RESEARCH PAPER

The Effect of Pharmaceutical Care on the Quality of Life of Type 2 Diabetes Mellitus: A Randomized Controlled Trial

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder that negatively impacts patients' quality of life (QOL), particularly in the elderly population. Pharmaceutical care interventions play a vital role in improving therapeutic outcomes, medication adherence, and patient satisfaction, yet limited data exist on their influence on QOL in older adults with T2DM.

Objective: To assess the impact of pharmaceutical care on the quality of life of geriatric patients with type 2 diabetes mellitus in a tertiary care hospital.

Methods: A randomized controlled trial was conducted among 80 geriatric patients with T2DM attending the diabetic clinic of a tertiary care hospital. Participants were randomly allocated to an intervention group (pharmaceutical care + standard care) and a control group (standard care only). Quality of life was assessed at baseline and after 9 months using the Modified Diabetes Quality of Life-17 (MDQoL-17) questionnaire. Statistical analyses were performed using SPSS v25, employing t-tests, Chi-square, and multiple linear regression, with $p < 0.01$ considered statistically significant.

Results: The mean baseline QOL scores were comparable between groups (intervention: 47.9 ± 14.7; control: 45.7 ± 13.4). After 9 months, the intervention group showed a significant improvement in QOL (55.6 ± 12.2; $p < 0.001$), whereas the control group exhibited a decline (42.0 ± 13.4; $p < 0.001$). Significant enhancement was observed in the emotional well-being and role limitation domains. Regression analysis revealed that group allocation ($\beta = 0.371$, $p < 0.001$), baseline QOL ($\beta = 0.743$, $p < 0.001$), and socioeconomic status ($\beta = 0.107$, $p = 0.031$) were significant predictors of post-intervention QOL.

Conclusion: Pharmaceutical care significantly improved the quality of life among elderly patients with type 2 diabetes mellitus, emphasizing the importance of structured, patient-centered interventions in chronic disease management..

Keywords: Type 2 diabetes mellitus, pharmaceutical care, quality of life, MDQoL-17, randomized controlled trial, geriatric patients..

How to cite this article: Manju CS, Chandini R, Mathew A, Arul K, Fairoos AM, The Effect of Pharmaceutical Care on the Quality of Life of Type 2 Diabetes Mellitus: A Randomized Controlled Trial .Int J Drug Deliv Technol. 2026;16(2s): 311-321; DOI: 10.25258/ijddt.16. 311-321

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Diabetes mellitus is a chronic condition that affects the metabolism of carbohydrates, fat, and protein, with long-term complications [1]. The global prevalence of type 2 diabetes is increasing rapidly in low and middle-income countries, with low treatment coverage [2]. Diabetes mellitus needs constant patient-centric management to reduce the burden of the disease [3]. The prevalence of diabetes worldwide will be 7079 to one lakh population by 2030. [4]

One of the underestimated complications of diabetes mellitus is a reduction in quality of life [5]. Quality of life broadly includes a person's ability to function physically, physiologically, and socially, and their general well-being [6]. The quality of life of a person with a diseased condition is greatly influenced by complications of the disease, medication use, and comorbidities. In the case of diabetes, all these factors will greatly influence the quality of life [7]. Many diabetic patients suffer from a lot of comorbidities like nephropathy, coronary artery disease, erectile dysfunction, peripheral neuropathy, and vision loss. Moreover, type 2 diabetes needs lifestyle modifications to control the progression of the disease. Because of medication use, co-morbidities, complications, lifestyle and behavioral changes, people find it difficult to adapt to the

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situation and can impose a lot of psychosocial consequences that can influence the quality of life [8]. There is much evidence that suggests that even the presence of diabetes alone, without other comorbidities, has a negative impact on quality of life [9]. As per the literature on the reduction in quality of life, there is no gender prevalence. A patient with diabetes is able to get tight glucose control, and mental quality of life will be increased, but it can still affect the patient physically [10].

In diabetes, individuals with improved quality of life have the capacity to manage the disease to maintain long-term health [11]. (Rubin 2000). The outcome of drug therapy and other interventions is observed as clinical and economic outcomes, and the humanistic outcome is the quality of life.(Kozma c M et al) Focusing on these aspects, along with therapeutic outcome, measures are necessary to improve the quality of life in diabetic patients since it is a chronic condition.

Old age and QOL in diabetes.

There are many measures to improve the quality of life by attaining good glycemic control. This includes medication adherence, lifestyle modifications, timely checkups, self-monitoring of glucose, and affordable medication. In all these areas, pharmaceutical care has a role. Medication adherence can be increased by medication counseling and understanding. The service offered by pharmacists in patient care may vary between countries and even between hospitals. A meta-analysis of beneficial outcomes with 8 randomized controlled trials out of 21. (Pickard A S et al)

This study is designed to assess the quality of life in older persons with type 2 diabetes mellitus and to evaluate the effectiveness of pharmaceutical care on quality of life. To assess the quality of life of patients before and after pharmaceutical care and compare the effectiveness of pharmaceutical care, using MDQOL -17 questionnaire.

