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The effect of clinical pharmacist-led services with one-year follow-up in patients with type 2 diabetes mellitus: a randomized controlled trial

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ABSTRACT: This prospective randomized controlled study aimed to assess medication adherence, diabetes-related knowledge, associated treatment outcomes, and quality of life in patients with type 2 diabetes mellitus (T2DM). The study was conducted in a training and research hospital in Istanbul with a one-year follow-up. Medication adherence, disease knowledge, and quality of life were measured using the Morisky–Green–Levine (MGL) scale, an 18-item self-structured scale, and the WHOQOL-BREF questionnaire, respectively. The main targets were a reduction in HbA1c levels, improvement in quality of life, knowledge levels, and medication adherence. The study included 114 patients. Of them, 57 patients were in the intervention group (IG) and received pharmaceutical care services. The mean duration of diabetes among the patients was 14.6±7.3 years. A total of 89.4% of patients had low levels of education, and half of the participants were female. Adherence and knowledge levels improved significantly by the end of the study ($p=0.021$ and $p=0.047$, respectively) in the IG compared to the CG. A statistically significant difference was observed only in the physical dimension of the WHOQOL-BREF questionnaire ($p=0.004$) in the IG compared to the CG. HbA1c levels decreased by 1.36%, and the reduction in fasting blood glucose was also statistically significant ($p<0.001$) in the IG. Additionally, the clinical pharmacist made 86 recommendations regarding drug-related problems to the specialist doctor, 81.39% of which were accepted. By the end of the study, 31.81% of patients in the IG achieved the treatment goal. The clinical pharmacist intervention resulted in decreased HbA1c levels and improved glycemic control by enhancing patients' knowledge and medication adherence over the one-year follow-up period.

KEYWORDS: Type 2 Diabetes Mellitus (T2DM); glycemic control; diabetes knowledge.

1. INTRODUCTION

Type 2 diabetes (T2DM), which accounts for over 90% of all cases of diabetes, is one of the most challenging and widespread public health problems globally and continues to rise [1]. According to the most recent data from the International Diabetes Atlas, in 2025, 589 million adults are living with diabetes, a figure projected to increase to 852.5 million by 2050 [2]. Moreover, according to the IDF, diabetes was responsible for over 3.4 million deaths in 2024, corresponding to 9.3% of all global deaths [3]. When it comes to Türkiye, the 11th Edition of the IDF Diabetes Atlas (2025) estimates that 9.6 million individuals aged 20–79 years in Türkiye have diabetes, with a prevalence of 16.3% in this age group [4]. In 2024, approximately 634.8 million adults worldwide—representing 12% of the adult population—were estimated to have impaired glucose tolerance (IGT).

The primary goal of diabetes treatment is to achieve glycemic control. The treatment also includes medical care, provision of diabetes self-care information, and prevention of acute and chronic complications [5]. Because diabetes is often associated with comorbidities and complications, managing the disease is particularly challenging. It requires patients to receive continuous medical care and be informed about self-care [5]. Notably, studies have demonstrated that a 1% reduction in HbA1c levels results in a 21% reduction

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in diabetes-related mortality, a 14% reduction in myocardial infarctions, a 37% reduction in microvascular complications, and a 43% reduction in peripheral vascular disorders [5, 6].

The role of pharmacists in healthcare has evolved from product-focused activities to patient-centered care [7-9]. Accordingly, the practice of pharmaceutical care services comprises the basis of pharmacy practice [10]. Hepler and Strand (1990) defined pharmaceutical care as "the responsible provision of medication therapy to achieve definite outcomes that improve a patient's quality of life". These outcomes were defined in the same study as curing a disease, eliminating or reducing its symptoms, stopping or slowing its progress, or preventing its symptoms [11]. The clinical pharmacist, creating a link between the patient and the physician, plays a vital role in diabetes management by providing pharmaceutical care and managing the design, implementation, and monitoring of a therapeutic plan [5, 12, 13].

Studies have shown that pharmaceutical care positively impacts medication adherence and glycemic control among patients with T2DM [5, 14-16]. Adherence, defined as "the extent to which a patient follows the recommendations of a healthcare professional", is crucial for treatment success [17, 18]. Although many effective treatments are available, low levels of adherence make achieving glycemic targets challenging [19, 20]. One underlying reason for this may be patients' lack of knowledge about diabetes [5, 21]. Therefore, individuals should learn self-management behaviors, including strategies such as dietary compliance, engaging in physical activity, self-monitoring blood glucose, using diabetes medications correctly, and making lifestyle changes, and maintaining these behaviors throughout life [22-27].

The primary goal of the present study was to evaluate the effect of pharmaceutical care service, that includes educating of the patients, medication reconciliation and medication review processes, provided by a clinical pharmacist during a one-year follow-up with weekly text message support on quality of life, medication adherence, disease knowledge, and related treatment outcomes of diabetic patients in Türkiye. The secondary goals include lowering fasting blood glucose, blood pressure, lipid levels, and hospitalization rates. Additionally, this study also mainly aims to indicate the importance of the contribution of clinical pharmacist-led services in diabetes management in Türkiye.

