BMJ Open

Patient perspectives on, and effects of, medication management in geriatric fallers (the EMMA study): protocol for a mixed-methods pre-post study

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To cite: Buchegger S, Iglseder B, Alzner R, *et al*. Patient perspectives on, and effects of, medication management in geriatric fallers (the EMMA study): protocol for a mixed-methods pre-post study. *BMJ Open* 2023;**13**:e066666. doi:10.1136/bmjopen-2022-066666

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-066666).

Received 17 July 2022
Accepted 03 February 2023

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ABSTRACT

Introduction Pharmacotherapy is critical in geriatric fallers owing to the vulnerability of this population. Comprehensive medication management can be an important strategy to reduce the medication-related risk of falling in this patient group. Patient-specific approaches and patient-related barriers to this intervention have rarely been explored among geriatric fallers. This study will focus on establishing a comprehensive medication management process to provide better insights into patients' individual perceptions regarding their fall-related medication as well as identifying organisational and medical-psychosocial effects and challenges of this intervention.

Methods and analysis The study design is a complementary mixed-methods pre-post study which follows the approach of an embedded experimental model. Thirty fallers aged at least 65 years who were on five or more self-managed long-term drugs will be recruited from a geriatric fracture centre. The intervention consists of a five-step (recording, reviewing, discussion, communication, documentation) comprehensive medication management, which focuses on reducing the medication-related risk of falling. The intervention is framed using guided semi-structured pre-post interventional interviews, including a follow-up period of 12 weeks. These interviews will assess patients' perceptions of falls, medication-related risks and gauge the postdischarge acceptability and sustainability of the intervention. Outcomes of the intervention will be measured based on changes in the weighted and summated Medication Appropriateness Index score, number of fall-risk-increasing drugs and potentially inadequate medication according to the Fit fOR The Aged and PRISCUS lists. Qualitative and quantitative findings will be integrated to develop a comprehensive understanding of decision-making needs, the perspective of geriatric fallers and the effects of comprehensive medication management.

Ethics and dissemination The study protocol was approved by the local ethics committee of Salzburg County, Austria (ID: 1059/2021). Written informed consent will be obtained from all patients. Study findings will be disseminated through peer-reviewed journals and conferences.

Trial registration number DRKS00026739.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ In-depth understanding of geriatric fallers' perceptions and experiences of medication-related risks.
⇒ Implementation of an embedded quasi-experimental design in mixed-methods exploring patient-centred and organisational barriers when conducting a comprehensive medication management process.
⇒ Qualitative and quantitative measures analysing co-management of care for geriatric fallers carried out in a geriatric fracture centre.
⇒ Mixed-methods approach complementing pre-post geriatric fallers' perceptions on medication-related risks with comprehensive medication management.
⇒ Reduced time span and number of participants may limit the external validity of the study.

INTRODUCTION

Falls are an increasing public health problem. Approximately 30% of community-dwelling people aged 65 years or older suffer from falls.[1] Approximately 5% of all fall events result in serious injuries requiring hospitalisation.[2] Most hospital admissions are due to hip fractures, fractures of the arm and head injuries.[3] In addition to serious physical injuries, patients often suffer from loss of quality of life,[4 5] fear of falling,[6] increased risk for institutionalisation[7 8] and enhanced rates of morbidity and mortality.[9] In Western Europe, the burden of disease after a fall represents 1.4 million disability-adjusted life-years and >50 000 geriatric patients die due to falls annually.[10]

The individual burden of geriatric fallers is complex and multifactorial.[11] Geriatric patients are frequently exposed to age-related changes in body function and composition, multimorbidity and polypharmacy, which increase the risk of adverse events such as falling.[12 13] Medication is a modifiable risk factor for falls and fall-related injuries.[14] Prescription and monitoring of drug therapy

in older patients is challenging for all involved healthcare professionals and requires a proper balance between optimising control of chronic diseases and minimising the risks of polypharmacy.[15 16] Furthermore, evidence regarding medical treatment of multimorbid patients is scarce.[17 18] Patients with complex healthcare needs frequently suffer because of fragmented and incomplete healthcare.[19] In Austria, similar to other European countries, regular reviews and adjustment of medication have rarely been established in hospital care.[20 21] Comprehensive medication management (CMM) defines a medication review process with a collaborative approach to assess patients' medication regimen and optimise medication therapy.[22] Collaboration with pharmacists can contribute to safe medication use and prevention of drug-related problems.[23] Several studies have investigated the impact of medication review to reduce the risk of falling, but outcome measures are heterogeneous, and results vary widely.[23–29] Furthermore, fall prevention programmes have been unsuccessful in the past because of the discrepancy between the perspectives of healthcare providers and those of their patients regarding individual fall risk assessments.[30]

Therefore, new approaches are required for this purpose. This study will address geriatric fallers' perceptions and experiences when implementing a CMM intervention to contribute to a patient-centred approach in fall prevention.

