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Development of a shared decision-making intervention to improve drug safety and to reduce polypharmacy in frail elderly patients living at home

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ABSTRACT

Objectives: For patients with geriatric frailty, reducing inappropriate medication is an important goal to improve patient safety in primary care. GP-side barriers include knowledge gaps, legal concerns, and lack of communication between the actors involved. The aim was to develop a multi-faceted intervention to facilitate deprescribing and shared prioritisation among frail elderlies with polypharmacy living at home.
Methods: Mixed methods study including: 1) scoping review on family conferences, expert panels; 2) group discussions with GPs, mapping of needs and challenges in Primary Care; 3) workshops and expert interviews with GPs, patient advocates, researchers as a basis for a theoretical intervention model; 4) piloting.
Results: A major challenge for GPs is to conduct a productive discussion with patients and family cares on deprescribing and drug safety. A guideline for a structured family conference with a medication check and geriatric assessment was developed and proved to be feasible in the pilot study.
Conclusion: The intervention developed to facilitate deprescribing and shared prioritisation of drug therapy based on family conferences seems suitable to be tested in a subsequent cRCT.
Innovation: Adapting family conferences to primary care for frail patients with polypharmacy.

1. Introduction

Patients aged 65 years and older show a marked increase in multimorbidity and thus in the prevalence of polypharmacy and frailty, which are associated with specific risks for poor health outcomes such as falls, hospitalisation, malnutrition, delirium or mortality [1,2]. The potential progression of the frailty syndrome especially at earlier stages could be countered with diverse interventions [3,4]. To address this, particularly the reduction of polypharmacy is promising [5]. In this context a mindful medication management that considers reducing potentially inappropriate medication (PIMs) in frail patients could help maintain or improve health-related quality of life and increase safety by reducing drug-related negative outcomes [6,7,8].

Despite the existence of studies which investigate the effectiveness of interventions to reduce PIMs, there is still uncertainty about how to stop them safely and effectively in daily routine. Although the majority of patients aged 65 years and older signalled a hypothetical willingness to stop taking medication if their physician deemed it appropriate, the willingness to actively do so may not be as high [9,10]. The process of discontinuing a long-term medication is often complicated by many factors on both sides, e.g. fear, lack of trust or information, perceived pressure, habits, uncertainty regarding medication prescribed by others. As studies have shown, polypharmacy and PIMs are often the result of mis- or non-communication during the doctor-patient interaction. Therefore, communication in the deprescribing process should be more patient-centred [11-13]. A comprehensive approach is needed to address this.

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There are comprehensive multidisciplinary approaches, e.g. Comprehensive Geriatric Assessment (CGA) that also aim to improve polypharmacy in frail elderlies. However, the effectiveness for primary care setting and the degree of patient and GP involvement seems unclear [14]. So, there is a need for further development of concepts facilitating the process of prioritising drug therapy and deprescribing in primary care.

This study corresponds to the first phase of the research project "Family conferences and shared prioritization to improve patient safety in the frail elderly" (COFRAIL) focusing on the development and piloting of a multifaceted intervention in primary care to be tested in a subsequent cluster-randomised controlled trial (cRCT) [15]. The intervention aims to support shared decision-making between GPs, patients and family carers and to promote the process of deprescribing PIMs in frail older patients living at home to improve patient safety by reducing hospitalisations and preventing falls.

2. Methods

This paper outlines the development of a complex intervention in collaboration with two German study sites (03/2018 – 02/2019). This process was conducted according to the first two stages of the Medical Research Council (MRC) framework by Craig [16] and its further development [17,18]. It was also guided by both our own research [19] and by intervention mapping [20,21]. An overview of all methods used can be found in fig. 1.

2.1. Identifying the evidence base (Step 1)

The first step was to identify existing evidence with focus on shared decision-making in the management of polypharmacy and to take into account own research in the development of educational interventions in primary care. To analyse the effectiveness and applicability of intervention elements a scoping review on family conferences was conducted for its use in primary care (publication in progress).

Decision-making in the research process and discussions of the results of literature reviews were conducted in regular meetings of the study panel and in workshops with participation of various experts from e.g. general practice, pedagogy, health services research and health economy, clinical pharmacology and self-help organisation for caregivers, palliative care, health insurance company.

2.2. Identifying and developing a theory (Step 2)

Based on the logic model by Saal et al. [19], for complex interventions, a framework was developed in interdisciplinary brainstorming sessions and by mind mapping as a theoretical basis for conducting family conferences. It was further elaborated on the basis of workshops with GPs and experts. First, barriers and challenges of deprescribing and shared prioritisation in family practice from the perspective of all parties involved were identified and processed. Then, didactic methods and intervention elements were assigned to these and intended learning objectives and effects/outcomes were named. The theoretical model was repeatedly discussed in an expert panel, adapted and agreed between all project partners.

2.3. Modelling process and outcomes (Step 3)

In a consensus meeting it was decided to further develop the following instruments to achieve the study goals: a) Guideline Family Conference, b) Deprescribing Manual, c) Toolbox on Non-Pharmacological interventions.