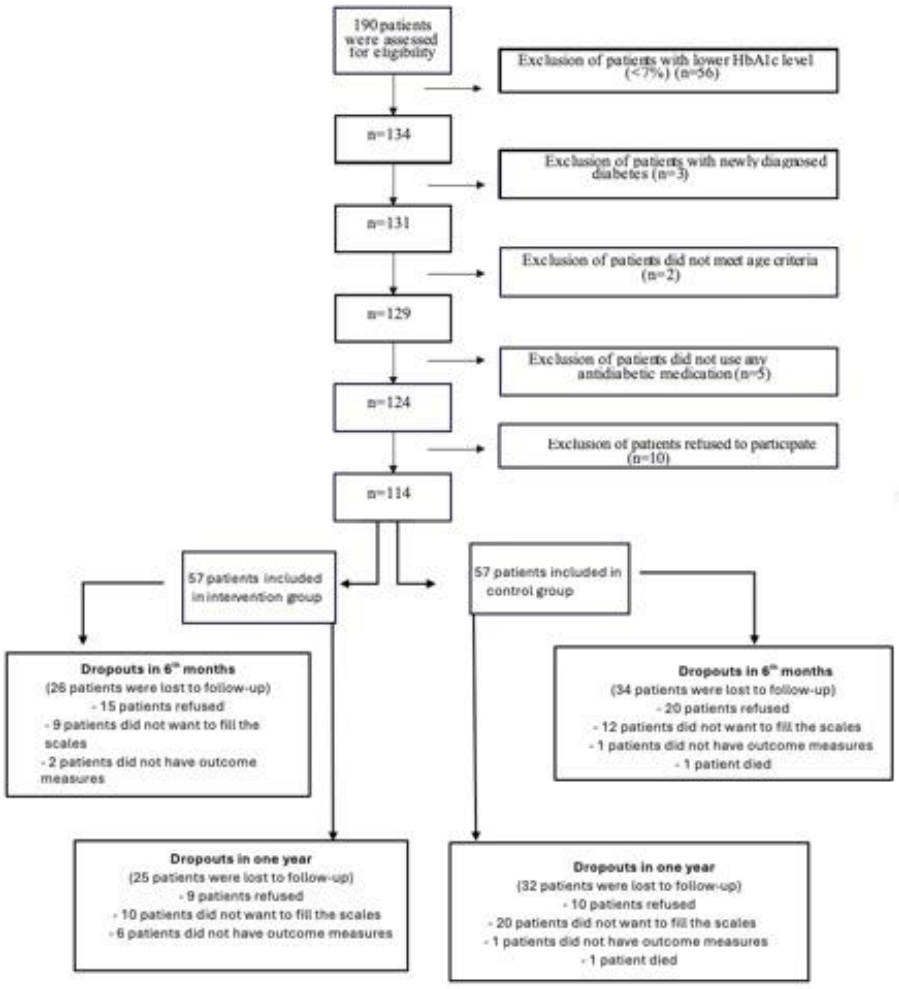


Figure 1. Study Design Flowchart

2. RESULTS

2.1. Sociodemographic Characteristics

A total of 114 patients participated in the study. Once the target sample size was reached, the study was completed by the clinical pharmacist. The mean ages of the patients in the IG and CG were 61.50 ± 8.67 and 58.75 ± 10.87 years, respectively, with no statistically significant difference found between the groups (p = 0.108) at baseline. Similarly, the duration of diabetes was evaluated, and no significant difference was observed between the groups (15.22 ± 7.77 vs. 13.95 ± 6.93 years; p = 0.917) at baseline. No statistically significant difference was found in the mean BMI of the patients (28.54 ± 5.43 vs. 30.72 ± 4.99; p = 0.062) at baseline. When comparing the initial BMI with the values at the end of the 6th month and 1st year, no statistically significant difference was observed in either group (p > 0.05). In Türkiye, a low level of education is defined as less than 12 years of schooling and 89.4% of participants had a low level of education in our study. The sociodemographic characteristics are presented in Table 1.