METHODOLOGY

Randomized controlled trial conducted in the diabetic clinic of a tertiary care hospital, after getting ethics committee approval. The sample size calculated was 38 in each arm using the equation n= (2(Z1-α/2 +Z1-β) 2. σ2/d2 whereas Z=1.96, α=level of significance (normally 0.05, β=power, σ=standard deviation, d=absolute precision [14]. Patients satisfying the inclusion and exclusion criteria after getting their informed consent were allocated to an intervention group and a control group.

The duration of the study was 9 months. during the study period, 40 patients were enrolled in the intervention group and control group based on the following inclusion and exclusion criteria. Enrolled patients were interviewed for demographic data. Administered with MDQoL-17 questionnaire, developed by Acharya et al. in 2010 in Kannada and English, with their permission [15]. This questionnaire contains 17 diabetic specific questions under 8 domains of physical functioning, social functioning, role limitations, psychological impact, energy, fatigue, body pain, and general health. All contents are scored and the score ranges from 0 – 100, and a high score indicates good QOL and a healthier state. Patients' QOL score is expressed as a percentage of the total score. QOL above 70% is considered better, 50-70 moderate, and below 50% is poor. Quality of life is assessed in both the intervention group and the control group before and after the intervention. Intervention is pharmaceutical care. Enrolled patients provided a detailed explanation, and the questionnaire is interviewer-administered. Data analysis was done by using SPSS 25 software for the demographic parameters. Descriptive statistics are used for expressing demographic parameters. For the comparison of quality-of-life score, the t-test is used. P-value < 0.01 is considered significant. Descriptive statistics, frequency, and percentage were used for socioeconomic characteristics to find out the association. For the comparison of patient characteristics between two groups, the chi-square test is used for categorical variables and the independent t-test for continuous variables

Inclusion criteria: Outpatients of both genders above the age of 65 diagnosed to have Type 2 DM using oral antidiabetic medications or insulin with HbA1C level above or equal to 7 to 10

Exclusion criteria: Patients having other diseases such as congenital heart diseases, cancer, renal failure, hepatic failure, and human immunodeficiency virus-positive patients, patients who are on therapy with steroids, or immunosuppressants.

Study procedure: Geriatric patients diagnosed with type 2 Diabetes mellitus and having been followed up study centre for one year will be recruited after obtaining informed consent.

Intervention Group: Type 2 DM geriatric patients with Pharmaceutical Care

Control group: Type 2DM geriatric patients without pharmaceutical care

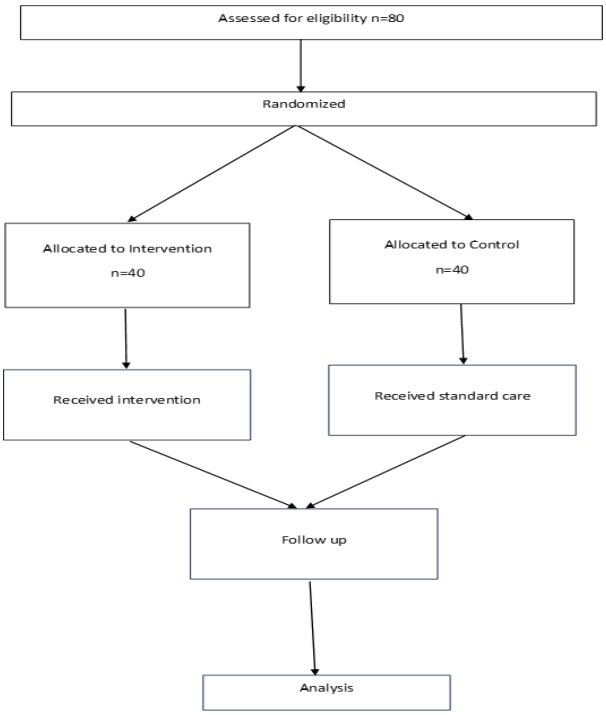

Figure 1: CONSORT flow diagram

Pharmaceutical Care Plan

Study Procedure: Patients who meet the inclusion criteria are randomly allocated to standard care (control group) and pharmaceutical care (intervention group). The intervention group receives pharmaceutical care in addition to medical care. Baseline data of both groups were collected at the time of the first meeting. Intervention group receives first month/ second month and sixth month structured pharmaceutical care meeting /visits and phone calls for 9 months.