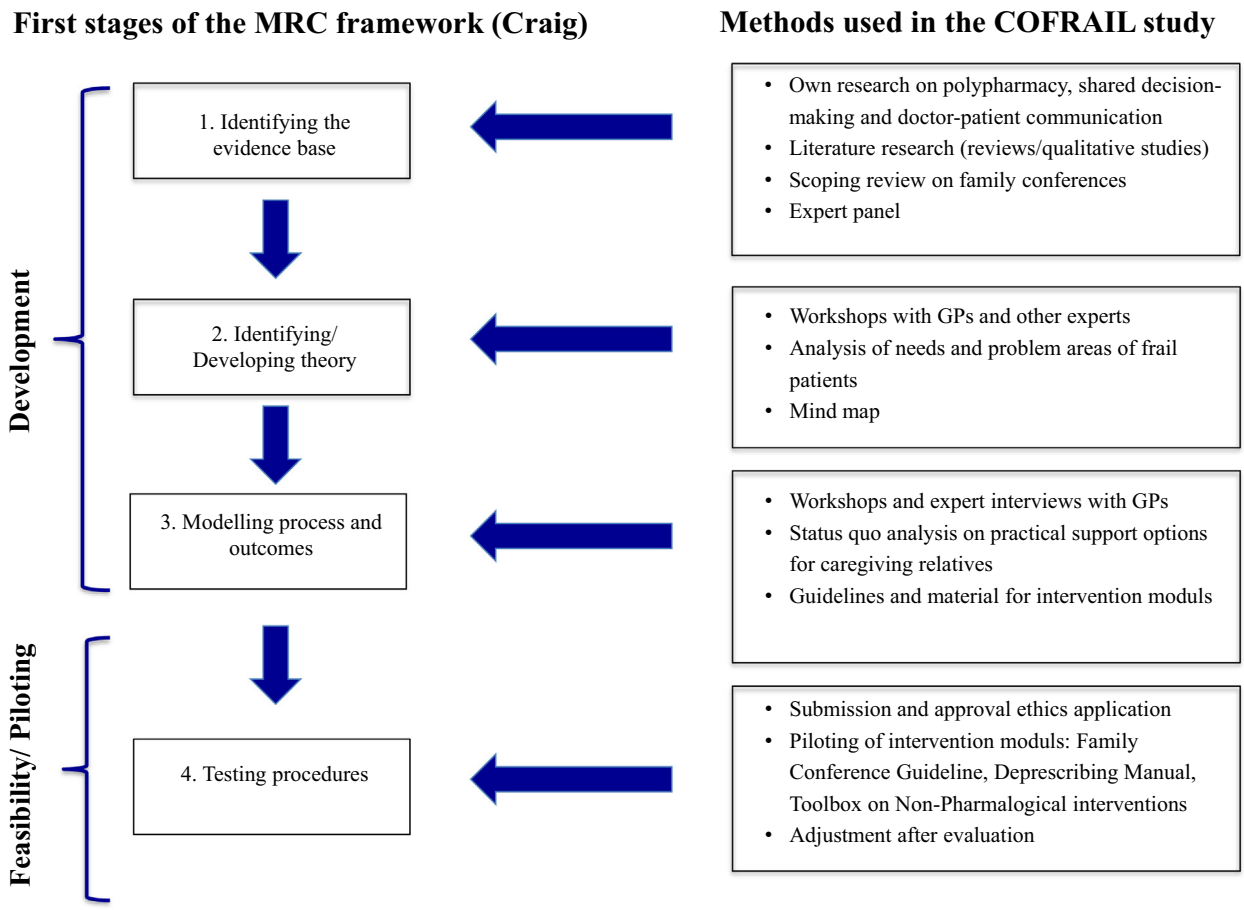

Fig. 1. Overview of the intervention development process and piloting.

GPs and health services researchers adapted the Guideline for primary care setting (a). The pharmacological intervention (b) was developed by clinical pharmacologists and pharmacists based on principles of deprescribing in geriatric patients [22-26]. The background of the Deprescribing Manual has been described elsewhere [27]. The non-pharmacological intervention (c) for the target group was based on a literature search, the assessment of existing tools and comprehensive and specific guidelines [28-34]. This was complemented by expert discussions (GPs, nurses) and focus groups with GPs on the care situation respectively problem areas of the target group and caring relatives to elaborate non-pharmacological needs.

These intervention elements were gradually presented and discussed among the project partners. The practicability was checked in trial training courses with GPs.

2.4. Testing procedures (Step 4)

Finally, recruitment strategy and practical implementation of the family conference were piloted with four GPs. Each selected two patients and involved their relatives [15,35] (See Table 1).

Then, GPs conducted one family conference regarding medication. Study staff supported them in recruiting patients and relatives, observed and protocoled the process. In addition, GPs were interviewed face-to-face (semi-structured) on their experiences with the process. Their feedback was categorised and analysed. In addition, feedback from patients and relatives was obtained through semi-structured telephone interviews as part of the process evaluation. Finally, the Non-Pharmacological Toolbox was tested separately by two GPs, for this was planned as topic of the second conference.

In preparation of the piloting, the study has been approved by the ethics committees of the study centres Rostock (no. A2018-0151) and Düsseldorf (no. 2018-283).

3. Results

The research results on topic related findings are presented according to Craig's MRC framework [16].

3.1. Identifying the evidence base

3.1.1. Communication and shared decision-making in the context of polypharmacy

There is strong evidence that the process of deprescribing is not only a question of the pharmacotherapeutic knowledge of the GPs, but also a matter of communication between doctors and patients. Furthermore, inadequate communication between those responsible for the medication management and the lack of awareness of polypharmacy as a problem were identified as another causality for adverse drug events (ADE). Hence, a patient-centred (knowledge, experience, attitude), holistic (non-pharmacological) and collaborative approach (caregivers, professionals, relatives) seems to be promising to reduce polypharmacy, ideally performed step-by-step [6,9,36-39]. From our own research on polypharmacy management, we derive the need to promote structured conversations by integrating sequences of active listening and exploration of patient views and beliefs [40-44].

Many frail elderly patients living at home are not able to manage the ordering and appropriate intake of drugs due to limitations in sensor-motoric functions, sense organs or memory. Very often professional or non-professional carers are involved in the medication management [45]. So, we concluded that all carers have to be included in this comprehensive process. In order to optimise communication processes in deprescribing we evaluated the concept of "family conferences" for its potential.

