



Adherence to self-care practices and empowerment of people with diabetes mellitus: a randomized clinical trial*

Adesão e empoderamento de usuários com diabetes mellitus para práticas de autocuidado: ensaio clínico randomizado

Adhesión y empoderamiento de usuarios con diabetes mellitus para prácticas de autocuidado: ensayo clínico randomizado

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ABSTRACT

Objective: To evaluate adherence to self-care and glycemic control and empowerment of people with diabetes mellitus in group education. **Method:** Cluster-randomized clinical trial, with participants with type 2 diabetes mellitus. All people in the sample were linked to Family Health Strategy Units from Divinópolis, state of Minas Gerais, Brazil, during 2014 and 2015. Data regarding adherence to self-care practices, empowerment and glycated hemoglobin were collected for comparison of groups in the baseline and of intergroup results before and after interventions. The chosen level of significance was 0.05. **Results:** The sample had 183 people, with 72 in the intervention group and 111 in the control group. A statistically significant decrease (< 0.001) in the value of glycated hemoglobin and an increase in the scores of adherence to self-care and empowerment scales were found for participants in the intervention group (< 0.001). **Conclusion:** Group education caused an increase in the scores of the scales of adherence to self-care practices and empowerment, in addition to an improvement in glycemic levels, as shown by glycated hemoglobin results. Brazilian Registry of Clinical Trials: RBR-92j38t.

DESCRIPTORS

Diabetes Mellitus; Self Care; Health Education; Public Health Nursing.

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INTRODUCTION

Type 2 diabetes mellitus is a health problem worldwide because of its high morbimortality rates, resulting from a sedentary lifestyle, inappropriate dietary habits, obesity, and ageing⁽¹⁻²⁾.

One of the ways to control diabetes is through health education to change behaviors. Education practices to achieve this goal have been reported in several studies. A survey carried out with 150 people in Londrina with diabetes mellitus type 2, state of Paraná, compared the effectiveness of two education strategies and showed that group education had a positive impact on self-care and glycemic control⁽³⁾.

A randomized clinical trial developed in an outpatient clinic in a public hospital in Belo Horizonte, state of Minas Gerais, revealed a statistically significant difference in the glycosylated hemoglobin indexes of people that joined group education⁽⁴⁾. A meta-analysis of randomized clinical trials examined 21 international studies and concluded that group education practices oriented to self-care in diabetes may result in improvements in clinical and psychosocial aspects and lifestyle⁽⁵⁾.

Education practices in this area are based on a dialogical approach, with the exchange of experiences and qualified listening. They are considered an environment in which people can express their doubts, feelings, and complaints, developing confidence and autonomy to make decisions consciously to meet the goal to keep their self-care together with a healthy dietary plan and the practice of physical activities^(3,6-7).

Taking that into account, the Federal University of Minas Gerais and the Family Health Strategy Units in the city of Divinópolis systematized an education practice oriented to people with type 2 diabetes mellitus to increase adherence to self-care practices and empowerment of patients with this disease and consequently help them obtain a better glycemic control. The objective of the present study was to evaluate the adherence and empowerment shown by people that engaged in these group activities.

METHOD

The present study is a cluster-randomized clinical trial carried out with people with type 2 diabetes mellitus from eight Family Health Strategy Units in a city in the state of Minas Gerais. The clusters allowed a randomization by groups of people and, in this particular case, by health units, which reduced the chances of contamination by contact between people from control and intervention groups⁽⁸⁾. The software R was used to obtain several combinations of health units until two homogeneous groups regarding glycosylated hemoglobin and level of education were obtained.

The initial sample had 200 patients, among whom 78 were selected in three health units allocated in the intervention group (IG) and 122 in five health units that were part of the control group (CG). Inclusion criteria were being between 30 and 79 years old, being available to

attend the education group sessions and having a phone number to be contacted.

Users from the intervention group participated in seven group meetings, each one lasting around two hours, totaling 14 hours of interaction. The set of sessions encompassed three cycles of activities: the two first cycles took three meetings and the last one demanded only one meeting. A three-month interval was standardized between adjacent cycles.

All the education practices employed with patients in the intervention group were guided by the empowerment approach, based on the Behavior Change Protocol. This set of rules presents five steps to encourage people with diabetes to think about their condition through a logical sequence of topics: 1) problem definition; 2) identification and handling of feelings; 3) definition of goals; 4) elaboration of a care plan to achieve these goals; 5) evaluation and experiences of the patients about the care plan⁽⁹⁾.