Table 1. Sociodemographic data of the patients at the beginning of the study

	IG N (%)	**CG N (%)**	**Total N (%)**	**p**
Gender				
Female	23 (40.4)	34 (59.6)	57 (50)	0.061
Male	34 (59.6)	23 (40.4)	57 (50)	
Education status				
PrimarySchool	27 (47.4)	32 (56.1)	59 (51.8)	0.446
Middle School	5 (8.8)	9 (15.8)	14 (12.3)	
High School	17 (29.8)	10 (17.5)	27 (23.7)	
University	7 (12.3)	5 (8.8)	12 (10.5)	
Literate	1 (1.8)	1 (1.8)	2 (1.8)	
Smoking	15 (26.3)	12 (21.1)	27 (23.7)	0.660
Alcohol consumption	7 (12.3)	2 (3.5)	9 (7.9)	0.165
History of hospitalization in the last 6 months	4 (7)	4 (7)	8 (7)	1.0
History of allergy	3 (5.3)	10 (17.5)	13 (11.4)	0.077

N: Number of participants

2.2. Medication Adherence

When comparing the medication adherence scores of the patients, it was observed that the adherence scores significantly improved from the beginning to the end of the study for the IG (p = 0.021). However, a significant difference was not observed in the CG (p > 0.05). The change in adherence over time is presented in Figure 2.

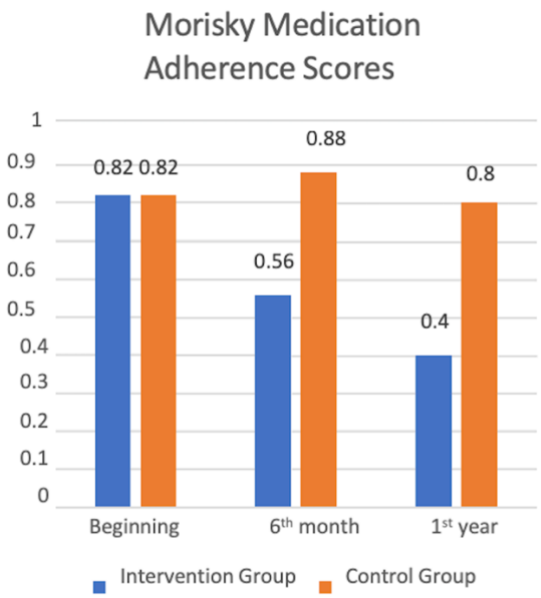


Figure 2. Distribution of Morisky Scale Scores in Intervention and Control Group

2.3. Knowledge Levels

At baseline, there were no significant differences between the groups regarding knowledge levels. However, statistically significant increases in knowledge levels were observed in the IG at both the 6th month and the 1st year following training by the clinical pharmacist. Additionally, the difference in the increase in knowledge levels between the two groups was also statistically significant (p = 0.027) (Table 2).

Table 2. Comparison of Knowledge Rate

	Intervention Group		**Control Group**		
	Mean±SD	**N**	**Mean±SD**	**N**	**p (Group)**
Knowledge Success Percentage					
Beginning	52.92±14.78	57	49.22±15.79	57	t=1.293 p=0.199
6th month	63.80±15.47	33	49.54±16.70	24	t=3.324 **p=0.002***
1st year	58.97±12.13	39	52.31±13.50	24	t=2.027 **p=0.047***
p (Time)	F=9.948; **p<0.001***		F=0.672; p=0.520		

t: Independent Sample t-Test, F: ANOVA Test for repeated measures Mean: Average, SD: Standard deviation
*p<0.05, N: Number of participants

2.4. Quality of Life

When the quality of life of the patients was evaluated, a statistically significant difference was found between the groups only in the physical health dimension of the scale's subdomains. However, when the IG was evaluated within itself, there was a statistically significant improvement in the physical health, psychological, and environmental sub-dimensions (Table 3). Additionally, we measured the Cronbach's alpha value of the WHOQOL-BREF questionnaire at baseline, six months, and one year in our study, with the results being 0.850, 0.851, and 0.789, respectively.

Table 3. Comparison of Quality of Life Scale Subdomain Scores

	Intervention Group		Control Group			
	Mean±SD (N)	**Median (IQR)**	**Mean±SD (N)**	**Median (IQR)**		**p (Group)**
Physical Health						
Beginning	15.35±2.42 (57)	15.43 (13.71-17.14)	14.10±3.09 (57)	14.29 (12.28-16.57)	t=2.391	p=**0.018***
6th month	16.28±2.54 (33)	17.14 (14.29-18.29)	13.66±3.43 (23)	13.14 (11.43-16.57)	z=2.905	p=**0.004***
1st year	16.92±2.56 (38)	17.14 (15.43-18.86)	16.09±2.39 (24)	16.28 (14.86-17.56)	z=1.651	p=0.099
p (Time)	χ^2=7.981; p=**0.018***		F=0.600; p=0.557			
Psychological						
Beginning	15.75±2.63 (57)	16.67 (14.00-17.33)	14.72±3.17 (57)	15.33 (12.67-17.33)	z=1.835	p=0.067
6th month	16.69±2.25 (33)	16.67 (15.00-18.67)	14.89±3.45 (23)	16.00 (11.33-17.33)	z=1.815	p=0.069
1st year	16.77±2.68 (38)	17.33 (14.67-19.33)	16.89±2.31 (24)	16.67 (15.49-18.67)	z=0.007	p=0.994
p (Time)	χ^2=8.963; p=**0.011***		F=1.251; p=0.304			
Environment						
Beginning	15.68±2.35 (57)	15.56 (14.22-17.33)	14.74±2.81 (57)	14.67 (12.89-16.89)	t=1.928	p=0.056
6th month	16.19±2.27 (33)	16.44 (14.67-17.78)	14.80±3.09 (23)	14.67 (12.89-16.89)	z=1.813	p=0.070
1st year	16.97±2.40 (38)	17.55 (15.44-18.78)	16.41±2.13 (24)	17.11 (14.78-18.22)	z=1.348	p=0.178
p (Time)	χ^2=12.234; p=**0.002***		F=1.799; p=0.187			
Social Relations						
Beginning	14.19±3.19 (57)	14.67 (12.00-16.00)	13.57±3.41 (57)	13.33 (10.67-16.00)	z=1.008	p=0.314
6th month	13.89±2.47 (33)	14.67 (12.66-16.00)	12.98±3.42 (23)	13.33 (10.67-14.67)	z=1.488	p=0.137
1st year	14.28±3.28 (38)	14.67 (12.00-16.00)	14.39±3.07 (24)	14.67 (12.00-14.67)	z=0.082	p=0.935
p (Time)	χ^2=1.103; p=0.576		χ^2=0.419; p=0.811			

