ORIGINAL RESEARCH

Humanistic outcomes and patient acceptance of the pharmacist-led medication review "Polymedication Check" in primary care in Switzerland: a prospective randomized controlled trial

Markus Messerli[1]
Noortje Vriends[2]
Kurt E Hersberger[1]

[1]Pharmaceutical Care Research Group, Department of Pharmaceutical Sciences, University of Basel, Basel, Switzerland; [2]Division of Clinical Psychology, Department of Psychology, University of Basel, Basel, Switzerland

Background: Since 2010, Swiss pharmacists have been offering their patients a Polymedication Check (PMC), a new cognitive pharmacy service in the form of a medication review for patients taking ≥ 4 prescribed medicines for a period >3 months. While a first publication of this project reported on the impact of the PMC on patients' adherence, the present paper focuses on humanistic outcomes.

Methods: This randomized controlled trial was conducted in 54 Swiss community pharmacies. After recruitment, the intervention group underwent a PMC in the pharmacy (T-0) and 28 weeks after T-0 (T-28), while the control group did not receive the PMC until 28 weeks after the study started (T-28). A clinical psychologist, blinded to the intervention, interviewed the patients 2 weeks (T-2) and 16 weeks (T-16) after T-0. Interviewer and patient both rated patient's knowledge of own medicines use. Furthermore, patients reported satisfaction with their pharmacy and appraisal of their medicines use. The availability of a written medication plan was assessed at T-16. Acceptance of the service was measured using a patient's self-report questionnaire at T-28.

Results: General linear model analysis for knowledge about medicines revealed a significant effect on the factor "group" (F=5.86, p=0.016), indicating that the intervention group had higher ratings for knowledge about their medication at T-2 and T-16 compared to controls. The majority (83%) of patients judged the counseling by the pharmacist as being helpful for their daily medication management. Availability of a written medication plan was comparable in both groups (52.5% vs 52.7%, $p>0.05$).

Conclusion: For the first time, the benefits of a complex pharmacist-led intervention were evaluated in Swiss primary care with a randomized controlled trial. The PMC increased patients' subjective knowledge of their medicines compared to no medication review. The effect remained sustainable over time. Recommendations resulting from the pharmacist-led service were highly appreciated by the patients.

Keywords: polypharmacy, community pharmacy, medication review, humanistic outcomes, patient knowledge, patient acceptance, pharmaceutical care

Introduction

The role of the community pharmacist in primary care has been undergoing change in Switzerland in parallel to international developments: it has become more clinically and patient oriented. Special services provided by community pharmacists addressing older patients taking long-term or multiple medications have been developed.[1] A recent Cochrane overview of systematic reviews by Ryan et al reported positive effects on

Correspondence: Markus Messerli
Pharmaceutical Care Research Group,
Department of Pharmaceutical Sciences,
University of Basel, Klingelbergstrasse 50,
CH 4056 Basel, Switzerland
Tel +41 79 751 1872
Email markus.messerli@unibas.ch

adherence to medication, knowledge about medicines, drug-related problems, and clinical outcomes when pharmacists were involved in medicines management interventions.[2] In particular, medication reviews were described as effective when they offer a consultation between pharmacist and patient to resolve drug-related problems, develop a care plan, and provide follow-up. Since 2010, Swiss pharmacists have been allowed to offer their patients a Polymedication Check (PMC), a new cognitive service in the form of a medication review involving patients using more than three prescribed medicines over a period of at least 3 months.[3] This reimbursed service aims at detecting drug-related problems[4] in a patient's medicines use in daily life and recommending interventions to optimize medicines management in order to prevent negative health outcomes through drug therapy.[1] This pharmacist-led service can be delivered independently from physician's prescriptions. With respect to this interface between pharmacy and general practitioner (GP), 7% of detected drug-related problems triggered a consultation with the patient's GP, with a high acceptance rate of pharmacists' recommendations (71%).[3] This change in the role of pharmacists is remarkable, as pharmacists often lack self-confidence about their role in patient care and acceptance by their clients.[5,6]

In Switzerland, new services remunerated by the basic health insurance require a proof of their efficacy, appropriateness, and economic effectiveness according to national criteria.[7] As an investigator-initiated project, we aimed at evaluating efficacy and appropriateness of the PMC by providing a randomized controlled trial in Swiss community pharmacies. We hypothesized that the PMC would increase adherence and improve patients' knowledge about their medications compared to the control group. While a first publication of this project reported on the impact of the PMC on patients' adherence,[3] the present manuscript highlights humanistic outcomes. It provides information about 1) the impact of the PMC on patients' knowledge about their medication, 2) effect of the PMC on the patients' relationship with the pharmacy and the appraisal of their medicines use, 3) acceptance of the PMC, and 4) the availability of organizational tools to enhance self-management such as a written medication plan.

