Meta-Analysis the Effect of Pharmaceutical Care on Blood Glucose Level in Type 2 Diabetes Mellitus Patients

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ABSTRACT

Background: Pharmaceutical care is a patient-oriented program carried out by pharmacists. In the management of type 2 diabetes mellitus (T2DM) several parameters have been determined as targets for the success of pharmaceutical care such as HbA1c and the level of patient compliance. This paper aims to evaluate the role of pharmaceutical care in improving clinical outcomes and compliance of patients with T2DM.

Subjects and Method: This study was conducted using a Systematic Review and Meta-analysis study design using PICO, population: Diabetes mellitus type 2 patients, Intervention: Obtaining pharmaceutical care. Comparison: Did not receive pharmaceutical care, Outcome: Hba1c. The articles used in this study came from 4 databases, namely Pubmed, ScienceDirect, ProQuest and Google scholar. Article keywords are Diabetes Mellitus, Type 2 OR T2DM OR Type 2 diabetes AND Pharmaceutical care OR Clinical pharmacy OR Community pharmacy OR Pharmacist* OR Pharmaceutical services OR Education OR Intervention OR Medication Management AND Knowledge OR adherence OR HbA1c OR glycemic control" Included articles in this study is a full paper article, RCT study design for 2011-2021.

Results: A total of 12 RCT studies with 1,746 T2DM patients in Asia (Jordan, Hong Kong, Northern Cyprus, Thailand, China, Malaysia and Indonesia), Americas (Brazil) and Europe (France and England). From the data processing, it was found that the provision of pharmaceutical care reduced HbA1c levels by 0.81 in patients with type 2 diabetes mellitus compared to those without pharmaceutical care. (SMD= -0.81; 95% CI= -1.11 to -0.52 p<0.0001).

Conclusion: The provision of pharmaceutical care can improve clinical outcomes in the form of decreasing HbA1c values.

Keywords: Pharmaceutical Care, Type 2 Diabetes Mellitus, HbA1c, Glycemic Control.

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BACKGROUND

Pharmaceutical care is a form of service and direct responsibility by the pharmacist profession in pharmaceutical work that aims to improve the quality of life of patients and handle patient non-compliance which can improve clinical outcomes of patients (DEP-KES RI, 2021). Patient non-compliance in undergoing treatment therapy is one of the Drug Therapy Problems (DTP) that needs special attention. Diabetes Mellitus patients include patients with a high level of non-adherence (Strand et al., 2013). Non-compliance with the established standards is the

basis that causes the development of complications of Diabetes Mellitus (Kazi and Blonde, 2021). Diabetes Mellitus is one of the second biggest health problems which is shown in data from a global study in 2011 namely the number of people with Diabetes Mellitus has reached 366 million people. So that if no action is taken this number will increase to 522 million by 2030. As many as 183 million people do not realize that they have DM with the largest age between 40-59 years (IDF, 2021). A greater role of pharmacists, namely the transition from product-oriented to service-oriented patient care (including education, monitoring of medication goals, adherence, assessment of drug-related problems), can improve patient medication adherence and can lead to better treatment outcomes (Casten et al. , 2020). Also, involvement of pharmacists in diabetes multidisciplinary healthcare teams is recommended by several studies (Levengood et al., 2019) including those by the American Diabetes Association (ADA) and Canadian Diabetes Association (ADA, 2021).

Controlling blood glucose and reducing the risk of diabetes complications is one of the main goals of treatment for diabetes (Eder et al., 2019). Medication adherence is very important for optimal diabetes treatment. Adherence is defined as "the degree to which a person's behavior – taking medication, following a diet, and/or making lifestyle changes – conforms to agreed recommendations from a healthcare provider" (Sharp et al., 2018). Pharmaceutical care (pharmaceutical care) as a pharmacist practice activity is an important element in health services, where pharmacists are responsible for service quality and ensure the suitability, effectiveness, safety of drug therapy by identifying, preventing, and solving drug therapy problems received by patients (DEPKES RI, 2021). This study aims to determine the effect of pharma-

ceutical care on blood sugar levels in T2DM patients.