z: Mann-Whitney U Test, t: Independent Sample t-Test, F: ANOVA Test for repeated measures, $\square^2$: Friedman TestMean: Average SS: Standard deviation, IQR: Interquartile range, *p<0.05, N: Number of participants

2.5. Clinical Outcomes

Comparing systolic blood pressure (SBP) and HbA1c values in the IG, SBP decreased significantly between baseline and six months (p = 0.024) and between baseline and the end of the study (p = 0.003). It was observed that the HbA1c levels of the patients decreased by 1.36% in the IG due to clinical pharmacy intervention. However, the difference in the reduction of HbA1c levels between the two groups was not statistically significant (p = 0.54). In addition, according to the American Diabetes Association (ADA) guidelines, reducing HbA1c levels below 7% in patients with diabetes is considered the primary treatment goal (28). However, it is also recommended that glycemic targets should be individualized. That is why we also evaluated the rates of patients reaching the ADA target value in the present study. In the IG, the percentages of patients achieving the treatment goal were 28.20% at the end of the sixth month and 31.81% at the end of the study, while in the CG, these values were 16.66% and 23.25%, respectively. In addition, the decrease in FBG of the IG was statistically significant (p<0.001). However, there was no statistically significant change in the lipid levels of the patients (p > 0.05) (Table 4).

Table 4. Comparison of FBG, HbA1c, Lipid and Blood Pressure Values

	Intervention Group		Control Group			
	Mean±SD (N)	**Median (IQR)**	**Mean±SD (N)**	**Median (IQR)**	**p (Group)**	
Systolic Blood Pressure (SBP) (mmHg)						
Beginning	142.10±20.99 (52)	145.00 (130.00-153.50)	145.25±21.00 (51)	140.00 (130.00-159.00)	t=0.763	p=0.447
6th month	134.31±20.59 (29)	130.00 (120.00-140.00)	141.55±16.69 (20)	140.00 (130.00-148.75)	z=2.261	**p=0.024***
1st year	132.55±15.13 (31)	130.00 (120.00-140.00)	140.00±17.98 (24)	140.00 (120.75-157.00)	z=1.539	p=0.124
p (Time)	χ^2=4.750; p=0.093		F=0.356; p=0.705			
Diastolic Blood Pressure (DBP) (mmHg)						
Beginning	81.42±14.11 (52)	80.00 (70.00-90.00)	81.96±12.84 (51)	83.00 (72.00-89.00)	t=0.202	p=0.840
6th month	78.31±10.15 (29)	80.00 (70.50-81.00)	84.30±12.49 (20)	86.00 (70.00-97.25)	t=1.846	p=0.071
1st year	78.29±9.03 (31)	80.00 (70.00-82.00)	79.96±10.31 (24)	80.00 (70.50-88.25)	t=0.639	p=0.526
p (Time)	F=0.302; p=0.741		F=0.133; p=0.877			
FBG (mg/dL)						
Beginning	186.21±61.23 (47)	180.00 (139.00-236.00)	197.09±71.56 (47)	178.00 (136.00-238.00)	z=0.204	p=0.838
6th month	161.09±40.49 (36)	148.00 (134.00-184.75)	171.38±59.81 (37)	159.00 (138.00-194.50)	z=0.552	p=0.581
1st year	149.07±35.54 (41)	148.00 (127.00-171.50)	170.58±57.07 (43)	155.00 (134.00-206.00)	z=1.678	p=0.093
p (Time)	F=20.717; **p<0.001***		χ^2=2.830; p=0.243			
HbA1c (%)						
Beginning	9.25±1.84 (57)	8.90 (7.60-10.60)	9.17±1.72 (56)	8.70 (7.80-10.47)	z=0.006	p=0.995
6th month	8.17±1.33 (39)	7.90 (7.10-9.00)	8.93±1.91 (36)	8.25 (7.45-10.25)	z=1.607	p=0.108
1st year	7.89±1.28 (44)	7.65 (6.92-8.67)	8.52±1.66 (43)	8.20 (7.40-9.30)	z=1.588	p=0.112
p (Time)	χ^2=19.504; **p<0.001***		χ^2=6.948; **p=0.031***			
Total Cholesterol (mg/dL)						
Beginning	182.35±42.96 (54)	183.00 (147.00-222.00)	185.59±38.34 (54)	180.50 (162.75-207.00)	t=0.414 p=	p=0.680
6th month	38±38.34 (34)	182.00 (152.75-210.00)	189.37±44.01 (35)	180.00 (156.00-213.00)	t=1.004 p=	p=0.319
1st year	04±47.33 (37)	178.00 (149.50-212.50)	187.38±39.28 (41)	186.00 (152.00-213.28)	t=0.340 p=	p=0.735
p (Time)	F=0.205; p=0.815		F=0.757; p=0.474			