PHARMACEUTICAL CARE PLAN FOR INTERVENTION GROUP

Pharmaceutical care is provided in three steps

First Visit: provided with general diabetes guidelines, self-care, physical activity, healthy eating, monitoring of medications, resolution of drug-related problems, adherence problems, and Risk minimization for chronic problems:

Second Visit is one month after the first: patient-specific guidelines, evaluation of the results of lab tests, provision of a pharmaceutical care plan, and the goals to be achieved will be provided.

Third visit: Evaluation of goals, Final guidelines

Data collection was done at baseline and after 9 months. The control group receives medical care only. No intervention in the standard medical care to both group s. Both groups are evaluated to find out if any difference occurred due to pharmaceutical care in quality of life using the MDQOL questionnaire. Patient interview is conducted with enrolled patients during their visit to the diabetic clinic during their waiting time and after consultation. Performed review of medication records, laboratory examination, and physical examination reports. after completing the interview, medication therapy review

Medical Care

All diagnostic and treatment services, including medication and prevention of a disease or condition.

Randomization

Random allocation of study subjects to the pharmaceutical care group and control group with the help of a statistician using baseline characteristics, age, gender, and HbA1C level at the time of enrolment. A computer-generated random table was used for randomization.

RESULTS

As per the inclusion criteria, 40 patients on each arm were randomly allocated. all the patients were in the age group of 65 to 80. All had a history of diabetes for more than 15 years.

DEMOGRAPHIC DETAILS

In the intervention group, the ages of enrolled patients range from 65 to 76 years, with a mean age was 67.9 years. The control group was 65 to 80, and the mean age was 70.2. The age difference is not statistically significant, indicating a fair age distribution between groups.

Sex: In the intervention group, there were 23 males and 17 females enrolled, and in the control group, 20 males and 20 females enrolled. Sex distribution is balanced between groups, ensuring sex is not a confounding factor in this study. Socio-economic status was analysed with the help of Kuppuswami s scale [16]. The majority of participants in the groups belong to the Upper lower class. Both the intervention group and control group had similar BMI, indicating a comparable nutritional status and ruling out BMI as a confounder. Mean BMI in the intervention group is 24.1, and in the control group it is 23.3. The mean of the history of diagnosis with Type 2 DM in the intervention group was 18.95 years, and the control group was 19.38. The duration of diabetes is comparable in both groups, ensuring consistency in disease progression. Comorbidities of hypertension, hyperlipidaemia, and coronary artery disease were evenly distributed in both intervention and control groups, supporting the internal validity of the comparison.

AGE in years	Mean	Median	Std. Deviation	Minimum	Maximum
Intervention group	67.9	66	3.7	65	76
Control group	70.2	70	4.0	65	80

		Intervention group	Control group	Total	Chi Square	p-value
Sex	Male	23(57.5)	20(50)	43(53.8)	0.453	0.501
	Female	17(42.5)	20(50)	37(46.3)		
	Total	40(100)	40(100)	80(100)		

SOCIOECONOMIC STATUS

		Intervention group	Control group	Total	Chi Square	p-value
Socioeconomic Status as per Kuppuswami scale	Upper	3(7.5)	1(2.5)	4(5)	4.896	0.298
	Upper Middle	11(27.5)	5(12.5)	16(20)		
	Lower Middle	5(12.5)	6(15)	11(13.8)		
	Upper Lower	20(50)	25(62.5)	45(56.3)		
	Lower	1(2.5)	3(7.5)	4(5)		

	Total	40(100)	40(100)	80(100)		

		Intervention group	Control group	Total	Chi Square	p-value
BMI	≤18.4	1(2.5)	2(5)	3(3.8)	2.851	0.415
	18.5-22.9	17(42.5)	14(35)	31(38.8)		
	23-24.9	9(22.5)	15(37.5)	24(30)		
	≥25	13(32.5)	9(22.5)	22(27.5)		
	Total	40(100)	40(100)	80(100)		

	Group	N	Mean	Std. Deviation	T	p-value
BMI	Intervention group	40	24.1	3.3	1.211	0.23
	Control group	40	23.3	2.2		

History of diabetes mellitus in years

	Group	N	Mean	Std. Deviation	T	p-value
History of DM (years)	Intervention group	40	18.95	7.551	-0.251	0.802
	Control group	40	19.38	7.564		

History of smoking

Smoking	Intervention	Control	Total	Chi Square	p-value
Yes	0(0)	2(5)	2(2.5)	2.616	0.27
No	31(77.5)	32(80)	63(78.8)		
Ex	9(22.5)	6(15)	15(18.8)		
Total	40(100)	40(100)	80(100)		

History of alcohol use

Alcohol	Intervention	Control	Total	Chi Square	p-value
No	30(75)	31(77.5)	61(76.3)	2.835	0.242
Ex	4(10)	7(17.5)	11(13.8)		
Occasional	6(15)	2(5)	8(10)		
Total	40(100)	40(100)	80(100)		

History of exercise

		Intervention	Control	Total	Chi Square	p-value
Exercise	Yes	12(30.8)	2(5.4)	14(18.4)	8.128	0.004*
	No	27(69.2)	35(94.6)	62(81.6)		
	Total	39(100)	37(100)	76(100)		

Co morbidities

Co morbidity	Yes/ no	Intervention	control	total	Chi square	P value
hypertension	yes	35(87.5)	30(75)	65(81.3)	2.051	0.152
	No	5(12.5)	10(25)	15(18.8)		
hyperlipidemia	yes	28(70)	29(72.5)	57(71.3)	0.061	0.805
	no	12(30)	11(27.5)	23(28.7)		
CAD	yes	13(32.5)	18(45)	31(38.8)	1.317	0.251
	no	27(67.5)	22(55)	49(61.3)		
Hypothyroidism	yes	2(5)	4(10)	6(7.5)	0.721	0.396
	No	38(95)	36(90)	74(92.5)		
Retinopathy	yes	22(55)	18(45)	40(50)	0.8	0.371
	No	18(45)	22(55)	40(50)		
Nephropathy	Yes	10(25)	5(12.5)	15(18.8)	2.051	0.152
	No	30(75)	35(87.5)	65(81.3)		

Neuropathy	Yes	27(67.5)	31(77.5)	58(72.5)	1.003	0.317
	no	13(32.5)	9(22.5)	22(27.5)		
MI	Yes	6(15)	6(15)	12(15)	0	1
	No	34(85)	34(85)	68(85)		
Foot ulcer	Yes	1(2.5)	2(5)	3(3.8)	0.346	0.556
	No	39(97.5)	38(95)	77(96.3)		

Alcohol	Intervention	Control	Total	Chi Square	p-value
Nil	2(5)	0(0)	2(2.5)	6.174	0.046
Yes	20(50)	12(30)	32(40)		
No	18(45)	28(70)	46(57.5)		
Total	40(100)	40(100)	80(100)		

Group		Patient's diabetic medication	N	Mean	Std. Deviation	t	p-value
Intervention	QOL (Before)	Insulin+OHA	24	44.7	14.0	-0.792	0.442
		OHA only	10	49.8	18.2		
	QOL (After)	Insulin+OHA	24	52.7	11.7	-0.893	0.386
		OHA only	10	57.1	13.8		
Control	QOL (Before)	Insulin+OHA	28	43.0	13.5	-1.927	0.067
		OHA only	11	51.2	11.3		
	QOL (After)	Insulin+OHA	28	39.2	13.7	-2.21	0.034
		OHA only	11	48.4	10.8		

Group		HYPOGLYCEMIA	N	Mean	Std. Deviation	t	p-value
Intervention	QOL (Before)	Yes	20	44.75	16.069	-1.611	0.116
		No	18	52.28	12.676		
	QOL (After)	Yes	20	53.1	14.264	-1.58	0.123
		No	18	59.28	8.897		
Control	QOL (Before)	Yes	12	38.58	17.197	-1.913	0.076
		No	28	48.79	10.304		
	QOL (After)	Yes	12	32.92	15.98	-3.115	0.003
		No	28	45.89	10.057		

COMPARISON OF QUALITY OF LIFE

Test of normality: As per the Shapiro-Wilk normality test data is normally distributed, so the parametric test 't' test is used in the analysis.

Paired sample t-test

		Mean	N	Std. Deviation	t	p-value
Intervention group	QOL (Before)	47.9	40	14.7	-7.12	0.000*
	QOL (After)	55.6	40	12.2		
Control group	QOL (Before)	45.7	40	13.4	4.739	0.000*
	QOL (After)	42	40	13.4		

*Statistically significant at p-value<0.01

Change in QOL in the intervention and control group before and after intervention is statistically significant.

Independent sample t-test

	Group	N	Mean	Std. Deviation	t	p-value
QOL (Before)	Intervention	40	47.9	14.7	0.676	0.501
	Control	40	45.7	13.4		
QOL (After)	Intervention	40	55.6	12.2	4.745	0.000*
	Control	40	42	13.4		

*Statistically significant at p-value<0.01

The average Quality of life of the intervention group is found to be increased from 47.9% to 55.6 % and the control group QOL is reduced from 47.9 to 42 % from baseline to after 9 months.

Analysis of QOL before and after intervention based on category of poor, moderate and better as per MDQOL-17 questionnaire

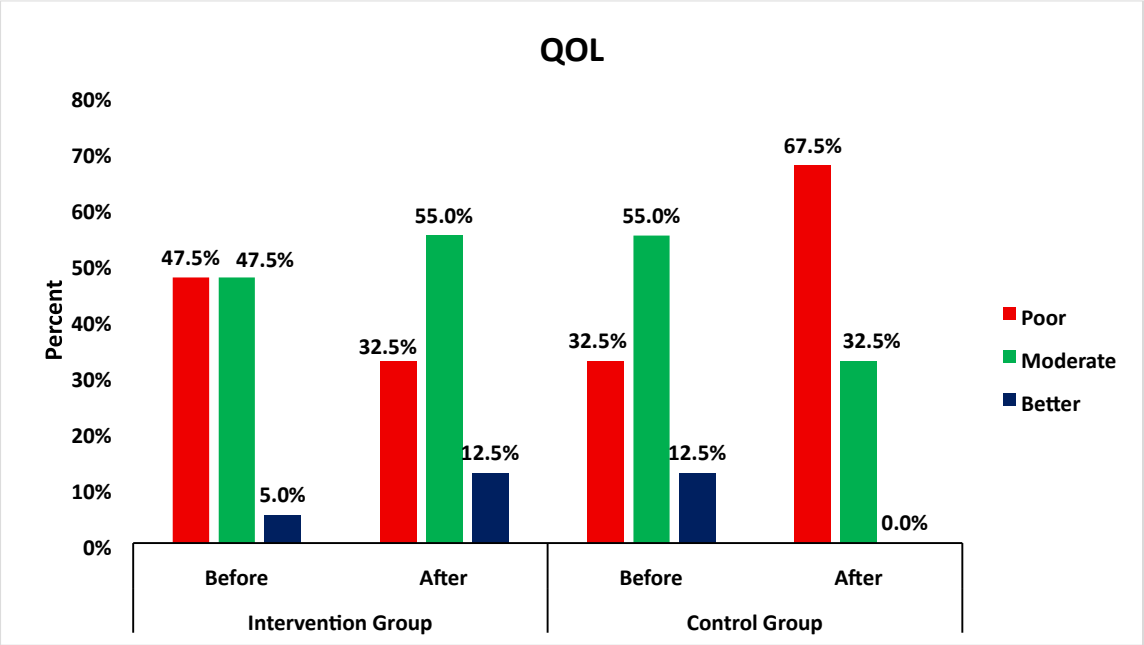

Figure 2: QOL representation graphical

The MDQOL questionnaire has seven domains, each of which is statistically tested for the change before and after intervention in the intervention and control groups.

Intervention Group		Mean	N	Std. Deviation	Z	p-value
Pair 1-Physical functioning	B1	43.2	40	27.7	-1.5	0.140
	A1	45.8	40	27.9		
Pair 2-Role limitation due to physical health	B2	49.4	40	24.3	0	1.000
	A2	49.4	40	24.3		
Pair 3-Role limitation due to emotional health	B3	51.6	40	23.0	-4.8	0.000
	A3	78.1	40	17.4		
Pair 4-Energy and fatigue	B4	47.5	40	24.3	-1.4	0.161
	A4	51.0	40	23.9		
Pair 5-Emotional well-being	B5	53.3	40	23.7	-4.9	0.000
	A5	74.3	40	21.1		
Pair 6-Social functioning	B6	53.6	40	19.4	-0.421	0.674
	A6	54.4	40	20.3		
Pair 7-General health	B7	32.2	40	16.1	-0.67	0.503
	A7	31.9	40	16.2		

In the intervention group, the increase in QOL of domains in Pair 3 and 5 is statistically significant. In the intervention group, total quality of life improved in a statistically significant manner, and specifically, there is improvement in the domain, role limitation due to emotional health and emotional well-being

Control Group		Mean	N	Std. Deviation	Z	p-value
Pair 1-Physical functioning	B1	42.5	40	25.0	-1.572	0.116
	A1	38.3	40	24.8		
Pair 2-Role limitation due to	B2	48.1	40	23.6	-0.447	0.665

Physical health	A2	48.8	40	23.3		
Pair 3-Role limitation due to Emotional health	B3	47.5	40	19.3	-3.82	0.000
	A3	43.0	40	19.5		
Pair 4-Energy fatigue	B4	45.0	40	20.1	-2.383	0.017
	A4	40.4	40	19.8		
Pair 5-Emotional well-being	B5	55.9	40	17.7	-4.238	0.000*
	A5	47.9	40	19.0		
Pair 6-Social functioning	B6	47.7	40	17.5	-1.202	0.229
	A6	46.7	40	19.6		
Pair 7-General health	B7	37.7	40	18.0	-2.559	0.010
	A7	33.6	40	16.8		

Within the control group, a reduction in QOL in pairs 3, 4,5,7 was statistically significant, which means role limitation due to emotional health, energy and fatigue, emotional well-being, and general health are found to be reduced.