SUBJECTS AND METHOD

1. Study Design
This was a systematic review and meta-analysis study design. The articles used in this study came from various sources. Article searches were carried out comprehensively through search engines with databases of "Pubmed", "ScienceDirect", "ProQuest" and "Google scholar". The articles used are articles published from 2011 to 2021. The selection of articles uses a flow chart, namely the PRISMA Flow Diagram. The keywords used in the article search were Diabetes Mellitus, Type 2 OR T2DM OR Type 2 diabetes AND Pharmaceutical care OR Clinical pharmacy OR Community pharmacy OR Pharmacist OR Pharmaceutical services OR Education OR Intervention OR Medication Management AND Knowledge OR adherence OR HbA1c OR glycemic control.

2. Inclusion Criteria
Articles must be full papers using a Randomized Control Trial (RCT) study design. The article must include an evaluation of the effectiveness of pharmaceutical care (either alone or in collaboration) in T2DM patients and report HbA1c values.

3. Exclusion Criteria
The exclusion criteria in this study were duplication of articles, articles published other than in English before 2011.

4. Study Variables
Research for articles was conducted by considering the eligibility criteria determined using the PICO model. PICO, Population: Type 2 Diabetes Miletus Patients, Intervention: Getting pharmaceutical care. Comparison: Did not receive pharmaceutical care, Outcome: HbA1c.

5. Operational Definition of Variables
Pharmaceutical care is defined as the pharmacist's direct responsibility for ser-

vices related to the patient's medication review of drug use; education about diabetes and its complications; and counseling on lifestyle modification with the aim of achieving the outcomes defined to improve the patient's quality of life

Blood sugar level was defined as HbA1c. Namely hemoglobin that is formed when glucose binds covalently to the beta chain of HbA. HbA1C is the ratio between glycated HbA1 and total HbA1 and reflects plasma blood sugar levels for the previous 2-3 months.

6. Instrument

The instrument in this study is the PRISMA Flow diagram using a research quality assessment using predetermined criteria, namely using the Critical Appraisal Checklist.

7. Data Analysis

From the articles that have been collected, data processing is carried out using the Review Manager application (RevMan 5.3) issued by the Cochrane Collaboration. Data processing is done by calculating the value of effect size and heterogeneity.

RESULTS

Figure 1 shows a step-by-step diagram of a meta-analysis of pharmaceutical care related to HbA1c values in T2DM patients.

Research related to pharmaceutical care related to HbA1c values in T2DM patients consists of 12 articles as shown in Figure 1 which produces 1026 articles, after deleting duplication of articles 579 articles are produced, then after the process of removing duplication of articles, further

checking the relevance of the title and study design used is generated. 126 articles. After that, the articles were checked according to the inclusion criteria and the exclusion criteria were obtained as many as 12 articles.

Figure 2 shows the Research Distribution Map used in this study. Research related to the effect of pharmaceutical care on HbA1c values consisted of 12 articles from three continents, namely Asia, Europe, and South America. The distribution map is shown in Figure 2. Seven studies came from the Asian continent (one from Thailand, two studies from Malaysia, China, Jordan, Hong Kong, Pakistan), two studies from the South American continent (Brazil), three studies from the European continent. (Northern Cyprus, France and England). Table 1 shows a summary of the research variables which are PICO.