3.1.2. Framing the concept of family conferences for primary care

Family conferences are defined as a meeting between physician, family members and, if possible, the patient to coordinate care or treatment changes. The concept has been applied and proven in several clinical settings, e.g. in palliative and intensive care. Thus, the reduction of hospitalisations, costs and mortality could be demonstrated. However, in these family conferences patients were less actively involved due to their critical health condition and the focus merely laid on family driven outcomes e.g. satisfaction with care [46,47].

Bangsbo and Gambhir also point out that well-structured family conferences are promising in inpatient setting to improve patient empowerment and satisfaction by including patient preferences. Patients with frailty syndrome could also be more actively involved in decision-making [48,49]. Furthermore, family conferences could effectively contribute to improve communication between doctor, patients and relatives and thus facilitated family satisfaction and the quality of care, e.g. in long-term care [50].

To date, there is a lack of evidence for the effectiveness of family conferences in primary care and with focus on polypharmacy. Its effectiveness could only be assessed in relation to other areas of care. Relevant studies mainly focus on feasibility and acceptance and also on specific process-related outcomes, e.g. improved communication. But also, a benefit for patients and their relatives in terms of strengthening patient autonomy and orientation during further therapy planning could be proven [51,52].

An effective family conference should be well-structured and encourage the involvement of the family. To ensure the greatest possible benefit for all participants it should be tailored to their needs, knowledge and skills. The coordinating doctor should have patient-centred communication skills (empathetic informing and questioning, checking and encouragement of shared decision-making) to promote this. Joint prioritisation of treatment goals could thus also promote the deprescribing process and address the lack of communication in medication management. The theoretical model of family conferences appears to be adaptable to the GP setting. [46,53-59].

3.1.3. Adaptation of the concept of family conferences to primary care

A step-by-step approach is recommended for conducting family conferences consisting of four main phases: Initiation, preparation, implementation and follow-up. First, participants should be identified that could benefit. The second phase includes informing and preparing participants, agreeing on the setting. The third phase is divided in introduction and consideration of communication rules, reassurance of the purpose, assessment of individual needs and goals. In addition, the level of knowledge about the patient's health status should be queried and gaps closed. Joint prioritisation and documentation of discussed needs and the agreement on further treatments mark the last sub-step. The fourth phase includes implementation of agreements and setting of appointments [59].

Qualifying GPs for the implementation of family conferences could be carried out in a tailored training and by providing supportive tools and documents. GPs need to be sensitised for its benefit. This might enable them to convince patients and their families of the advantages of family conferences. In a next step, GPs should learn how to conduct family conferences successfully, taking communication rules, the active involvement of all participants and shared decision-making into account [46,59,60].

Findings of the literature review flowed into a comprehensive concept by intervention mapping (fig. 2).

3.2. Identifying and developing a theory

The theoretical framework (fig. 3) includes barriers and challenges of deprescribing and shared prioritisation in family practice on the level of

Table 1
Patient recruitment: inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• frailty level 5-7 (Clinical Frailty Scale)	• moderate or severe dementia
• age $\geq$ 70 years	• legal guardianship
• regular intake of $\geq$ 5 drugs	• life expectancy $\leq$ 6 months
• care dependency or comparable status	• nursing home resident
• receiving nursing care in domestic environment	• insufficient German skills
• availability of a trust person	

