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Effect of a Community Pharmacist–Delivered Diabetes Support Program for Patients Receiving Specialty Medical Care

A Randomized Controlled Trial

Purpose

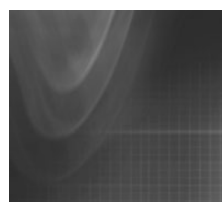
The purpose of the study was to investigate the efficacy of a community pharmacist–delivered diabetes support program for patients receiving specialty medical care in a middle-income country (Iran).

Methods

A randomized controlled trial was conducted on 101 patients who received diabetes care from an endocrinologist. A qualified community pharmacist educated patients about medications, clinical goals, self-care activities, and self-monitoring of blood glucose. The pharmacist trained patients in the intervention group for 5 months (5 follow-up visits and 5 phone calls) and recommended physician visits when necessary. The primary outcome was A1C, and the secondary outcomes included self-care activities, medication adherence, blood pressure, and body mass index. Satisfaction and willingness to pay was assessed in the intervention group.

Results

Eighty-five patients completed the study, and baseline A1C was similar between groups (intervention: 7.6 ± 1.6 [59 mmol/mol] vs control: 7.5 ± 1.9 [58 mmol/mol]). No significant difference was observed between study groups at the end of the trial period; however, the amount of A1C reduction was higher in the intervention group (1.0% ± 1.5% vs 0.5% ± 1.5%). Self-care activity was



Zahra Jahangard-Rafsanjani, PharmD
Amir Sarayani, PharmD, MPH
Marzieh Nosrati, PharmD
Navid Saadat, MD
Arash Rashidian, MD, PhD
Molouk Hadjibabaie, PharmD
Asieh Ashouri, PhD
Mania Radfar, PharmD
Mohammadreza Javadi, PharmD
Kheirollah Gholami, PharmD

From Clinical Pharmacy Department, Faculty of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran (Dr Jahangard-Rafsanjani, Dr Radfar); Research Center for Rational Use of Drugs, Tehran University of Medical Sciences, Tehran, Iran (Dr Sarayani, Dr Ashouri); Community and Institutional Pharmacies, Tehran University of Medical Sciences, Tehran, Iran (Dr Nosrati); Prevention of Metabolic Disorders Research Center, Research Institute for Endocrine Science, Shahid Beheshti University of Medical Sciences, Tehran, Iran (Dr Saadat); Department of Health Management and Economics, School of Pubic Health, Tehran University of Medical Sciences, Tehran, Iran (Dr Rashidian); and Research Center for Rational Use of Drugs and Clinical Pharmacy Department, Faculty of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran (Dr Hadjibabaie, Dr Javadi, Dr Gholami).

Correspondence to Amir Sarayani, PharmD, MPH, Research Center for Rational Use of Drugs, Tehran University of Medical Sciences, 92 Karimkhan-Zand Ave, Tehran, Iran (Sarayani@ufl.edu; a-sarayanib@razi.tums.ac.ir).

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improved in general diet, blood glucose monitoring, and foot care subcategories in the intervention group. Medication adherence and body mass index were significantly improved in the intervention group at the end of study.

Conclusions

A community pharmacist intervention improved self-care activity, medication adherence, and body mass index in patients receiving specialty medical care. Baseline A1C values and the presence of specialty medical care should be considered in the interpretation of clinical findings.

Introduction

Diabetes is a major chronic health condition with an estimated worldwide prevalence of 8.3% among adult population; approximately 80% of the patients with diabetes live in low- or middle-income countries.[1,2] Management of diabetes is challenging because patients should adopt several self-care behaviors including dietary modification, physical activity, weight loss, medication adherence, and blood glucose monitoring,[3,4] and several studies have shown major deficiencies in self-care practice.[5,6] Therefore, a multidisciplinary team approach, namely, contribution of all health care professionals, has been suggested for diabetes management to reduce costs of disease complications. Such teams may include physicians, pharmacists, nurses, and dietitians with adequate expertise in diabetes management and education.[7]

Community pharmacists have expanded their professional roles beyond dispensing medications, particularly for diabetes screening and management.[8,9] Today, the American Diabetes Association recognizes registered pharmacists as vital members of the multidisciplinary teams responsible for delivering diabetes care and education.[10] Pharmacist-led diabetes care may include diabetes education, nutrition/exercise consultation and reinforcement, proper foot/eye care, monitoring and promoting medication adherence, identifying drug-related problems, and optimization of pharmacotherapy.[11]

