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Pharmacy Students' Care Improved HBA1c Levels and Quality of Life of Patients with Diabetes

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Citation

Abstract

The objective of the current study was to examine the pharmacy student care effect on HbA1c levels and quality of life (QoL) of T2DM patients. For this purpose pharmacy students received an academic course on theoretical and clinical aspects of T2DM management. Students carried out a psycho-educational intervention among T2DM patients. T2DM patients (n=135) participated in two projects. Within each project a random allocation to intervention group (IG) or control group (CG) was conducted. In the first project, HbA1c levels were taken from patients' medical files before the intervention commenced (t1), after half a year (t2) and after one year (t3). In the second project, HbA1c levels and QoL values were measured pre-intervention (t1) and after one year (t2). In both projects, the results showed that HbA1c levels declined at t2 among participants in the IG group only. In the second project, IG patients exhibited improvement on the physical and psychological QoL scales compared to no improvement among CG. It was therefore concluded that Integrative intervention by pharmacy students decreased HBA1c levels and improved aspects of quality of life among T2DM patients. Practically, pharmacy students play an important role in bridging the gap between physician recommendations and patients' optimal metabolic-control, by conducting continuous psycho-educational interventions.

1. Introduction

This study examined the effect of pharmacy student care on HbA1c (glycated hemoglobin) levels and quality of life of T2DM patients.

Diabetes Mellitus type 2 (T2DM) is a worldwide health concern. In Israel, 8.3% of the population suffers from T2DM [1]. The highest rates of T2DM (15.9%) are reported in Mexico [2]. Patients represent a high risk of cardiovascular disease and mortality [3, 4].

Current knowledge on diabetes management acknowledges the importance of promoting healthy lifestyles and medication adherence. Healthy lifestyles described in the scientific literature are daily physical activity, suitable nutrition for diabetics, smoking cessation, having a social support system, and efficient psychosocial habits

such as stress management [5-8].

The practice of the above strategies is a complicated task for T2DM patients; patients characterized with low levels of health literacy, low economic status, lack of social support, irrational health beliefs and comorbidity, poorly adhere to self-management practices [9, 10].

Clinicians' attitudes, beliefs and knowledge about T2DM, influence diabetes management of patients as well [11]. The clinician role involves providing psycho-educational knowledge on diabetes and lifestyle. Results from previous studies showed an ongoing educational and supportive care provided by dietitians led to long term metabolic improvement of T2DM patients [12]. Hence, the commitment and availability of patients and clinicians to a long term process are important factors for long term metabolic improvement of T2DM patients [13-15].

Newcomers to the field of diabetes education and care are the pharmacists [16]. Over the last few decades, pharmacists enlisted in the multidisciplinary medical teams. Within these teams, pharmacists deal with classical pharmacy, as well as ongoing "Pharmaceutical care" (PC) [17, 18]. PC consists of activities such as medical management as well as patients' home visits, follow-ups of patients with comorbidity, who, for example, use anticoagulation. The role of the pharmacist is to provide patients with medical management, teach self-monitoring activities, concepts of food care, and physical activity, all in all to control weight, manage high blood pressure, cholesterol, heart disease and other chronic diseases [19-21]. In recent years, pharmacists also teach chronic patients stress management strategies [22].

Results from previous studies showed T2DM patients, followed by pharmacists knowledgeable in PC, adhered better to their medical regime and improved metabolically, in comparison with control groups which received regular care [16, 23].

Very few studies focused on pharmacy students as care providers who can induce behavioral change among T2DM patients. For example, findings from a previous study reported pharmacy students' intervention increased the intake of aspirin among T2DM patients [24]. Delea et al. [25], described a course for third year pharmacy students in which the students learned skills such as glucose monitoring, and physical activity. The results showed students' confidence in their diabetes self-management education skills increased. Yet, the acquisition of knowledge and skills as a PC provider requires a long period of education and practice [25]. Therefore, in the current study, the authors constructed an academic course which consists of PC concepts relevant to T2DM patients together with practical skills in behavioral interventions. To the best of our knowledge, this is the first study which measured the effect of an educative course given to pharmacy students on objective measures of T2DM patients, i.e., metabolic, and subjective, i.e., quality of life improvements.

2. Method

Two prospective interventional projects were conducted among T2DM patients. Pharmacy students carried out the intervention in their fourth and final year of studies.

