PIL: Polypharmacy intervention Limburg, too much or too little?

Gepubliceerd: 07-01-2010 Laatst bijgewerkt: 18-08-2022

The ultimate goal of this project is to increase quality of life through optimization of the medication use of people with multimorbidity and polypharmacy. Goal is not to decrease the number of medications, but to optimize use of medication, and to...

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

Samenvatting

ID

NL-OMON26167

Bron
Nationaal Trial Register

Verkorte titel
PIL

Aandoening

polypharmacy, polyfarmacie
elderly, ouderen
pharmacist, apotheker
general practitioner, huisarts

Ondersteuning

Primaire sponsor: Maastricht University
School for Public Health and Primary Care (Caphri)
Department of General Practice
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Patient physical and mental health]
outcomes (using data from the MDS);
2. Patient psychosocial outcomes, including
quality of life outcomes, well-being and
measures of disability
of functional status (using data from the
MDS).

Toelichting onderzoek

Achtergrond van het onderzoek

Polypharmacy (the long-term use of 5 or more drugs) is a relevant and costly health problem among the
elderly. The proportion of people with polypharmacy is rising as a result of the increasing number of
people suffering from multimorbidity and the ageing of the population. Guidelines for medical practice
are mainly disease-specific and pay little attention to disease-disease, drug-disease and drug-drug
combinations and interactions with their potential harmful adverse effects.

A significant part of chronic medication is prescribed within a specific medical specialism, often lacking
an integrated view of indications, treatment goals and medication. Polypharmacy increases the risk of
side-effects and problems with patient compliance. At the same time polypharmacy may induce
suboptimal treatment because the probability of underprescription increases with the number of drugs
used, thus increasing the chance of inappropriate prescription.

The GP should play a pivotal role in the improvement of this process, with the availability of comprehensive data from his own practice, from the patient, the pharmacists and from other medical
specialists. Furthermore, the GP is in a good position to discuss possibilities to change medication with
the patient.

The ultimate goal of this project is to increase quality of life through optimization of the

medication use of
people with multimorbidity and polypharmacy. The goal is not to decrease the number of medications
per se, but to optimize use of medication, and to assure appropriate prescription.

This project consists of a randomized controlled trial. Randomization takes place at practice level, to
avoid within-practice, inter-patient contamination. Twelve academic practices, related to Maastricht
University will take part in the trial. These practices will include a total of 1240 patients with five or more
medication prescriptions and aged 60 years or older.
The intervention tested is an integral medication control and monitoring system. Information of the
pharmacists is completed with the GPs' electronic patient record and with information from the patients,
gathered by the nurse practitioner during home visits. GPs then formulate a medication advice, which is
sent to other involved medical specialists to ask for their consent. The GPs formulates a final advice and
discusses this with the patient. Modifications are carried through after the patient's consent.
Main outcome measures are measured at baseline and after 1, 6 and 12 months. Important outcome
measures are:

1.Physical and mental health outcomes (using data from the minimal data set (MDS));

2. Patient psychosocial outcomes, including quality of life outcomes, well-being and measures of disability
of functional status (using data from the MDS);

3. Laboratory results with deviating results at baseline;

4. Measures of patient medication adherence, utilization of health services(including the number of
prescriptions, number of hospitalizations);

5. Acceptability and feasibility of the intervention according to patients, GPs, nurse practitioners and
pharmacists (barriers and facilitators).

Doel van het onderzoek

The ultimate goal of this project is to increase quality of life through optimization of the medication use of people with multimorbidity and polypharmacy. Goal is not to decrease the number of medications, but to optimize use of medication, and to assure appropriate prescription.

Onderzoeksopzet

1. Maand 0: 0-meting, Start Interventie groep A (10 deelnemende praktijken);

2. Maand 3: 0-meting, Evaluatie groep A (1 maand), Start interventie groep B (10 deelnemende praktijken;

3. Maand 6: 0-meting, Evaluatie groep B (1maand), Evaluatie groep A(3 maanden), Start interventie groep C (10 deelnemende praktijken);

4. Maand 9: Evaluatie Groep C (1maand), Evaluatie Groep B (3 maanden), Evaluatie en HA consult Groep A (6maanden);

5. Maand 12: Evaluatie Groep C (3 maanden), Evaluatie en HA consult Groep B, (6maanden), Evaluatie Groep A (9 maanden);

6. Maand 15: Evaluatie en HA consult Groep C (6 maanden), Evaluatie Groep B (9 maanden), Evaluatie en HA consult Groep A (12 maanden);

