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The Improve Drug Therapy Trial

Submission date
25/02/2025

Recruitment status
No longer recruiting

Registration date
27/02/2025

Overall study status
Completed

Last Edited
26/03/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Pharmacy

Study type(s)
Other, Prevention, Screening, Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2021

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
150 Years

Sex

Both

Target number of participants
200

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
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1220

Study participating centre
Ameis Apotheke
Linzer Straße 140
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1140

Study participating centre
DaVinci Apotheke
Davidgasse 82 - 90
Vienna
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1100

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Marco-Polo-Apotheke
Ruthnergasse 89
Vienna
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Thalia Apotheke
Thaliastraße 1
Vienna
Austria
1160

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Ludwigs-Apotheke
Simmeringer Hauptstraße 128
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Study participating centre
Apotheke Spinnerin am Kreuz
Wienerbergerstraße 6
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Industry

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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

Publication and dissemination plan
The manuscript is finished and ready for submission to a peer-reviewed journal.

Intention to publish date
01/04/2025

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