Evaluation of the use of a patient questionnaire in measuring patient reported outcomes of medication reviews

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The medication review is a well-structured pharmaceutical care service, developed to optimize pharmaceutical care for patients with polypharmacy. Patient reported outcome measurements (PROMs) aim to measure the outcome for patients. Implementation...

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

Samenvatting

ID

NL-OMON28732

Bron
Nationaal Trial Register

Verkorte titel
PROMISE (Patient Reported Outcome Measurement – Inquiry into Side Effects)

Aandoening

adverse drug reactions (ADRs), side effects of drugs, medication adherence (MARS), beliefs about medicines necessity and concerns (BMQ), self efficacy (MUSE)

Ondersteuning

Primaire sponsor: Radboud university medical center, Radboud Institute for Health Sciences, IQ Healthcare, Nijmegen, The Netherlands
Overige ondersteuning: Royal Dutch Pharmacists Association, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Total number of ADRs, as reported through the PROM questionnaire at follow up measurement.

Toelichting onderzoek

Achtergrond van het onderzoek

Background

Patient reported outcome measurements (PROMs) aim to measure the outcome for patients. Implementation might be more successful when they are used as part of the care process. Therefore the questionnaire is developed to help patients in preparing themselves for the medication review and to facilitate the pharmacist in detecting drug related problems (DRPs) from patient perspective. For instance, Adverse Drug Reactions (ADRs) which burden a patient or problems with the use of their medication. The patient reported outcomes can be used in addition to existing structure, process en outcome indicators (reported by the pharmacists). The questionnaire is developed and will be tested using baseline data from the trial.

Our aim is to evaluate if a community pharmacist-led medication review results in changes in patient reported outcomes as detected with the PROM questionnaire.

Methods

We have planned a randomised controlled trial, with 3-months follow-up, comparing patients receiving a community pharmacist-led medication review (according to the guidelines) with patients receiving usual care. The total sample comprises 200 patients from 10 community pharmacies. Primary outcome measure is: the difference in the number of patient reported ADRs between baseline and follow up measurement compared between the intervention and control group. Patients with at least 5 systemic drugs in chronic use are selected with an existing online tool within 10 pharmacies. All patients who meet the inclusion criteria and give informed consent are randomised by a research collaborator and will be asked to fill in the PROM questionnaire at baseline. Patients in the intervention group are invited for a community pharmacist-led medication review, starting with a patient interview, followed by an intervention and a follow up measurement three months later. Patients in the control group receive usual care until the follow up measurement; their medication review starts subsequent to this follow up measurement.

Doel van het onderzoek

The medication review is a well-structured pharmaceutical care service, developed to optimize pharmaceutical care for patients with polypharmacy. Patient reported outcome measurements (PROMs) aim to measure the outcome for patients. Implementation might be more successful when PROMs are used as part of the care process. Therefore the questionnaire is developed to help patients in preparing themselves for a medication review and to facilitate the pharmacist in detecting drug related problems (DRPs) from patient perspective. For instance, Adverse Drug Reactions (ADRs) which burden the patient or problems with the use of their medication. The patient reported outcomes to be measured at follow up can be used in addition to existing structure, process en outcome indicators (reported by the pharmacists).

Our aim is to evaluate if a community pharmacist-led medication review results in changes in patient outcomes as detected with the PROM questionnaire.

Onderzoeksopzet

Baseline measurement 2 weeks before patient interview.

Follow up measurement 3 months after the interventions as part of the medication review, just before the evaluation call between pharmacist and patient.

Onderzoeksproduct en/of interventie

All participating pharmacists receive material and written instructions for patient selection, interventions and process registrations. Pharmacists are supported by the researcher in following the study protocol. Medication reviews will be conducted according to the professional guidelines (‘KNMP Richtlijn Medicatie review’).

Patients in each pharmacy are selected with an existing online tool, which was developed to identify patients eligible for a medication review.

All patients who are included and give informed consent are randomised by a research collaborator into an intervention and control group. Patients from both groups are asked to fill in the PROM questionnaire at baseline.

Patients in the intervention group are invited for a community pharmacist-led medication review, starting with a patient interview to identify drug related problems and patient needs by means of the questionnaire.

Information from the patient interview, analysis of patient medication, and clinical records can lead to pharmacists interventions (in agreement with the patient and GP). The PROM questionnaire will serve as a follow up measurement three months after interventions.

Patients in the control group receive usual care until the follow up measurement; their medication review starts subsequent to this measurement.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients eligible for a community pharmacist-led medication review according to the guidelines (use of 5 or more prescribed chronic systemic drugs).
Other criteria to achieve the intended study population of 20 patients per pharmacy to be determined by the pharmacist, like: age over 65, specific chronic diseases, general practitioner (GP) of the patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

To be assessed by the community pharmacists considering:

- cognitive or communication impairments;

- other recently performed pharmacotherapy interventions;

- not willing or unable to participate in study according to GP.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-11-2014
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	NL4690
NTR-old	NTR4895
Ander register	Arnhem-Nijmegen ethical committee : 2014/320

Resultaten