The Improve Drug Therapy Trial

Submission date 25/02/2025	Recruitment status No longer recruiting	Prospectively registered		
23/02/2023	No longer recruiting	☐ Protocol		
Registration date 27/02/2025	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 23/09/2025	Condition category	[] 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 assessorblind 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

Type(s)

Principal investigator

Contact name

Prof Christian Schoergenhofer

ORCID ID

https://orcid.org/0000-0002-2286-1077

Contact details

Waerhinger Gürtel 18-20 Vienna Austria 1090 +43 (0)14040029810 christian.schoergenhofer@meduniwien.ac.at

Type(s)

Scientific

Contact name

Mr Thorsten Bischof

ORCID ID

https://orcid.org/0009-0003-8288-8591

Contact details

Waehringer Gürtel 18-20 Vienna Austria 1090 +43 (0)14040029810 thorsten.bischof@meduniwien.ac.at

Type(s)

Public

Contact name

Mr Stefan Deibl

Contact details

Spitalgasse 31 Vienna Austria 1090 +43 (0)40414100 stefan.deibl@apothekerkammer.at

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

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 Austria 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes