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Patient beliefs about medicines and quality of life after a clinical medication review and follow-up by a pharmaceutical care plan: a study in elderly polypharmacy patients with a cardiovascular disorder

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Abstract

Objective To determine the effect of a clinical medication review, followed up by a pharmaceutical care plan, on the beliefs about medicines and quality of life (QoL) of older patients with polypharmacy and a cardiovascular disorder.

Methods Patients were randomly assigned to an intervention or control group. Intervention patients received a clinical medication review with a follow-up that developed a pharmaceutical care plan. Control group patients received care as usual. All patients received two standardised questionnaires: the general part of the Beliefs about Medicines Questionnaire (BMQ) and the EuroQoL EQ-5D questionnaire, at the start of the study (\(t=0\)) and after 1-year follow-up (\(t=1\)). Answers on both questionnaires were linked to patient data.

Key findings 512 patients were included from eight primary care settings. Analysis of the BMQ-General questionnaire showed that after 1-year intervention patients were more positive about medicines use, while control patients were more neutral or even more negative compared with baseline. For the first part, general harm, this result is statistically significant for the intervention group (\(P=0.014\)). The EQ-5D questionnaire showed no significant results in QoL. Increasing the number of episodes documented had a significant effect and resulted in more negative patient beliefs about medicines. Advanced age, female gender, increasing number of episodes documented and medicines dispensed resulted in a lower QoL.

Conclusion A medication review followed by a pharmaceutical care plan resulted in a significant positive effect on patient beliefs about medicines, but had no significant effect on QoL in elderly patients suffering from cardiovascular diseases. Female patients using multiple medicines, who visit their general practitioner regularly, might benefit most.

Keywords health belief; intervention study; patients; quality of life

Introduction

In order to solve possible drug-related problems (DRPs) it is important that pharmacists perform medication reviews. A medication review can be performed with different levels of cooperation between healthcare providers, with or without patient participation.\textsuperscript{[1]} A medication review on the highest level, known as a clinical medication review, involves pharmacists, general practitioners (GPs), and patients. This type of review is important for the long-term success of patient outcomes.\textsuperscript{[2]} The medication review should be repeated periodically. It is also important that patients are allowed to become partners in the pharmaceutical care process.\textsuperscript{[2]}

During a patient consultation in the medication review process, the patient’s beliefs about medicines can be discussed. Shared decision-making with patients is generally accepted as a method that enhances patients’ interest in their treatment and has a positive influence on the effectiveness of that treatment.\textsuperscript{[3]} Different studies are reporting associations between doctor–patient relationships, patient health beliefs, and patient adherence.\textsuperscript{[4–7]}
Patient consultation provides an opportunity to involve patients in their treatment, along with discussing their questions and concerns. Performing a clinical medication review as part of a patient consultation may result in a pharmaceutical care plan that systematically structures patients’ medical and pharmaceutical information in one overview, and documents interventions and follow-up. The aim was to have patients make better use of their medicines, but this may also result in more positive patient beliefs about medicine use and increased quality of life (QoL). However, this has not been the subject of studies in the international literature up until now.

The objective of this study was to determine the effect that a clinical medication review, followed up with a pharmaceutical care plan, has on the beliefs about medicines and QoL of elderly polypharmacy patients with a cardiovascular disorder. Different subgroups of patients with non-adherence and/or medication-related problems have been defined in the literature.\[^8,9\] Elderly patients with cardiovascular disease are the second most frequently observed patient group in medication-related hospital admissions.\[^8\] Furthermore, these patients are relatively easy to monitor in terms of parameters related to cardiovascular risk assessment. Therefore, elderly patients with a cardiovascular disorder using multiple medicines were chosen as our study population, as they could benefit from a clinical medication review followed by a pharmaceutical care plan.

**Methods**

**Procedure**

The study was performed in a number of primary care settings in the Netherlands. An Independent Ethics Committee (RTPO Leeuwarden, the Netherlands) reviewed the study protocol. The protocol was marked as a clinical intervention study with no additional risk for participating patients.

Community pharmacists (n = 500; 25% of all pharmacies in the Netherlands) were invited by letter to participate in the study. Pharmacies were randomly selected in an area defined by the sponsor of the study. Pharmacists were asked to contact the researchers, if they were interested in participating, and they then received further information. After consenting, the pharmacists subsequently contacted the GPs and asked for their participation. Good cooperation between pharmacists and GPs, and the willingness to share patient data, were prerequisites.

We developed a web-based pharmaceutical care plan application (W-PCP) in order to collect and document all patient data.\[^10\] A learning module for the W-PCP application was given by the researchers to participating pharmacists and GPs. During the study period technical assistance was available. Before the start of the study all participating pharmacists received a 1-day training course on communication skills with GPs and patients. Additional written information about performing a clinical medication review was provided, including three cases for practice. A course teacher was available for additional questions. During the study period, researchers visited study locations regularly in order to monitor the time schedule of the study and to provide assistance.