Study aim and objectives

The aims of this mixed-methods pre-post study are to (1) obtain an in-depth understanding of perceptions and experiences of medication-related risk of falling among hospitalised geriatric patients and (2) identify organisational and medical-psychosocial factors which facilitate or hamper the outcome of a CMM with a focus on reducing falls.

The objectives of this study are to explore the following research questions:

- How do geriatric fallers experience their falls, and how do they link the associated feelings and conditions to their medication?
- What are the patient-related and medication-related challenges that can affect the implementation of CMM?
- To what extent can the patients' medication be optimised using CMM while considering the medication appropriateness according to the weighted and summated Medication Appropriateness Index (MAI) score, reducing fall-risk increasing drugs (FRID) and potential inappropriate medication (PIM)?
- What are the medical-psychosocial and organisational factors that may facilitate or hamper the acceptability, feasibility and sustainability of CMM?

METHODS AND ANALYSIS

Study design

The Medical Research Council (MRC) guidance will serve as the overarching framework for this study. The MRC network focuses on developing and evaluating complex interventions and helps making appropriate methodological and practical choices.[31 32] Using a mixed-methods approach in intervention research can address more questions which provide implications for decision makers.[33] The EMMA (Effects of, Medication Management in geriatric fAllers) study is designed as a mixed-methods pre-post study consisting of qualitative semi-structured patient interviews and quantitative medication-related data in a complementary approach. Specifically, the mixed-methods approach follows the design of an embedded experimental model according to Creswell, with the qualitative part framing the quantitative part in a two-phase sequential approach collecting qualitative data before and after the intervention.[34] Recommendations for interventional trials (Standard Protocol Items: Recommendations for Interventional Trials 2013) were used to develop the study protocol and are shown in the online supplemental file 1.[35] Regarding the research question, a single population, intervention, comparison, outcome and study type (PICOS) question was generated.[36] The PICOS question is based on:

- Population: community-dwelling patients aged ≥65 years receiving polypharmacy (taking ≥five medicines) and admitted to a geriatric fracture centre (GFC) after an injurious fall.
- Intervention: five-step CMM intervention.
- Comparison: pre-post interventional comparison of patient perspectives.
- Outcomes: individual pre-post perceptions of patients regarding medication-related risks of falling and the medical-psychosocial effects of CMM (qualitative). Changes in weighted and summed MAI scores, FRID and PIM (quantitative).
- Study type: prospective, monocentric, single-arm, longitudinal mixed-methods pre-post interventional study using a complementary approach based on an embedded quasi-experimental model.

The rationale of the study design was set out as follows:

In the first step, the complementary approach, also defined as 'additional coverage', aims to provide a better illustration and extension of understanding the findings of patients' perceptions and their medical characteristics as different types of data produce different types of knowledge.[37 38] Furthermore, the complementary approach contributes to a more comprehensive answer to the research questions.[37]

Second, the embedded experimental approach allows the analysis of qualitative information in a pre-post interventional process which enhances the comparability of patients' views. To strengthen the pre-post approach and avoid an increased risk of treatment bias in light of the CMM intervention, no during-interventional qualitative phase will take place.

Third, the embedded experimental model specifically follows the design of a quasi-experimental approach, including a non-randomised allocation to strengthen the balance between internal (in-depth

patients' perceptions) and external (exploration of CMM in a real-life clinical setting among geriatric fallers) validity.[39 40]

Fourth, the mixed-methods approach is beneficial for providing a holistic picture of the impact of patient-centred interventions.[41]

Finally, using a mixed-methods approach enables the exploration of whether the implementation of the CMM intervention is feasible to contribute to a better outcome in reducing the medication-related risk of falling by strongly focusing on patient-centred care.[42] The Consolidated Framework for Implementation Research (CFIR) will underpin the study when investigating interventional barriers and facilitators to improve understanding.[43] Proctor *et al* present a model to distinguish implementation outcomes (eg, feasibility measures) and programme outcomes (eg, service-level outcomes and patient-level outcomes), emphasising that a programme is only effective when it is well implemented.[44] The CFIR is combined with conceptual model of implementation research by Proctor *et al* to better represent outcomes (both implementation and programme outcomes).[45] Findings could help to plan and execute a larger study and to investigate the effectiveness of an optimised CMM process in geriatric fallers and contribute to the development of recommendations on fall prevention and drug therapy safety in a geriatric fracture practice setting.

The study starts with the qualitative arm to explore the phenomenon of the participants' fall events and perspectives on their medication by conducting guided, semi-structured, pre-interventional interviews. The interviews will be arranged as face-to-face interviews lasting approximately 45 min. Next, the quantitative, interventional phase, that is, CMM, with the overall aim of enhancing the quality of medication will be conducted. Continuing the sequence, qualitative, postinterventional interviews in a guided semi-structured approach will be conducted at three time points (2, 6 and 12 weeks) after discharge. Interviews will be conducted remotely via telephone to assess the acceptability, feasibility and sustainability of the CMM, including the reoccurrence of falling. Telephone interviews are intended to last approximately 25 min. Retention of participants will be promoted by an appointment card reminding them of upcoming follow-up telephone interviews. With the participants' consent, interviews will be audio recorded. All answers will be de-identified by using an eight-digit code which allows linking of qualitative and quantitative data. The interviews will be held by a trained researcher (SB). Both interview flows, pre-post interventional, are displayed in figure 1 and are explained below.