Table 4. Comparison of FBG, HbA1c, Lipid and Blood Pressure Values (continued)

	Intervention Group		Control Group		
	Mean±SD (N)	**Median (IQR)**	**Mean±SD (N)**	**Median (IQR)**	**p (Group)**
Total Cholesterol (mg/dL)					
Beginning	182.35±42.96 (54)	183.00 (147.00-222.00)	185.59±38.34 (54)	180.50 (162.75-207.00)	t=0.414 p=0.680
6th month	38±38.34 (34)	182.00 (152.75-210.00)	189.37±44.01 (35)	180.00 (156.00-213.00)	t=1.004 p=0.319
1st year	04±47.33 (37)	178.00 (149.50-212.50)	187.38±39.28 (41)	186.00 (152.00-213.28)	t=0.340 p=0.735
p (Time)	F=0.205; p=0.815		F=0.757; p=0.474		
LDL (mg/dL)					
Beginning	104.12±37.58 (50)	102.00 (76.75-128.25)	105.78±34.10 (51)	101.00 (83.00-123.00)	t=0.233 p=0.816
6th month	104.24±36.46 (31)	98.00 (77.00-137.80)	113.17±37.25 (35)	104.00 (91.00-133.00)	z=0.681 p=0.496
1st year	107.78±38.43 (37)	102.00 (80.70-125.00)	111.14±33.60 (39)	109.00 (86.40-133.00)	z=0.624 p=0.533
p (Time)	$\chi 2$=1.273; p=0.529		$\chi 2$=1.787; p=0.409		
HDL (mg/dL)					
Beginning	45.11±11.30(52)	42.00 (38.00-50.00)	44.93±11.16 (54)	43.00 (37.75-51.25)	z=0.158 p=0.874
6th month	46.43±11.73 (34)	43.50 (37.75-52.75)	45.47±9.92 (34)	44.50 (38.00-50.75)	z=0.061 p=0.951
1st year	43.01±11.42 (35)	42.00 (36.00-46.00)	45.39±13.07 (39)	42.00 (35.00-53.00)	z=0.715 p=0.475
p (Time)	$\chi 2$=4.025; p=0.134		$\chi 2$=3.064; p=0.216		
Triglyceride (mg/dL)					
Beginning	165.37±85.10 (51)	147.00 (113.00-200.00)	169.31±68.19 (54)	154.50 (113.25-223.25)	z=0.712 p=0.477
6th month	145.73±72.54 (33)	122.00 (94.50-190.50)	154.41±65.36 (32)	148.00 (106.75-201.00)	z=0.761 p=0.447
1st year	157.47±78.00 (36)	128.00 (100.00-230.25)	158.39±82.17 (41)	140.00 (106.50-164.00)	z=0.296 p=0.767
p (Time)	$\chi 2$=4.280; p=0.118		$\chi 2$=0.813; p=0.666		

z:Mann-Whitney U Test, t: : Independent Sample t-Test F: ANOVA Test for repeated measures, χ^2: Friedman Testi

2.6. Drug-Related Problems and Hospitalization Rates

When the DRPs of the patients in the IG were evaluated, 86 suggestions were made to the specialist, and 70 (81.39%) of them were accepted. The most common DRPs observed were untreated indications (n = 44), subtherapeutic dosage (n = 12), and drug use without indication (n = 5) in our study.

The number of hospitalizations in both groups was identical at baseline (n = 4). When the data at the end of the sixth and 12th months were evaluated, there were no hospitalizations among the patients in both groups.