Research design

Students received an academic, three hour weekly course "health promoting program for T2DM patients" throughout the year. It was comprised of 20 classes which combined theoretical and clinical aspects of T2DM management. Each lesson dedicated 1.5 hours to a didactic lecture followed by 1.5 hours of a clinical theme and practice. The educational themes included knowledge on diabetes from biochemistry (3 lessons), physiology (2 lessons), pathology (2 lessons) and pharmacology aspects of the illness (3 lessons). Students studied the concept of stress (2 lessons), stress related depressive and anxiety symptoms (2 lesson), concepts of physical activities in and outdoors (3 lessons), T2DM diet and recommended eating habits (3 lessons). The clinical themes and practices included teaching empathic skills, such as listening and reflecting; learning stress management skills, such as breathing relaxation and mindfulness techniques. Students were urged to practice physical activities with the patients.

Each student met once a week for 50-60 minutes with 2-3 patients, of whom they were in charge. A meeting consisted of medication management, emphatic listening, and practicing skills learned in class. Following their weekly meeting with the patients, students submitted a written report summing up their thoughts, and emotional difficulties regarding the meetings with each patient.

Participant Recruitment and Eligibility

T2DM patients (n=135) were recruited through primary care clinics in the southern part of Israel. Inclusion criteria consisted of patients with uncontrolled type 2 diabetes (HbA1c>7%), Hebrew speaking, able to walk at least ten minutes in continuum. Exclusion criteria consisted of confused patients, patients reluctant to participate or patients with axis I psychiatric disorders.

Upon their acceptance to participate, patients were randomly allocated either to the described intervention group (IG, n=61) or to a control group (CG, n=74) that received usual care. In the study group, each patient attended 20 meetings. Patients in the CG received regular care.

The institutional review board at Soroka University Medical Center, Beer-Sheva, Israel, approved the study. All participants gave written informed consent for participation in the study, upon the knowledge that they participate on a voluntary basis and may leave the study at any point in time

Project 1

Examined the impact of IG vs CG (control group) provided by pharmacy students on patients' HbA1c levels.

A total number of 67 patients comprised the sample. 35 were in the study/ integrative-care group (IG), 32 patients comprised the control group (CG). Women accounted for 60% of the sample. The average age of participants was 57 years (SD=9). About 80% of the participants accomplished eight years of elementary school education. Dropout rate was 25% in the IG and 37% in the CG.

Procedure

The data collection was taken from patients' medical files at 3 measuring timepoints: time 1 (t1): pre-intervention-before students met the patients, time 2 (t2): after half a year of meeting with the students, and time 3 (t3): after one year.

Measures

Physiological measure: HbA1c levels measured at t1, t2, and t3. Values were taken from the patients' medical files.

Data analysis

Repeated measures were conducted. Two independent variables were used: group (IG vs. CG) X time (within-subject; t1, t2 and t3). The dependent variable was the physiological parameter (HbA1C).

Results

Table 1 shows the mean values of HbA1c.

Table 1. *Patients' HbA1C values: IG and CG Means and Standard Deviations.*

Group	Time-1 (t1)	Time-2 (t2)	Time-3 (t3)
IG	9.40 (1.39)	8.44 (1.53)	8.28 (1.41)
CG	9.20 (1.32)	9.30 (1.61)	9.67 (1.31)

Results indicate a significant main effect of the time points $F(2,88) = 3.92$, MSe = 0.58, $p < 0.05$, $\eta_p^2 = 0.08$ (not shown in Table 1), as the HbA1c level decreased from t1 to t2 and from t1 to t3. More importantly, the interaction between group and time was significant, $F(2,88) = 12.85$, MSe = 0.58, $p < 0.05$, $\eta_p^2 = 0.23$ (not shown in Table 1). Lower levels of HbA1c were observed in t2 and t3 only among patients in the IG.

Planned comparisons in the intervention group, IG, showed a statistically significant decrease of HbA1c levels between t1 and t2, $F(1,44) = 19.46$, MSe = 0.62, $p < 0.00$, $\eta_p^2 = 0.44$, and between t1 and t3, $F(1,44) = 29.17$, MSe = 0.56, $p < 0.00$, $\eta_p^2 = 0.66$. (not shown in Table 1).