Development of patient interviews

Two interview guides (pre-interventional face-to-face interview questions and postinterventional telephone interview questions) were created and are shown in online supplemental files 2 and 3. Based on the research questions, a focused review using PubMed and Google Scholar was initiated to determine the themes. Recommendations from Bolderston were considered as a quality guide to optimise interview questions.[46] The plausibility and face validity of the questions were scrutinised by clinical experts, including geriatricians, orthopaedists/traumatologists, pharmacists, nurses, social researchers and members of the project team.

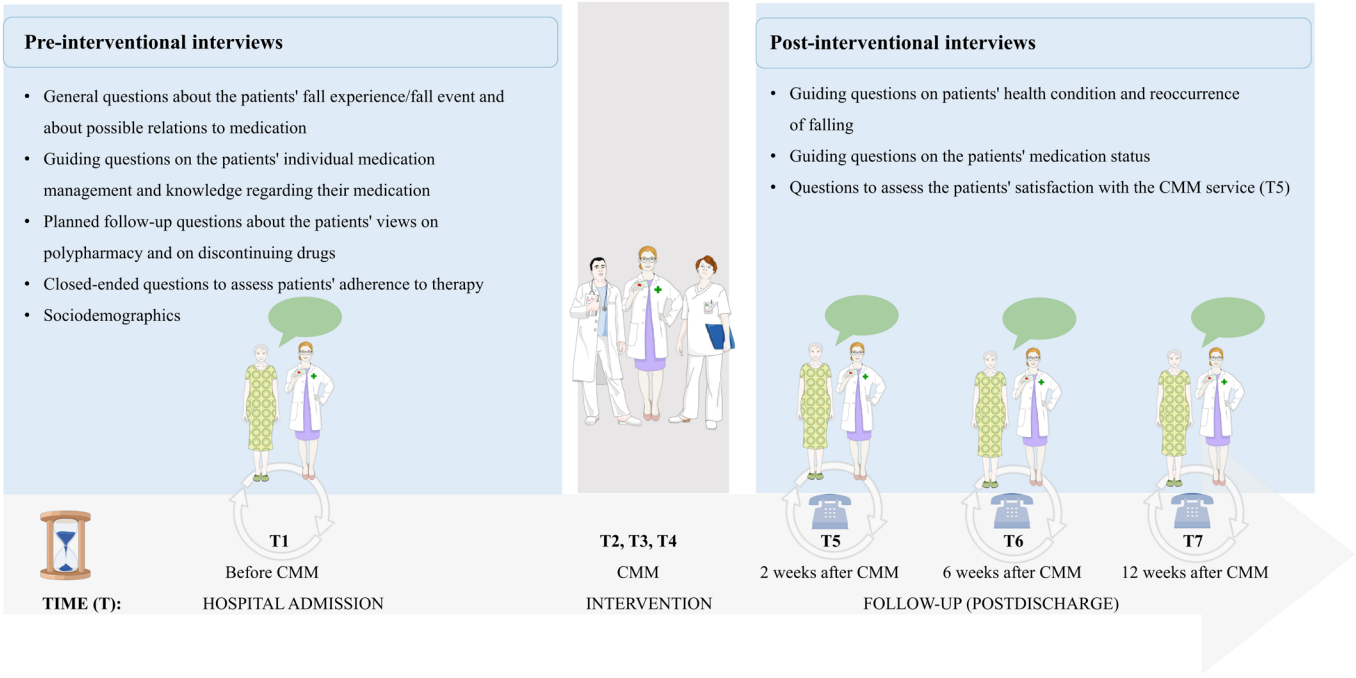


Figure 1 Patient interview flow (created with Servier Medical Art).[106] CMM, comprehensive medication management.

To test comprehensibility, interview questions will be piloted with patients.[46]

Pre-interventional face-to-face semi-structured interviews

General questions about the patients' fall experience/fall event and about possible relations to medication

Questions in this category will have a strong focus on the evaluation of the patients' fall events, estimated causes of the fall and any possible, subjective connection with the individual medication.[47] Furthermore, participants' history of falling and how they perceive the importance of fall prevention strategies will be evaluated.[48]

Guiding questions about the patients' individual medication management and knowledge regarding their medication

Guiding questions will be asked to assess the participants' knowledge of their medication related to indication. Patients' individual medication management (medication plan, help in taking medication and why help is needed), as well as the latest changes in their medication, will be administered.[49 50] Furthermore, participants will be asked how they enquire about their medication information.[51]

Planned follow-up questions about the patients' views on polypharmacy and on discontinuing drugs

