

The Improve Drug Therapy Trial

Submission date 25/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/09/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Medication reviews involve structured patient interviews and a systematic evaluation of medication history to optimise drug use by identifying and addressing drug-related problems (DRPs). DRPs include dosage errors, duplicate prescriptions, adherence issues, lack of effectiveness, potential drug-drug interactions (pDDIs), side effects, storage issues, and patient-reported concerns. Implementing medication reviews in community pharmacies may help mitigate the burden of polypharmacy. This study is the first randomised, patient- and assessor-blind trial investigating the effects of structured medication reviews (Type 2a) in outpatients with polypharmacy.

Who can participate?

Patients aged over 18 years with an intake of eight or more systemically available drugs (in case of combination products, eight or more active ingredients, also including over-the-counter drugs, especially if they are on the list of interaction-relevant over-the-counter drugs)

What does the study involve?

Medication review type 2a focuses on prescribed medication and consists of an assessment of DRPs and personalised recommendations to improve DRPs (both oral and written). The study involves up to three study visits: in the intervention group patients receive one (baseline) or two (baseline + month 3 to 4) medication reviews with a follow-up assessment of drug-related problems after 6 to 9 months. In the control group patients receive an assessment of drug-related problems without any recommendations to improve (baseline) and one "full" medication review with recommendations (months 3 to 4) with a follow-up assessment of drug-related problems after 6 to 9 months.

What are the possible benefits and risks of participating?

Patient benefits:

1. Improved understanding of their treatment through pharmacist-led reviews.
2. Identification of contraindications or serious DRPs, prompting immediate intervention through consultation with treating physicians or clinical pharmacologists.
3. Optimised drug treatment and personalised therapy discussions.
4. All pharmacist recommendations were reviewed with treating physicians to ensure the best possible patient care.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
January 2021 to June 2024

Who is funding the study?
1. Austrian Chamber of Pharmacists
2. Austrian Federation of Social Insurances

Who is the main contact?
Christian Schoergenhofer, christian.schoergenhofer@meduniwien.ac.at

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Effects of a community pharmacy-based structured medication review on drug-related problems and patient-reported outcomes in all-comers with polypharmacy: a randomised, controlled, double-blind, parallel-group trial

Study objectives

The aim of this study is to investigate the prevalence of drug-related problems in outpatients with polypharmacy, and the effects of medication reviews on drug-related problems.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/01/2022, Ethics committee of the Medical University of Vienna (Borschkegasse 8b /6, Vienna, 1090 Wien, Austria; +43 (0)14040021470; ethik-kom@meduniwien.ac.at), ref: 2029 /2021

Study design

Prospective multi-centre randomized-controlled patient and observer-blind parallel-group study

Primary study design

Interventional

Study type(s)

Other, Prevention, Screening, Safety

Health condition(s) or problem(s) studied

Polypharmacy

Interventions

According to the Pharmaceutical Care Network Europe (PCNE) definition, medication reviews are structured patient interviews with systematic evaluations of their medication history with the aim of optimising their drug use by identifying drug-related problems (DRPs) and recommending interventions to improve health outcomes. At baseline, pharmacists conducted a medication review, interviewing patients and assessing drug-related problems (DRPs)—a summative measure of potential pharmacotherapy issues. Patients were randomised (1:1) via an interactive web-response system to either:

Intervention group: Pharmacists addressed DRPs and provided recommendations to patients.
Control group: DRPs were documented but not addressed - patients did not receive recommendations to address them.

After 3 to 4 months, a blinded independent pharmacist reassessed DRPs, maintaining study blinding until this point. Subsequently, all patients received personalised recommendations—for the second time in the intervention group and for the first time in the control group.

Follow-up: An optional third appointment after 6 to 9 months allowed all patients a final DRP assessment.