Several studies have reported positive outcomes for patients with diabetes who receive pharmacists' interventions, namely, improvement of blood glucose levels or concurrent cardiovascular risk factors.[12-14] A meta-analysis of 16 studies (2247 patients) demonstrated that pharmacists' interventions could significantly improve A1C levels (intervention group, –1.00% ± 0.28%; $P < .001$; controls, –0.28% ± 0.29%; $P = .3$).[15] Nevertheless, a majority of the trials evaluating the effect of pharmacists' interventions have been conducted in high-income countries.[16] In addition, most trials have been conducted in collaboration with primary care physicians while patients receiving diabetes care from endocrinologists have often been excluded.[8,10] These knowledge gaps necessitate further trials in low- and middle-income countries and on patients receiving specialty care.

In the present study, a randomized controlled trial was designed to evaluate the effect of a community pharmacist's diabetes support program on patients with type 2 diabetes receiving specialty care in a middle-income country.

Methods

Trial Design

This study was a parallel group, randomized controlled trial to assess the effect of a community pharmacist–based diabetes education program (registration ID: NCT01525992). In a parallel trial, each study group receives only 1 treatment or intervention during the trial; For example, A and B are the treatments, and 1 group receives only A while another group receives only B. The study protocol was approved by the Ethics Committee, Tehran University of Medical Sciences (Tehran, Iran). Participants were recruited between March 2012 and April 2013, and they provided written informed consent.

Sample Size and Randomization

Study sample size was calculated based on the effect size of 0.7% for A1C and standard deviation of 1.3%. A significance level of .05 was considered, and the study power was assumed to be 80%. The calculated sample size was 108; however, a sample of 135 patients was assumed to be sufficient to compensate for a 20% attrition rate. Randomization sequence was generated based on a block randomization algorithm (1:1 allocation ratio; block size: 4), and 2 authors who were not involved in the recruitment process had access to the randomization list. The community pharmacist requested an allocation order using telephone calls after a patient signed the informed consent form.

Participants

Patients with a diagnosis of type 2 diabetes who were using oral hypoglycemic medications and had a history of A1C >7% within the preceding month were eligible for the study. Patients' ability to use a blood glucose self-monitoring device was confirmed before recruitment. Patients were excluded if adjunct insulin therapy was required or if they had concurrent stage 4 heart failure, fasted during Ramadan, or had received diabetes education within the previous 6 months.

The community pharmacist who conducted the program attended the office of an endocrinologist once a month and evaluated medical records to find eligible patients. Patients were invited to participate in the study via telephone. If a patient was willing to participate, an appointment was set to attend the pharmacy for recruitment and baseline assessments.

Study Settings

The study was carried out at the Nemooneh-Taleghani Community Pharmacy, affiliated with the College of Pharmacy, Tehran University of Medical Sciences, Iran. Tehran is the capital city of Iran, and the community pharmacy is located in the northern part of the city where the socioeconomic status is relatively high. The community pharmacist used the manager's office on predefined days of the week as a private counseling area to deliver diabetes education. An endocrinologist (a faculty member) whose office was located near the pharmacy was invited to collaborate with the research team and facilitate patients' recruitment.

Interventions

Diabetes Education Program

A community pharmacist was trained before the study commencement. The pharmacist was instructed by a diabetes pharmacotherapy specialist in pathophysiology and pharmacotherapy of diabetes (one 4-hour session). Afterward, the pharmacist attended a 3-day workshop for health care professionals on diabetes education conducted by a reputable nongovernmental organization (NGO) advocating diabetes education since 2006.

The program consisted of 5 follow-up visits with the community pharmacist (once a month). The duration of each follow-up visit was estimated to be 30 minutes. The community pharmacist made a telephone call between visits to reinforce treatment adherence and resolve any therapy-related problems. A step-by-step protocol was designed to deliver education on diet management, physical activity, and diabetes complications during the intervention. However, each patient received individualized consultations based on individual needs. The community pharmacist used a predefined checklist to document the education procedure for each patient during the study period. At the recruitment visit, patients were provided with a blood glucose self-monitoring device and the required test strips were supplied for 1 month. Patients were trained how to use the device and were requested to document blood glucose levels every other day in a rotating schedule (fasting, post prandial, before lunch, before sleep). Each patient was provided with a special logbook and educational pamphlets for the diabetes medications. At each follow-up visit, medication-related problems, self-care issues, and the logbook were discussed with the patient. Patients were supplied with the test strips for the following month.

