Empowering Patients to Improve Safety in Polymedication

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To assess the feasibility of using the developed medication management centre to empower polypharmacy patients, thereby improving drug safety. Secondary objectives are to explore if the tool is able to identify patients at risk for a drug-drug-gene...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON57343

Source
ToetsingOnline

Brief title
EmPaSafe

Condition

- Other condition

Synonym
concurrent medication use, multiple drug use

Health condition

polyfarmacie

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: DDGI, Empowerment, Polymedication

Outcome measures

Primary outcome

The primary outcome is the sense of empowerment and health literacy for

participants before and after use of the MMC.

Secondary outcome

Secondary outcomes include an evaluation of the drug-drug-gene interactions and

adverse drug events in the study populations compared to matched historical

controls.

Study description

Background summary

The research focuses on the challenges and risks associated with polypharmacy, where patients chronically use five or more medications. Polypharmacy presents significant risks, such as adverse drug reactions and decreased medication adherence, particularly in elderly and multimorbid patients. Despite the interconnected nature of drug-drug and drug-gene interactions, these are often treated as separate entities. Ignoring these interactions can be hazardous to patients. Due to the rapidly increasing complexity of these interactions, extensive patient variability, and the high costs, ethical, and logistical challenges of large-scale studies, clinical investigations into these interactions are unfeasible. As a result, there is a substantial knowledge gap in managing complex medication regimens in practice and providing scientifically-based guidelines. The SafePolyMed project aims to develop a patient-centered framework to define, assess, and manage these interactions, ultimately improving medication safety and empowering patients in their own

health management.

Study objective

To assess the feasibility of using the developed medication management centre to empower polypharmacy patients, thereby improving drug safety. Secondary objectives are to explore if the tool is able to identify patients at risk for a drug-drug-gene interaction and lower the adverse drug event rate.

Study design

The study is a proof of concept study conducted at four institutes located in Germany, Greece, Slovenia and The Netherlands. Polypharmacy patients will use the medication management centre (MMC), which provides curated, patient-specific information about drug interactions and pharmacogenetics. To assess patient empowerment, patients will receive questionnaires during a 12 week follow-up period.

Intervention

The MMC that provides patient centred information on drug-drug interactions and pharmacogenetics affecting personal polytherapy. The MMC will show a selection of high quality publicly available information such as details on different types of medications, including their uses, side effects and instructions for use, in the language of the patient. This information is targeted at an individual patient*s medication profile to inform patients to better understand and deal with their personal health information, with regard to drug therapy. Patients in the Netherlands, Slovenia and Greece also will receive their PGx profile to further personalise the MMC experience.

Study burden and risks

Patients are exposed to the regular treatment. In addition, patients will receive questionnaires at baseline, two, and twelve weeks regarding the use and experience of the medication management centre, and a close-out interview at week twelve. In addition, 10ml of blood will be collected during a venipuncture for pharmacogenetic analyses.

Benefits include having access to the medication management centre for the duration of the study. Additionally, patients will receive their PGx profile. This can be used to individualize drug treatment, based on the Dutch Pharmacogenetics Working Group (DPWG) guidelines.

Overall, minimal risks are expected for subjects as they will receive normal clinical care. Information from the MMC will be a curation of existing publicly available data. Any information regarding DDIs and DGIs will be supplemented

with a disclaimer that the patient should not adjust their treatment without talking to a healthcare provider.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Polypharmacy defined as the use of 5 or more drugs
• Start usage of at least one index drug according to the list (amitriptyline, atorvastatin, citalopram, codeine, escalitopram, paroxetin, sertraline, simvastatin, tramadol of venlafaxine), for at least 7 con-secutive days.
• Subject must be >= 18 years old
• Subject is able and willing to take part and be followed-up for at least 12 weeks
• Subject is able to provide a blood or saliva sample

• Subject has signed informed consent

Exclusion criteria

• Pregnancy or lactating
• Life expectancy estimated to be less than three months by treating clinical team
• Unable to consent to the study
• Unwilling to take part
• Subject has no fixed address
• Subject has previously been genotyped for PGx genes
• Subject has no current general practitioner
• Subject is, in the opinion of the Investigator, not suitable to participate in the study
• Estimated glomerular filtration rate (MDRD) of less than 15 ml/min per 1,73m2
• Patients with advanced liver failure (stage Child-Pugh C)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-12-2024
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	14-03-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL87027.058.24