By contrast, in the control group, no statistically significant differences were found between t1 and t2 ($F < 1$). Between t1 and t3 $F(1,44) = 3.68$, MSe = 0.56, $p = 0.05$, $\eta_p^2 = 0.10$ (not shown in Table 1). Higher levels of HBA1c were observed at t3 indicating aggravation of the metabolic control (see Figure 1).
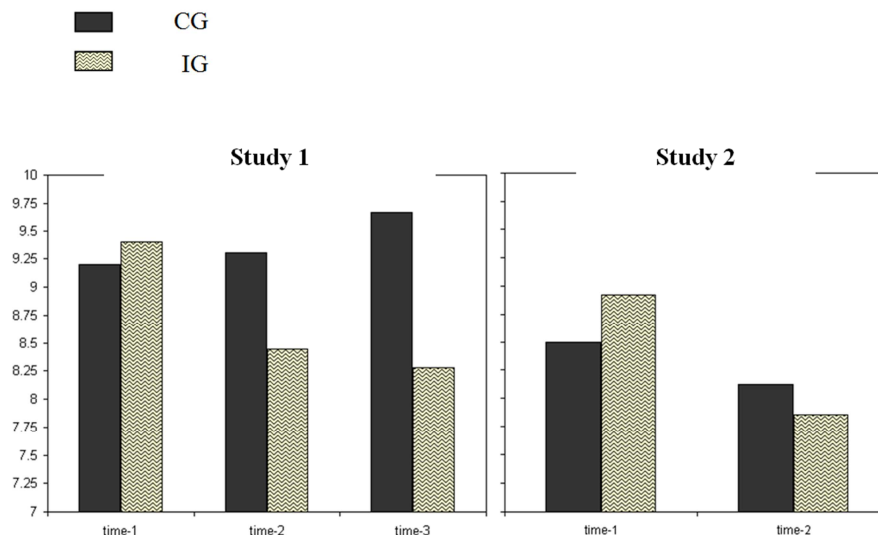

Figure 1. *HbA1C mean levels at time-1, time-2 and time-3 in two projects/studies: IG and CG.*

In sum, the results above show a significant decrease in HbA1c values in patients with diabetes under student care. The improvement achieved at t2 was preserved throughout the year. This pattern was not observed in the control group.

Project 2

Examined the impact of IG vs CG provided by pharmacy students on patients' HbA1c levels and on subjective rating of quality of life (WHOQOL-Bref).

Participants

A total number of 68 patients comprised the sample: 26 patients participated in the study/ integrative-care group (IG), 42 patients comprised the control group (CG). Women were 50% of the sample. The average age of participants was 58 years (SD=9). About 80% of the participants accomplished eight years of elementary school education. Dropout rate was 11% in the IG and 12% in the CG.

Procedure:

The physiological data were taken from patients' medical files at two measuring time points t1: pre-intervention-before students met the patients, t2: after one year. The psychological measure of QOL was collected at the same measuring points.

Measures

Physiological measure: HbA1c levels were measured at t1 and t2. Values were obtained from the patients' medical files.

Psychological measure: WHOQOL-Bref (The World Health Organization Quality of Life) self-report questionnaire [26] is an instrument that conceptually fits with the WHO definition of QOL. The WHOQOL-BREF is grouped into four domains of QOL (physical health, psychological health, social relationships, and environment), and two items which measure overall QOL and general health. Each of the two items can be answered on a 5-point Likert scale ranging from 1 (not at all) to 5 (completely). The respondents express to what extent they experienced the items in the preceding 2 weeks. The WHOQOL-Bref internal

consistency, as measured by Cronbach's α, is 0.80 for physical health; α=0.73 for psychological health; α=0.72 for social relationships and environment dimension. A previous study reported similar values [27].

Data analysis

The authors conducted general linear model-repeated measures ANOVA. Two independent variables were used; group (IG vs. CG) X time (within-subject; t1 and t2). The

dependent variables consisted of physiological parameter (HbA1C) and psychological parameter (QOL).

3. Results

The means and SD of the HbA1C and QOL measures are presented in Table 2.