Patients were referred to the physician whenever the disease was not controlled after the first 2 months of the intervention or a drug therapy modification was required. The community pharmacist recorded the number of physician visits and the drug therapy modifications during the study period.

Control Group

Patients in this group received usual care from the physician during the study period. Baseline assessments were performed by the community pharmacist at the recruitment visit. Patients were invited to the pharmacy for final assessment at the end of the study. The community pharmacist provided a brief education on diabetes self-care and helped them find an appropriate diabetes education program. The community pharmacist recorded the number of physician visits and the drug therapy modifications during the study period.

Study Outcomes

Primary Outcome

A1C was measured as the primary outcome at baseline and 5-month follow-up. Patients received a signed letter from the community pharmacist at the recruitment and final visits to attend the laboratory. A pathobiology laboratory accredited by the Ministry of Health assessed A1C

based on a chromatography method certified by NGSP to give DCCT compatible results (DS5 A1C Analyzer, Drew Scientific Inc, Dallas, TX). The laboratory was located near the pharmacy to increase patients' cooperation.

Secondary Outcomes

Medication adherence was evaluated using a translated version of Morisky Medication Adherence Scale at baseline and 5-month follow-up.[17] The scale consists of 7 yes/no items and 1 Likert-type item about the patients' drug-taking behavior and possible barriers to medication adherence. The total score of the scale is 8, which reflects "high adherence." Scores of 6 to 8 are considered as "moderate adherence," and below 6 is "low adherence." The questionnaire was translated into Farsi language and was pilot tested in a group of 18 patients with type 2 diabetes not participating in the study. Internal reliability of the translated questionnaire was acceptable (Cronbach's $\alpha = .69$). Test-retest reliability (2-week period) assessment revealed a significant correlation of .63.

Self-care activity was measured using Diabetes Self-care Activity Measurement Scale questionnaire at baseline and 5-month follow-up.[18] The revised tool assesses 6 domains of diabetes self-care including general diet, specific diet, exercise, blood glucose testing, foot care, and smoking habit (11 items). The first 5 domains are evaluated by 2 items that ask about the patients' behavior during the last 7 days. For example, blood glucose testing is measured by the following items: (1) "On how many of the last SEVEN DAYS did you test your blood sugar? (0 1 2 3 4 5 6 7)"; (2) "On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider? (0 1 2 3 4 5 6 7)." Smoking is measured by a yes/no item considering behavior during the last 7 days. The mean of the 2 items in each domain is calculated for each patient and the median of study groups are compared. Due to low inter-item correlation, each domain should be compared separately, and the total score of the scale is not valid for interpretation. The original scale was translated into Farsi language and the test-retest reliability (2-week period) showed significant correlations in all domains ($R > .7$).

Blood pressure, weight, and body mass index (BMI) were also evaluated as cardiovascular secondary outcomes. Blood pressure was assessed using a digital upper arm device (SHB-200F, Samsung C&T Corporation, Seoul, Korea).

Participants' Satisfaction and Willingness to Pay

Patients' satisfaction with the program was assessed using 6 Likert items (strongly satisfied to strongly dissatisfied, 5-point scale). Moreover, 3 Likert items and an open-ended question were designed to assess patients' satisfaction with the service delivery environment (community pharmacy).

A questionnaire was designed to evaluate patients' willingness to pay for a diabetes education visit with the community pharmacist. The introduction section of the questionnaire provided a brief review of the diabetes education program, and the objective was mentioned at the end of the section. In the monetary evaluation section, a question asked whether the patient was willing to pay or not. If the answer was yes, 8 fee options were suggested according to the tariffs usually charged by different health care professionals in Iran.

An anonymous questionnaire was employed; patients were asked to complete them in a private area and drop them into a special box to prevent social desirability bias.

Statistical Methods

Main effect of the intervention on A1C was analyzed using analysis of covariance test (ANCOVA) to adjust for the baseline values. Paired *t* test was used to analyze within-group effects. A post hoc analysis was carried out on a subgroup of patients with baseline A1C <7%. The assumption was to detect different patterns of A1C in this subgroup because achieving a 7% value was the physician's goal of therapy. Demographic factors, blood pressure, weight, medication adherence, and self-care activity were compared between groups using Pearson chi-square test for categorical variables, independent *t* test for continuous variables, and Mann-Whitney U-test for ordinal variables or non-normal distributions. Patients' satisfaction and willingness to pay was summarized using frequency statistic. *P* values <.05 were reported as significant.

