Original Article

Effect of comprehensive medication management on patient empowerment 'type II diabetes mellitus patients in primary care'

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ABSTRACT

The treatment of Type 2 Diabetes in the health care system can undergo a transition among health care facilities which may lead to drug-related problems. Pharmacists have clinical knowledge and skills to conduct pharmacotherapy workup and enable patients to achieve therapeutic goals. This study aims to prove a comprehensive medication management model to be implemented in primary care and to evaluate the effect on patient empowerment and HbA1c. This study used the experimental design on the implementation of a comprehensive medication management model in diabetic patients who were divided into the intervention and control groups with a total of 42 patients at the Surabaya Primary Health Care using the form of patient empowerment assessment. The implementation of a comprehensive medication management model significantly improved all domains of patient empowerment and HbA1c (pre-post study, $p<0.050$) in the intervention group; and significantly differ in the intervention compared to the control group of patient empowerment of understanding, attitude, and participation ($p<0.050$). The empowerment of the patient's experience, ability to use medication, and HbA1c did not differ between the intervention compared to the control group ($p\geq0.050$). Comprehensive medication management models can be implemented in primary care to improve patient empowerment and diabetes treatment outcome through pharmacotherapy workup as the foundation of the patient care process. Lack of patient's medication experience can be the cause\q of inappropriate decisions.

Keywords: Comprehensive medication management, Type 2 diabetes, Patient empowerment, Primary care

Introduction

Healthcare services in Indonesia have applied the National Health Insurance which is managed by the government [1, 2]. Persons with chronic diseases with stable conditions that require continuity of care will be managed by Referral Program (PRB) to provide easy access to medicines through primary health care facilities [3].

Diabetes is a concern in PRB, especially in the prevention of acute and chronic complications [4]. Only one-third of the people with diabetes who underwent drug therapy reached the target, where the average HbA1c was still 8%. This is due to the high number of patients who are not adherent to treatment. Therefore, diabetes management needs to be improved [5].

Pharmacists have the clinical knowledge and skills to resolve non-adherence problems and enable patients to achieve therapeutic goals through pharmaceutical care [6]. One of the models developed to optimize drug therapy in the management of chronic diseases with collaboration between health professionals in primary care is known as Comprehensive Medication Management (CMM) [7, 8]. The pharmacist's role

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in CMM is to conduct a study of the overall drug therapy used by patients at all levels of health care to ensure that all drugs received by the patient are appropriate, effective in the dosage regimen given, safe for the patient's condition and other possible drugs interaction, and the patient can use the medicine properly [9].

Patient empowerment in managing diabetes needs to be the concern of health professionals, which can be obstacles for the patients in making decisions to use drugs according to the prescription to control their disease. Pharmacists can implement CMM in carrying out drug control functions to patients who have not reached therapeutic outcome, have low understanding and adherence to medication in the transition of health care.

Materials and Methods

This study used a quasi-experimental design carried out in 18 Surabaya Public Healthcare Centers (Puskesmas) appointed by the Surabaya Health Department, which were divided into 9 intervention groups and 9 control groups. Pharmacists in the intervention group implemented the CMM model, and pharmacists in the control group carried out pharmaceutical care according to the standard of care at the Puskesmas. The unit of analysis for this study was 21 diabetic PRB patients in each group. The size of the research sample was the total population according to the research criteria (purposive sampling). This research was conducted from August 2019 to January 2020.

The CMM model framework in this study used a therapeutic relationship process between pharmacists and the patients [10], and the framework was developed following the aim of the study to evaluate diabetes patient empowerment in experiencing a health care transition with a pharmacotherapy study approach (indication, effectiveness, safety, and adherence). Patient empowerment was assessed based on 5 domains **(Table 1)**.

Table 1. The Patient Empowerment in Comprehensive Medication Management Model

1. Patient empowerment in understanding drugs usage	Patients' understanding of taking the medication can be evaluated through interviewing the patients in terms of the purpose of drug usage, effectiveness, safety, and adherence.
2. Patient empowerment in their experience on drugs usage	Patients' experience in taking the medication can be evaluated by assessing the needs of drug therapy of the patients in terms of their understanding of the purpose of drug usage, effectiveness expectation, concern to safety, and adherence behavior.
3. Patient empowerment in their attitudes toward medication	Patients' attitudes in taking the medication can be evaluated by compiling pharmaceutical care plans in terms of the purpose of drug usage, effectiveness, safety, and adherence.
4. Patient empowerment in their participation in medication	Patients' participation in taking the medication can be evaluated by establishing an intervention or referring to the doctor in terms of the purpose of drug usage, effectiveness, safety, and adherence.
5. Patient ability in performing medication	Patients' ability to perform medication can be evaluated by monitoring and evaluating in terms of the purpose of drug usage, effectiveness, safety, and adherence.

