# PIL:Polypharmacy Intervention Limburg: too much or too little?

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32535

**Source**
ToetsingOnline

**Brief title**
PIL

### Condition

- Other condition

**Synonym**
daily use of 5 medications or more, polypharmacie

**Health condition**

polyfarmacie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** CAPHRI, department of general practice
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** elderly, integrated medication-advise, multimorbidity, polypharmacy

## Outcome measures

### Primary outcome

Primary study parameters:

physical and mental health outcomes (using data from the minimal data set (MDS))

-patient psychosocial outcomes, including quality of life outcomes, well-being

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### Secondary outcome

Secundary study parameters:

- measures of patient medication adherence, utilization of health

services(including the number of

prescriptions, number of hospitalizations)

-acceptability and feasibility of the intervention according to patients, GPs,

nurse practitioners and

pharmacists (barriers and facilitators)

- costs of medication, costs of extra care, costs of total used care

# Study description

### Background summary

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.

### Study objective

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.

### Study design

This project consists of a randomized controlled trial. Randomization takes place at practice level, to avoid within-practice, inter-patient contamination. We will use the stepped wedge design. Patients from all practices will eventually undergo intervention.

### Intervention

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.

### Study burden and risks

During the intervention-study, the patient have to fill in 6 8 questionnaires, depending on start of the intervention. A nurse practitioner will visit the patient at home once, for an interview. Furthermore he will have 4 consultations with his GP and a monthly collection (instead of 3-monthly) of his chronic medication at his pharmacist.
Expectations are, because of the integrated medication review, the patient will suffer less adverse effects, medication interactions and will eventually receive optimal medical treatment.

## Contacts

**Public**
Selecteer

Postbus 616
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NL
**Scientific**
Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

age 60 years and older AND daily use of 5 medications or more
competency
adequate knowledge of Dutch language
written informed consent

### Exclusion criteria

critical ill patients with a life expectancy less than 1 year

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Other |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-10-2010 |

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| Enrollment: | 1200 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 15-12-2009 |
| 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 | NL30375.096.09 |