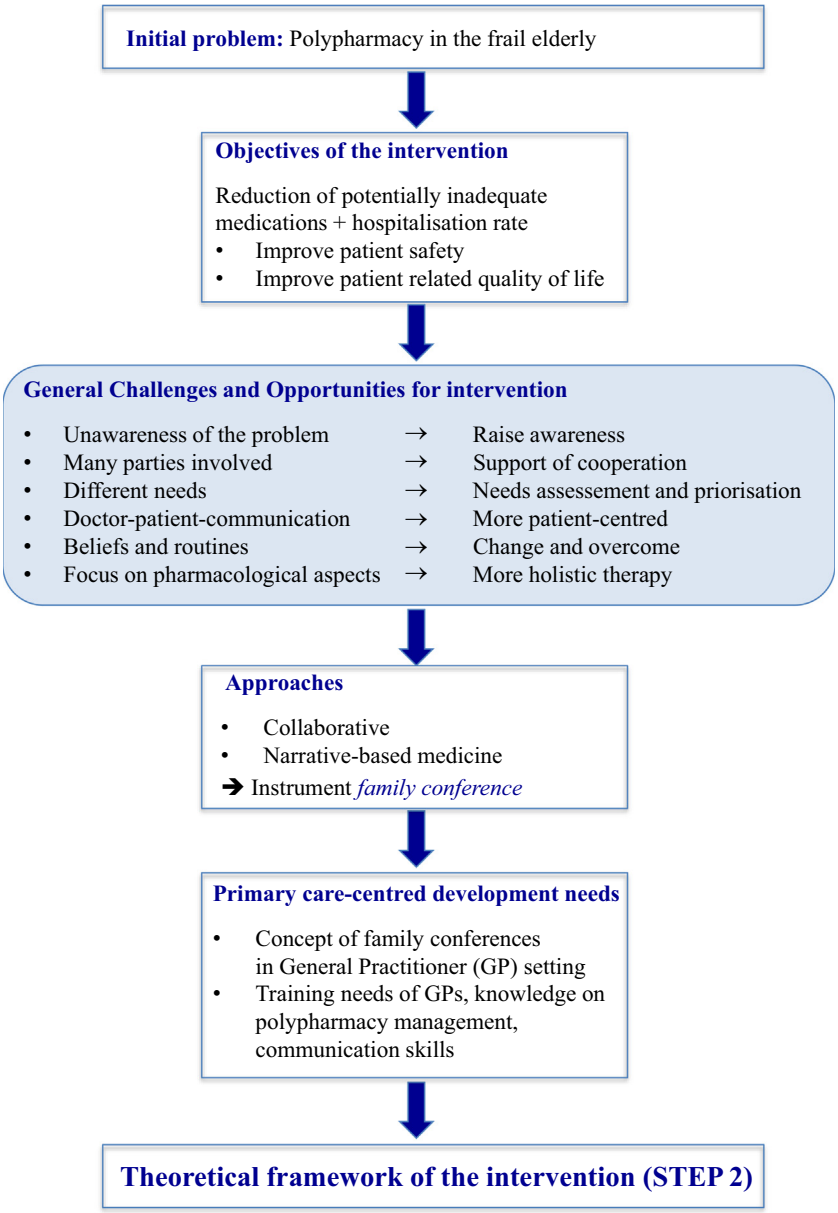

Fig. 2. Overview of results of STEP 1 of the intervention development.

GPs, patients and relatives (e.g. understanding of roles, knowledge gaps, resources, fears). To overcome these obstacles specific intervention elements and didactic methods were integrated. The family conference, as module 1, forms the frame for planning drug management (module 2) and for jointly recording and prioritising non-drug needs (module 3). The content of the modules is to be taught in two consecutive training courses including impulse lectures, group and case discussions. To enable GPs to conduct a family conference, they are provided with a guideline, an instructional video and communication training with simulation patients. Overall objective is to modify GPs behaviour (attitudes, norms) and to introduce them to a more structured approach of deprescribing. Finally, the intended outcomes of all intervention steps in relation to GPs, patients and relatives were integrated in the framework.

3.3. Modelling process and outcomes

3.3.1. COFRAIL family conference guideline

For the intervention, three consecutive family conferences with respective guidelines were designed. Main focus of the first conference is drug management (module 2). The second family conference offers the opportunity to discuss non-pharmacological needs and treatment options (module 3). The third conference serves to individually deepen the contents of the first and second one. The procedure of each family conference is basically the same, but they differ according to the respective topic in content and tools. The guideline of each conference is divided into three phases: preparation, implementation, follow-up. Each of them is subdivided into further steps. The guideline for the first family conference can be found in fig. 4.

3.3.2. COFRAIL deprescribing manual

In the first training course, GPs are introduced to the concept of family conferences and its conduction in frail elderly patients with polypharmacy. The process of deprescribing is defined as the discontinuation of inappropriate drugs [61], which should be based on an individual risk-benefit assessment [62]. The potential benefit of drug reduction is seen in an improvement in quality of life and survival time [63,64]. Hilmer et al. [65] consider the limitation of the number of drugs, regardless of their possible indication, as a quality goal. Possible discontinuation effects include the rebound effect, the discovery of interactions, the recurrence of

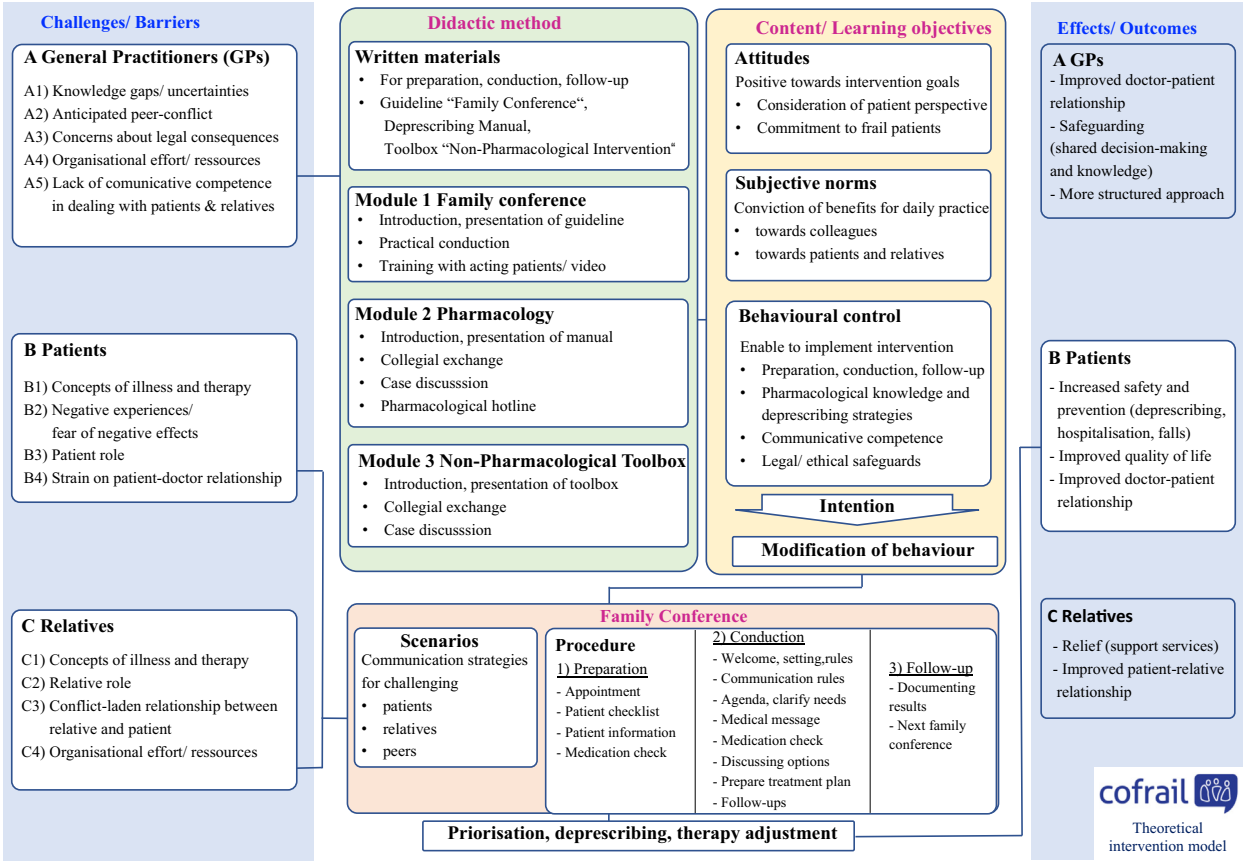

Fig. 3. Theoretical framework of the COFRAIL intervention.

symptoms originally treated and a deterioration in the long-term statistical prognosis.

