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

No registrations found.

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

Summary

ID

NL-OMON28732

Source
Nationaal Trial Register

Brief title
PROMISE (Patient Reported Outcome Measurement – Inquiry into Side Effects)

Health condition

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

Sponsors and support

Primary sponsor: Radboud university medical center, Radboud Institute for Health Sciences, IQ Healthcare, Nijmegen, The Netherlands
Source(s) of monetary or material Support: Royal Dutch Pharmacists Association, The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Patient reported scores on health perception, beliefs about medication (BMQ) necessity, beliefs about medication (BMQ) concerns, self efficacy (MUSE), and medication adherence (MARS) at follow up measurement.

Change of the number of patients who report ADRs at follow up measurement.

Change of the ADRs that were reported at baseline at follow up measurement compared between the intervention and the control group.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

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):	01-09-2014
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	05-11-2014
Application type:	First submission

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
NTR-new	NL4690
NTR-old	NTR4895
Other	Arnhem-Nijmegen ethical committee : 2014/320

Study results