Older persons with multi-drug use aged ≥ 60 years with a cardiovascular disorder were selected. Patients were using at least five medicines for chronic conditions, with at least one of these medicines prescribed for a cardiovascular disorder or cardiovascular risk factor (Anatomical Therapeutic Chemical (ATC) class C\[^11\]). Patients who did not speak the Dutch language or were mentally not coherent were excluded. Patient inclusion occurred between August 2009 and June 2010. Patients were approached in the form of a letter containing information about the study and a reply form, which they could send to their pharmacy to consent for participation in the study. After informed consent, patients were randomised into either an intervention or a control group. Randomisation occurred based on unique patient identification numbers (IDs) in the pharmacy computer system (odd number: intervention group; even number: control group).

Intervention group patients received an invitation to consult their pharmacist for a clinical medication review. The pharmaceutical care plan was developed in cooperation between patients’ pharmacist and GP, and agreed upon with the patient. The pharmaceutical care plan documents possible DRPs and pharmaceutical care issues (CIs) and interventions proposed in order to resolve possible DRPs and CIs. Patients from the control group received care as usual and were not treated differently. We expect that the intervention will have a positive influence on beliefs about medicines and QoL.

**Questionnaire**

All participating patients received two standardised questionnaires, the general part of the Beliefs about Medicines Questionnaire (BMQ)\[^12,13\] and the EuroQoL (EQ)-5D questionnaire.\[^13,14\] Both questionnaires were sent to the participants at the start of the study (t = 0) and after 1-year follow-up (t = 1). Answers on both questionnaires were entered in a separate Microsoft Access datasheet and linked to patient data.

The BMQ-General questionnaire is divided into two parts: General Harm (questions 1–4) and General Overuse (questions 5–9). The measurement consists of a 5-point Likert scale and scores may vary from 1 (strongly agree) to 5 (strongly disagree). Mean scores for both parts were calculated for each patient. A higher score (range 4–5) indicates a positive orientation towards medicine use in general. The EQ-5D questionnaire consists of two parts: the EQ-5D descriptive system and a visual analogue scale (VAS). The descriptive system consists of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with three levels each (no problems, some problems and extreme problems). EQ-5D index values were computed from the five dimensions of the EQ-5D descriptive system, using a syntax of the time trade-off valuation technique for the Netherlands.\[^15\] When a patient reports no problem for all five dimensions this provides a score of 1.000. A high score indicates high QoL. The EQ-VAS score is a VAS ranging from 0, worst imaginable health state, to 100, best imaginable health state.

**Data**

The participating pharmacies and GP practices were connected to our W-PCP application.\[^16\] This web-based application uploaded all patient data from pharmacy and GP computer systems in order to combine information about
diagnoses, medicines prescribed and dispensed, and clinical and laboratory parameters in one patient file, accessible to both pharmacist and GP.

During the study period, patient data were uploaded regularly, depending upon patient consultations, and collected in the W-PCP application. Patient data consisted of general patient information (age, gender), episodes (International Classification of Primary Care (ICPC)-coded[16]), medicines dispensed (ATC-coded[11]), and clinical and laboratory parameters. Episodes are diagnoses defined by the GP (only ICPC-coded) and are related to the number of GP visits. Patient data were provided to the researchers in a database, Microsoft Access 2010.

Statistical analyses were performed using SPSS (version 21) and SAS (version 9.3). Differences in general patient characteristics were calculated using independent samples t-test and Pearson’s chi-squared test. Multilevel analysis was used to analyse the nesting structure. This involved measurements ($t=0$ and $t=1$) (level 1) being nested within patients (level 2), and patients being nested within GPs (level 3). Significance was tested at $P<0.05$.

A sample size calculation was performed to determine the number of patients needed for both groups. A 10% improvement of mean scores for both the BMQ-General and EQ-5D questionnaires was chosen as a meaningful change after the intervention. Based on two independent proportions (power analysis using alpha $=0.05$ and a power of 0.80), we needed approximately 400 patients for each group, with patients recruited from 10 to 12 study locations. Considering dropouts as a consequence of losses to follow-up, our aim was to include 100 patients per study location.

To guarantee patient privacy, patient data from the W-PCP were made anonymous before the database was provided to the researchers. Patient questionnaires were sent by the pharmacy with only a unique patient number allowing linkage of the questionnaire to patient data.

The total study period per location was 18 months, with consultations and medication reviews performed during the first 6 months. The last study location finished data collection in December 2011.