At this point, the participants will be asked about their satisfaction with the number of medications. Another focus is on determining the extent to which patients are generally willing to reduce the dosage or discontinue any inappropriate medication by physicians.[52]

Closed-ended questions to assess patients' adherence to therapy

Questions with a closed-ended character will be asked to explore the participants' behaviour in taking their medication corresponding to the recommendations for medication use. Based on Likert-type scale questions, the frequency of how often the participants forget to take their medication and whether they discontinue their medication on feeling better will be gauged.[53 54] Since questions about the patients' adherence represent a very sensitive topic and are more likely to be discovered once a patient's relationship has been built up during the interview, this category will be chosen for the later parts of the interview.[55]

Sociodemographics

Lastly, study participants will be asked questions regarding sociodemographic factors, including age, sex and highest education level. This category will also assess the participants' social situation.

Postinterventional semi-structured telephone interviews

Guiding questions on patients' health condition and reoccurrence of falling

In this section, a 5-type Likert scale question (from poor to excellent) will be asked to categorise the patients' health status after hospital discharge.[56 57] Furthermore, patients will be asked about further falls events. The subquestions of this category will be strongly designed according to the questions regarding fall occurrence in face-to-face interviews to enable a comparison.

Guiding questions on the patients' medication status

To assess the acceptability, feasibility and sustainability of CMM, patients will be asked about the current status of their medication. For each changed/newly prescribed/discontinued drug in the hospital, patients will be asked how they feel about the change and if further changes (eg, newly prescribed drugs) occur after discharge. If further changes occur, patients will be asked about the reason and the prescriber (eg, general practitioner, specialists). Furthermore, patients will be asked if they are satisfied with their medications.[58]

Questions to assess the patients' satisfaction with the CMM service

The interview will be closed with a general, binary question about the patients' satisfaction with the CMM included in the clinical routine care procedure.[56] Hereby, an important question will be the patients' perspectives on improvement suggestions. This question will only be asked during the telephone interview at T5, as this will be the first interview after hospital discharge.

Data collection

Data will be collected at eight different time points to describe the process and measure the outcomes. Following the mixed-methods approach in an embedded experimental design, data collection will include both qualitative and quantitative sources. The parameters listed in figure 2 will be recorded to explore patients' perspectives and the effects of CMM.

Setting

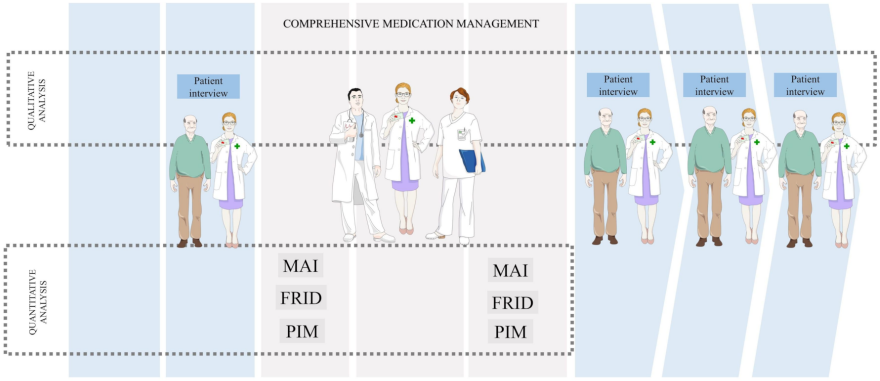
Participating individuals suffering from a fall will be recruited by the geriatrician (RA) of the GFC of a tertiary care, academic hospital in Austria.[59] The GFC is certificated according to the German Trauma Society's guidelines with the aim to improve geriatric trauma care.[60] Between planning and implementing this study, the COVID-19 pandemic has had profound clinical and social repercussions for geriatric patients. Nevertheless, it is important to continue and include older adults in non COVID-19-related research.[61] All relevant COVID-19 measures will be considered while conducting this study. Recruitment commenced in May 2021 with anticipated completion by May 2023.

Participants

Recruitment and sampling

Recruitment of patients is based on a criterion sampling strategy by eligibility criteria with the aim to achieve maximum variation sampling in participants regarding the patients' experiences of their fall and subsequent medication changes and in demographic characteristics (ie, age, sex) and living situation.[62 63] Approximately 30 geriatric patients will be recruited. The target sample size was inspired by other mixed-methods studies, which were

Data collection	Study Period							
	Admission		Intervention (CMM)		Discharge	Follow-up 2 weeks	6 weeks	12 weeks
	Enrolment	Face-to-face interview	Recording Review	Discussion Communication	Documentation	Telephone interview	Telephone interview	Telephone interview
	T0	T1	T2	T3	T4	T5	T6	T7