Methods

Data were available from the previously described randomized-controlled trial conducted in 54 Swiss community pharmacies.[3] Eligible patients used ≥4 prescribed medicines for >3 months. After recruitment and randomization, the intervention group received a PMC in the pharmacy (T-0) and another PMC 28 weeks after T-0 (T-28), while the control group received a PMC only at T-28 (Figure 1). Study pharmacists were required to take part in a 3-hour training session provided by the study center. This training session included an overview of the study, highlighted the need for compliance to the study protocol, and clarified rights and responsibilities of the study pharmacists. As the study aimed at assessing and evaluating current practice, no other qualification criteria were applied other than being a pharmacist and no further training on the execution of a PMC was offered. This study was conducted according to the guidelines laid down in the Declaration of Helsinki. Written informed consent was obtained from all participants. All procedures involving human subjects were approved by the responsible local ethic commission "Ethikkommission beider Basel (EKBB)" (23.05.2012, registry number EKBB 50/12) as the leading committee for this multisite study. The project was registered at the trial database www.ClinicialTrials.gov (Identifier NCT 01739816, first entry in November 2012).

Outcome measures

Both patient groups filled out self-report questionnaires at study start (T-0) and study end after 28 weeks (T-28). Telephone interviews were carried out 2 weeks (T-2) and 16 weeks (T-16) after T-0 by a trained telephone interviewer (Figure 1). Interviewers were intensively trained (4 hours of teaching and two exercise interviews) and regularly
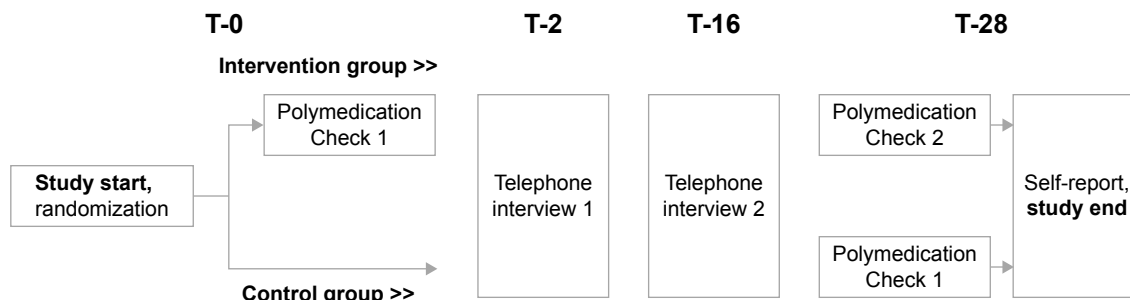

Figure 1 Study flow chart with relevant outcome measurements at study start (T-0), after 2 and 16 weeks (T-2 and T-16), and at study end after 28 weeks (T-28).

supervised by the second author (clinical psychologist). The semi-structured interviews and the self-report questionnaire were newly developed in a collaborative, interprofessional approach,[8–10] as validated questionnaires assessing patients' knowledge about medicines did not exist in acceptable length when the study was conducted. Further detailed description of the development and piloting of these measurement instruments is published elsewhere.[3] The interviews included additional questions that are not reported here. These items were beyond the scope of the study and we believe they did not influence the presented results.

Rating of patients' knowledge of their medicines

At T-2 and T-16, the patient completed an in-depth telephone interview about their medicine use. For each product that he/she mentioned, the interviewer asked

> Do you know why you take this medicine? How often do you take this medicine? When exactly do you take this medicine? Do you have to watch out for anything in particular when dealing with and applying/taking this medicine?

After the interview, the interviewer rated the knowledge of the use of their medicine on a scale from 1 (=poor knowledge) to 10 (=very good knowledge). Patients also rated their subjective knowledge about the use of their medicine on this scale. Both patient and telephone interviewer used an identical scale. The patients were not informed about the interviewers' rating.

Patient satisfaction and relationship with study pharmacists

Patients' satisfaction concerning the relationship with the involved study pharmacies and related pharmacist was assessed at T-2 with six items using a rating scale from 1 to 10 with specific descriptive hints, eg, "How satisfied are you with your pharmacy on a scale of 1–10? (1=very dissatisfied; 10=very satisfied)".