Results

Two hundred eighty potentially eligible patients were invited to enroll in the study. Of them, 101 participants were recruited and randomized to either the intervention group (n = 51) or the control group (n= 50). Six patients in the intervention group and 10 patients in the control group discontinued the study. The flow of participants

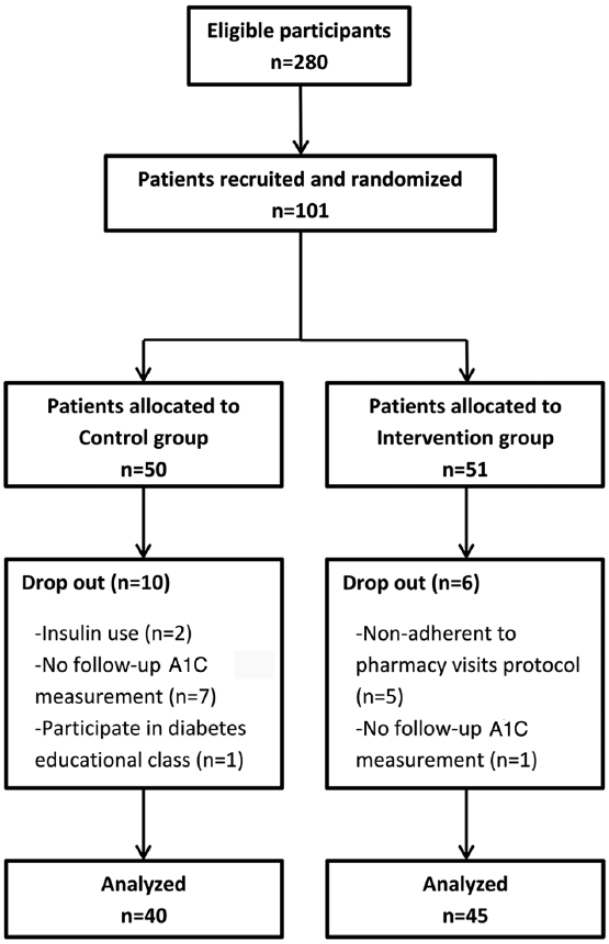

Figure 1. The flow diagram of study participants.

through the study is shown in Figure 1. The demographic characteristics were similar between the study groups. Moreover, there were no significant differences between groups in the duration of diabetes, number of diabetes medications, baseline A1C, and systolic/diastolic blood pressure (Table 1).

Summary of clinical endpoints and statistical comparisons between groups is shown in Table 2. In the intervention group, A1C reduction was 1.03% (1.5) (*P* value = .0001), and the corresponding figure in the control group was 0.52% (1.5) (*P* value = .03). However, no significant difference was observed between study groups at the end of trial period (intervention: 6.6 ± 1.5 [49] vs control: 7.0 ± 1.7 [53]; *P* = .09).

In a subgroup analysis of 41 patients with baseline A1C <7%, we observed a significantly improved level of A1C in the intervention group. At baseline, A1C was 6.2 ± 0.5 (44) in the intervention group and 6.4 ± 0.6 (46) in the control group (*P* = .25). At the end of trial, patients in the intervention group achieved A1C level of 5.8 ± 0.8 (40) while A1C increased in the control group up to 6.7 ± 1.4 (50) and the difference between groups was significant (*P* = .02).

The BMI was significantly lower in the intervention group compared to the control group at the end of study period. The systolic and diastolic blood pressures did not change significantly during the study (Table 2).

Prevalence of "low medication adherence" was 51% in the intervention group and 46% in the control group at baseline. At the follow-up, medication adherence significantly improved in the intervention group. Low medication adherence was 24% in intervention group and 49% in the control group at the end of study (*P* = .02). In the intervention group, self-care activity was improved in general diet, blood glucose monitoring, and foot care subcategories. However, there were no significant differences in the exercise and specific diet domains between study groups (Table 3).

During the study period, number of patients with at least 1 visit with the physician was significantly higher in the intervention group (71.7% vs 32.5%, *P* = .0001). In addition, the number of patients with drug therapy modification was higher in the intervention group (21.3% vs 7.5%, *P* = .07).