Table 2 shows the assessment of research quality, all articles that meet the assessment of research quality will be included in the quantitative synthesis using meta-analysis. The quality and design of the research analyzed in the meta-analysis is very important because it can affect the results. Quality research in this study uses critical appraisal tools randomized controlled trial (RCT) published by CEBM University Of Oxford 2014. Data processing is carried out by calculating effect size and heterogeneity values. Interpretation of the results of the meta-analysis process can be seen through the Forest plot.
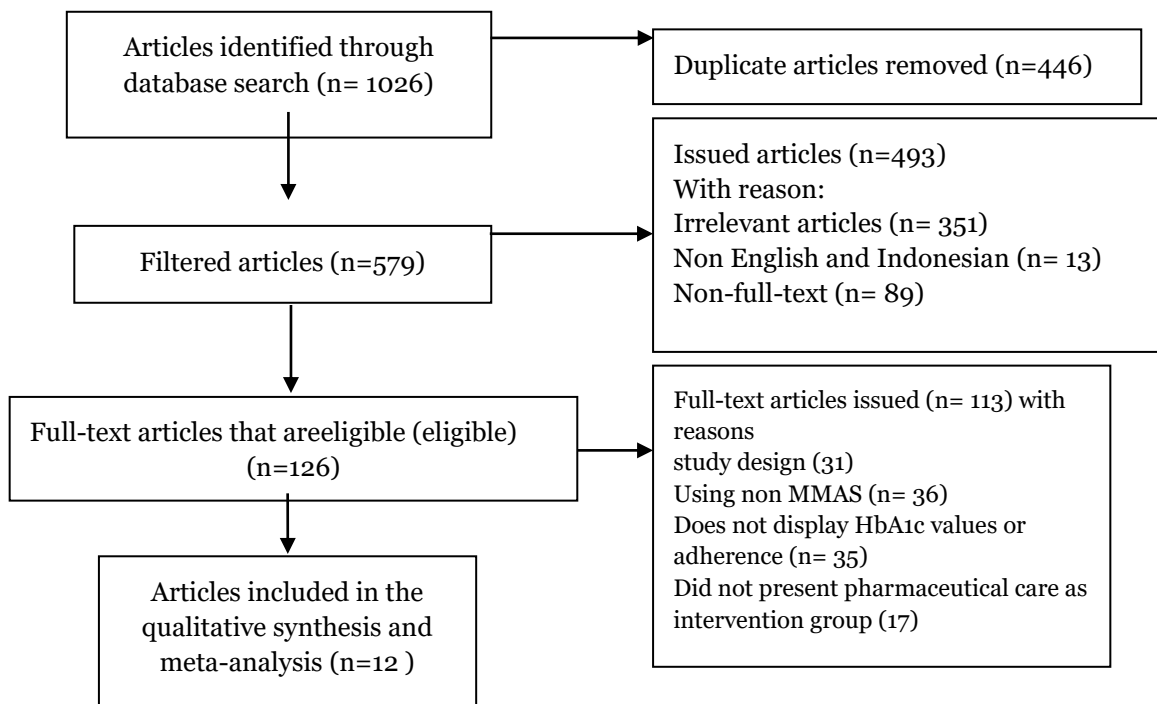
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┌─────────────────────────┐          ┌──────────────────────────────────────┐
│ Articles identified     │ ───────► │ Duplicate articles removed (n=446)     │
│ through database search │          └──────────────────────────────────────┘
│ (n= 1026)               │          ┌──────────────────────────────────────┐
└─────────────────────────┘          │ Issued articles (n=493)                │
            │                        │ With reason:                           │
            ▼                        │ Irrelevant articles (n= 351)           │
┌─────────────────────────┐          │ Non English and Indonesian (n= 13)     │
│ Filtered articles        │ ───────►│ Non-full-text (n= 89)                  │
│ (n=579)                  │         └──────────────────────────────────────┘
└─────────────────────────┘          ┌──────────────────────────────────────┐
            │                        │ Full-text articles issued (n= 113)     │
            ▼                        │ with reasons                           │
┌─────────────────────────┐          │ study design (31)                      │
│ Full-text articles that  │ ───────►│ Using non MMAS (n= 36)                 │
│ areeligible (eligible)   │         │ Does not display HbA1c values or       │
│ (n=126)                  │         │ adherence (n= 35)                      │
└─────────────────────────┘          │ Did not present pharmaceutical care    │
            │                        │ as intervention group (17)             │
            ▼                        └──────────────────────────────────────┘
┌─────────────────────────┐
│ Articles included in the │
│ qualitative synthesis    │
│ and meta-analysis (n=12) │
└─────────────────────────┘
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Figure 1. PRISMA FLOW Diagram