Patient appraisal of their medicines use

Patients' appraisal concerning their medicines use was assessed at T-2 with six items using a rating scale from 1 to 10 with specific descriptive hints, eg, "How difficult do you find it to administer your medication? (1=very easy; 10=very difficult)".

Availability of a written medication plan

At T-16, patients reported during the telephone interview if they were in possession of a written medication plan (yes/no).

Patient acceptance of the service

At T-28, patients reported acceptance of the service with a self-report questionnaire after both groups received a PMC (for the intervention group, the second PMC). Patients further reported whether they knew about the service before they were invited to the study (yes/no), if, from their perspective, the price for the service (CHF 48.60 per PMC) was 1) accurate, 2) too high, or 3) too low, and if they were able to benefit from the pharmacist's advice provided within the PMC (yes/no). They also rated eight positive and two negative judgments concerning the PMC and the performance of the pharmacist using a 4-point Likert scale (1=disagree, 2=tend to disagree, 3=tend to agree, 4=agree). Ratings ≤2 were considered as negative, ratings ≥3 as positive statements.

Statistical methods

For statistical analysis, IBM SPSS Statistics 22 (IBM Corporation, Armonk, NY, USA) was used. Numerical scales are presented as mean and standard deviation. Ordinal scales were tested with the non-parametrical Mann–Whitney U-test. Analysis regarding patients' knowledge about their medicines were provided by using a general linear model (GLM) for repeated measures with "time" (T-2 and T-16) and "rater" (interviewer vs patient) as within-subject factor and "group" (intervention versus control) as a between-subject factor to analyze the main and interaction effects of the intervention on the knowledge of the patient. To describe internal consistency of relevant items, Cronbach's alpha was used. Statistical tests were performed with a significance alpha level of 5%.

Results

Of 450 patients enrolled at T-0, 372 (82.7%, dropout rate: 17.3%) completed the study (T-28). In total, 243 (54%) were women. The mean age of the patients was 67 years.[3]

Rating of patients' knowledge of their medicines

Mean patients' knowledge concerning their medicines at T-2 and T-16 rated by the interviewer and by the patient himself/herself are summarized in Table 1. GLM analysis revealed a significant main effect for the factor "group" (intervention vs control) as the mean of both ratings (self and interviewer) of the intervention group's knowledge about medication was higher at both measure points (F=5.86, p=0.016) compared to controls. A significant main effect for "time" (F=45.99, p<0.001) showed that the knowledge ratings of both groups increased between T-2 and T-16. A significant main effect for the factor "rater" (interviewer vs self) revealed that the patients rated their knowledge about their

Table 1 Patient knowledge concerning medicine use at T-2 and T-16, rated by the interviewer and by the patient

	Intervention			Control		
	n	Mean	SD	n	Mean	SD
T-2 Interviewer*	202	7.38	1.85	214	7.11	1.87
T-2 Patient**	201	9.27	1.22	213	9.21	1.34
T-16 Interviewer*	198	7.99	1.83	203	7.62	2.10
T-16 Patient**	198	9.66	0.80	203	9.49	1.18

Notes: *Please rate the patient knowledge of the administration of his medication on a scale of 1–10. 1=poor knowledge; 10=very good knowledge. **If you had to rate your knowledge on a scale of 1–10, how sure are you of the administration of your medication?' 1=poor knowledge; 10=very good knowledge.

medicines higher compared to the ratings of the interviewer ($F=435.59$, $p<0.001$). A significant "time x rater" interaction ($F=3.99$, $p=0.046$) indicated that the ratings of the interviewers increased more from T-2 to T-16 compared to the increase of the patients' ratings. Other interactions were not significant ($p>0.05$).

Patient satisfaction and relationship with study pharmacists

Patient satisfaction with the study pharmacies assessed at T-2 is shown in Table 2. Cronbach's alpha of this scale was 0.693 in the intervention group and 0.749 in the control group. All six questions on satisfaction with PMC provision by the community pharmacy show very high satisfaction with no significant difference between control and intervention ($p>0.05$).

Patients' appraisal of their medicines use

Patients' appraisal of their medicines use at T-2 is shown in Table 3. Cronbach's alpha of this scale was 0.031 in the intervention group and −0.078 in the control group. No significant difference between the groups was observed ($p>0.05$).

Availability of a written medication plan

At T-16, availability of a written medication plan was reported by 104 (52.5%) individuals in the intervention group and 107 (52.7%) individuals in the control group. There was not significant group difference ($p>0.05$).