Time	T0	T1	T2	T3	T4	T5	T6	T7
Enrolment								
Eligibility screen	x							
Information to patients	x							
Collection of consent	x							
Qualitative pre-interventional patient face-to-face interview								
Fall experience/fall event and relation to medication		x						
Knowledge on medication indication		x						
Perceptions on poly-medication and discontinuing drugs		x						
Therapy adherence		x						
CMM Intervention								
MAI			x		x			
FRID			x		x			
PIM			x		x			
Changes in medication			x		x			
Pill burden			x		x			
Pharmacologic subgroups of medication			x		x			
Implementation measures								
Acceptance rate of pharmaceutical interventions				x				
Transfer of medication plan in patients' letters of discharge					x			
Qualitative post-interventional patient telephone interview								
Health condition and reoccurrence of falling						x	x	x
Medication status, acceptance/ feasibility/sustainability of the CMM						x	x	x
Satisfaction with the CMM service						x		
Characteristics								
Socio-demographics		x						
Highest education level		x						
Living and caring situation		x						
Cognitive performance	x							
Comorbidities	x							
Injurious fall/fracture	x							
Duration of hospital stay					x			

Figure 2 Data collection following the mixed-methods approach in an embedded experimental design (created with Servier Medical Art).[106] CMM, comprehensive medication management; FRID, fall-risk increasing drugs; MAI. Medication Appropriateness Index; PIM, potential inappropriate medication.

initiated to investigate interventional effects through patient perspectives.[64–66] Furthermore, according to Morse, the number of participants was determined by considering the intensity of interviews, the qualitative method (semi-structured interviews) and the general study design (longitudinal mixed-methods pre-post study; embedded experimental design).[67] The study enrolment will take place during hospital admission. Individuals who may be interested and eligible to participate will be approached by their consultant geriatrician (RA), who will explain the background, purpose and scope of the project. If a patient is willing to participate, written informed consent will be obtained. It will be pointed out that, even if consented, participation is free to withdraw from the study at any time without any consequences. Once informed consent is obtained, face-to-face pre-interventional interview will be conducted.

Eligibility criteria

Eligible patients are 65 years or older, present to the GFC after an injurious fall, take five or more long-term medications, speak German and are able to provide written informed consent. Patients must be community-dwelling or live in assisted or independent living communities. Eligible participants must manage their medication independently in order to be able to provide sufficient information about the medication and must be mentally capable participating an interview. The cognitive status will be measured by the Salzburg Dementia Test Prediction (SDTP).[68] Here, a predicted Mini-Mental State Examination with a cut-off of >25/30 (=no cognitive impairment) is targeted. To explore medication-related risks of falling, patients with falls out of bed or wheelchair as well as falls caused by collision with vehicles are excluded.

Professional groups cover geriatricians, orthopaedists/traumatologists and pharmacists at the GFC.

Intervention

The rationale of the CMM intervention is based on the statements of the International Pharmaceutical Federation which describes a model of Collaborative Pharmacy Practice with advancing models that facilitate interprofessional collaboration and greater pharmacist accountability.[69] The intervention will consist of a five-step CMM practice by reviewing medication appropriateness, including PIM and FRID. Results of a focused review will be used to identify FRID. Screening tools of the MAI, PRISCUS list and Fit fOR The Aged (FORTA) list will be used to assess medication use. The MAI represents a reliable and valid measure of medication appropriateness and appears to be a useful tool for research studies, quality improvement studies and patient care programmes.[70 71] The FORTA list was recently updated in 2021 and comprises four categories classified by an expert Delphi panel.[72] The PRISCUS list was developed for the German market and includes inappropriate substances comprising antidepressants, antihypertensives and hypnotics/sedatives which are linked to increased risk of falling.[73–75] Identified drug-related problems, recommendations and acceptance will be documented by the Pharmaceutical Care Network Europe V.9.1 classification system.[76] Final clinical decisions on medication optimisation will be based on clinical expertise, patients' perceptions and ultimately by the geriatrician as the approving authority. CMM interventions and a digitally created medication plan will be included in the patients' letters of discharge (process results from T2 and T3). The medication plan includes medication (name, dose, frequency) and start/stop dates. Orthopaedists/Traumatologists prepare the information (digital and printed) at T4 to enable availability for patients and physicians at the inpatient and outpatient care sector. The five-step CMM process consists of recording, reviewing, discussion, communication and documentation. Core elements of a Medication Therapy Management Service of the American Pharmacists Association and National Association of Chain Drug Stores Foundation inspired the design of the process which underwent setting-specific adaption.[77] The five interventional steps are shown in figure 3.

Outcomes

Two different methodological approaches will be used for measuring outcomes: patient-reported outcomes (primary outcomes) will be investigated qualitatively by means of guided semi-structured patient interviews; clinical and organisational outcomes of the CMM intervention (secondary outcomes) will be assessed quantitatively.