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	14213.311	11	1292.119	44.395	.000[b]
	Residual	1804.526	62	29.105		
	Total	16017.838	73			
a. Dependent Variable: A QOL						
b. Predictors: (Constant), Duration of illness in years, Sex, Group, Total number of medications, B QOL, Co morbidity, AGE, BMI, Exercise, Socioeconomic Status, history of DM in years						

A multiple linear regression analysis was conducted to examine whether demographic and clinical variables predicted post-intervention Quality of Life (A QOL) among the participants. The predictor variables included group (intervention vs. control), age, sex, socioeconomic status, BMI, years of diabetes history, comorbidities, exercise, total number of medications, duration of illness, and baseline Quality of Life (B-QOL).

The regression model was statistically significant, $F(11,62)=44.40, p<.001$, indicating that the set of predictors explained a substantial proportion of the variance in post-intervention QOL ($R^2 = .887$, Adjusted $R^2 = .867$).

Coefficients						
Model		**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**Sig.**
		B	**Std. Error**	**Beta**		
1	(Constant)	12.123	16.498		.735	.465
	Group	10.926	1.471	.371	7.427	.000
	AGE	-.165	.172	-.045	-.961	.340
	Sex	1.737	1.354	.059	1.283	.204
	Socioeconomic Status	1.583	.719	.107	2.202	.031
	BMI	-.416	.241	-.082	-1.728	.089
	history of DM in years	.328	.188	.170	1.741	.087
	Co morbidity	.410	2.665	.007	.154	.878
	Exercise	-.347	1.786	-.009	-.194	.847
	B QOL	.784	.051	.743	15.249	.000
	Total number of medications	.344	1.001	.016	.344	.732
	Duration of illness in years	-3.507	1.968	-.176	-1.782	.080
a. Dependent Variable: A QOL						

Three predictors were statistically significant:

Group ($B = 10.93$, $\beta = .371$, $t = 7.43$, $p < .001$): Participants in the intervention group had significantly higher post-intervention QOL scores compared to those in the control group, after controlling for other variables.

Baseline QOL (B QOL) ($B = 0.784$, $\beta = .743$, $t = 15.25$, $p < .001$): Higher baseline QOL scores were strongly associated with higher post-intervention QOL scores.

Socioeconomic Status ($B = 1.58$, $\beta = .107$, $t = 2.20$, $p = .031$): Higher socioeconomic status was significantly associated with higher post-intervention QOL.

The remaining variables — age, sex, BMI, history of diabetes, duration of illness, comorbidities, exercise, and number of medications — were not statistically significant predictors ($p > .05$).

DISCUSSION

The study aimed to assess and analyze the effect of pharmaceutical care on the QOL of geriatric type 2 DM patients in a tertiary care hospital. As per the literature, diabetes mellitus has a negative impact on quality of life. The participants in this study were above the age of 65, with a history of having diabetes for more than 15 years. For chronic diabetes patients, a complete resolution cannot be achieved, but with proper intervention, we can achieve a good estimate of disease control, and the ultimate aim is to prevent the worsening of QOL. The study was a randomized controlled trial with an intervention group and a control group. Both groups received standard medical care, and the intervention group received structured pharmaceutical care.

Demographic details

In the intervention group, the ages of enrolled patients ranged from 65 to 76 years, with a mean age was 67.9 years. In the control group, the range was 65 to 80, and the mean age was 70.2. The age difference between groups is not statistically significant, indicating a fair age distribution between groups. In the intervention group, there were 23 males and 17 females enrolled, and in the control group, 20 males and 20 females enrolled. Research conducted by Masoud et al observed that the QOL of diabetic patients decreased with age [17]. In this study, with Pearson correlation analysis, there was no significant correlation between age and QOL in both groups. This is in contrast with other studies conducted below the age of sixty-five, but in this study, all were above 65 years, all diagnosed to have diabetes more than 15 years before, so there is a reduction in QOL

Sex distribution is balanced between groups, ensuring sex is not a confounding factor in this study. There is no statistically significant difference observed in enrolled patients in the intervention and control group in BMI, history of Diabetes mellitus, history of smoking, alcoholism, comorbidities like hypertension, hyperlipidaemia, and coronary artery disease. Complications like nephropathy, neuropathy, retinopathy, myocardial infarction, and foot ulcer are also equally distributed. There is no statistically significant difference observed between groups. P-value less than 0.01 observed in the case of exercise. 30.8% of patients in the intervention group and 5.4 % in the control group are doing exercise.