Patient acceptance of the service

Response rate of the self-report questionnaire was 100% (n=372). One hundred sixteen patients (31.2%) knew about the PMC before being invited for the study. The price of the service was accepted as appropriate by 327 patients (87.9%) or too low by 13 patients (3.8%), while another 13 patients (3.8%) stated the cost as too high and 19 (5.1%) did not answer. In total, 308 patients (83.1%) appraised the counseling by the pharmacist as, in general, being helpful for their daily medication management. In Table 4, the patients' rating of the service is shown after both groups had received at least one PMC.

When aggregating the results from Table 4 (ratings ≤2 were considered as negative, ratings ≥3 as positive statements), 306 patients (82.3%) stated improved confidence in their medicines and 290 (78.0%) reported enhanced security in their medicines use after the PMC. Most patients (n=358, 96.2%) agreed to recommend the PMC to other patients.

Discussion

We report secondary outcome measures of a randomized controlled trial. In the present evaluation of the cognitive pharmacist-led service, PMC patients showed a significantly greater subjective knowledge about their medication after the PMC compared to usual care. Although the effect appears small, the difference to the control group is remarkable since the organizational structure of the enrolled population was

Table 2 Patient satisfaction with study pharmacy and judgment about relationship with study pharmacists at T-2 (mean and standard deviation are given)

	Intervention (n=202)	Control (n=214)	p-value
1. How satisfied are you with your pharmacy on a scale of 1–10? (1=very dissatisfied; 10=very satisfied)	9.61 (0.79)	9.68 (0.68)	0.518
2. Do you generally accept recommendations made to you by your pharmacist? (1=you never accept recommendations; 10=you always accept recommendations)	9.34 (1.26)	9.36 (1.20)	0.891
3. How competent would you consider your pharmacist, in his/her field of work, on a scale from 1 to 10? (1=very incompetent in his/her field; 10=very competent in their field)	9.72 (0.68)	9.74 (0.65)	0.768
4. On a scale of 1–10, how satisfied are you with the amount of time your pharmacist has for you? (1=very dissatisfied; 10=very satisfied)	9.71 (0.81)	9.75 (0.60)	0.695
5. On a scale of 1–10, how strongly do you feel your interests to be in good hands with your pharmacist? (1=not in good hands at all; 10=in very good hands)	9.68 (0.76)	9.75 (0.64)	0.366
6. On a scale of 1–10, how much better do you understand your medications and their application after you consulted your pharmacist? (1=not at all better; 10=much better)	9.19 (1.85)	9.15 (1.84)	0.753
	9.57 (0.66)	9.58 (0.70)	0.605

Table 3 Patient appraisal of their medicine use at T-2 (mean and standard deviation are given)

	Intervention (n=202)	Control (n=214)	p-value
1. How satisfied are you on a scale from 1 to 10 with your daily medication intake (eg, number of medicines, condition)? (1=very unsatisfied; 10=very satisfied)	9.12 (1.39)	8.95 (1.56)	0.208
2. How competent do you feel administering your medication? (1=very incompetent; 10=very competent)	9.33 (1.18)	9.29 (1.49)	0.529
3. How comfortable do you consider administering your medication? (1=very uncomfortable; 10=very comfortable)	8.23 (2.23)	8.35 (2.20)	0.613
4. How difficult do you find it to administer your medication? (1=very easy; 10=very difficult)	1.50 (1.26)	1.42 (1.12)	0.965
5. How unappetizing do you find taking medication? (1=delicious; 10=very unappetizing)	2.06 (1.95)	2.08 (1.80)	0.472
6. Do you think that your medicines are necessary? (1=you consider them absolutely unnecessary; 10=you consider them very important)	9.46 (1.11)	9.39 (1.38)	0.661
	6.58 (0.68)	6.56 (0.65)	0.935

high at the start of the study leaving only little room for improvements.[3] In both interviews, both groups reported an overall high and constant satisfaction with individual care offered by community pharmacists and a fairly high appraisal of their medicines use during the study. This important result underscores that pharmacists should not be concerned about unsettling the patient in his/her medicine use or causing harm when performing medication reviews as previously postulated by Holland et al.[11]