During the period that preceded the group meetings, activity protocols were designed, encompassing the steps of the Behavior Change Protocol and other contents related to diabetes. With the use of group dynamics and materials adapted to education practices, different subjects were addressed, such as feelings and issues related to diabetes, nutrition, practice of physical activity, possible complications, and main difficulties in health care. Even with these predefined topics, the discussions included the participants' interests.

The main theme of the first meeting of cycle 1 was feelings, problems, and meanings of patients before the confrontations demanded by diabetes. In the second meeting, the focus was diet, food frequency, quality of meals and ingestion of fibers. Practice of physical activity occupied the last session of cycle 1.

The first meeting of cycle 2 resumed discussions and patients' experiences in the first cycle and allowed new reflections on feelings and meanings related to the condition to bring up the difficulties that these people face routinely. To fulfill a demand of the participants, the second meeting addressed the main complications caused by the disease and care with feet. The third meeting was dedicated to the discussion of general health care and the resumption of the main points to implement self-care practices.

In accordance with the third step of the Behavior Change Protocol, in the end of each meeting, the patients were encouraged to define goals that they considered important to change their habits and design a care plan aligned with their routine to improve self-care.

Cycle 3 was executed as one single meeting and took place after the last data collection stage. This session was reserved to hand exam results in and discuss them with each patient, which provided a comparison between the results found before the group sessions and the outcomes registered after people joined the program. This conversation aimed to encourage patients to think about and evaluate behaviors

that changed throughout the education practices to meet the proposed goals. In addition, this moment was used to clarify doubts, guide on the care continuity in respective health units, thank and say goodbye.

The education process took place through a dialogical approach, with qualified listening and reflection on the problems experienced by each patient living with diabetes. By following the steps of the Behavior Change Protocol, people could make decisions consciously and independently about their health care and determine and meet goals based on a care plan compatible with their life context, which allowed adherence and empowerment to execute self-care practices. This protocol is centered on patients and questions related to their routine, such as feelings, barriers that have to be overcome to keep self-care, achievement of goals, and search for solutions to problems⁽¹⁰⁾.

Between consecutive cycles, the patients received a phone call that lasted around 20 minutes. The objective of this contact was to encourage them to keep the self-care practices that were established during the elaboration of the goals list.

The patients in the control group were monitored by the Family Health Strategy teams, participating in individual and collective education practices already implemented in the daily care offered in these units. In addition, these people received two phone calls, one before cycle 1 and another after cycle 3, to collect data to fill out the instruments applied in this survey and keep these participants connected with the team that conducted the research. At each cycle, people in this group received informative leaflets about diabetes, with tips on food and physical exercises, and clarification on complications and the importance to take the prescribed medication.

Data collection used the validated instruments of adherence to self-care practices for diabetes mellitus (ESM) and empowerment for self-care in diabetes mellitus, short version (Diabetes Empowerment Scale-Short Form – DES-SF), and was complemented by blood samples for assessment of glycated hemoglobin.

The ESM instrument evaluates adherence of patients with diabetes to self-care practices. It has a total score of 8 points and encompasses questions about self-care activities, food and physical exercise in the past seven days. A minimum score of 5 points is necessary to indicate an improvement in adherence to self-care practices⁽⁴⁾.

The instrument DES-SF has domains that take into consideration the psychosocial aspects of diabetes, dissatisfaction management, readiness to changes and the establishment and achievement of goals. It has eight closed-ended questions that can be answered with the help of a 5-point Likert scale that ranges from “significant disagreement” to “significant agreement”. Scores varied from 1 to 5 points for each question and the total value was calculated by averaging the points of each of the eight items. The higher the total score, the higher

the patient’s empowerment. A score between 3.8 and 5 is considered high, values between 2.4 and 3.7 are classified as intermediate and an outcome between 1 and 2.3 is labeled low⁽¹¹⁾.

The assessment of glycated hemoglobin (HbA1c) was performed through ion-exchange chromatography⁽¹²⁾, the most used method to quantify this substance currently, recommended by national and international diabetes associations⁽¹⁻²⁾. Values of HbA1c lower or equal to 7% were considered as an indicator of glycemic control. Patients were contacted previously and oriented to go to a laboratory to have their blood samples collected. This exam was done before and after the set of cycles.