Figure 2. Research Distribution Map

Table 1. Description of Primary Research included in the Meta-Analysis

No	Author (Year)	Country	Study Design	Population	Intervention	Comparison	Out-come	HbA1c	
								IG	CG
1	Ali et al., (2012)	UK	RCT	T2DM patient visiting 2 Pharmacy branches (Letchworth and Harpenden) in Hertfordshire Town (IG: 23 OG: 23)	Pharmaceutical services includeing review of drug use; education about diabetes and its complications; and counseling on lifestyle modification with referrals to other health care professionals where appropriate	Usual services from general practitioners, practicing nurses, and community pharmacists	HbA1c	6.6 (0.69)	7.5 (0.64)
2	Butt et al., (2016)	Malaysia	RCT	T2DM patients who visited the Endocrine Specialist Clinic Universiti Kebangsaan Malaysia Medical Center (UKMMC) (IG: 33 OG: 33)	Get pharmaceutical care	Getting care as usual by a doctor without pharmaceutical care	HbA1c	8.47 (1.61)	9.26 (1.45)
3	Cani et al., (2015)	Brazil	RCT	T2DM patients who visited the Hospital das Clınicas da Faculdade de Medicina da Universidade de Sa˜o Paulo, located in Sa˜o Paulo, Brazil. (IG: 36 OG: 34)	Pharmaceutical care includes drug reviews; DRP resolution; and education about diabetes, hypertension, hyperlipidemia, and drugs, emphasizing the importance of monthly medication adherence	Standard medical care	HbA1c	9.21 (1.41)	9.53 (1.68)
4	Chan et al., (2012)	Hongkong	RCT	T2DM patient at diabetes clinic Tung Wah Eastern Hospital (TWEH) (IG: 51 OG: 54)	Pharmacy care programs address medication adherence, knowledge and beliefs, skills, perceived health and cognitive function, and identification of DRPs	Routine medical care	HbA1c	8.13 (0.50)	9.1 (0.8)
5	Chung et al., (2015)	Malaysia	RCT	T2DM patients in 2 teaching hospital clinics in Malaysia (IG: 120 OG: 121)	Pharmaceutical care includes drug reviews; DRP resolution; and education about diabetes, hypertension, hyperlipidemia, and drugs, emphasizing the importance of medication adherence	Routine medical care	HbA1c	8.2 (1.50)	9.1 (1.19)
6	Gautier et al., (2021)	Perancis	RCT	T2DM patients who visited 10 pharmacies in France (IG: 156 OG: 140)	The intervention consisted of providing information and advice that was sent and delivered on one of the following topics: food, physical activity, daily lifestyle choices, information about diabetes, follow-up medi-	Ordinary care without any intervention regarding education such as the intervention group	HbA1c	7.05 (1.27)	6.94 (0.94)