Improved knowledge on medicines use

The PMC positively influenced the patient's knowledge on his/her medicine use. Patients seemed to subjectively know more about their medication use after the intervention compared to controls. This finding may be explained with the observed pattern of addressed drug-related problems during the intervention at T-0. In 27% of cases, need for further information on safe and effective use of medicines or potential adverse drug reactions represented a cause for further recommendations by the study pharmacist.[3] While Grymonpre et al did not show any impact on patients'

knowledge through a pharmaceutical care model,[12] Ryan et al concluded in their Cochrane review that pharmaceutical care services were affected, with positive effects on adherence and knowledge.[2] Similarly, Latif et al investigated improvement of knowledge through Medicines Use Reviews (MUR), a service similar to the Swiss PMC. Thereby, they reported that MURs did little increase patients' knowledge and rarely affected medicine use. Nevertheless, some patients felt reassured about their medicines use.[13]

Interestingly, we found that patients overestimated their own knowledge about their medication in comparison to the external ratings of the interviewers about patients' knowledge. This might indicate an overestimation of capabilities by the patients comparable to subjective adherence ratings.[14,15] The "one question fits all" approach (eg, "Do you know how to use your medicines"?) represents a first step for a loose detection of individual issues with medication intake, but needs further in-depth assessment. This should include evaluating patients' knowledge on "why", "how often", and "when exactly" they take their medicines in order to provide individualized patient education to address these

Table 4 Statements regarding the PMC rated by all 372 patients using a self-report questionnaire at study end after having received at least one PMC (4-point Likert scale; 1=disagree, 2=tend to disagree, 3=tend to agree, 4=agree; NA=no answer)

Statement	Likert scale 1–4 (n/%)				NA
	1	2	3	4	
1. The consultation took place in a pleasant atmosphere	0/0.0%	0/0.0%	12/3.2%	359/96.5%	1/0.3%
2. The aims of the PMC were clearly explained to me	0/0.0%	3/0.8%	20/5.4%	347/93.8%	2/0.5%
3. The time spent was worth it for me	4/1.1%	8/2.2%	51/13.7%	296/79.6%	13/3.5%
4. I would recommend the service	2/0.5%	3/0.8%	49/13.2%	309/83.1%	9/2.4%
5. The instructions of the pharmacist helped me in handling my medication	9/2.4%	5/1.3%	42/11.3%	293/78.8%	23/6.2%
6. Thanks to the pharmacist' advice, I do have more confidence in my medication	17/4.6%	13/3.5%	72/19.4%	234/62.9%	36/9.7%
7. The pharmacist had enough time to answer all my questions	0/0.0%	2/0.5%	10/2.7%	356/95.7%	4/1.1%
8. Until today, I felt left alone with my medication	259/69.6%	44/11.8%	22/5.9%	31/8.3%	16/4.3%
9. Thanks to the advice, I feel safer than before in the use of my medication	31/8.3%	21/5.6%	83/22.3%	207/55.6%	30/8.1%
10. Until today, I had far too little information about my medication	180/48.4%	65/17.5%	65/17.5%	45/12.1%	17/4.6%

Abbreviation: PMC, Polymedication Check.

knowledge gaps. In this context, further research might investigate sensitivity and specificity in detecting critical gaps in patients' knowledge about their medicines.

Within this context, we also found that the knowledge of controls (usual care) improved between T-2 and T-16. We assume that the interview at T-2 affected this increase in the control group. When answering detailed questions about every medication, both groups showed their in-depth knowledge concerning medicine use, which could have influenced the measurement at T-16. Implicitly, the impact of the intervention on the outcome "knowledge" has to be assumed reliable and valid at T-2 only.

High acceptance of pharmacists' interventions

While pharmacists reported being uncertain about their role in patient-centered care and lack of self-confidence,[6] patients from this study highly appreciated the pharmacists' recommendations resulting from the PMC. Furthermore, patients agreed on the price of the PMC. This very positive feedback is a valuable argument in favor of the new service. However, only 31.2% of the patients knew before the start of the study of the possibility of this pharmacist-led service, indicating a huge gap in communication of new services to the target population 2 years after implementation. While the pharmacists' willingness to provide the service remains unclear, legal barriers hamper the public announcements of new services, since it is forbidden by Swiss law to advertise for remunerated health care services.

Room for improvement of patients' medication management

The fact that 47% of patients stated having no written medication plan to organize their complex medication schedule raises the question of responsibility to provide such an important tool. A written medication plan, which is accepted and understood by any individual patient, would probably empower them in daily medicine management and is highly recommended by current guidelines when optimizing a patient's medicines.[16] Since in Switzerland pharmacists are obliged by law to keep records of all dispensed medication, they are in an excellent position to initiate a written overview and validate its actuality in collaboration with the corresponding GP. Such initiatives are currently in development in Germany.[17] Unfortunately, the current PMC guidelines do not mention it as a part of the service. The detection of this issue also lack in the structured protocol form as a screening approach.