It is worth mentioning that the instruments ESM and the Brazilian version of DES-SF were filled out by the patients before cycle 1 and after cycle 3 through a phone call. Each contact lasted approximately 15 minutes and the answers were registered in the online tool e.surv.

Data analysis was run by the software Statistical Package for the Social Sciences® (SPSS), version 20.0. A descriptive analysis was performed, with the calculation of frequencies and measurements of central tendency and dispersion. The Shapiro-Wilk test was applied to check the normality in the distribution of the continuous variables.

Student’s t-test and Mann-Whitney U test were applied to compare means and medians of independent variables, respectively. For comparison of proportions, Pearson’s chi-square test was used. Last, to evaluate the effectiveness of the intervention, paired Student’s t-test and Wilcoxon test were applied to compare means and medians, respectively.

For the variables glycated hemoglobin, self-care, and empowerment, the effect of the experiment was defined as the difference between their values after the cycles and the values before the cycles (Δ) shared by the initial value. The results were multiplied by 100 to be converted into percentages. In all analyses, a level of confidence of 95% was used ($p < 0.05$).

The study was approved by the Research Ethics Committee of the Federal University of Minas Gerais, Brazil, under protocol n. 426.968/2013. All the participants that agreed to join the survey signed the free and informed consent form. The registry number in the international clinical trial database was NCT02132338 and in the national registry the identification was RBR-92j38t.

RESULTS

After randomization, the intervention group (IG) consisted of 78 patients and the control group (CG) had 122 people originally. A few issues caused the total number of participants to be reduced to 183, 72 in IG and 111 in CG.

Figure 1 shows a flowchart with the phases of the randomized clinical trial, in accordance with the guidelines for this type of study⁽¹³⁾.

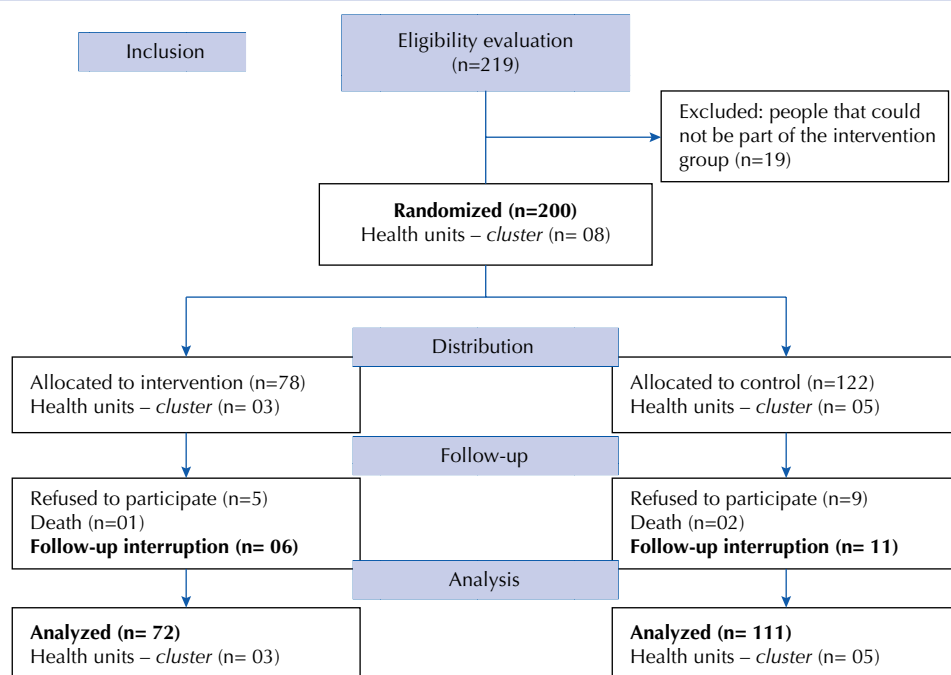


Figure 1 – Flowchart of the allocation of clusters and patients in the phases of the randomized clinical trial - Divinópolis, Minas Gerais, Brazil, 2016.

Most losses in the sample were justified by a lack of interest to continue in the study, but there was not a statistically significant difference regarding gender, age, level of education and HbA1c levels between the people that left the trial and those who remained ($p > 0.05$).

The results revealed that patients in IG and CG were homogeneous in the baseline regarding sociodemographic characteristics, such as gender, level of education, marital status and occupation, glycated hemoglobin levels and the answers to the two questionnaires. These characteristics are gathered in Table 1.