In the intervention group, patients' satisfaction with the program was relatively high with all 3 domains: the pharmacist as service provider, the content of education, and the community pharmacy as the service providing environment (Table 4). Regarding willingness to pay, 87.2% of patients in the intervention group were ready to pay for the service. The mean and median amount of willingness to pay was 105 000 and 100 000 Iranian Rials per visit, respectively (~USD$4 based on official conversion rate at the time of study). During the same time, the official fee for service for general practitioners was 98 000 Rials per visit.

Discussion

In the present study, the community pharmacist–based diabetes education program improved medication adherence, self-care practice, and weight control. Although the amount of A1C reduction was higher in the intervention group (1.03 vs 0.52), it was not statistically significant.

Table 1

Baseline Characteristics of the Study Participants

Characteristic	Intervention (n = 45)	Control (n = 40)	*P* Value[a]
Female, n (%)	25 (49)	26 (52)	.76
Age (y), mean (SD)	57.3 (8.6)	55.9 (8.7)	.41
Body mass index (kg × m^{-2}), mean (SD)	29.3 (4.85)	29.4 (3.98)	.27
Education, n (%)			
No secondary education	11 (22)	10 (22)	.28
High school/college	20 (40)	22 (48)	
Bachelor of science	11 (22)	9 (20)	
Master of science	7 (14)	2 (4)	
PhD or above	1 (2)	3 (6)	
A1C (%), mean (SD)	7.6 (1.6)	7.51 (1.9)	.82
Duration of diabetes (y), mean (SD)	4.6 (4.3)	5.7 (5.9)	.29
Systolic blood pressure (mmHg), mean (SD)	132.0 (17.6)	136.4 (19.7)	.40
Diastolic blood pressure (mmHg), mean (SD)	81.7 (9.92)	83.3 (11.63)	.50
Number of diabetes medications, n (%)			
1	25 (49)	21 (42)	.89
2	23 (45)	25 (50)	
3	2 (4)	3 (6)	
4	1 (2)	1 (2)	

[a]Comparisons were performed using Pearson's chi-square test for categorical variables, Student *t* test for continuous variables, and Mann-Whitney test for non-normal distributions.

Table 2

Comparison of Clinical Endpoints Between Study Groups

	Baseline			Follow-up		
Variable	Intervention (n = 45)	Control (n = 40)	*P* Value[a]	Intervention (n = 45)	Control (n = 40)	*P* Value[b]
A1C (%), mean (SD)	7.6 ± 1.6 (59)	7.5 ± 1.9 (58)	.8	6.6 ± 1.5 (49)	7.0 ± 1.7 (53)	.09
Systolic blood pressure (mmHg), mean (SD)	132.0 (17.6)	136.4 (19.7)	.40	132.8 (17.6)	134.2 (18.7)	.5
Diastolic blood pressure (mmHg), mean (SD)	81.7 (9.9)	83.3 (11.6)	.50	82.2 (9.7)	82.0 (11.8)	.5
Body mass index (kg × m^{-2}), mean (SD)	29.3 (4.8)	29.4 (4.0)	.3	29.1 (4.8)	29.7 (4.2)	.02

[a]Comparisons performed using Student *t* test for continuous variables distributions.
[b]*P* value according to ANCOVA test.

The study participants had 2 distinctive clinical characteristics in comparison to previous studies on pharmacists' intervention for patients with diabetes. First, most studies have investigated the efficacy of pharmacists' interventions in collaboration with "primary care physicians"[10] and have shown significant improvements in patients outcomes.[15] However, the study patients received specialty care prior to recruitment and "one endocrinologist" managed patients' diabetes. Evidence shows this approach could provide a higher quality of care.[19] Second, the effect of quality improvement strategies for diabetes care including pharmacists' interventions has

Table 3

Comparison of Adherence and Self-care Activity Measures Between Two Groups

Variable	Baseline			Follow-up		
	Intervention Group (n = 51)	Control Group (n = 50)	*P* Value[a]	Intervention Group (n = 45)	Control Group (n = 40)	*P* Value
Medication adherence, n (%)						
Low	26 (51)	23 (46)	.49	11 (24)	20 (49)	.02
Moderate/high	25 (49)	27 (54)		34 (76)	21 (51)	
Self-care activities[b]						
General diet	0 (0-0)	0.0 (0-0)	.45	5.0 (3-6)	0.0 (0)	<.01
Specific diet	2.5 (1.5-3)	2.5 (1.5-3.5)	.14	2.0 (1.5-3.25)	2.5 (2-3.5)	.33
Exercise	1.5 (1-3)	1.5 (0-3.5)	.64	2.5 (1.5-3.5)	1.5 (0.25-3.5)	.12
Blood glucose monitoring	1.0 (1-2)	2.0 (1-4.75)	.001	4.0 (3-4)	2.0 (0-3.25)	<.01
Foot care	1.5 (0-3.5)	3.5 (1-3.5)	.02	3.5 (2.25-4)	3.5 (1.5-3.5)	.02

[a]Comparisons performed using Mann-Whitney test and Pearson chi-square test.
[b]Median of days per week.