**Results**

In total, eight study locations (12 pharmacies and 38 GPs) were recruited. One location consisted of a cluster of five pharmacies (with five pharmacists), and the remaining locations consisted of one pharmacy with one or two pharmacists participating in the study. The number of GPs per location varied between 1 and 11. In total, 512 patients (24.4% of patients approached) were included: 248 in the intervention group and 264 in the control group (Figure 1).

![Flow diagram patients](image-url)
After 1-year follow-up, it turned out that 70 patients from the intervention group had never received the intervention because of time limitations on the part of the healthcare providers. Analyses were first performed for these three groups: the intervention group (group 1; \( n = 178 \)); patients from the intervention group who did not receive the intervention (group 2; \( n = 70 \)); and the control group (group 3; \( n = 264 \)) (Figure 1). As no significant differences occurred between patients from groups 2 and 3, and patients from group 2 received care as usual, it was decided to analyse patients from group 2 as if they were patients from the control group.

General patient characteristics at the beginning of the study (\( t = 0 \)) were comparable between both intervention group (\( n = 178 \)) and control group (\( n = 334 \)) (Table 1). Both samples are homogeneous based on age, gender, number of episodes and number of medicines used, all \( P \) values are > 0.05. Average age at time of inclusion was 72.5 years (intervention group) and 72.8 years (control group), and a little over half of the participants were women. Patients were diagnosed with a mean of more than 14 documented episodes and eight medicines.

Response rates for the questionnaires were 92% (\( t = 0 \)) and 82% (\( t = 1 \)). Table 2 shows that patients do not have negative beliefs about medicine use in general, with all BMQ-General mean scores > 3. Both parts of the BMQ-General questionnaire (General Harm and General Overuse) show that intervention patients became more positive about medicines use (increase in mean scores), while patients without intervention indicated no difference or even became more negative (small decrease in mean scores). For the first part, General Harm, the mean score increased significantly from 3.297 at \( t = 0 \) to 3.423 at \( t = 1 \) in the intervention group (mean 0.126; confidence interval of \(-0.227 \) to \(-0.025 \); \( P = 0.014 \)). The EQ-5D descriptive system and VAS scores shows slight changes, but the results were not consistent with each other and not statistically significant.

Table 3 shows the effect of four covariates (age, gender, number of episodes documented and number of medicines dispensed) on the scores of both questionnaires. Number of episodes documented had a significant effect on both parts of the BMQ-General questionnaire, with an increasing number resulting in decreased scores and thus a lower QoL. Significant effects were also found for the EQ-5D questionnaire, both on the EQ-5D and EQ-VAS. Higher age, female gender, increased number of episodes documented, and a higher number of medicines dispensed resulted in decreased scores and thus a lower QoL.

### Discussion

Our results show that a medication review with a follow-up of a pharmaceutical care plan may improve patient beliefs about medicines, but does not affect QoL in patients suffering from cardiovascular diseases. As hypothesised, the intervention patients became more positive about medicine use in general. When questions and concerns about medicine use are discussed with a healthcare provider, patients will feel more secure about their medicines use. Fewer unanswered questions and concerns will lead to a more positive feeling about their medicine use. These results might have a positive influence on patient adherence.\[^{[5,7]}\] Our data do not include information about patient adherence, further research on this aspect will be necessary in the future. Patient beliefs about medicines are important in order to solve possible DRPs. When interventions are defined to solve possible DRPs, it is important that patients have possible beliefs about their medicines in order to have a successful intervention.\[^{[2,3]}\]

The EQ-5D questionnaire showed small, inconsistent differences between both measurements, which indicates that the intervention had no significant effect on QoL. Thus, a consultation with patients’ pharmacists, followed by the development of a pharmaceutical care plan, might have more influence on patient beliefs and concerns about medicine use than it has on their QoL. We did find a significant increase for the General Harm part of the BMQ questionnaire, but question whether this is clinically relevant. Scores at baseline showed that patients did not have negative beliefs about medicine use in general. This meant that any room for improvement would be small.

According to the effects of covariates, elderly female patients using multiple medicines and visiting their GP regularly may have a lower QoL compared with younger male

### Table 1 General patient characteristics (\( n = 512 \)) at time of inclusion (\( t = 0 \))

<table>
<thead>
<tr>
<th></th>
<th>Intervention (( n = 178 ))</th>
<th>Control (( n = 334 ))</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>( t = 0 )</td>
<td>( t = 1 )</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>72.5 (7.735)</td>
<td>72.8 (7.926)</td>
<td>0.687(^a)</td>
</tr>
<tr>
<td>Gender, male (%)</td>
<td>46.1%</td>
<td>48.5%</td>
<td>0.599(^a)</td>
</tr>
<tr>
<td>Number episodes</td>
<td>14.6 (8.210)</td>
<td>14.7 (8.263)</td>
<td>0.859(^a)</td>
</tr>
<tr>
<td>Number medicines</td>
<td>8.3 (2.721)</td>
<td>8.0 (2.998)</td>
<td>0.338(^a)</td>
</tr>
</tbody>
</table>

\(^a\)Independent-samples \( t \)-test.