For preparation and follow-up of the first family conference the GPs are given the Deprescribing Manual in a paper version. It intends to serve as a tool or reference work in drug management and in the reduction of polypharmacy (fig. 5).

For optional use a preparation sheet, a table and a short version of the deprescribing algorithm is provided to the GPs. During the COFRAIL study a pharmacological hotline will also be available to support the GPs.

3.3.3. COFRAIL non-pharmacological toolbox

Additionally, a toolbox was developed for needs assessment and non-pharmacological options (fig. 6) and is topic in the second training course. According to literature research the use of brief multidimensional screening instruments to identify commonly overlooked problems in older patients in primary care and to plan further assessments and treatment interventions in a patient-centred manner is recommend [66]. Comprehensive guidelines of the World Health Organization (WHO) and the German College of General Practitioners and Family Physicians (DEGAM) [28,29], as well as guidelines on specific health problems (e.g. malnutrition) [30,31] have proven to be important here. The WHO provides information on the assessment of problem areas of elderly patients with regard to physical and mental limitations as well as recommendations for their treatment. The DEGAM recommends the use of the MAGIC questionnaire [32-34] to survey patient-related problems. It focuses on nine problem areas of relevance to daily life of older people and provides information on medication review.

Based on these findings, 13 problem areas were considered as relevant. The toolbox is intended as a complement to the Deprescribing Manual and focuses more on the everyday limitations of diagnoses (e.g. falls) and their prevention rather than on indications itself (e.g. cardio-vascular problems). To identify and prioritise non-pharmacological patient-related problems in a structured way, the toolbox contains a preparation sheet, a checklist and the "COFRAIL Needs Analysis Manual with information on non-drug therapies for patients with geriatric frailty syndrome".

Centrepiece is the checklist for joint problem identification and determination of non-pharmacological actions (supplement 1). Initially, used medical services, aids, check-ups and preventive examinations can be recorded. Afterwards, patient's everyday problems can be assessed. Finally, a joint prioritisation of existing problems should take place, and concrete steps should be defined and documented.

Additionally, the manual can be used for preparation and follow-up of the second family conference. Each problem area is presented in one chapter. Also, a plan for domestic emergencies is attached with the intention to provide important patient information to those present on site (e.g. personal data, diagnoses, telephone numbers, living will, power of attorney for preventive medicine).

3.4. Testing procedures

The piloting results on GP level with focus on adaptation needs, experiences on implementation of family conferences as well as training needs can be found in table 2.

Analysis of the feedback from patients and relatives led to the following results: Due to the health status of frail patients in some cases only their relatives could provide information. Altogether, feedback was obtained from four patients and five relatives (spouse, children). Participants emphasised the trustful relationship to their GP and appreciated the family conference, which they perceived like a "normal home visit". The duration seemed appropriate. All participants were able to discuss and clarify satisfactorily relevant issues and felt involved. They were particularly positive that the GP has taken sufficient time for their concerns in a familiar environment. The main responsibility for medication management often lay with the relatives, decisions on discontinuation were usually made between them and the GP. However, patients and relatives relied on the GPs' assessment.

