Medication Review in patients with Polypharmacy in primary care: Effects of the Clinical Rules Engine and the Outcome Prioritisation Tool on Patient and Clinical Outcomes: CRE-OPT study

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In the proposed project we evaluate the potential benefits and feasibility of including (a) a decision support system, *Clinical Rules Engine* (CRE) and (b) patient preferences, using the *Outcome Prioritization Tool* (OPT) in a comprehensive...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46017

Source
ToetsingOnline

Brief title
CRE-OPT study

Condition

- Other condition

Synonym
daily use of 5 medications or more, Polypharmacy

Health condition

polyfarmacie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Decision support software, Medication review, Outcome prioritization, Polypharmacy, Treatment satisfaction

Outcome measures

Primary outcome

The primary outcome measure is treatment satisfaction measured with the

Treatment Satisfaction Questionnaire for Medication (TSQM-II). .

Secondary outcome

Secondary outcome measures are:

a. Patient related: medication adherence, measured with the Medication

Adherence Report Scale (MARS-5), and quality of life measured with EQ-5D .

b. Medication related: Drug Burden Index, changes in medication prescriptions,

number and type of alerts (all extracted by CRE).

c. Process related: time needed in general practice (by GP and nurse

practitioner) and by the community pharmacist; number of contacts between GP

and medical specialist to discuss medication changes; satisfaction of patients

and professionals with CRE-OPT.

Study description

Background summary

Polypharmacy * the use of five or more chronic medications * is widely recognized as a serious health problem. For health care professionals, patients with complex multimorbidity (meerdere chronische ziekten, met tegenstrijdige adviezen in ziekte specifieke richtlijnen) unrelated multiple chronic diseases, with contradictory advice resulting from disease specific clinical guidelines) are difficult to manage. For patients, having to meet a complex medication regime with many different medicines can seriously burden them and can decrease satisfaction with prescribed medication. This *treatment satisfaction* is associated with treatment-related behaviours such as medication adherence, and hence indirectly with successful treatment outcomes and fewer adverse events. Dutch studies incorporating patients with different chronic diseases reported medication adherence between 25% and 99%, with higher percentages in RCTs compared to observational studies, indicating there is a lot to gain here.
In the Netherlands, about 180 patients per general practice have polypharmacy. In 2012, the Multidisciplinary Guideline Polypharmacy (MDR) was introduced to support the care for patients with complex multimorbidity who often receive care from different medical specialists. The Dutch Health Care Inspectorate (IGZ) has even decreed the implementation of this guideline. However, IGZ has adapted the MDR criteria to reduce the number of yearly medication reviews from 700,000 Dutch inhabitants to an estimated 220,000: GPs and pharmacists should perform regular medication reviews at least for all patients aged over 75, who use seven or more chronic medicines, with a decreased kidney function. Nevertheless, these adapted criteria seem highly pragmatic and lack evidence. Limiting the population in this way might result in a large group of patients being exposed to medication errors and adverse events.

Using an intelligent guideline-based software programme (e.g. using clinical guidelines and STOPP/START criteria) that could identify possible medication issues in the medical record (based on diagnoses, patient characteristics such as age and sex, laboratory test results and medication) could decrease the time to prepare the actual review. Moreover, it would standardize the process of medication review, providing a method that is consistent, objective and always alert.
The doctor-patient conversation on treatment preferences may be supported by a simple decision support tool, like the *Outcome Prioritization Tool* (OPT; www.OPTool.nl). OPT combines four visual analogue scales, on four universal health values *Extend life*, *Preserve independence', *Reduce or eliminate pain', and 'Reduce or eliminate other symptoms', respectively. Research has shown that older people with multimorbidity can make a meaningful rank of the relative importance of these values, which might support GPs in patient-centred clinical decision-making.

It is hypothesized that the CRE-OPT will result in better treatment satisfaction with prescribed medication, fewer or less medication alerts from CRE, changes in medication prescription, better medication adherence, lower drug burden index and increased quality of life compared to usual care.

Study objective

In the proposed project we evaluate the potential benefits and feasibility of including (a) a decision support system, *Clinical Rules Engine* (CRE) and (b) patient preferences, using the *Outcome Prioritization Tool* (OPT) in a comprehensive integrated multidisciplinary medication review as compared to usual care. The joined intervention will be further indicated as CRE-OPT.

This results in two research questions:
1. Does the application of CRE-OPT in patients with complex multimorbidity and polypharmacy result in:
a. better treatment satisfaction with prescribed medication as compared to usual care?
b. fewer or less serious medication alerts from CRE, different changes in medication prescriptions ,better medication adherence, lower drug burden index, and increased quality of life as compared to usual care?
2. What is the perceived added value and feasibility of including CRE-OPT in the medication review?
a. Patient perspective: Do patients experience that their preferences are heard and taken into account in the medication review? How do patients evaluate OPT? Do patients experience difficulties using OPT?
b. GP / nurse practitioner / pharmacist perspective: Does CRE-OPT support the GPs / pharmacists in their medication review? Do GPs and pharmacists consider the inclusion of CRE-OPT an added value to the medication review? Do GPs, nurse practitioners and pharmacists consider CRE-OPT a feasible tool to implement in daily practice?

Study design

Cluster randomized clinical trial. Randomization is at practice level stratified to region (Maastricht/Groningen). Per treatment arm 9 practices together with their preferred pharmacist will recruit 180 patients (total 360 patients).

Intervention

Intervention: integral medication review including a consultation with GP, augmented with sophisticated medication review software (*Clinical Rules Engine* (CRE)) and including an explicit assessment of patient preferences using a feasible tool (*Outcome Prioritization Tool* (OPT)). Patients in the control group receive care as usual; GPs are roughly informed about the intervention and are stimulated to evaluate the prescribed medication of the patients participating in the study, in their usual way.

Study burden and risks

At the beginning of the study patient will receive a questionnaire. Thereafter the patient will visit the general practitioner at least one time. After one year the patient will receive the same questionnaire. It is expected that patients will be involved in the medication prescription and wil expierence less adverse events en side effects. In the end patiets will therfore receive a more optimalised version of standard care.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged * 60 years with at least 5 chronic medication prescriptions in at least two different organ systems.

Exclusion criteria

Patients who cannot act for themselves, patients with insufficient knowledge of Dutch language,
patients with a life-expectancy of less than one year.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	360
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-11-2018
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL66019.096.18