No	Author (Year)	Country	Study Design	Population	Intervention	Comparison	Out-come	HbA1c	
								IG	CG
7	Jarab et al., 2012	Jordan	RCT	T2DM patients in the Internal Medicine Polyclinic Royal Medical Services (RMS) Hospital (IG: 77 OG: 79)	cal appointments, and proper use of medications. Pharmaceutical care includes education about diabetes, medication and lifestyle changes; review of prescribed treatment; referrals to smoking cessation programs; and provision of booklets about diabetes	Usual care from medical and nursing staff	HbA1c	7.7 (0.75)	8.5 (0.6)
8	Korcegez et al., (2017)	Northern Cyprus	RCT	T2DM patients who come to the Diabetes Polyclinic General Hospital in Gazimagusa City, Northern Cyprus (IG: 75 OG: 77)	Pharmaceutical care includes education about diabetes, medication and lifestyle changes; review of prescribed treatment; referrals to smoking cessation programs; and provision of booklets about diabetes	Not getting pharmaceutical care	HbA1c	7.55 (0.57)	8.26 (0.74)
9	Mourão et al., (2013)	Brazil	RCT	T2DM patients in 6 health activity units integrated with General Hospitals in Brazil (IG: 65 OG: 64)	Pharmaceutical care, including identification of DRPs; proposed changes in pharmacotherapy are forwarded to the PCP; and education about diabetes, non-pharmacological issues, and pharmacological treatments	Routine medical care	HbA1c	9.3 (0.6)	10.2 (0.7)
10	Shao et al., (2017)	China	RCT	Patients with T2DM who visited the endocrine clinic at Zhongda Hospital, Southeast University (Nanjing, People's Republic of China). (IG: 100 OG: 99)	Pharmaceutical services including review of drug use; education about diabetes and its complications; and counseling on lifestyle modification with referrals to other health care professionals where appropriate	Getting care as usual by a doctor without pharmaceutical care	HbA1c	6.25 (1.00)	7.74 (1.71)
11	Wishah and Albsoul, (2015)	Jordan	RCT	A T2DM patient visiting the Diabetes clinic at the Educational Hospital in Amman, Jordan's Capital City. (IG: 52 OG: 54)	Pharmaceutical care, including optimization of drug therapy; education and counseling about diabetes and treatment; increased adherence to medication and self-care activities; and provision of educational leaflets and brochures	Usual care from medical and nursing staff	HbA1c	7.2 (0.9)	7.9 (1.3)

No	Author (Year)	Country	Study Design	Population	Intervention	Comparison	Out-come	HbA1c	
								IG	CG
12	Withidpan yawongand Saengchar oen, (2019)	Thailand	RCT	T2DM patient visiting Southern Thailand diabetes clinic. (IG: 88 OG: 92)	the intervention group received an education package for the partici-pants and their relatives. education about diabetes, the importance of medication adherence, proper nutri-tion for diabetes, hypertension and dyslipidemia as well as proper physical activity.	Usual care from medical and nurs-ing staff	HbA1c	7.84 (1.96)	8.87 (1.81)

Table 2. Research Quality Assessment with Critical Appraisal Skills Program (CASP) Randomized Controlled Trial

No	Korcegez et al., (2017)	Jarab et al (2012)	Butt et al (2015)	Ali et al (2012)	Shao et al (2017)	Cani et al (2015)	Chan et al (2012)	Chung et al (2014)	Muorao et al (2013)	wishah et al (2014)	Gautier et al (2021)	Withid panyawong et al (2019)
							Research					
1	2	2	2	2	2	2	2	2	2	2	2	2
2	2	2	2	2	2	2	2	2	2	2	2	2
3	2	2	2	0	2	0	2	2	2	2	2	2
4	2	2	2	2	2	2	2	2	2	2	2	2
5	2	2	2	2	2	2	2	2	2	2	2	2
6	2	2	2	2	2	2	2	2	2	2	2	2
7	2	2	2	2	2	2	2	2	2	2	2	2
8	2	2	2	2	2	2	2	2	2	2	2	2
9	2	2	2	2	2	2	2	2	2	2	2	2
10	2	2	2	2	2	2	2	2	2	2	2	2
11	2	2	2	2	2	2	2	2	2	2	2	2
12	2	2	2	2	2	2	2	2	2	2	2	2
	24	24	24	22	24	22	24	24	24	24	24	24