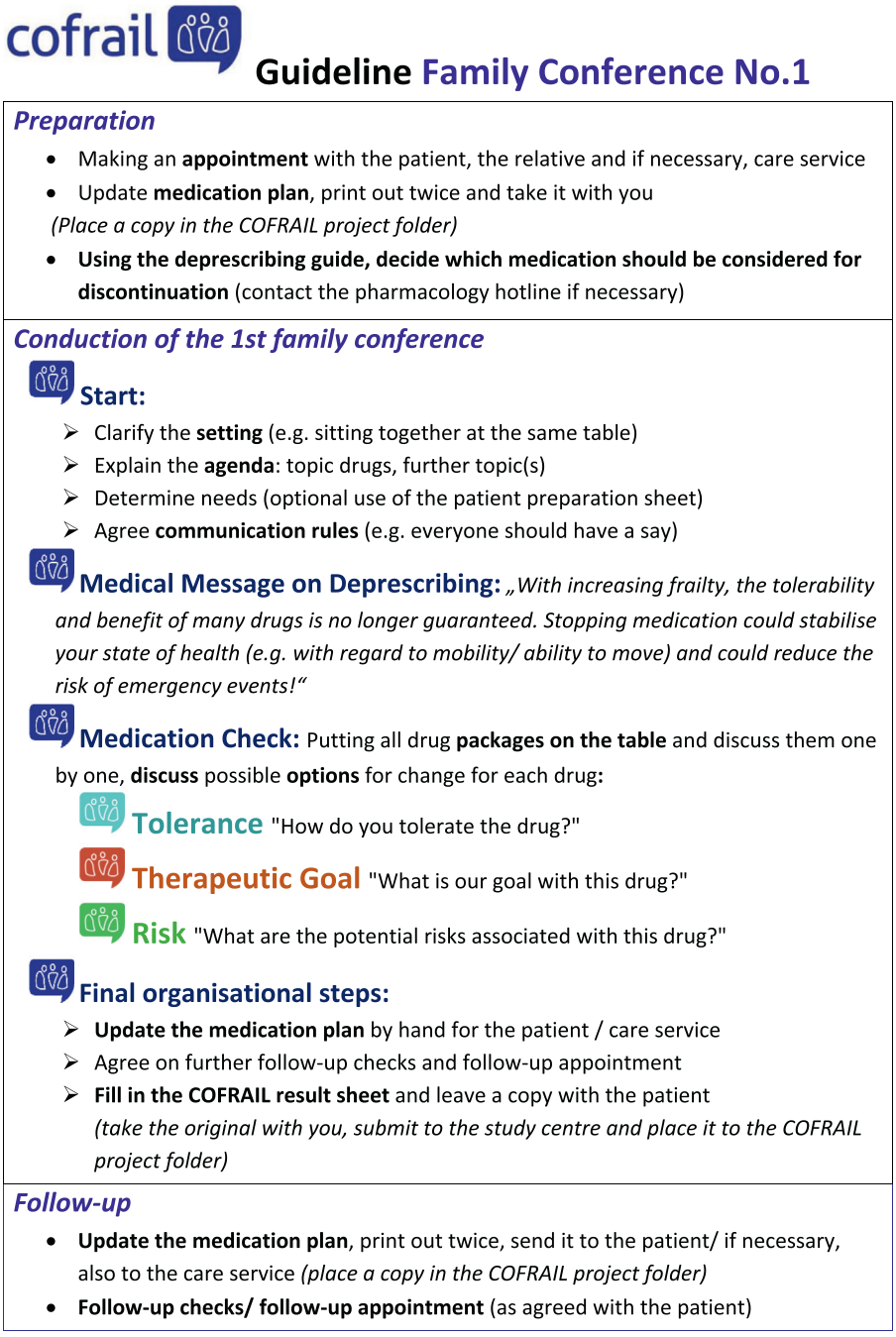

Fig. 4. COFRAIL Guideline Family Conference No. 1.

Patients suggested that further aspects should be addressed (e.g. care, therapies, socio-legal aspects), which was already intended with the "Non-Pharmacological Toolbox" as focus of the second family conference. As the piloting of this toolbox showed it is basically suitable for structured recording of patient needs and gaps in care as well as for further therapy planning. Nevertheless, sufficient time should be planned for narrative questions and a follow-up should be carried out. Based on GPs' feedback, there was no need to adapt the toolbox.

Overall, the procedures of the family conferences proved to be feasible and promising for elderly patients with frailty-syndrome and polypharmacy. There was no necessity for major adjustment of the COFRAIL Family Conference Guideline. In addition, the need for intensive preparation of GPs for family conferences, e.g. in the form of training, has been confirmed.

4. Discussion and conclusion

4.1. Discussion

The development of an intervention to improve polypharmacy management in frail elderlies results in a collaborative concept promoting family conferences to enhance communication on drug safety and therapeutic goals between GPs, patients and carers.

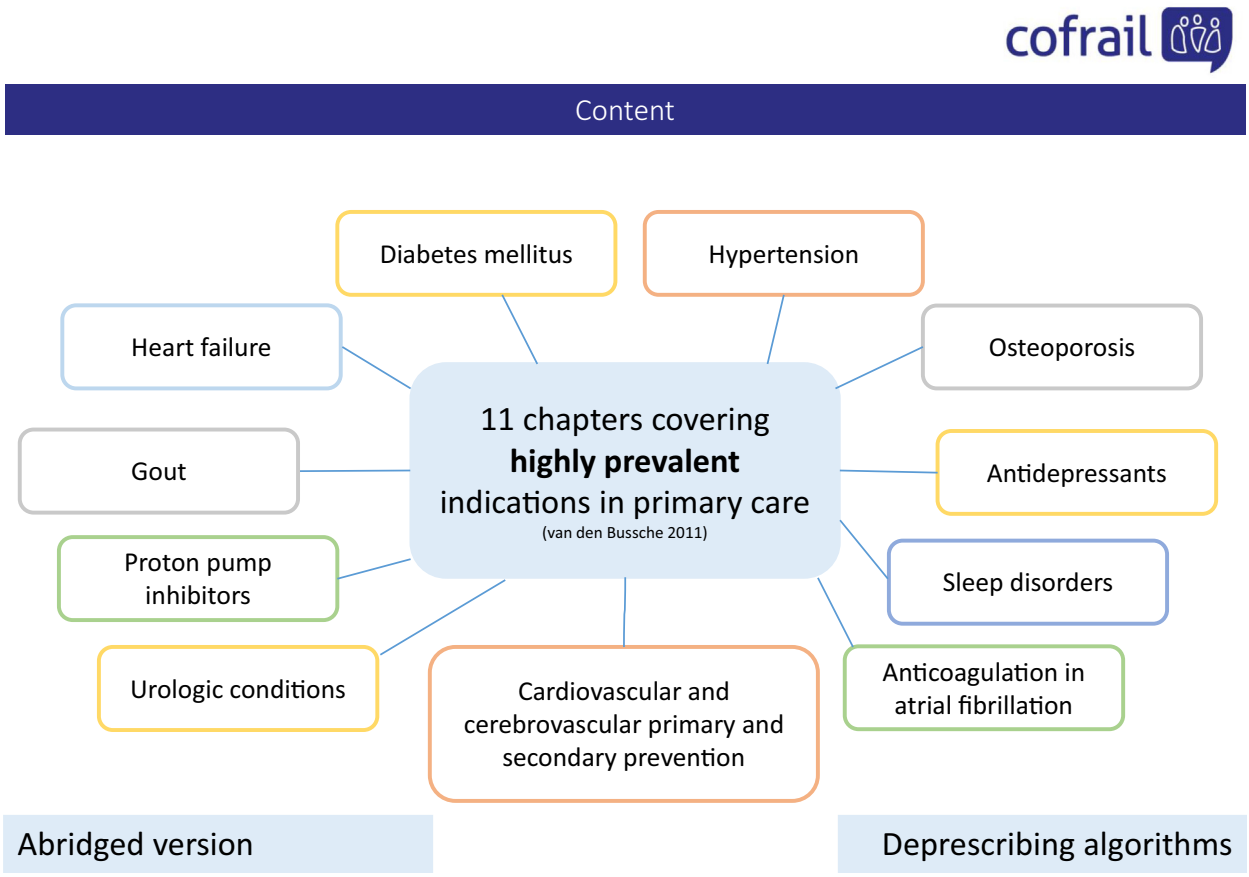

Fig. 5. Content of the COFRAIL Deprescribing Manual.