Statistical Analysis

Data was coded, validated, and analyzed using SPSS, version 23. Frequencies and proportions were used to present the data. Wilcoxon Sign Rank Test and Mann Whitney was used as the test of significance at the 5% level**.**

Results and Discussion

Patient Empowerment in Understanding Drugs Usage

Pharmacists conducted the CMM model **(Table 1)** and performed the analysis on patient empowerment in understanding presented in **Table 2**. The average scores of patient empowerment in understanding drugs usage (pretest-posttest) on the intervention group were 64.76±20.46 and 87.62±14.50 (p=0.000), while the control group were 67.94±18.93 and 71.43±16.21 (p=0.050).

Patient Empowerment on The Medication Experience

Pharmacists conducted the CMM model **(Table 1)** and performed the analysis on patient empowerment on the medication experience presented as a subdomain in **Table 3**. The average scores of patient empowerment in their experience in drugs usage (pre-and post-test) on the intervention group were 78.68±11.31 and 92.06±8.98 (p=0.000), while the control group were 86.28±7.64 and 88.32±8.18 (p=0.126).

Patient Empowerment in the Attitudes in Medication

Pharmacists conducted the CMM model **(Table 1)** and performed the analysis on patient empowerment in their attitudes presented as a subdomain in **Table 4**. The average scores of patient empowerment in their attitudes toward medication (pre-and post-test) on the intervention group were 83.81±10.36 and 94.05±7.35 (p=0.000), while the control group were 85.48±9.99 and 87.14±8.74 (p=0.659).

Patient Empowerment in the Participation in Medication

Pharmacists conducted the CMM model **(Table 1)** and performed the analysis on patient empowerment in their

participation presented as a subdomain in **Table 5**. The average scores of patient empowerment in their participation in medication (pre-and post-test) on the intervention group were 61.19±20.49 and 85.48±13.31 (p=0.000), while the control group were 61.43±19.57 and 60.24±20.52 (p=0.517).

Patient Ability in Performing Medication

Pharmacists conducted the CMM model **(Table 1)** and performed the analysis on patient ability in performing medication presented as a subdomain in **Table 6**. The average scores of patient ability in performing medication (pre-and post-test) on the intervention group were 73.72±9.84 and 88.92±8.67 (p=0.000), while the control group were 84.30±10.16 and 86.25±10.29 (p=0.421).

Blood Glucose Control Target

Considering the follow-up time of the patients, it is possible to observe that regardless of their follow-up period, there was a decrease in HbA1c levels, presented in **Table 7**.

Table 2. Empowerment Domain in Understanding Drugs Usage

Understanding Drugs Usage	Intervention Group (n=21) % Good Understanding		Control Group (n=21) % Good Understanding	
	Pretest	Posttest	Pretest	Posttest
Indication				
Able to mention the items of the drugs used	85.71	95.24	95.24	95.24
Able to mention the name and the form of the drugs used	76.19	90.48	71.43	76.19
Able to read/memorize the instruction on the drugs label	90.48	100.00	80.95	85.71
Understand the purpose of the drugs on the health problems	33.33	80.95	71.43	76.19
Effectiveness				
Know the frequency of use of the drugs	90.48	100.00	80.95	85.71
Know when to take the drugs	76.19	95.24	76.19	71.43
Know the interval of drugs usage	47.62	71.43	57.14	61.90
Know the effectiveness expected (drug therapy target)	33.33	71.43	57.14	57.14
Safety				
Know the potential unwanted side effect of the drugs	28.57	57.14	9.52	9.52
Know how to prevent or overcome the unwanted side effect of the drugs	57.14	90.48	52.38	61.90
Know the interval of the drugs to prevent potential interaction with other drugs	57.14	71.43	28.57	33.33
Know how to store the drugs according to the stability conditions	76.19	90.48	71.43	71.43
Adherence				
Understand and use drugs regularly according to the instructions	47.62	100.00	76.19	90.48
Know the number of drugs that should be obtained	76.19	100.00	90.48	95.24
Know the control schedule to get the next medication	95.24	100.00	100.00	100.00

Note % good understanding: (the number of subjects with the scoring average per domain=1/total subject each group) x 100%