Table 1 – Distribution of sociodemographic variables, HbA1c levels and questionnaire answers of the participants of the trial - Divinópolis, Minas Gerais, Brazil, 2016.

Variable	Mean \pm SD or Median (min. – max.)		p^*
	IG (n=72)	CG (n=111)	
Age (mean \pm SD)	60.4 \pm 8.0	57.5 \pm 9.7	0.033
Gender (N(%))			
Male	27 (37.5)	38 (34.2)	0.652
Female	45 (62.5)	73 (65.8)	
Level of education (N(%))			
Up to incomplete elementary school	52 (72.02)	73 (65.8)	0.359
Complete elementary school to graduate course	20 (27.8)	38 (34.2)	
Marital status (N(%))			
No partner	53 (73.6)	87 (78.4)	0.457
Has a partner	19 (26.4)	24 (21.6)	
Occupation (N(%))			
Active	26 (36.1)	55 (49.6)	0.074
Inactive	46 (63.9)	56 (50.5)	
Diabetes time (N(%))			
\leq 5 years	28 (38.9)	21 (18.9)	0.003
$>$ 5 years	44 (61.1)	90 (81.1)	
HbA1c	8.3 (5.7-13.1)	7.9 (5.0-14.4)	0.083
MHN	3.5 (1.2-7.5)	3.3 (1.0-6.8)	0.158
DES-SF	3.7 (2.7-4.7)	3.6 (2.7-4.7)	0.903

SD: standard deviation. *Student's t-test or chi-square test.

CG: control group; IG: intervention group; HbA1c: glycated hemoglobin; MHN: self-care questionnaire for people with type 2 diabetes; DES-SF: Portuguese version of empowerment questionnaire for people with type 2 diabetes, short version.

The age of the participants varied from 31 to 76 years, with an average of 58.6 years \pm 9.2 standard deviations (SD). Most (64.5%) were women and declared to have diabetes for over five years ($n=134$). More than three fourths (140 or 76.5%) lived with a partner, almost half (90 or 49.18%) had incomplete elementary school and 44.8% considered themselves inactive, that is, had no paid occupation. The sociodemographic characteristics

of the patients included in this study are presented in Table 1.

There was a statistically significant difference in the average level of HbA1c after the intervention with people in IG ($p < 0.05$). The opposite was observed for the results of the participants in CG ($p > 0.05$). These data are shown in Table 2. The difference between the medians Δ HbA1c was statistically significant ($p < 0.001$), as exhibited in Table 3.

Table 2 – Intragroup comparison of HbA1c levels and questionnaire answers in the baseline after intervention - Divinópolis, Minas Gerais, Brazil, 2016.

Variables	IG			CG			p^*
	Ti Median (min. and max.)	Tf Median (min. and max.)	p^*	Ti Median (min. and max.)	Tf Median (min. and max.)	p^*	
HbA1c	8.3 (5.7-13.1)	7.4 (5.2-11.9)	<0.001	7.9 (5.0-14.4)	8.1 (4.9-13.9)	0.296	
MHN	3.5 (1.2-7.5)	4.1 (1.7-6.2)	<0.001	3.3 (1.0-6.8)	3.3 (1.2-6.1)	0.970	
DES-SF	3.7 (2.7-4.7)	4.1 (2.7-4.9)	<0.001	3.6 (2.7-4.7)	3.9 (2.5-4.9)	<0.001	

*Wilcoxon test for intragroup comparison (before and after period of study).

CG: control group; IG: intervention group; Ti: initial time; Tf: final time; HbA1c: glycated hemoglobin; MHN: self-care questionnaire for people with type 2 diabetes; DES-SF: Portuguese version of empowerment questionnaire for people with type 2 diabetes, short version.

Regarding adherence to self-care practices, evaluated through the application of MHN, there were statistically significant results in the comparison of the periods pre- and post-education in IG (Table 2), evidenced by an increase in its average score ($p < 0.05$). The other group behaved differently. The intergroup score difference for the

MHN questionnaire was statistically significant ($p < 0.05$, Table 3). Last, the findings about the DES questionnaire revealed that there was a statistically significant increase in the score in both groups ($p < 0.05$, Table 2) and no statistically significant difference was measured between them ($p=0.159$).

Table 3 – Intergroup comparison for Δ HbA1c, Δ MHN and Δ DES-SF - Divinópolis, Minas Gerais, Brazil, 2016.