Intervention Type

Behavioural

Primary outcome(s)

Drug-related problems assessed using a structured medication review type 2a (questionnaire) at baseline, after 3 to 4 months, and after 6 to 9 months

Key secondary outcome(s)

1. Therapy adherence assessed using a structured medication review type 2a (questionnaire) at baseline, after 3 to 4 months, and after 6 to 9 months
2. Health literacy was assessed using a structured medication review type 2a (questionnaire) at baseline, after 3 to 4 months, and after 6 to 9 months
3. The effects of one structured medication review type 2a at months 3 to 4 compared to two structured medication reviews type 2a at baseline and month 3 to 4 on drug-related problems (questionnaire)
4. The number of drug-related problems assessed using a structured medication review type 2a (questionnaire) at baseline, after 3 to 4 months, and after 6 to 9 months
5. The number of medications and active ingredients assessed using a structured medication review type 2a (questionnaire) at baseline, after 3 to 4 months, and after 6 to 9 months
6. Relative and absolute frequency of contraindications or severe drug-related problems that require intervention by clinical pharmacologists/clinical pharmacists or treating physicians, assessed using a structured medication review type 2a (questionnaire) at baseline, after 3 to 4 months, and after 6 to 9 months
7. Associations of gender, age, and number of medications/active ingredients at baseline with the number of drug-related problems assessed using a structured medication review type 2a at baseline

Added 26/03/2025:

1. Descriptive statistics of patients participating in part 2 of the study per group and presentations of reasons why the study was terminated before part 1
2. Absolute and relative number of contributors to drug-related problems (e.g., double prescriptions, dosing errors, etc) and the impact of a structured medication review type 2a (questionnaire) on these parameters at baseline, after 3 to 4 months, and after 6 to 9 months
3. Change in drug-related problems (or contributors) within each group from baseline to month 3 to 4 or month 6 to 9 using a structured medication review type 2a (questionnaire) will be analysed with non-parametric, pairwise comparisons

Completion date

01/06/2024

Eligibility

Key inclusion criteria

1. Patients with intake of ≥ 8 systemically available drugs (in case of combination products, ≥ 8 active ingredients, also including over-the-counter drugs, especially if they are on the list of interaction relevant over the counter drugs)
2. Patients > 18 years of age
3. Patients signing informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

150 years

Sex

All

Total final enrolment

220

Key exclusion criteria

1. Patients not willing to adhere to the study's requirements
2. Patients unable to understand the nature and purpose of the study
3. Previous participation in a structured medication review type 2a

Date of first enrolment

01/06/2022

Date of final enrolment

01/01/2024

Locations**Countries of recruitment**

Austria

Study participating centre**Apotheke U1 Troststraße**

Favoritenstraße 163

Vienna

Austria

1100

Study participating centre**Apotheke Neu Kagran**

Erzherzog-Karl-Straße 84-88

Vienna

Austria

1220

Study participating centre**Ameis Apotheke**

Linzer Straße 140

Vienna

Austria

1140

Study participating centre**DaVinci Apotheke**

Davidgasse 82 - 90

Vienna

Austria

1100

Study participating centre**Marco-Polo-Apotheke**

Ruthnergasse 89

Vienna

Austria
1210

Study participating centre

Thalia Apotheke

Thaliastraße 1

Vienna

Austria

1160

Study participating centre

Ludwigs-Apotheke

Simmeringer Hauptstraße 128

Vienna

Austria

1110

Study participating centre

Apotheke Spinnerin am Kreuz

Wienerbergerstraße 6

Vienna

Austria

1100

Study participating centre

Humanitas Apotheke

Jedleseer Straße 66-94

Vienna

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1210

Sponsor information

Organisation

Medical University of Vienna

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

Other

Funder Name

Austrian Chamber of Pharmacists

Funder Name

Austrian Federation of Social Insurances

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during the study will be available upon request to the corresponding author (Christian Schoergenhofer, MD, PhD, christian.schoergenhofer@meduniwien.ac.at)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/09/2025	23/09/2025	Yes	No