3. DISCUSSION

The study evaluated the effect of the pharmaceutical care service provided by the clinical pharmacist during a one-year follow-up with weekly text message support on patients' quality of life, medication adherence, disease knowledge level, and related treatment outcomes. The clinical pharmacist's intervention, which included optimizing pharmacotherapy with medication review and medication reconciliation processes, individualized self-management education, adherence support, and regular face-to-face or telephone follow-up, resulted in significant improvements in primary and secondary outcome measures. Consistent with previous studies, the glycemic outcomes of the patients improved, evidenced by decreases in HbA1c levels and fasting blood glucose (FBG) values. Additionally, the clinical pharmacist's intervention

contributed to increased medication adherence, higher knowledge levels, and improved quality of life for the patients.

In the study, a statistically significant increase was observed in medication adherence among patients in the IG due to the pharmaceutical care service ($p = 0.021$). This finding is consistent with the results from Jarab et al. and Erku et al., who also used the MGL scale and studied T2DM patients with a similar sample size, but their studies lasted only six months [5, 16]. Our study adds long-term results to the literature and contributes to demonstrating the long-term benefits of pharmaceutical care services with weekly text messages.

In our study, the IG showed a statistically significant improvement in knowledge achievement percentages at both the sixth month and the end of the study. Additionally, there was a statistically significant increase in the knowledge achievement percentage values between the baseline, sixth month, and first year measurements in the IG. This improvement likely contributed to better adherence. There are limited studies measuring diabetes knowledge levels in patients receiving pharmaceutical care services. Subish et al. conducted a study evaluating the effect of pharmacists on disease knowledge levels, finding a significant increase in knowledge levels among intervention patients at the end of the study [29]. Unlike Subish et al., our study also measured adherence levels to assess their relation to knowledge.

A statistical difference was identified between the groups only in the sixth-month physical quality of life scores. Additionally, there was a significant difference between time-dependent measurements (baseline, sixth month, and first year) in physical health, psychological, and environmental quality of life scores for the IG. Cani et al. and Al Mazroui et al., who also conducted RCTs with T2DM patients, determined significant differences between groups. This discrepancy may be attributed to Cani et al. measuring only diabetes-related quality of life, while we assessed general quality of life, and Al Mazroui et al. using a larger sample size in their study [30, 31]. Furthermore, the lack of change in the social relations subdomain of the quality of life measurement may be due to the impact of the COVID-19 pandemic in our study.

Diabetes management also includes improving related treatment outcomes regarding glycemic control. Taking together with our findings, it is clear that pharmaceutical care services provided by clinical pharmacists contribute to significant improvements in glycemic control across multiple settings. When the studies were evaluated, it was observed that the decrease in HbA1c levels varied between 0.42% and 2%, with an average decline of around 1% [5, 15, 31-36]. Consistent with the literature, the present study determined a 1.36% decrease in HbA1c levels in the IG. Additionally, a significant difference was observed between the time-dependent measurements of HbA1c values (baseline, sixth month, first year) in both groups. Despite the IG showing a greater decrease in HbA1c levels compared to the CG, this difference was not statistically significant. The underlying reason for this may be due to the small sample size and a higher-than-expected number of dropouts in our study.

Earlier studies investigating the effect of clinical pharmacy services on fasting blood glucose (FBG) also indicated that these services significantly reduced FBG [14, 15]. In our study, a statistically significant difference was observed between the time-dependent measurements (baseline, sixth month, first year) of FBG values in the IG.

In the present study, when the SBP values of the IG were analyzed, a significant difference was observed between the baseline and the end of the study. However, patients were evaluated in terms of DBP, and no significant difference was observed between the baseline and the end of the study in either group. Consistent with our study, a meta-analysis conducted by Machado et al. indicated that SBP was more sensitive to pharmacist-led interventions than DBP in their study [37].

Studies in the literature have shown that the effect of clinical pharmacy services on the lipid values of patients with T2DM indicates varying results. Al Mazroui et al. and Johnson et al. reported significant improvements in lipid levels [31, 38]. In contrast, Nola et al. and Hening et al. found no significant changes in lipid levels [15, 39]. Consistent with the literature, changes in lipid levels were not statistically significant, and only triglyceride levels showed a decrease in our study. The underlying reason for this finding may be the limited use of antilipidemic medications due to potential adverse reactions in Türkiye. Variations in laboratory results among diabetic patients receiving pharmaceutical care may also suggest that dietary and exercise habits are important factors and should be considered in such studies.

The ADA guideline suggests individualized HbA1c goals and also recommends considering hypoglycemia episodes for determining HbA1c targets for patients. In our study, individualized targets for each patient were decided, and a higher percentage of patients in the IG achieved the ADA target goal at the six-month and one-year assessments compared to the CG. Disease duration, life expectancy, comorbidities,

vascular complications, and hypoglycemia risk were taken into account for determining HbA1c targets for each patient. In the IG, the percentages of patients reaching the treatment goal at six months and at the end of the study were 28.20% and 31.81%, respectively. In the RCTs conducted by Al Mazroui et al., 45.4% of patients in the group receiving clinical pharmacy services achieved the ADA target for HbA1c levels (<7%) at a one-year follow-up assessment. Additionally, Jarab et al. found that 23.4% of patients in the IG reached the ADA target at the six-month follow-up [5, 31]. The differences between findings may be attributed to factors such as the lower education status of our patients, as well as the larger sample sizes and younger participants in the studies conducted by Al Mazroui et al. and Jarab et al. Another reason may be that we used individualized targets for each patient in our study, while Al Mazroui et al. and Jarab et al. used a general suggested target (<7%) in their studies.

