Original Article

Educational intervention on description of the insulin delivery technique: randomized clinical trial*

Intervenção educativa sobre descrição da técnica de aplicação de insulina: ensaio clínico randomizado

Tatiana Victória Carneiro Moura[1]
Antonia Fabiana Rodrigues da Silva[1]
Ana Larissa Gomes Machado[1]
Gerdane Celene Nunes Carvalho[2]
Ana Roberta Vilarouca da Silva[1]

*Extracted from the dissertation "Efetividade do suporte telefônico no conhecimento sobre a técnica de aplicação da insulina", Universidade Federal do Piauí, 2019.

[1]Universidade Federal do Piauí.
Picos, PI, Brazil.
[2]Universidade Estadual do Piauí.
Picos, PI, Brazil.

Corresponding author:
Ana Roberta Vilarouca da Silva
Rua Cícero Duarte, 905, Junco
CEP: 64607-670. Picos, PI, Brazil.
E-mail: vilarouca@ufpi.edu.br

ABSTRACT

Objective: to analyze the effect of educational intervention on insulin delivery technique. **Methods:** randomized clinical trial, carried out with 79 patients with Diabetes Mellitus, in two groups, 42 from the control group and 37 from the intervention. Four telephone calls were made in two months to the intervention group. The control group received only conventional follow-up. **Results:** when comparing the application of insulin in the pre and post-test, there was no significant difference (p>0.05) in the control group, but an improvement of 80.0% in the correct answers on the appropriate technique, with p<0.021 . In the intergroup comparison, the description of self-administration of insulin, after the telephone intervention, was better in 70.0% of the items, with p<0.030. **Conclusion:** the educational intervention via telephone improved the description of the technique of insulin application in patients with Diabetes Mellitus and their caregivers. Brazilian Registry of Clinical Trials number U1111-1228-3200.

Descriptors: Diabetes Mellitus; Insulin; Telephone; Motivational Interviewing; Clinical Trial.

RESUMO

Objetivo: analisar o efeito de intervenção educativa via telefone sobre a descrição da técnica de aplicação de insulina. **Métodos:** ensaio clínico randomizado, realizado com 79 pacientes com Diabetes Mellitus, composto por dois grupos, 42 do grupo controle e 37 da intervenção. Realizaram-se quatro ligações telefônicas, em dois meses, para o grupo intervenção. O grupo controle recebeu somente acompanhamento convencional. **Resultados:** ao comparar a aplicação de insulina no pré e pós-teste, não houve diferença significativa (p>0,05) no grupo controle, mas melhoria de 80,0% no acerto das respostas sobre a técnica adequada, com p<0,021. Na comparação intergrupo, a descrição da autoaplicação de insulina, após a intervenção telefônica, foi melhor em 70,0% dos itens, com p<0,030. **Conclusão:** a intervenção educativa via telefone melhorou a descrição da técnica de aplicação de insulina em pacientes com Diabetes Mellitus e respectivos cuidadores. Registro Brasileiro de Ensaios Clínicos número U1111-1228-3200.

Descritores: Diabetes Mellitus; Insulina; Telefone; Entrevista Motivacional; Ensaio Clínico.

Introduction

With the increase in the population's perspective on life, there were changes in lifestyle, such as an increase in Chronic Non-Communicable Diseases, including Diabetes Mellitus. In 2019, 463 million adults worldwide were diagnosed with Diabetes Mellitus, of which 79.0% lived in low and middle income countries[1].

Insulin therapy is one of the main strategies for glycemic control in patients who have the disease. Adequate levels of glycated hemoglobin (HbA1c) are associated with a decrease in disease-related macro and micro vascular complications[2]. With the advancement of technology and the great ease of adhesion to telephone sets, there was also an increase in the use of applications that facilitate communication[3].

Information and communication technologies are considered promising in the field of health promotion, enabling support for self-care, adoption of healthy habits, exchange of information and emotional support. Among these technologies, the use of the telephone, used to make calls, send messages and access information via the internet, stands out for being cost-effective, in addition to being effective in adhesion to treatment[4].