Implications for practice

Based on patients' overestimation of knowledge about the correct use of their medications observed within our study, we propose to investigate pharmacists' techniques in identification of knowledge gaps during patient counseling. Pharmacists should be aware of knowledge gaps as a drug-related issue and should be provided with specific communication techniques for patient education. The high acceptance of the service should encourage community pharmacists to increase their involvement in patients' medicines management, eg, by compiling an individual medication plan in collaboration with the corresponding GP as a remunerated service.

In order to streamline implementation of this pharmacist-led medication review, further evaluation and development of the service should follow a validated process, such as was proposed by Craig et al.[18] In order to allocate human and financial resources in the most cost-effective manner, re-engineering of the service should be considered, eg, by revising the selection process for patients qualifying for a PMC with a pre-screening for obvious adherence issues using individual medication records,[19–21] specific validated questions triggering hints for non-adherence to medication,[22] or knowledge gaps. Similarly, the eligibility criteria for the comparable MUR service in the UK were changed 6 years after its implementation, adding specific target groups in the intervention's focus.[23] This proposal is aligned with recent recommendations of the National Health Institute of Excellence, which highlights the importance of medicine optimization, approaching patients at highest risks for medicine-related problems or patients with special needs, eg, people with physical problems such as arthritis or inability to swallow.[16]

Strengths

Firstly, the randomized controlled trial design is a distinct strength of this study. Second, the trial was performed under real-life conditions with a representative sample of pharmacies from the German and French speaking parts of Switzerland. Thus, the results of the present study are likely to be highly generalizable. Third, development of the telephone interview measurement tools was conducted by a collaborative, interprofessional approach. Fourth, well-trained and supervised interviewers, blinded to the intervention, performed the in-depth telephone interviews on patients' acceptance and knowledge. Fifth, patients' written self-reports were blinded to the pharmacists; thus a Pygmalion effect could be avoided.

Limitations

Firstly, patients enrolled in clinical trials may be more conscientious than a more general population. Second, during the consent process, patients were told that the purpose of the study was to learn more about their daily medicines use. Thus, all our patients knew they were monitored, which may have led to a higher baseline in self-reported knowledge about their medicines in both groups. The pharmacists, on the other hand, knew that they were being studied, which may have led them to increase their efforts in delivering pharmaceutical care for both groups, also known as the Hawthorne effect.[24] Third, in order to keep the questionnaires and interviews to an acceptable length, instead of using pre-existing validated instruments, new ones were developed with extensive piloting but they lacked in-depth validation. Fourth, rating of patients' knowledge about their medicines remained a subjective judgment. Fifth, the score for patients' appraisal of their medicines use showed a low Cronbach's alpha as a marker for limited reliability of the measure. Sixth, due to limited human resources, the registration of the project in a WHO database was delayed for some months. However, this lag in registration had no influence on the study protocol, patient recruitment, or data analysis. The relevant ethics approval was obtained before the study was initiated.

Conclusion

For the first time in Switzerland, the benefits of a complex pharmacist-led intervention were evaluated. The randomized controlled trial revealed important results in order to better understand the acceptance of cognitive services provided by community pharmacists. The PMC as an intermediate medication review offers a promising starting point for in-depth counseling and for providing pharmaceutical care. Knowledge about medication rated by interviewer and patients themselves was higher in the PMC group when measured directly after the PMC and 4 months later compared to controls. The community pharmacist-led intervention was highly appreciated by the patients, as a majority rated the counseling as helpful for their daily medication management. Patients would recommend the service to other patients and were willing to pay for it. However, almost half of the polypharmacy patients seemed to lack a written medication plan, offering room for improvement concerning the patients' self-management of medicines use.

Data sharing statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Acknowledgments

Author contributions

All the authors have full access to all the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. MM and KEH conceived the trial design and wrote the ethical proposal and study protocol. NV helped in developing the measurement tools (namely designing, piloting, and supervising the telephone interviews) and ensured independent training and support of the involved staff. As the main investigator, MM recruited and coordinated the study pharmacists and their patients and ensured compliance to study protocol. MM and NV accessed and analyzed the retrieved data. MM prepared the draft of a first report, while KEH and NV contributed to the discussion and revised the manuscript. They all read and approved the final version to be published.

Disclosure

The authors report no other conflicts of interest in this work.

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