Primary outcomes

T1 (pre-interventional interview)

- Symptoms, conditions and feelings before the fall.[47]
- Reason(s) of the fall. Can potential causes be linked to medication?[47]
- Knowledge on medication indication.[49]
- Views on polypharmacy and willingness of discontinuing drugs.[52]
- Adherence to medication.[54]

T5, T6, T7 (postinterventional interviews)

- Changes in patients' individual medication status including reasons and drugs (acceptability, feasibility and sustainability of the intervention) (=programme outcomes according to CFIR and Proctor *et al*).[44 78]
- Reoccurrence of falling including why/how and correlation to pre-interventional fall events (comparison of patients' previous fall description).[47]
- Satisfaction with the CMM service including suggestions for improvement[56] (=programme outcome assessed only at T5).[44 78]

Categories regarding falls and medication will be compared pre-interventional and postinterventional (T1 vs T5, T6, T7). To illustrate the condensed findings, the outcomes will be underpinned by quotations of participants' terminology.

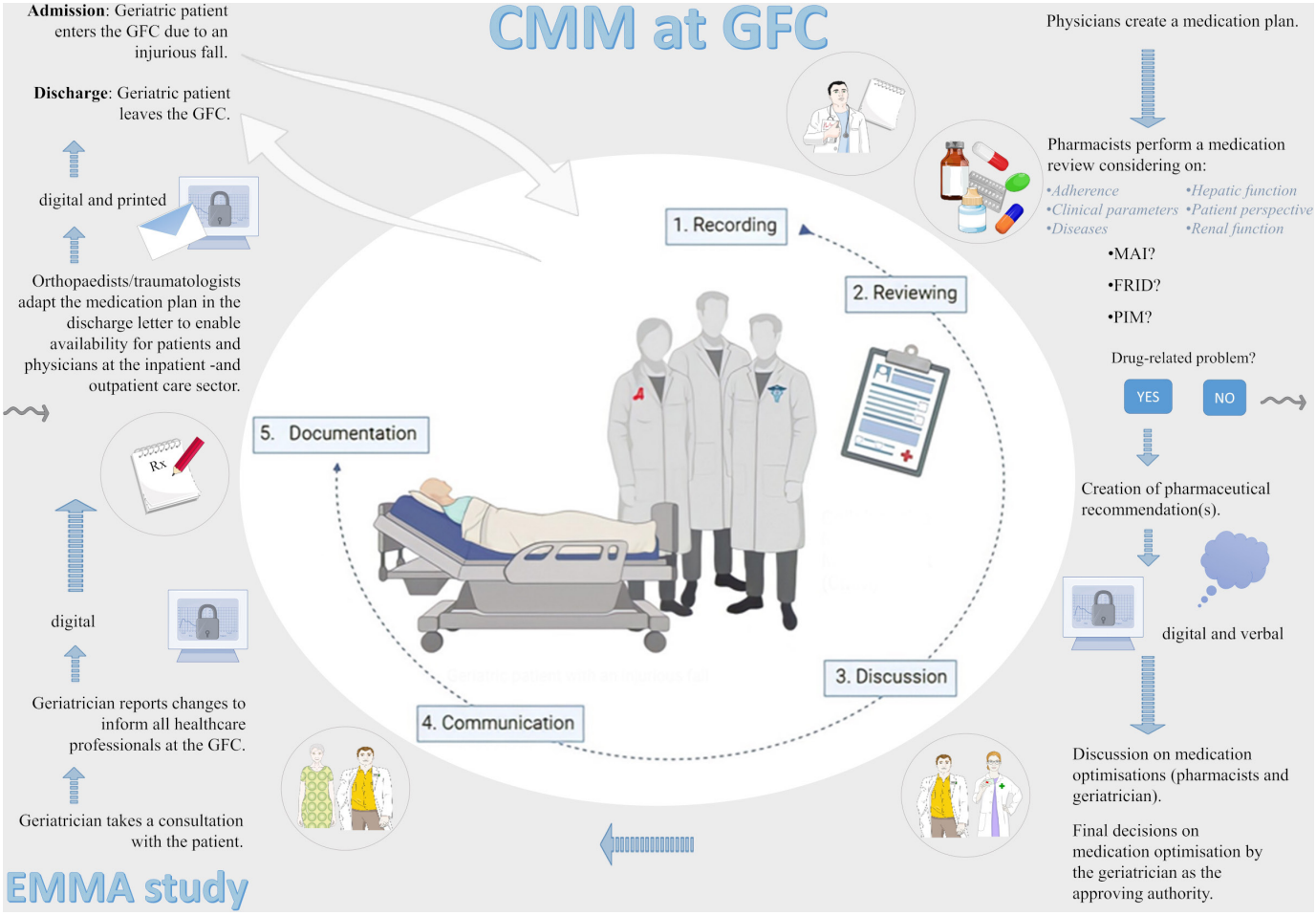


Figure 3 Five-step interventional CMM process as conducted in the EMMA study (created with BioRender and Servier Medical Art).[106 107] CMM, comprehensive medication management; FRID, fall-risk increasing drugs; GFC, geriatric fracture centre; MAI. Medication Appropriateness Index; PIM, potential inappropriate medication.