Baseline quality of life

The average quality of life of the intervention group was 47.9 ± 14.7, and that of the control group was 45.7 ±13.4. The presence of diabetes itself can reduce the quality of life. Many studies concluded that diabetes had a negative impact on quality of life. An independent sample t-test is performed to compare the means of QOL at baseline in the intervention group and control group. there is no statistically significant difference between the means of QOL, indicating both groups are comparable. The number of patients in different QOL groups is mentioned in the table (NO). In our study, the majority of patients had comorbidities and diabetes related difficulties. Age is also a factor affecting the quality of life. In this study, the majority of patients had a diagnosed history of diabetes for more than 15 years. King et al observed that most of the people with diabetes are in the age group of 45-65 [18]. In our study, the participants were 65 or above 65, so there is definitely a low baseline quality of life because, upon increasing age, there is a decrease in QOL in the case of diabetes mellitus [19]. (Glasgow et al.) In India, the occurrence of type 2 diabetes starts from the age of

The QOL score for patients taking insulin and oral antidiabetic agents was lower than that of those taking only oral drugs in both groups, but the difference is not significant. Even though the combination of insulin with OHA had better glycaemic control, there is a greater chance of hypoglycaemia episodes that can adversely affect QOL. As per statistical analysis, it is found that the total number of medications has got no influence on QOL. The majority of the patients in either group have neuropathy, nephropathy, retinopathy, MI, and foot ulcer, but these comorbidities also have no significant influence on the change in quality of life in either group from baseline to the ninth month.

Mean BMI scores of the groups were comparable. In both groups, patients with BMI ≤18.4Kg/m2 had better QOL than those with BMI≥25Kg/m2 at baseline and after the intervention. Other researches point out that obesity has a negative impact on quality of life.

Analysis of the quality of life after intervention

Baseline Quality of life of the intervention group was 47.9±14.7, and of the control group was 45.7±13.4. After the intervention, that is, structured pharmaceutical care in the intervention group, QOL was again measured in both groups, after 9 months, and in the intervention group, it was found to be increased to 55.6±12.2, and in the control group, it was found to be decreased to 42±13.4. This indicates the effectiveness of pharmaceutical care in diabetes. Intervention was effective in significantly improving QOL in the intervention group, while in the control group without intervention, QOL was found to be decreased, highlighting the value of pharmaceutical care.

After the intervention, the change in quality of life in the intervention group and the control group varies significantly, which means the increase in QOL from baseline in the intervention group and the reduction in QoL in the control group from baseline after 9 months are statistically significant. An independent sample t-test analysed the mean difference in QOL at baseline between the intervention group and control group, and after nine months of the intervention, the mean difference in QOL between the intervention and control groups. The difference in quality of life between the means of the intervention group before and after the intervention was statistically significant. This indicates the impact of pharmaceutical care on improving the QOL. Baseline quality of life was higher in males than in females in both groups, but this difference was not statistically significant. Both males and females in the intervention group showed an increase in mean QOL. In

the control group, there is a decrease in QOL, but it is not statistically significant at a p-value of 0.01. Mean QOL score in the three QOL ranges intervention group was found to be improved, and in the control group, mean QOL decreased, but not statistically significant.

As per MDQOL-17, quality of life is categorized into poor, moderate, and better. In the intervention group, the percentage of patients with poor QOL decreased from 47.5% to 32.5% from baseline, and there was an increase in the percentage of patients in the moderate and better category from baseline. Similarly, in the control group, the percentage of poor QOL patients increased from 32.5% to 67.5%. this shift indicates the effectiveness of pharmaceutical care in improving QOL.

For further understanding, the MDQOL17 questionnaire was further divided into 7 domains and analysed. The results are given in the table respectively. In the intervention group with 9 months of pharmaceutical care, QOL improved in all 6 domains except general health, which remained the same. A statistically significant improvement was observed in role limitation due to emotional health and emotional well-being at a significant level of 0.001. In all the other domains except general health, QOL is found to be increased, but it is not statistically significant.

In the control group, there is a statistically significant reduction in QOL observed in three domains of role limitation due to emotional health and personal problems, energy and fatigue, emotional well-being, and general health. All other domains except role limitation due to physical health QOL decreased, but statistically not significantly. The presence of co-morbidities, complications, lifestyle changes, dietary changes, and medication can inversely affect the quality of life. Other factors, such as pain of insulin injection, on-time injection needs, and frequent injection site changes, all can influence quality of life. All these factors make them lose confidence in their emotional aspects, abilities, and functioning. Domain 7 is general health. In the intervention group, general health seems to be reduced slightly, but it is highly reduced in the control group, indicating that the presence of comorbidities, fear of hypoglycaemia, and hypoglycaemia episodes has a significant impact on health-related quality of life. Our structured pharmaceutical care plan was based on providing 15 minutes for each patient in each sitting

Factors that can give emotional support, like family support, accepting the health and emotional conditions positively, diabetes health talks, identifying and understanding medication-related problems, measures to improve compliance, advice on diet and exercise, can positively influence quality of life. All these we included in our structured pharmaceutical care. Helping individuals adapt to the symptoms and lifestyle behaviors, understanding about proper use of medications maintains the highest possible level of QOL. During the study period, it is ensured that all intervention group are getting their prescribed medication promptly. Dietary restriction, lifestyle changes are causes of reduction of happiness, as per participants' opinion, most of them are worried about seeking help from others for travelling and attending family functions. These factors can contribute to stress that can affect the quality of life. Problems with self-confidence, Diabetic health education and professional drug therapy management are essential for control and management of the condition, which motivates patient adherence to therapy and to take charge of their condition. Statistically significant change in HbA1C observed in both groups. In the intervention group, the mean HbA1C was 8.3%, decreased to 7.1% after 9 months, and in the control group, the baseline mean was 8.0%, which increased to 9.2 % indicating the strength of the pharmaceutical care.