Our results indicated that clinical pharmacist intervention contributed to the identification and elimination of adverse drug reactions. The clinical pharmacists also provided recommendations to the physician for identifying and addressing drug-related problems caused by medication use. Of these recommendations, 81.39% were accepted, which contributed to a decrease in the problems experienced by patients and helped increase medication adherence. Corresponding data from RCTs showed that clinical pharmacy services led to a significant reduction in the rate of adverse drug reactions compared to the CG [40-42].

The present study indicates no statistical difference in hospitalization rates between the IG and CG. In an RCT, clinical pharmacist intervention significantly reduced hospitalization rates in the IG compared to the CG at the end of the 3rd and 6th month follow-ups [16]. This discrepancy may be attributed to the small sample size in our study and the fact that we focused exclusively on diabetes-related hospitalization rates, whereas Erku et al. reported hospitalization numbers for all causes.

The strengths of the research are that it is a randomized controlled study, and it is the first study in Türkiye to apply this method to diabetic patients. In addition, it was designed with a long period of 1-year follow-up to see the full effect of the pharmaceutical care service.

However, there were limitations. Since this study was conducted during the COVID-19 pandemic, the ability of patients to attend routine hospital visits was negatively affected. As a result, the number of patients decreased more than expected during the follow-up period. The study is single-center, and the results cannot be generalized. Although the necessary precautions were taken, there remains a possibility that participants may have altered their behavior due to being observed, which could introduce a Hawthorne effect due to the nature of such studies.

4. CONCLUSION

The clinical pharmacist intervention contributed to improve in patients' knowledge levels and medication adherence by applying the pharmaceutical care practice within a one-year follow-up. This resulted in a statistically significant decrease in HbA1c levels among patients in the IG and helped to improve their glycemic control. Our results indicated that the active involvement of a clinical pharmacist in diabetes management may facilitate better diabetes control. In the literature, pharmaceutical care services that include the assessment of patients' knowledge levels are relatively scarce. Our study also contributes to the literature by measuring knowledge levels in addition to assessing adherence and quality of life.

5. MATERIALS AND METHODS

5.1. Study Design and Setting

The effectiveness of the pharmaceutical care service was evaluated by a clinical pharmacist in a prospective randomized controlled trial (RCT) with a one-year follow-up of patients with T2DM, who visited an outpatient diabetes clinic in a training and research hospital in Istanbul, Türkiye. The study was conducted between 8 September 2021 and 2 September 2023. The clinical pharmacist worked 8h to conduct the study during three days of the week at the diabetic outpatient clinic. Our study was single-blind, and there was no risk of possible cross-combination because of the different timing of interviews of patients assigned to the IG and CG. Figure-1 illustrates the study design.

5.1.1. Sample Size

Assuming that the mean HbA1c targeted at the end of the study would be 1% lower in the intervention group (IG) than in the control group (CG), and using a standard deviation of 1.72 as reported in the literature,

it was determined that 46 patients per group would be sufficient with an alpha of 0.05 and 80% power. After accounting for a 15% margin of error, it was determined that 53 patients should have been included in each group. Thus, 57 patients were included in each group.

5.1.2. Randomization Principle and Inclusion Criteria

Patients included in the parallel group trial design study were assigned to either the control or intervention group in a 1:1 ratio. This assignment was done using a simple randomization method based on random numbers and appointment numbers generated by a computer program. A clinical pharmacist generated a random allocation sequence, the clinical pharmacist enrolled participants and assigned participants to interventions. Each patient was included in the study only once. Patients who were diagnosed with diabetes at least 6 months ago, had an HbA1c level greater than 7%, used at least 1 diabetes medication, were older than 18 years, and younger than 80 years were included in the study, while those with uncontrolled psychological problems, pregnancy, cancer, or dementia were excluded. Interviews were conducted either face-to-face or via telephone in response to the COVID-19 pandemic.

5.6. Study Instruments

In the present study, the medication adherence of the patients was evaluated using the Morisky-Green-Levine (MGL) scale [18, 43]. A lower score on the MGL scale indicates higher medication adherence. The patients' quality of life was evaluated using the WHOQOL-BREF scale created by the World Health Organization, which is scored in four sub-domains [44]. Each domain is scored out of a maximum of 20 points, with higher scores indicating better quality of life. Validity and reliability studies have been conducted for both scales in the literature. The level of patient knowledge was assessed using a tool developed by the researchers, inspired by existing literature [29, 45, 46]. Patients' answers were recorded as correct or incorrect, and success rates were calculated mass index (BMI).