Secondary outcomes

T2 versus T4 (intervention)

- Medication optimisation, measured by changes in medication appropriateness according to the MAI sum score and changes in the number of FRID and PIM.[70 72 79]
- Medication change rate, measured by changes in medication (reduced dosage, discontinued, newly prescribed)[80] and pill burden (total number of doses per day including over-the-counter products).[81]
- Pharmacological subgroups of patients' medication (Anatomical Therapeutic Chemical Classification (ATC)).[82]

T3, T4 (implementation)

- Acceptance rate of pharmaceutical interventions by physicians[77] and transfer of the optimised medication plan by orthopaedists/traumatologists into the patients' letters of hospital discharge according to CFIR and Proctor *et al*.[44 45]
- Lengths of hospital stay (in days).[60]

T0, T1 (patient characteristics)

- Morbidity (Charlson Comorbidity Index).[83]
- Cognitive performance (SDTP).[68]
- Fracture/Type of injury.
- Sociodemographic data (age, sex, highest level of education and social situation).

Data analysis

Qualitative analysis

Recordings of patients' interviews will be transcribed verbatim and then analysed by qualitative content analysis according to Mayring.[84] Particularly, the technique of 'structuration' with the aim of assessing the material based on categories (inductive-deductive categories) will be chosen. In the coding process, transcription passages will be assigned to categories and subcategories. During the process, inductive categories will be formed. A corpus of the data will be created by abstraction, including quotations of the participants.[84 85] Main categories are consistent across data which enables crosschecking. The corpus allows the distinction between simple category lists (nominal scale level) and ordinal category systems (eg, 5-type Likert scale). Formed categories can then be integrated in the synthesis of qualitative and quantitative data of the mixed-methods design. The analytical

process provides a practical, transparent summarisation of large data material which is strictly rule-governed and thus strongly intersubjectively verifiable.[85] To ensure the credibility, results will be discussed in the research team. The qualitative software package MAXQDA 2022 (VERBI Software) will be used to assist the analysis.[86] Standards for Reporting Qualitative Research (SRQR) are used as a checklist in manuscript preparation and in providing transparency when writing up the study findings.[87]

Quantitative analysis

Patients' medication will be analysed through

a. medication appropriateness by using the weighted and summated MAI according to Samsa *et al* receiving a final range up to 18 for each medication.[70] Not applicable or not assessable items will be scored 0 for each item;
b. PIM by using the FORTA and PRISCUS lists;[72 79]
c. FRID by using results of a focused review.

Results of medication optimisation (eg, reducing FRID) will be reported stratified by subgroups using ATC codes.[82]

Statistical analysis will be of a descriptive nature with a complementary approach to qualitative data. Basic exploratory analysis will be used to investigate correlations between scores on the weighted and summated MAI scores and further secondary outcome measures by using non-parametric tests and will be stratified according to age-related groups and sex.

Mixed-methods analysis

Data integration of the qualitative and quantitative arms represents the key to the EMMA study. Different types of data will be analysed separately and subsequently integrated at the 'results point of integration'. Integration will be facilitated by a visual joint display which can be achieved by arranging related data in a figure, table, matrix or graph.[37 88–90] Meaningful integration facilitates the synthesis of results by creating a whole beyond the sum of the individual parts.[91] The integration process will be justified through the mixed-methods purpose of complementation by seeking a better understanding and holistic picture of the study findings. Qualitative findings will be used to identify unexpected effects and perspectives which are not covered by quantitative data.[92]

Missing data

Missing data (clinical data, patient-reported data) are anticipated and will be indicated on their exact number and reasons. Multiple imputations will be used to treat missing data under a 'missing at random' assumption.[93] Regarding the qualitative part of the study, missing data are limited to no more than ≤20% attrition (dropout by design, loss to follow-up, study withdrawal) of the first and the last follow-up time points (T5, T7). For the quantitative part (T2, T3, T4), the dropout rate must not exceed ≤5%.[94]

Patient and public involvement

Patients were involved in the development of the interviews. Patients were asked to participate in a pretest of both interview guides to improve the feasibility of the process. According to patients' suggestions, interview questions were adapted in wording which increased comprehensibility and clarity. The results of the optimised medication due to CMM will be communicated with patients during the study. Additional study materials (ie, pharmaceutical interventions and medication-related information) and published outcomes will be made available to the participants on request.

ETHICS AND DISSEMINATION

Ethical considerations

This mixed-methods pre-post study protocol is in accordance with the ethical principles of the Declaration of Helsinki and current Good Clinical Practice. Moreover, the study protocol was approved on 3 May 2021 by the local ethics committee of Salzburg County, Austria (ID: 1059/2021). After obtaining the participant's consent, interviews will be recorded on an audio device, transcribed verbatim and deleted afterwards. Patient information will be stored in locked file cabinets. All data will be pseudonymised (using the code number of each respondent) and generalised in data sheets. The research data will be stored separately from personal identifiable information. The principal investigator (BI), study physician (RA) and pharmacists (MK, SB, CD) will be provided access to the cleaned data files. To ensure confidentiality, data dispersed to the project team members will be delinked from any identifying patient information. A descriptive analysis of the quantitative data will be performed after checking the database. Before the formal phase of qualitative research is conducted, pretest interviews will be conducted to assess the rigour of the instrumentation.