Table 2. *Patients HbA1C values and WHOQOL-Bref values: IG vs. CG Means and Standard Deviations (n=36).*

	IG		CG	
	t1	t2	t1	t2
HbA1C	8.92 (1.30)	7.86 (1.36)	8.50 (1.72)	8.12 (1.37)
Physical health	12.45 (2.69)	12.96 (2.92)	13.51 (3.27)	12.85 (2.78)
Psychological health	13.37 (1.80)	14.66 (2.47)	14.03 (2.21)	14.10 (2.61)
Social relationships	13.91 (3.51)	13.33 (3.87)	14.14 (3.39)	13.05 (3.79)
Environment	14.41 (2.62)	14.4 (1.79)	13.93 (2.05)	13.80 (2.23)

HbA1C: Two way ANOVA showed a statistically significant effect for time $F(1,68) = 24.08$, MSe = 16.36, $p < 0.05$, $\eta_p^2 = 0.26$ (not shown in Table 2). HbA1C values decreased between t1 and t2. More importantly, the interaction between group and time was statistically significant $F(1,68) = 5.43$, MSe = 3.69, $p < 0.05$, $\eta_p^2 = 0.07$ (not shown in Table 2). Planned comparison showed that patients within the IG had a statistically significantly improvement in their HbA1C values in t2 $F(1,68) = 13.54$, MSe = 0.67, $p < 0.00$, $\eta_p^2 = 0.29$, compared to patients in the CG $F(1,68) = 4.84$, MSe = 0.67, $p < 0.05$, $\eta_p^2 = 0.07$ (not shown in table 2). The effect size in the IG is strong $\eta_p^2 = 0.29$ whereas the effect size in the CG is rather low $\eta_p^2 = 0.07$.

To further examine the decrease of HbA1C between groups, a new variable which presents the change between t1 to t2 was created. T-test analysis for independent samples showed a statistically significant effect between groups presenting a higher decrease within the IG compared to CG (t (68)=2.33, $p < 0.05$).

Quality of life: as presented in the data analysis section, a

2 (group) X 2 (time) ANOVA for the equated measure of the four domains of the WHOQOL-Bref was computed. Only the physical health domain interacted with time and group, $F(1,49) = 4.49$, MSe = 1.60, $p < 0.05$, ηp2 = 0.08 (not shown in table 2). Further analysis showed, while no difference was observed in the subjective rating of physical health in the CG patients [$F(1,49) = 1.18$, MSe = 1.60, ns.], a significant increase in the subjective rating of physical health was observed in the IG, [$F(1,49) = 4.95$, MSe = 1.60, $p < 0.05$, ηp2 = 0.09], (not shown in Table 2). It should be noted, although the psychological well-being did not show significant interaction between group and time ($F(1,49) = 2.89$, MSe = 6.04, p=0.09, ηp2 = 0.06), planned comparison showed a significant increase in the psychological well-being for the IG group but not for the CG ($F(1,49) = 4.79$, MSe = 2.08, p<0.05, ηp2 = 0.09 and F < 1; respectively). The other two domains regarding social and environment well-being were not statistically significant (in both F<1. See values of the domains in Figure 2).
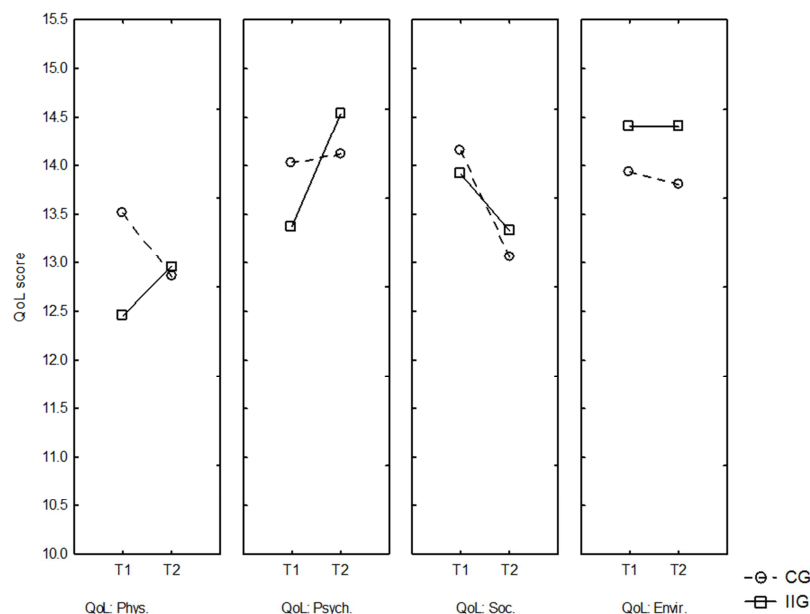

Figure 2. *WHOQOL-BREF scores for the IG and CG patients, before and after intervention.*

4. Discussion

Two prospective interventional projects were conducted in the community among T2DM patients with poor metabolic control by pharmacy students. The results pointed to a significant decrease in HbA1c values of participating patients. A reduction in HbA1C levels was observed after half a year (project 1) and metabolic control was maintained throughout the rest of year (project 1 & 2). This pattern was observed in the study group but not in the control group. Findings from project 1 demonstrate that physiological changes occurred within six months and continued for one year. Findings from project 2 added the important changes in physical health domain reported by the patients.