5.7. Clinical Outcomes

While primary endpoints were changes in HbA1c levels, improvement in quality of life, patient knowledge level, and medication adherence, secondary endpoints were changes in fasting blood glucose (FBS), blood pressure (BP), blood lipid levels, hospitalization rates, and body mass index.

The primary and secondary endpoints of the study were measured during the baseline data collection period, at the end of the 6th and 12th months. In addition, MGL was also assessed end of the 3rd month. Endpoints of the present study were collected through medical records, voluntary patient reports and scales.

5.8. Data Collection Process

5.8.1. Control Group Receiving Usual Care

Patients in the CG continued to receive routine health services. When the patients in this group came to the hospital for routine controls at baseline, at the end of the 6th and 12th months, their HbA1c levels were recorded, hospitalization rates were evaluated, and quality of life, medication adherence, and disease knowledge levels were measured in each interview. Any conditions potentially harmful to the patient were reported to the physician during these interviews.

5.8.2. Intervention Group Receiving Pharmaceutical Care

Patients in IG received pharmaceutical care delivered by the clinical pharmacist. The pharmaceutical care plan includes providing processes of medication reconciliation and medication review, besides educating patients by the clinical pharmacist in the present study. Patients were followed for one year after baseline data collection. Each interview lasted approximately 10-15 minutes, and all participants were supposed to bring their medications to the interviews for recording. In all interviews, the clinical pharmacist created a medication list by comparing medication records and declarations of the patients to prevent medication discrepancies. In face-to-face or telephone interviews, it was assessed whether the weekly messages were successfully delivered to the patients and whether they were correctly understood.

Baseline data collection

Patients were initially informed about diabetes. Medication reconciliation was conducted. Knowledge level, MGL, and quality of life (QOL) of the patients were also measured by the clinical pharmacist. Patients also received brochures related to a healthy diabetic diet, hypoglycemia, and living with diabetes prepared by the Turkish Endocrine and Metabolic Society and the Turkish Ministry of Health.

At the end of the 3rd month

Patients were informed about efficacy, adverse drug reactions, warnings of their medications, and how and when they should use their medications. They were also informed about what they should do if they missed a dose of their medications. The clinical pharmacist also explained the usage of the glucometer for all

the patients and the insulin pen if patients were using it. Patients also received brochures related to diabetic medications prepared by the Turkish Endocrine and Metabolic Society and the Turkish Ministry of Health.

At the end of the 6th month

Microvascular and macrovascular complications resulting from diabetes were clarified for patients. In addition, MGL, QOL, and disease knowledge levels were also measured. Patients also received brochures related to diabetic complications prepared by the Turkish Endocrine and Metabolic Society and the Turkish Ministry of Health.

At the end of the 12th month

The clinical pharmacist measured MGL, QOL, and disease knowledge level of the patients, and eventual medication use was recorded.

For aiming to increase medication adherence, patients in this group also received weekly information messages from the clinical pharmacist. In addition, the eight-item drug-related problems (DRPs) table developed by Hepler and Strand was used to determine the DRPs of the patients in the IG. DRPs are evaluated under the following headings: drug use without indication, drug interactions, adverse drug reactions, overdosage, failure to receive drugs, subtherapeutic dosage, improper drug selection, and untreated indications. DRPs were recorded through voluntary reporting, medical records, and direct observation from the clinical pharmacist.

The clinical pharmacist collected patients' medical data, evaluated the data using the up-to-date clinical guidelines, determined drug-related problems, created a pharmaceutical care plan (required actions and monitoring), and recommended it to the specialist. The final decision of the pharmaceutical care plan was determined by consensus of two clinical pharmacists and a specialist physician. The recommendations were evaluated by examining the patient files, and the accepted or rejected recommendations were noted by the clinical pharmacist with their justifications. The clinical pharmacist also monitored the patients for a year at regular intervals.

5.9. Ethical Approval

The study received approval from the Ethics Committee of Research Hospital (approval no. 2021/155). The study was conducted according to the Declaration of Helsinki, and written informed consent was obtained from the patients who were informed of the procedures to be applied.

5.10. Statistical Analysis

In the present study, the normality of continuous variables was evaluated graphically using the Shapiro-Wilk test. In comparing the group parameters, the independent samples t-test and the Mann-Whitney U test were used. To examine whether the parameters included in the study differ over measurement times (beginning, 6th month, 1st year), repeated measures analysis of variance (repeated measures ANOVA) and Friedman's test for repeated measures were used. Additionally, the McNemar test was used to compare time-dependent conditions. All data obtained during the study were analyzed using IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) which was used for statistical analyses. Statistical significance was accepted at $p < 0.05$ with a 95% confidence interval.

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