There is no need for a data monitoring committee because expected study risks are minimal.[95] Patients can contact responsible study physicians at any time. Any concerns regarding patients' medication will be actively listened to. According to the type of concern, patients will receive education, counselling or an appointment whenever needed. Adverse events will be reported to the relevant groups (sponsor and research ethics committee).

Dissemination

The participants will receive a verbal summary in lay terms of the preliminary research findings at the end of the last telephone interview. Another aim of this study is to disseminate findings to patients suffering from falls (beyond study participants) through talks. Understanding patients' opinions on their medication should contribute to developing recommendations for fall prevention and drug therapy safety. Therefore, the findings of this study will be disseminated in peer-reviewed journals and conference presentations. Furthermore, the

results are intended to provide assistance and improvements for further roll-out of CMM service at a GFC.

DISCUSSION

The EMMA study protocol uses a mixed-methods pre-post approach to examine the medical-psychosocial and organisational effects and challenges when implementing a CMM intervention for geriatric patients after a fall. Evidence of patient-centred interventions in reducing falls is scarce, and previous approaches of CMM are inconsistent.[96–98] Findings from these previous studies demonstrate that: (a) drug therapy optimisation can reduce inappropriate prescribing[96] but does not reduce drug-related hospitalisations, that is, risk of falling[97] and (b) withdrawing FRID as a single intervention is not effective in reducing the risk of falling.[98] However, these studies did not explore patients' perceptions, needs and organisational implications regarding the CMM. The EMMA study is innovative for the following reasons:

1. Application of an embedded experimental design according to Creswell and Clark in mixed-methods represents a strategic method to reveal effects and challenges of CMM for geriatric fallers.[34] As such, the design allows for pre-post comparison and providing information on the intervention as well as on acceptability, sustainability and on reoccurrence of falling. The integration of qualitative and quantitative data at the end of the study helps to create a clearer and more holistic picture of the results.[92]
2. Exploring the perspective of geriatric fallers at different time points provides an in-depth understanding of the medication-related risk of falling and helps assess the needs of patients within the CMM. Shuman *et al*[99] used an exploratory qualitative design to investigate patient perceptions at two different time points (in-hospital and postdischarge) to obtain perceptions of fall risks, fall prevention interventions and fall-related discharge instructions. They found that patients did not perceive their risk of falling and that there was a high need for healthcare providers to engage patients and their families in understanding fall prevention (eg, due to conversations). However, this study was limited by a follow-up period of 8 days postdischarge and did not investigate the medication-related risk of falling.
3. The EMMA study is the first of its kind to be conducted in a GFC. This setting supports the development of new solutions to geriatric falls. While previous studies have explored patients' perceptions of falls and fall prevention programmes in community care settings, little evidence describes this issue in an inpatient care setting.[100–104] Radecki *et al*[105] interviewed 12 hospitalised patients to understand the individual fall risks and fall prevention interventions implemented by nursing staff. They found that fall risk factors (eg, laboratory values and medication changes) may not be tangible to patients. However, this study did not explore perceptions and experiences of medication-related interventions to improve fall prevention efforts. Therefore, there is a strong need to develop and implement patient-centred fall prevention programmes with true patient involvement.

Despite being an innovative approach, the study design hides several limitations. Some of these include potential risks of recall bias, such as under-reporting or over-reporting experiences which could affect the classification of categories in the analysis. Patients with pre-existing osteoporosis are prone to be included into the study. There is an absence of controls; thus, researchers should be cautious when interpreting the results. The sample size of 30 geriatric fallers undergoing CMM at a single medical centre is limited. While this study does not provide generalisable outcomes, the findings can help to modify future CMMs for better results in patient-centred care, facilitating fall prevention and drug therapy safety. A qualitative investigation of CMM focusing on pharmacist and physician experiences and outcomes is planned in the future.

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Acknowledgements We would like to thank Professor Dr Thomas Freude and Dr Andreas Hartmann for their permission to conduct this study at the GFC of the University Hospital Salzburg. We express our gratitude to Dr Martin Wolkersdorfer for organising the pharmaceutical personnel. We thank all participants for their support in this study. We would like to thank Editage (www.editage.com) for English language editing.

Contributors SB established the study protocol and organised the application for ethical approval under the supervision of BI and JP. BI implemented the project and coordinated the study. SB designed the study and provided the guided semi-structured interviews. PK and SK are responsible for methodological expertise. RA and MK will deliver interventions (medical and pharmaceutical, respectively). SB is responsible for conducting patient interviews, collecting data and performing research assessments. OR, CD and MF are part of the project team and participated in the drafting of the manuscript. All authors have read and approved the final manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the 'Methods' section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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