Note: 2 : Yes, 1 : Hesitant, 0 : Can't tell

Figure 3 shows the results of the analysis in the form of a pharmaceutical care forest plot against Hba1c. From the results of the analysis, it was shown that diabetic patients who received pharmaceutical care would decrease the HbA1c value by 0.81% and statistically significant ($p < 0.001$). The heterogeneity of the research data shows $I^2 = 89\%$ so that the distribution of the data is declared heterogeneous (random effect model). A funnel plot is a plot that describes the approximate size of the effect of each study on its estimate of accuracy, which is usually the standard error. Figure 4 shows the results of the forest plot of pharmaceutical care against Hba1c. Based on Figure 4, it shows that there is a publication bias which is indicated by the asymmetry of the plot. The plot on the left of the graph appears to have a standard error between 0.4 and 0 and the plot on the right has a standard error between 0.3 and 0. Bias also occurs from the imbalance of distances between studies on both the right and left sides of the funnel plot.
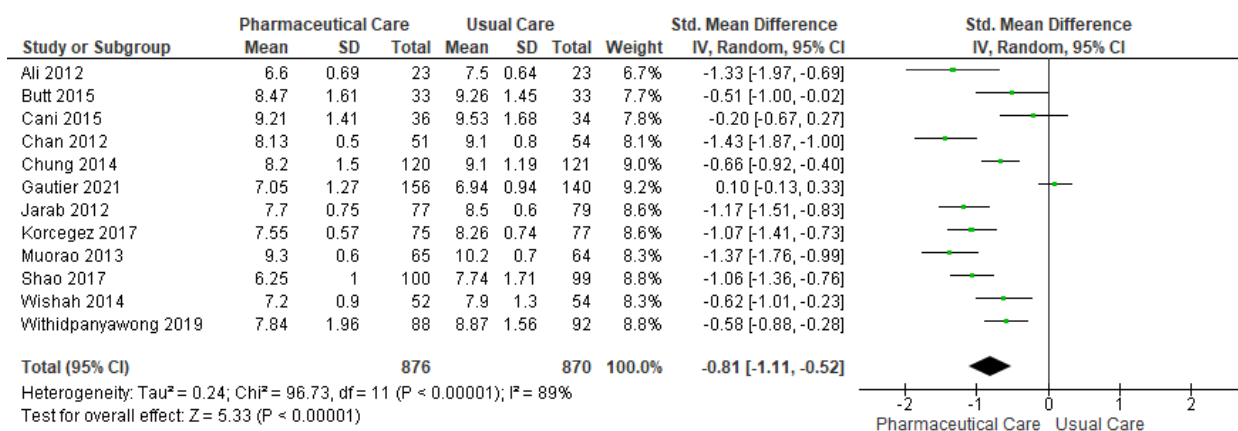

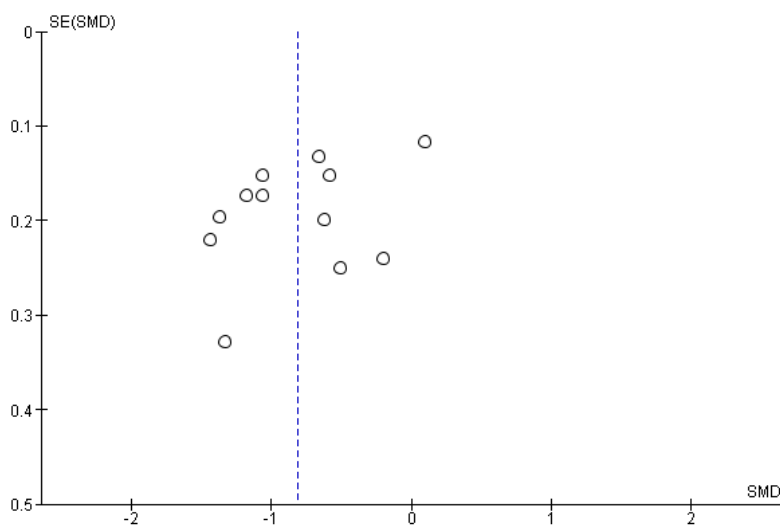**Figure3. Forest plot pharmaceutical care against HbA1c**

Figure 4. Funnel plot of pharmaceutical care against HbA

DISCUSSION

This systematic study and meta-analysis raised the theme of Analysis of the Effect of Pharmaceutical Care on Blood Sugar Levels and Medication Adherence to Type 2 Diabetes Mellitus Patients. The independent variables analyzed were pharmaceutical care. Research that discusses data on the effect of pharmaceutical care in diabetic patients that can help improve patient outcomes is considered important because of its rarity. The number of relevant studies published and accessible is still small and also has data excess problems (data duplication) (Murti, 2018) The number of relevant research published and accessible is quite a lot, but most of the statistical results reported and published are still in the form of percent and many of the analysis results are still in the form of Odds Ratio where the research does not control for confounding factors. These confounding factors affect the relationship or effect of exposure to the studied output (Murti, 2018).