Variables	IG	CG	IG - CG
	Median Δ (min.; max.)	Median Δ (min.; max.)	p^*
HbA1c	-6.36 (-40 ; 32.94)	0 (-45.87 ; 90.42)	<0.001
MHN	17.92 (-57.01 ; 284.48)	0 (-61.54 ; 435)	0.026
DES-SF	11.62 (-21.43 ; 44.08)	9.27 (-42.66 ; 59.09)	0.159

*Mann-Whitney test for intergroup comparison.

CG: control group; IG: intervention group; HbA1c: glycated hemoglobin; MHN: self-care questionnaire for people with type 2 diabetes; DES-SF: Portuguese version of empowerment questionnaire for people with type 2 diabetes, short version.

DISCUSSION

The present study revealed favorable outcomes in glycemic control, self-care, and empowerment of patients in the intervention group. The average person with diabetes in this survey was a woman, 58.6 years old, with incomplete elementary school. These results are compatible with the profile of the population with the condition enrolled in Family Health Strategy units in Divinópolis⁽¹⁴⁾.

It is known that glycemic control and behaviors to increase adherence to self-care practices can be influenced by several sociodemographic factors, such as age, gender, cultural and economic aspects and level of education. Both age and low level of education can impact on adherence to self-care practices and empowerment of people with diabetes, given that they can affect the understanding of these

people of their own responsibility in the necessary care to manage this chronic condition daily⁽¹⁴⁻¹⁷⁾.

Most participants declared to live with a partner, a characteristic considered positive because family support can contribute to the execution of healthcare practices⁽¹⁸⁾. As for the time living with the disease, most claimed to have the condition for five years or longer, which increases the chances to develop complications, since the condition duration can be linked to the complications existence⁽¹⁴⁾.

The findings regarding empowerment demonstrated an improvement in people in both groups, which results in an increase in confidence to make decisions and act to manage their condition. Despite the increased score in this variable, CG did not show advances in other monitored aspects, an evidence that the improvement experienced by IG was related to the education practices. Several studies

have shown a relationship between these practices and a reduction in HbA1c levels^(17,19-20). In addition, the empowerment approach in the group meetings was considered a basis for the control and treatment of diabetes, requiring commitment and participation of people with this condition in health care.

In the control of chronic diseases, the empowerment approach has the potential to contribute to improving clinical and psychological outcomes, because it influences and promotes a behavior change towards self-care, as it increases patients' autonomy to deal with their own health issues and needs. In this context, the education practice is relevant, given that it provides knowledge, and awareness of their condition and of the necessary behaviors to control diabetes⁽¹⁹⁻²¹⁾.

As for adherence to self-care practices, the medians of the IG scores increased after the education process, and the comparison between IG and CG revealed a statistically significant difference ($p=0.026$), pointing to an improvement in self-care habits. Contrarily to IG, CG did not present a significant score alteration. These results corroborate a survey⁽³⁾ in the field of supplemental health in which the authors reported an improvement in self-care scores in people that joined group education sessions in comparison with patients that developed individual education practices.

These findings are also remarkable because it has been proven that self-care procedures, together with proper dietary habits and physical activities, bring benefits to patients, once they are fundamental to glycemic control⁽¹⁻²⁾. It is a healthcare professional's responsibility to use tools that allow patients with type 2 diabetes to have knowledge, skills, and attitudes to adhere to self-care practices⁽²²⁾.

The education group sessions affected glycated hemoglobin levels in IG in comparison with CG. The intergroup comparison of the difference in final and initial times ($T_f - T_i$) also pointed to a significant reduction in the concentration of this molecule. This finding reinforces the importance of the education program, given that the patients were homogeneous in the baseline. It is worth emphasizing that glycated hemoglobin is considered a gold standard to determine glycemic control in people with diabetes and was used as a clinical marker in other studies in which empowerment was the philosophical framework for the development of education practice⁽¹⁶⁻¹⁷⁾.

The HbA1c levels obtained in the present trial were compatible with those reported in other publications, evidencing that group education is more effective to reduce HbA1c concentration^(3,16-17,21). In addition, this result is relevant because it has been demonstrated that reduced levels of glycated hemoglobin decrease the occurrence of microvascular lesions and neuropathies⁽¹⁻²⁾.