Table 3. Empowerment Domain in The Medication Experience

The Medication Experience	Intervention Group (n=21) % Good Experience		Control Group (n=21) % Good Experience	
	Pretest	Posttest	Pretest	Posttest
The patient understands the drugs used according to the diseases (indication)	61.90	90.48	76.19	80.95
The patient understands the drugs used for slowing the disease progress (indication)	14.29	42.86	9.52	14.29
Patient expects the drugs to give positive result (effectiveness)	19.05	76.19	61.90	76.19
The patient expects the dosage of the drug is suitable to achieve the therapeutic outcome (Effectiveness)	71.43	95.24	76.19	61.90
Patient concerned about the symptoms thought to be the unwanted side effect of medications (safety)	33.33	71.43	66.67	71.43
The patient is not worried about the dosage and direction (safety)	38.10	76.19	57.14	80.95
The patient intends to take the drugs (adherence)	47.62	61.90	57.14	71.43
The patient can follow the directions (adherence)	14.29	52.38	23.81	33.33

Note % good experience: (the number of subjects with the scoring average per domain=1/total subject each group) x 100%

Table 4. Empowerment Domain in The Attitudes Toward Medication

The Attitudes Toward Medication	Intervention Group (n=21) % Positive Attitude		Control Group (n=21) % Positive Attitude	
	Pretest	Posttest	Pretest	Posttest
Understand the effort to achieve diabetes therapy target using drugs and lifestyle management (indication)	47.62	80.95	57.14	47.62
Expect to achieve the result of medication (Effectiveness)	85.71	95.24	85.71	95.24
Care and behave positively towards medication (safety)	33.33	57.14	38.10	47.62
Adhere to medication direction (Adherence)	61.90	95.24	61.90	76.19

Note % Positive Attitude: (the number of subjects with the scoring average per domain=1/total subject each group) x 100%

Table 5. Empowerment Domain in The Participation in Medication

The Participation in Medication	Intervention Group (n=21) % Active Participation		Control Group (n=21) % Active Participation	
	Pretest	Posttest	Pretest	Posttest
Communicate with the pharmacist to understand the purpose of medication (Indication)	9.52	52.38	28.57	9.52
Communicate with the doctor to set the target of medication (Effectiveness)	85.71	90.48	76.19	76.19
Able to prevent and overcome the unwanted side effect of medication (Safety)	28.57	76.19	14.29	23.81
Able to participate in medication (Adherence)	4.76	42.86	23.81	14.29

Note % Active Participation: (the number of subjects with the scoring average per domain=1/total subject each group) x 100%

Table 6. The domain of Ability in Performing Medication

The domain of Ability in Performing Medication	Intervention Group (n=21) % Ability		Control Group (n=21) % Ability	
	Pretest	Posttest	Pretest	Posttest
The patient can access the medication (an effort to obtain therapy according to the indication)	42.86	66.67	76.19	76.19
Patient understands the instructions (effort to have effective medication)	23.81	61.90	19.05	47.62
The patient can make decisions on using medications (effort when they felt that the drugs are unsafe)	38.10	80.95	90.48	85.71
Patient routinely take the medication (an effort to adhere to taking medication)	23.81	38.10	28.57	33.33
The patient can make decisions when the drugs are not available effort when drugs are unavailable)	28.57	61.90	47.62	47.62
The patient can take the medication properly (an effort to take medication properly)	85.71	100.00	95.24	95.24

Note % ability: (the number of subjects with the scoring average per domain=1/total subject each group) x 100%

Table 7. Characteristics of HbA1c level

Blood Glucose Control		Intervention Group (n=21)		Control Group (n=21)	
		Pre	Post	Pre	Post
HbA1c (%)	Average	8.90	7.63	7.68	7.67
	SD	1.82	1.28	1.61	1.58
	Minimum	5.50	5.60	5.90	5.90
	Maximum	12.5	10.30	12.2	12.30
	Median	7.80	7.40	7.30	7.50

The HbA1c testing has fulfilled the NGSP (*National Glycohaemoglobin Standardization Program*) [11]

The patient's level of understanding will determine what kind of education is needed and explain the steps to achieve the effectiveness and safety of the medication [6]. Patients who have a good level of understanding of their medical condition and treatment will have control over feelings and have a preference for information and feel capable to manage the disease condition which must be managed in a long term [12]. At the stage when pharmacists tried to collect information, continuity of information regarding the purpose of drug use, the desired therapeutic effect, and unwanted drug effects that could potentially occur during treatment would play an important role. They can encourage patients to understand and use drugs as instructed regularly.