Table 4

Patients Satisfaction With Pharmacy Diabetes Care Program

Satisfaction Item[a]	Level of Satisfaction (%) (very satisfied or satisfied)
I am satisfied with	
the pharmacist as my diabetes educator	100
the pharmacist's method of education delivery	100
the pharmacist's communication style and attitude	100
the pharmacist's availability for consultation	100
the pharmacist's consultations in a holistic view	100
I am satisfied with	
the duration of sessions	97.4
the content of diabetes education	100
I am satisfied with	
the ease of access to the community pharmacy	97.4
the pharmacy environment for receiving education	94.9

[a]For each item, responses on the 5-point Likert scale were recoded into 3 categories and the highest proportion of responses is presented in the table.

been documented mostly in poor control diabetes, namely, A1C >8%,[12,20] while few studies have focused on relatively controlled patients.[21,22] In the present study, the baseline A1C was 7.54%, and approximately half of the participants had an A1C level lower than 7%.

The primary clinical outcome, namely, A1C, was not significantly different between study groups at the end of trial, possibly due to not achieving the targeted sample size; however, the clinical relevance of the effect seems to be promising in the study population. The intervention resulted in an overall 1% reduction of A1C level, and according to the UKPDS study, every 1% decrease in A1C could lead to 35% reduction in diabetes complications.[23] In the subgroup analysis of patients with baseline

A1C <7%, patients in the intervention group had significantly lower A1C levels at the end of trial (<6%). In contrast, the counterparts in the control group showed an elevated level of A1C. This observation may imply that the program could be successful for patients who require intensive diabetes management with target A1C level lower than 6%.

A statistically significant reduction in A1C was observed in the control group, and this could be attributed to the specialist's care throughout the study, which was aimed to achieve the goal of A1C <7%. Adherence to medications and self-care practice significantly improved in the intervention group. These 2 surrogate outcomes might have resulted in the higher A1C reduction for these patients. Another secondary outcome was patients' BMI, which was significantly higher in the control at the end of trial. Although the intervention was not specifically designed to manage patients' weight, it might have been successful in weight maintenance because of promoting healthy eating patterns. Pharmacists' role in weight management is an area of evolving research[24,25] and could be merged with diabetes education programs in community pharmacy practice.

Patients' satisfaction with the diabetes services provided by community pharmacists has been reported to be relatedly high in previous studies.[26,27] In the present study, a high level of satisfaction was observed in the intervention group. The study patients received specialty care, which was mostly focused on evidence-based medication therapy rather than diabetes education. Not having enough time for patient education is a common characteristic of specialty physicians, particularly in Iran. Therefore, the collaborative program could have resulted in patients' high satisfaction.

Strengths and Limitations

The present study was a rigorous randomized controlled trial on the effect of diabetes education and support program in a community pharmacy of a middle-income country. In addition, it was a collaborative program including a local community pharmacy and diabetes specialty care. Regarding the method of A1C assessment, all tests were performed by 1 laboratory to minimize bias. However, there are some limitations to mention. Data from 85 patients were available for analysis, which was fewer than the targeted sample size (108) to detect 0.7% difference of A1C between groups; nevertheless, the observed difference was 0.5%. Another caveat was supplying the self-monitoring blood glucose device and the required test strips for the intervention group. Although the self-monitoring support might result in better glycemic control and clinical outcomes,[28,29] further studies are required to quantify the effectiveness of these devices in the clinical settings of resource-limited countries.[30] The study follow-up period was relatively short, and future studies should investigate the long-term effects of such interventions.

Implications/Relevance for Diabetes Educators

A community pharmacist–based intervention improved several outcomes in patients with type 2 diabetes, including self-care, medication adherence, and body mass index in patients receiving specialty medical care. Baseline A1C values and the presence of specialty medical care should be considered in the interpretation of clinical findings.

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