\(^a\)Pearson’s chi-squared test.

SD, standard deviation.

### Table 2 Mean scores Beliefs about Medicines Questionnaire (BMQ)-general and EuroQol EQ-5D questionnaire before intervention (\( t = 0 \)) and after 1-year follow-up (\( t = 1 \))

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>( P ) value(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMQ-General harm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>3.297(^a)</td>
<td>3.423(^a)</td>
<td>0.014(^a)</td>
</tr>
<tr>
<td>Control</td>
<td>3.349(^a)</td>
<td>3.345(^a)</td>
<td>0.927</td>
</tr>
<tr>
<td>BMQ-General overuse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>3.387(^a)</td>
<td>3.416(^a)</td>
<td>0.541</td>
</tr>
<tr>
<td>Control</td>
<td>3.408(^a)</td>
<td>3.385(^a)</td>
<td>0.540</td>
</tr>
<tr>
<td>EQ-5D index values</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>0.733(^b)</td>
<td>0.741(^b)</td>
<td>0.706</td>
</tr>
<tr>
<td>Control</td>
<td>0.748(^b)</td>
<td>0.756(^b)</td>
<td>0.548</td>
</tr>
<tr>
<td>EQ-VAS score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>65.6(^c)</td>
<td>65.1(^c)</td>
<td>0.679</td>
</tr>
<tr>
<td>Control</td>
<td>65.8(^c)</td>
<td>64.9(^c)</td>
<td>0.359</td>
</tr>
</tbody>
</table>

\(^a\)1, strongly agree; 2, agree; 3, no clear opinion; 4, disagree; 5, strongly disagree.

\(^a\)Index values: \(-0.329 \) = worst imaginable health state; 1.000 = best imaginable health state.

\(^a\)Visual analogue scale (VAS): 0 = worst imaginable health state; 100 = best imaginable health state.

\(^a\)Multilevel analysis.

\(^a\)Significant.
patients with fewer GP visits and lower medicine use. Older persons will meet with their GP more often and use more medicines compared with younger persons. Therefore, a higher age is linked to a higher number of episodes registered and a higher number of medicines prescribed. A higher number of episodes registered was interpreted as a measure of the number of GP visits by one patient. The covariates we studied are determinants associated with potentially preventable medication-related hospital admissions (HARM).[8]

Patients who visit their GP regularly and have one or more HARM determinants might well comprise a target group for a consultation and a pharmaceutical care plan.

Limitations

Because of randomisation at the patient level it could mean that control patients are treated differently and did not receive care as usual. The intervention might have an influence on the daily activities of participating healthcare providers.

Twelve pharmacies out of 500 participated in the study. Reasons not to participate were mostly lack of time. With this data we cannot tell if the study population is representative for the Netherlands. Despite multiple visits to the study locations in order to monitor study progress, not all the patients from the intervention group actually received the intervention (group 2). Pharmacists began performing medication reviews at random from the list of participating patients. It could be that pharmacists began with those patients using less complex medicines. This might have created a bias in our results, if the most complex patients did not receive a medication review. Performing a medication review took a great deal of time, and it was not always easy to implement this service in the daily activities of the pharmacies. Another limitation of this study was the number of patients included, since we failed to reach the numbers needed according to our sample size calculation. For future studies, a higher number of patients is needed in order to determine the effect of a clinical medication review on patients’ QoL.

The BMQ-questionnaires are Likert scales with five possible answer options. Respondents might not choose the extreme options, which means if a patient agrees or disagrees, there is not much room for improvement. Also the space between answer categories might not be clear. Another disadvantage is that respondents might focus on one side of answer categories (disagree or agree).

Conclusion

A medication review followed by a pharmaceutical care plan resulted in a significantly positive effect on patient beliefs about medicines, but had no significant effect on QoL in elderly patients suffering from cardiovascular diseases. Female patients using multiple medicines and visiting their GP regularly might benefit most from a clinical medication review that is followed by the development of a pharmaceutical care plan. More research is necessary in order to define the effect of a clinical medication review on patient beliefs about medicines and QoL.

Declarations

Conflict of interest

The author(s) declare(s) that they have no conflicts of interest to disclose.

Funding

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Authors’ contributions

M.M.E.G. contributed to the design of the study, data collection and analysis and writing the article. R.E. Stewart contributed to data analysis and made corrections on the manuscript. J.R.B.J. Brouwers made corrections on the manuscript. P.A.dG made corrections on the manuscript. J.J.dG contributed to the design of the study and made corrections on the manuscript. All authors state that they had complete access to the study data that support the publication.
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