The role of pharmacists in assessing the need for drug therapy is a process of empowering patients in treatment which is carried out systematically according to categories arranged sequentially starting from indication, effectiveness, safety, and adherence [6]. Empowerment can be measured through the patient's experience in the treatment process, namely changes in self-perception after diagnosis and receiving therapy by assessing how the patient minimizes the impact on himself and as a result feels controlled [12]. The patient's experience of symptoms that do not improve with drug therapy, or that there are symptoms that have not been treated, and concerns about symptoms that are suspected of being an adverse drug effect can contribute to adherence to drug use.

The attitude described as perceptions of self-control in managing long-term conditions outside of routine consultations is the third result of empowerment. Patients who exhibit feelings of 'empowered' were described as having developed strategies toward themselves to stay in control. It was characterized by the involvement of patients in internal dialogue which involves considering their thoughts regarding activities that must be carried out every day and continuously [12]. The positive attitude of drug use in the intervention group shows a sense of trust in the drug used from the aspect of the effectiveness and safety of the drug. The formation of this empowerment attitude is a stage that cannot be separated from the previous process, namely understanding and experience that support aspects of the effectiveness and safety of treatment.

There were findings that in Chronic Disease Management Program (Prolanis) activity, patient involvement and participation are still lacking, and existing communication has not encouraged patients to participate in understanding treatment options together with health workers. Prolanis was designed to improve chronic disease treatment outcomes and prevent disease progression [13]. Based on this research, it can be recommended to arrange pharmacotherapy assessment activities in Prolanis activities and to compile a comprehensive treatment plan as a collaborative effort in empowering chronic disease patients.

In the intervention group, there was the highest increase in the patient's ability to make medication decisions (efforts when they felt the drug was unsafe), whereas there was a decrease in the control group. However, they were still unable to use the drug routinely (efforts to adhere in taking medication), this is also shown in the patient's ability to make decisions when drugs were not available (efforts when the drug is unavailable) was also low. This phenomenon shows that the management of drug availability also plays a role in achieving patient empowerment and treatment targets. Even though clinical pharmacy services have been running well, if they are not supported by the availability of good drugs, it can have an impact on patient decision-making related to treatment. Based on the Mann Whitney Test analysis, there was a difference between the empowerment of the intervention group and the control group in understanding the usage of the drug ($p=0.000$), the attitudes toward medication ($p=0.009$), and the participation in medication ($p=0.000$), but there was no difference in the empowerment in their experience ($p=0.090$) and ability ($p=0.275$).

HbA1c was the main clinical parameter used to evaluate patient empowerment. According to the Diabetes Control and Complication Trial, a 0.5% decrease in HbA1c yield led to a significant decrease in diabetes-related complications [14, 15]. Every 1% increase in HbA1c from the target value of 7% was followed by a 38% increased risk of macrovascular complications, a 40% increased risk of microvascular complications, and a 38% increased risk [16]. There was a decrease in the average HbA1c of 1.27% in the intervention group, while in the control group there was a decrease of 0.010%. There was a significant HbA1c difference in the intervention group (pre-and post-test; $p=0.010$), but there was no difference in the control group ($p=0.940$)

Conclusion

Based on these results, it can be concluded that in PRB drug services, pharmacists can play a role in monitoring treatment through activities related to detecting, understanding, and preventing side effects or other undesirable effects, collaborating with the prescribing doctors. *Puskesmas* has a coordination function between pharmacists and doctors in a system that is improved in this study in a collaborative understanding to establish a pharmaceutical care plan and provision of interventions/referrals. Problems that occur in the management of PRB drugs require collaboration with health workers at secondary level health facilities who authorize referrals to health workers at primary level health facilities and need to be maintained during the PRB period.

A comprehensive drug therapy management model can be implemented in primary healthcare to improve patient empowerment and diabetes treatment outcomes through pharmacotherapy workup as a basis for the pharmaceutical care process. The patient's lack of experience with treatment can be a potential cause of inappropriate decision making, due to the understanding that drugs are used for slowing the disease progress and ability to follow the directions. The significant reduction in HbA1c in the intervention group demonstrated the patient's empowerment in managing diabetes independently.

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Ethics statement: This study has obtained Ethical Approval on the 1st of August 2019 No: 198/EA/KEPK/2019 from the Ethical Commission of Public Health Faculty of Airlangga University according to the guidelines of the Council for International Organizations of Medical Sciences (CIOMS) 2016.

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