4.1.1. Implications of findings in context of existing research

Other relevant studies focus mainly on reducing medication without directly involving patients in the decision-making process. Depending on the setting, the studies pursue strategies of delivering relevant information to GPs including case-related advice by pharmacists or implementation of alerting systems in the electronic patient files [6,37,38]. However, regular reviews of the medication actually taken by the patient is an essential part of many interventions on polypharmacy in accordance to our approach of an initial medication check within the family conference [9,36,67,68].

The COFRAIL Family Conference takes a collaborative approach, which has been proven to be effective in other settings and for other target groups [46,48]. Some studies have introduced case conferences mainly under the participation of different professionals [37,39]. Although some approaches (e.g. CGA) aim to take patient needs and preferences into account, degree and manner of patient involvement in the entire process of decision-making remains unclear. Moreover, the importance and potential of a long-term trusting GP-patient relationship does not seem to be sufficiently taken into account. In addition, the effects with regard to patient-relevant outcomes, e.g., reduction of hospitalisation rate and PIMs, seem to be rather low or unclear for primary care [14]. The active involvement of patients and family carers in family conferences on polypharmacy management has to our knowledge not yet been focused on and adapted for primary care. The development of the COFRAIL intervention is intended to close this gap.

The communication process in the COFRAIL Family Conference is supported by a Deprescribing Manual and a Non-Pharmacological Toolbox for further prioritisation and treatment planning. The intervention presented also includes peer-guided workshops for GPs to learn about the content and implementation of family conferences. This is in contrast to interventions where doctors only received educational material, which had rather little impact on reducing polypharmacy [6].

The GP's safeguarding and the patient's security are provided by additional follow-up appointments after the family conference. This is ensured by the Family Conference Guidelines and by the optional use of a result sheet to note follow-ups for GP and patient (fig. 4). Additionally, two further family conferences are planned to keep up with changes. Moreover, the GPs are given the opportunity for collegial exchange within sequential training courses, that intend to change GPs deeply rooted beliefs and routines [42].

4.1.2. Strengths and limitations of the study

The evidence-based intervention development was done according to Craig's MRC framework [16], which enables quality assurance and comparability with other concepts. This also contributes to the traceability and transparency of the steps taken and the methods used. An interdisciplinary group of researchers consented methods and steps and was continuously accompanied by an international advisory board. Furthermore, the experiences and opinions of GPs regarding the care of the target group and their further needs were collected and considered. All findings were transferred into a theoretical framework. The selection of the intervention elements was based on a comprehensive target group-specific and intervention-related needs analysis taking into account already established instruments.

A detailed survey and analysis of the patients' views was not carried out, because the inclusion of this patient group is fundamentally more difficult and resource-intensive due to their age and existing communication restrictions. Although a representative of family caregivers was included to take their perspective into account in the intervention development, but this access and exchange could be intensified. A more detailed presentation of the