Intervention group and control group were analyzed in terms of type of mediations, number of mediations, comorbidities, complications, and hypoglycemia episodes are having any influence on the quality of life, but a statistically significant difference was not observed. A multiple linear regression analysis was conducted to examine whether demographic and clinical variables predicted post-intervention Quality of Life (A QOL) among intervention and control groups. The predictor variables included group (intervention vs. control), age, sex, socioeconomic status, BMI, history of diabetes in years, comorbidities, exercise, total number of medications, duration of illness, and baseline Quality of Life (B QOL).

The regression model was statistically significant, F (11, 62) = 44.40, p < .001, indicating that the set of predictors explained a substantial proportion of the variance in post-intervention QOL (R^2 = .887, Adjusted R^2 = .867).

Three predictors were statistically significant:

Group (B = 10.93, β = .371, t = 7.43, p < .001): Participants in the intervention group had significantly higher post-intervention QOL scores compared to those in the control group, after controlling for other variables.

Baseline QOL (B QOL) (B = 0.784, β = .743, t = 15.25, p < .001): Higher baseline QOL scores were strongly associated with higher post-intervention QOL scores.

Socioeconomic Status (B = 1.58, β = .107, t = 2.20, p = .031): Higher socioeconomic status was significantly associated with higher post-intervention QOL.

The remaining variables — age, sex, BMI, history of diabetes, duration of illness, comorbidities, exercise, and number of medications — were not statistically significant predictors (p > .05)

CONCLUSION

The physical and mental well-being of a person is negatively affected by the presence of diabetes, and the presence of co-morbidities further worsens the quality of life. Living with diabetes has a significant impact on QOL. The onset of Type 2 diabetes can be prevented with primordial prevention strategies, or we can delay the onset. With the implementation of health screening, early detection, proper management, and pharmaceutical care, the occurrence of complications can be prevented or delayed. All these strategies can improve the quality of life of people living with diabetes. Identifying the various factors influencing the quality of life during the course of diabetes and resolution will definitely improve the quality

of life. Pharmaceutical care or patient empowerment can do a lot in this area by supporting the patients with lifestyle and behavioral changes, dietary modifications, medication adherence, self-monitoring of blood glucose, and identification and resolution of side effects and adverse events.

LIST OF ABBREVIATION

A QOL – Post-intervention Quality of Life; **ANOVA** – Analysis of Variance; **BMI** – Body Mass Index; **B QOL** – Baseline Quality of Life; **CAD** – Coronary Artery Disease; **CONSORT** – Consolidated Standards of Reporting Trials; **DM** – Diabetes Mellitus; **HbA1c** – Glycated Hemoglobin; **MDQoL-17** – Modified Diabetes Quality of Life-17 Questionnaire; **MI** – Myocardial Infarction; **OHA** – Oral Hypoglycaemic Agents; **PC** – Pharmaceutical Care; **QOL** – Quality of Life; **RCT** – Randomized Controlled Trial; **T2DM** – Type 2 Diabetes Mellitus.

ACKNOWLEDGMENT

I would like to thank, all involved members and faculty staff for their collaboration. Special thanks are due to **Manju C. S. (Professor of Pharmacy, Govt. Medical College, Kozhikode, Kerala. Affiliated To Kerala University of Health Sciences)** for their guidance and support throughout the project.

AUTHOR CONTRIBUTION

Manju C. S. contributed to conceptualization, study design, methodology, data analysis and interpretation, and preparation of the original draft of the manuscript. Chandini R. contributed to methodology development, data collection, and preliminary data analysis. Anny Mathew contributed to data collection, experimental execution, and data interpretation. Arul K. contributed to statistical analysis, data validation, and critical inputs during manuscript preparation. Muhammed Fairoos A. contributed to literature review, drafting support, manuscript formatting, and final proofreading. All authors have read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

ETHICAL APPROVAL

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

HUMAN AND ANIMAL ETHICAL RIGHT

Not applicable.

CONFLICT OF INTEREST

The authors declare no conflict of interest, and no funding was required to conduct these review data.

AVAILABILITY OF DATA AND MATERIALS

The data supporting this study's findings will be available in the cited references.

FUNDING

The research received no external funding.

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