7. Maand 18: Evaluatie Groep C (9 maanden), Evaluatie en HA consult Groep B (12 maanden);

8. Maand 21: Evaluatie en HA consult Groep C (12 maanden).

Onderzoeksproduct en/of interventie

Intervention. The integral medication control and monitoring system exists of an integrated approach:

1. The pharmacist selects patients aged 60 years or older who have polypharmacy;

2. Patients are visited by the nurse practitioner, who makes an inventory of all medication currently used by the patient as well as length and weight of the patient, and blood pressure during a home visit. The patient is also asked about his last visit to a medical specialist and when the next visit will be, because the correspondence of the specialists is not always up to date. Finally the nurse practitioner will measure the relevant patient related outcomes (including the minimal data set (MDS));

3. Information from the electronic patient record (EPR) in general practice is added (medication according to the GP, medical problem list (diagnoses), recent correspondence from other medical specialists and lab results from the last year (kidney, liver enzymes, TSH, glucose, cholesterol, electrolytes and others if relevant for the condition of the patient));

4. If lab results are incomplete or when they are older then 1 year, additional blood tests (kidney, liver enzymes, TSH, glucose, cholesterol, electrolytes and others if relevant for the condition of the patient are performed to complete the file;

5. Based on this comprehensive set of information the pharmacist and general practitioner define an integral medication advice (if appropriate including a reconstruction scheme and fitting in the patient's specific profile (tailor made));

6. This medical advice is reached by following the next six steps:

A. Rubricating medication prescribed in the following seven groups;

a. Cardiovascular;

b. Diabetes mellitus;

c. Tractus digestivus;

d. Pulmonary diseases;

e. Psychofarmaca;

f. Pain medication;

g. Other.
B. Current medication use by the patient, including over the counter drugs and herbs;

C. Indication of the prescriptions. Medication prescriptions are compared with the indications (medical problem list) registered by the GP, and correspondence of the different medical specialists. Possibly patients are undertreated or an indication is not relevant anymore. Different guidelines are used as basis;

D. Side effects;

E. Drug-drug interactions;

F. Evaluation of the way medication is given, and adjustment of dose. In this step we will use the patient parameters like kidney-function and BMI.
7. The integral advice is sent to the medical specialist(s) involved, together with an accompanying letter.
The two main questions for the specialists are:

A. Which of the medication they had prescribed do they consider absolutely indispensable;

B. Whether they can support the medication advice as formulated;

8. After this analyses, the GP integrates the reaction of the medical specialists with the original advice, based on a protocol that takes into account the indication using the Beers-list (Vingerhoets et al, 2005), replacement of certain drugs, interactions, pseudo-double medication, side-effects, contra-indications and dose;

9. The GP discusses the final advice with the patient, and modifications are carried through after patient's consent;

10. In case of new medication prescribed by another medical specialist the patient is asked to visit his/her GP first, in order to evaluate the new medication from the perspective of or in relation to the former integral medication advice.

GPs will be trained to interpret the medication advice and to communicate this advice to their patients (knowledge, communication skills). Eventually, the GP and the pharmacist working together in practice, are trained to make the analysis of the polypharmacy patients. Every month a new practice will start implementing the intervention. During the first two months there will be an intensive training of the GP how to interpret the comprehensive set of information and how to make the medication advice.

The proposed intervention was developed in a pilot project in an academic primary care center in Kerkrade (MCWK) also built on the experiences of two other academic primary care centers. Important experiences, some also reported by others, were that 1) the GP and pharmacist need to cooperate to get a realistic overview of medication and indications (Hanlon 1996); 2) the analysis reveals not only cases of too many, but also cases of too few medications (Kuijper et al, 2007); 3) grouping medication and relating it to diagnoses and treatment aims is very helpful; 4) data on renal and hepatic function were often lacking; 5) early involvement of the patient is necessary to reach effective change in a later stage: patients need to be convinced that his specialist(s) were involved in the medication preview (Denneboom, 2008); 6) it is necessary to involve other medical specialists in the medication review; 7) a home visit by the practice nurse is necessary, not only to explain the project and ask for informed consent, but also to get insight into the real use of medication prescribed (Barat, 2000) and the use of over-the-counter medication.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients older than 60 years with use of five ore more different prescription drugs;

2. Good knowledge of the Dutch language;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Critically ill patients with a life expectancy less than one year;

2. Patients who are incompetent to act for themselves.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart

(Verwachte) startdatum:	01-10-2009
Aantal proefpersonen:	1240
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-01-2010
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	NL2037
NTR-old	NTR2154
Ander register	ZonMW : 60-61900-98-214
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A