTR5713
CCMO	NL54715.041.15
OMON	NL-OMON44034

Study results