Diabetes mellitus is one of the second largest health problems, data from a global study in 2011 showed the number of people with diabetes mellitus had reached 366

million people. If no action is taken, this number will increase to 522 million by 2030. A total of 183 million people do not realize that they have DM with the largest age being between 40-59 years (IDF, 2021). The International Diabetes Federation states, currently diabetes affects 382 million people worldwide, with type 2 diabetes mellitus (T2D) being the largest prevalence comprising 85-95% of the diabetes population (Goedecke et al., 2017,)

The largest diabetes prevalence in the world is currently dominated by various countries from several continents, including the Asian continent, China occupies the first position with a prevalence of 114.9 million sufferers, Indonesia ranks 6th in the world with a prevalence of 10.3 million sufferers. The Americas have 30.2 million sufferers and in global data, the top 10 highest prevalence of diabetes are dominated by European countries (IDF, 2021)

In this study, there were 14 studies identified worldwide from 2011 to 2021. The forest plot results showed that pharmaceutical care reduced HbA1c levels by 0.81 in type 2 diabetes mellitus patients compared to no pharmaceutical care. (SMD= -0.81; 95% CI -1.11 to -0.52 p<0.001). The hetero-

geneity of the research data shows I2 = 70% so that the distribution of the data is declared heterogeneous (random effect model). Research conducted by Butt et al. (2016) measurement of HbA1c was the main outcome in this study; the mean HbA1c value showed a significant decrease in the intervention group compared to the control group (p= 0.04). The results of glycemic control in our study are comparable to other findings. A randomized controlled trial reported a significant reduction of 0.6% in the intervention group after six months of pharmacist intervention (Mehuys et al., 2011).

The smaller baseline HbA1c values in this study account for the small final changes in HbA1c compared to our study; patients with higher HbA1c values showed greater improvement in final scores (Choe et al., 2012; Presley, et al, 2019). In the second six-month randomized control trial, the HbA1c value in the intervention group decreased significantly by 0.8% in contrast to the increase in the control group (Jarab et al., 2014). Another study with a 6-month pharmacist intervention reported a 0.8% decrease in HbA1c values in the intervenetion group. This reduction was clinically significant but was reported to be statistically insignificant in the control group. The insignificant change explained by the structure of the intervention led to contamination of both groups in addition to the relatively smaller initial HbA1c values. In addition to the RCT, studies with other experimental designs also yielded similar results after six months of pharmacist intervention. A 6-month prospective study resulted in a 1.9% reduction in HbA1c levels from baseline to the end of the study period. Intensive intervention with a high initial HbA1c value of 10.8% (Ipingbemi et al., 2021). In a 6-month retrospective chart review, patients reported a 1.4% reduction

at the end of the study after frequent and indefinite encounters between patient and pharmacist (Goruntla et al., 2019).

Pharmacist-led care programs are very important in improving the clinical outcomes of T2DM patients. Some of the literature presented previously proved that with pharmaceutical care the clinical indicators of DM patients, such as HbA1C, became better. Short-term (3-12 months) or long-term (36 months) programs of pharmaceutical care show good results in the management of T2DM patients. Pharmaceutical care also has an impact on health service providers (providers). With the pharmaceutical care program, patients feel cared for by the provider. The involvement of a solid team consisting of various disciplines will give the impression that the provider provides maximum and comprehensive service to the patients being treated. The limitations in this study are language bias because in this study only articles published in English were used, thus ignoring articles using other languages and search bias because in this study the researchers only used 4 databases (Google Scholar, PubMed, Springer Link, and Clinical key) thus ignoring other search sources.

AUTHOR CONTRIBUTION

Muthia Syafira is the main researcher in selecting topics, finding and collecting research data and processing this research data. Setyo Sri Rahardji and Bhisma Murti assisted in providing input and direction related to writing and the ongoing research process.

CONFLICT OF INTEREST

There is no conflict of interest in this study.

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