A recent study carried out in China, similar to the present investigation, reported a significant increase in HbA1c levels and a behavior alteration regarding empowerment and self-care in the participants after the implementation of strategies focused on the patients and on changing their habits⁽²³⁾.

The co-responsibility of patients raised during the group meetings, based on the empowerment philosophy, resulted in positive effects in self-care, empowerment, and glycated hemoglobin indicators in IG patients. According to the results, it is possible to state that the education process allowed to control diabetes and also enhanced the participation of the patients in the management of their condition.

The limitation of the present study is related to the offering of secondary treatment by the health teams to both groups. Most participants needed help to read the questions in the applied instruments for having a low level of education. The periodicity of the meetings with IG patients may have interfered with their willingness and caused some losses throughout the investigation.

CONCLUSION

The group education practice based on the empowerment approach provided the possibility to access new knowledge through the exchange of experiences and an active participation in the learning process, which led to finding new meanings for the experienced realities. The use of the Behavior Change Protocol helped people to recognize the importance and responsibility of their participation in the execution of self-care practices.

The results suggest that the developed education practice was effective, because it brought control and management of type 2 diabetes mellitus, intensified the participation of the patients in managing the disease, and increased empowerment and adherence to self-care practices, especially a healthy diet and the regularity of physical activities, and improved glycemic levels, as shown by glycated hemoglobin results.

RESUMO

Objetivo: Avaliar a adesão e o empoderamento do usuário com diabetes mellitus para as práticas de autocuidado e controle glicêmico na educação em grupo. **Método:** Ensaio clínico randomizado por *cluster*, com a participação de usuários com diabetes mellitus tipo 2. Todos os usuários estavam vinculados às Unidades de Estratégia de Saúde da Família do município de Divinópolis/MG, Brasil, durante os anos de 2014 e 2015. Foram coletados dados com relação à adesão às práticas de autocuidado, ao empoderamento e à hemoglobina glicada para comparação entre grupos na linha de base, assim como comparação entre o antes e o depois intragrupo. Foi considerado um nível de significância de 0,05. **Resultados:** Participaram do estudo 183 usuários, sendo que 72 foram alocados no grupo intervenção e 111 no grupo controle. Os resultados revelaram uma redução estatisticamente significativa ($<0,001$) para o valor de hemoglobina glicada e um aumento dos escores referentes à adesão ao autocuidado e à escala de empoderamento para os participantes do grupo intervenção ($<0,001$). **Conclusão:** Os efeitos da educação em grupo proporcionou o aumento nas escalas da adesão e empoderamento às práticas de autocuidado, além de melhora dos níveis glicêmicos, evidenciada pelos resultados da hemoglobina glicada. Registro Brasileiro de Ensaio Clínicos: RBR-92j38t.

DESCRITORES

Diabetes Mellitus; Autocuidado; Educação em Saúde; Enfermagem em Saúde Pública.

RESUMEN

Objetivo: Evaluar la adhesión y el empoderamiento del usuario con diabetes mellitus para las prácticas de autocuidado y control glucémico en la educación en grupo. **Método:** Ensayo clínico randomizado por *cluster*, con la participación de usuarios con diabetes mellitus tipo 2. Todos los usuarios estaban vinculados a las Unidades de Estrategia de Salud de la Familia del municipio de Divinópolis/MG, Brasil, durante los años de 2014 y 2015. Fueron recogidos datos con relación a la adhesión a las prácticas de autocuidado, al empoderamiento y la hemoglobina glicada para comparación entre grupos en la línea de base, así como comparación entre el antes y el después intragrupo. Fue considerado un nivel de significación de 0,05. **Resultados:** Participaron en el estudio 183 usuarios, siendo que 72 fueron ubicados en el grupo intervención y 111 en el grupo control. Los resultados revelaron una reducción estadísticamente significativa ($<0,001$) para el valor de hemoglobina glicada y un aumento de los scores referentes a la adhesión al autocuidado y a la escala de empoderamiento para los participantes en el grupo intervención ($<0,001$). **Conclusión:** Los efectos de la educación en grupo proporcionaron el incremento en las escalas de adhesión y empoderamiento a las prácticas de autocuidado, además de mejora de los niveles glucémicos, evidenciada por los resultados de la hemoglobina glicada. Registro Brasileño de Ensayos Clínicos: RBR-92j38t.

DESCRIPTORES

Diabetes Mellitus; Autocuidado; Educación en Salud; Enfermería en Salud Pública.

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