Several possible explanations for the above findings follow: The first and second explanations focus on the type and length of the intervention. Duke et al [28], in their review, raised a question regarding the effectiveness of short term individual patient education on metabolic control, diabetes knowledge, and psychosocial outcomes in comparison to usual care. In nine of their reported studies, T2DM patients received individual face-to-face patient education, while patients in the control group received usual care, routine treatment, or group education. Duke et al concluded that individual education did not significantly improve glycemic control [28].

As previously noted, individuals with diabetes find it difficult to adhere to a different lifestyle and implement behavioral and psychological changes necessary to promote effective management of diabetes [29]. Our findings showed HbA1c levels decreased after six months. This improvement was preserved in the subsequent months. In all probability, acquiring and practicing new health behaviors takes time and is manifested in the reduction of metabolic values. As findings from another study have pointed out, changes in nutrition and exercise are achieved after an intensive and consistent follow up routine [30]. It is possible that the studies, analyzed by Duke et al [28], lack to achieve metabolic improvement due to the relatively short time intervention span.

A previous study shows, helping individuals manage their diabetes more effectively is conducted by interventions that attempt to increase motivation to change and remove barriers and ambivalence [29]. It is possible that once patients knew they were under observation, they paid more attention to themselves and managed themselves better. The majority of patients had poor educational backgrounds and less knowledge of promoting health behaviors. It is possible that being under observation led to better awareness, behavioral change, and better metabolic control.

A third possible explanation focuses on the care takers' identity, the future health professional. Findings from previous psycho-educational studies, conducted among T2DM patients by different health professionals in different countries, pointed to a significant reduction in HbA1c values, regardless the identity of the carer: a reduction was reported among T2DM patents who received psychosocial care from nurses [31] and pharmacists [16, 32]. In the current study, the future health professionals, i.e., the pharmacy students intervened with T2DM patients on a monthly basis and helped them to practice new behaviors. Findings from previous studies show that students with high motivation and availability formed meaningful relationships with patients [33, 34]. It is possible to attribute the improvement of the patients' metabolic rates to the availability and care of the pharmacy students.

A noteworthy point in the second project — two domains of quality of life, physical health and psychological wellbeing, improved only among patients participating in the intervention group. These results corroborate findings from another study which reported improvement in metabolic rates, physical and emotional quality of life among individuals at risk for diabetes [35].

The limitations of the study need to be mentioned as well. The first limitation is the relatively small sample size. Larger samples of T2DM patients in the community are needed to evaluate the associations between practice of health behaviors and improvement of metabolic control and quality of life. The second limitation - the sample consists of patients with poor educational backgrounds. It is possible that patients coming from higher educational backgrounds need less professional care and a shorter intervention. Future studies are called for to assess the impact of socio demographic variables on the improvement of aspects of quality of life and metabolic control. Another limitation lies in the fact that, although this study used basic measures of diabetes, other measures should be considered, such as blood pressure and liver function tests. Future intervention studies should consider the addition of these measures The last limitation - patients in the intervention group may have improved due to the pharmacy students' motivation and relations, and not only because the patients practiced health promoting behavior. Future study should add another control group of home visits without the component of teaching and practicing new health related behaviors.

5. Implications for Diabetic Educators

The promotion of glycemic control and quality of life of T2DM patients generates significant health interest.

In recent decades, a shift in the classical occupation of pharmacists occurred. The pharmacist is now viewed as a therapist and part of the medical team [36, 37], as such, his duties include: dispensing drugs, advising patients and teams, educator, mentor, follow up, and patient feed-back, especially for the chronic patients such as patients with T2DM. Educational efforts to socialize pharmacy students into integrative-therapeutic roles, reflect the continual process of change within the pharmacy profession. An implementation and integration of academic courses could

improve the academic curriculum and raise awareness levels in the treatment of T2DM patients.

6. Conclusions

To summarize, this paper concludes that integrative intervention by pharmacy students decreases HBA1c levels and improves aspects of quality of life among T2DM patients. Practically pharmacy students play an important role in bridging the gap between physician recommendations and patients' optimal metabolic-control, by conducting continuous psycho-educational interventions.

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