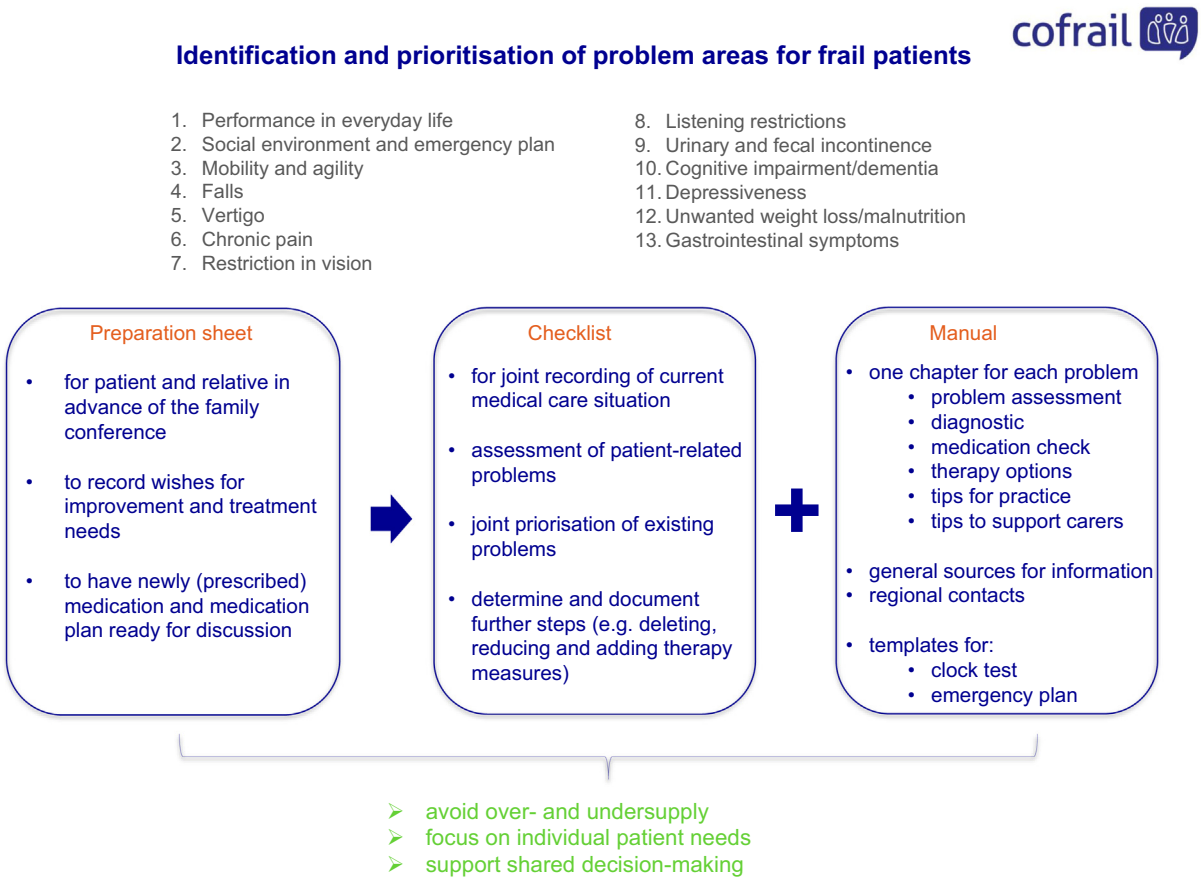

Fig. 6. Elements and objectives of the COFRAIL Non-Pharmacological Toolbox.

Table 2
Procedures Testing of the COFRAIL Family Conference: General Practitioners (GPs) perceptions and analysis results.

Stages	Sub-steps	Feedback of GPs (challenges & benefit)	Derived adjustments/ educational needs
Preparation/ organisation	Recruitment (patients)	- inclusion of unsuitable patients (e. g. with dementia)	- raise awareness for importance of inclusion & exclusion criteria among GPs & medical assistant
		- inhibitions to invite long-term patients with frailty (fear of stigmatising them and of losing trust)	- GP training (empathic communication & motivational/ convincing arguments)
	Recruitment (persons of trust)	- difficulties to recruit persons of trust/ relatives with decision-making authority for participating (lack of time and distance)	- provide flexible approach of conduction (e. g. separate telephone call with them additionally to home visit)
	Content preparation	- underestimated effort for preparation of deprescribing (in terms of identifying needs and potential for optimisation)	- more intensive preparation of the current care situation (laboratory values, treatment plan incl. medication, review & update) by using Deprescribing Manual
Conduction	Communication	- sometimes challenging to communicate with different types of people	- further communication strategies and rules
		- overall satisfying and successful communication for all participants	
	Discusssion agenda	- unplanned change of the GPs agenda	- predefinition of agenda, purpose, role of participants
		- perceived pressure to implement a predetermined topic	- to have an alternative topic up one's sleeve
	Process of deprescribing	- successful conduction of the brown bag review	
		- some GPs perceived fundamental barrier to discontinuing medication on patient side, e. g. prescription of other specialists	- concrete strategies or arguments to deal with patients' fears (e. g., regular check-ups after medication change)
		- most patients felt secure and appreciate the time taken	- communication between GP and other specialists
	Application of Deprescribing Manual	- information missing for regional differences in laboratory units	- more user-friendly design/ content/ handling
		- difficult orientation within the guide and between the chapters	- colour chapter marking
		- lack of consideration of current guidelines	- consideration of current guidelines
			- appendix on medication complexity added incl. communication tips on identification of patient-related problems in medication management and on promotion of adherence and reduction of patient-related problems
Overall aspects	Time	- 60-105 min. required per patient for preparation, conduction & follow-up	- GP training/ routine to reduce amount of time
			- medical assistant supports with recruitment & appointment
	Comparison with usual care	- added value of family conference vs. usual home visit	
		- chance to deepen knowledge about patients and their needs	

educational training concept for GPs, which has an essential influence on the implementation and possible effectiveness of interventions will be published elsewhere. The piloting was carried out on a reduced scale. It was not possible to assess the feasibility of the entire intervention (e.g. multi-stage training concept, material of second and third family conference), as this would have required a longer follow-up period per patient and thus a more extensive pilot study.

4.2. Innovation

Adapting family conferences for primary care of frail patients with polypharmacy is unique of the COFRAIL intervention. This includes the active involvement of patients and family carers throughout the entire process of polypharmacy management. Furthermore, the stepwise educational intervention consists of several personal training sessions and aims in particular at a sustainable change of routines and attitudes of GPs.

4.3. Conclusion

We conclude, that polypharmacy management of frail elderlies living at home is a major challenge for GPs, not only because of knowledge gaps or concerns about legal consequences deprescribing. Particularly difficult for GPs is initiating a conversation and shared decision-making with patients and family carers about drug safety and potential benefit of deprescribing. This goal could be facilitated within a structured family conference. The COFRAIL intervention not only includes guidelines for improved communication but also for an obligatory medication check and geriatric assessment elements. We expect that a well-prepared deprescribing process will also save costs for health care in a sustainable way. Even if this may initially mean more and longer consultations, in the long term the reduction of PIMs will save costs for these drugs and reduce hospitalisations due to ADE.

However, an intensive and practical training of GPs seems to be necessary to ensure that the COFRAIL Family Conference will be carried according to the defined quality standards. From the procedures piloted we conclude that the COFRAIL intervention is eligible to be tested in a subsequent cRCT with regard to clinical outcomes, cost-effectiveness and GP and patient satisfaction.

If effectiveness has been proven for the care of frail patients with polypharmacy living at home, the concept of family conferences could be implemented in routine care. For this purpose, the applied instruments could be further developed and supplemented by other tools, such as electronic decision aids. Regular refreshing communication trainings may be required for GPs, supplemented by trainings on polypharmacy management. The concept of family conferences may also be adapted for other target groups or clinical issues in primary care.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pecinn.2022.100032.

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