However, the implementation of telephone intervention as an educational practice in Brazil, in the context of Diabetes Mellitus, is recent and has gaps to be filled, to enhance the effectiveness of telephone intervention, as in any educational practice, making it necessary to use adequate instruments and protocols that support the health professional who will make the telephone calls[5].

The telephone intervention, as a health technology in nursing care, can be considered an effective strategy for the user's adhesion to the practice of self-care in patients with Diabetes Mellitus, in even one year of monitoring, as it was found an improvement in self-care about adequate nutrition, regular physical exercise, abstinence from smoking and alcoholism[6]. In addition, other studies have shown that telephone intervention has a positive impact on improving glycohemoglobin and self-care in diabetes[7-9].

From this perspective, diabetes self-management requires awareness of the importance of lifestyle changes, glycemic self-control and insulin administration methods, the most common route being subcutaneous, with different ways of administering it, such as the use of syringes, insulin pens and insulin pumps. However, studies have shown concerns and barriers associated with treatment, particularly regarding errors or inaccuracies associated with injectable therapies[6,10-11].

Therefore, there is a need to use a strategy to overcome these barriers, reducing errors and inaccuracies in the management of insulin therapy that impacts the quality of life of these patients, such as the use of telephone interventions to promote health, as it is simple, comfortable, fast and low cost, in addition to bringing new possibilities for nurses. Thus, the objective was to analyze the effect of educational intervention via telephone on the description of the insulin delivery technique.

Methods

Randomized clinical trial, with Control Group (CG) and Intervention Group (IG), following the Consolidated Standards of Reporting Trials(CONSORT)[12], performed with insulin-dependent patients in Picos, Piauí, Brazil.

The sample, calculated from the formula for comparison studies between groups[13] and added 10.0% more for eventual losses, obtained a total of 84 people, 42 in each group. Patients who self-administered insulin and caregivers responsible for this practice were included. All received insulin at the city's Municipal Health Department and had a landline or cell phone line.

The monitoring offered by the aforementioned city was conducted in a centralized manner, in which patients obtained insulin at the health department and did not receive the care of the health team responsible

for the patient and the patient's living area, impairing the professional's involvement with the patient.

The research was carried out from December 2018 to March 2019. Health professionals were excluded, in addition to patients with cognitive, auditory or speech deficits, informed by the participant/family member. Discontinuity criteria were: not answering calls or non-complementary calls; refuse to continue the research; not responding to the post-intervention instrument or interrupting the use of insulin.

Data collection took place in three phases, in the first, participants were recruited and the study objective and protocol explained (group allocation and telephone calls). Data on patient identification, demographic data and application form were collected, based on the Guidelines of the Brazilian Diabetes Society, for analysis of knowledge about insulin therapy of patients/caregivers, used in the pre and post-test, which contained questions regarding receiving insulin, transporting, storing, using and disposing of the materials used by patients and the correct application technique.

In the second phase, the participants were randomized homogeneously in the IG or GC, using the Research Randomizer program, with allocation secrecy, with each group having a number of caregivers established by the program. The participants of the IG were informed via telephone call, to the cell phone or landline, about the care regarding the handling of insulin and the application technique, according to the guidelines of the Brazilian Diabetes Society[14].

The calls were made on pre-established dates between the researcher and the participant, taking place in a systematic manner with the IG, by the researcher. The intervention was carried out with patients who self-administered insulin and, for those who did not; it was carried out with the person responsible for applying it to the patient (caregiver).

Four telephone calls were made per user, with intervals of fifteen days and a maximum duration of twenty minutes, following a pre-established script for each call. In the first contact, information about care with insulin care and conservation, hand washing; in the second contact, about the techniques for insulin preparation, knowledge of the locations for insulin administration and rotation of regions; in the third contact, information on the technique of insulin application and preparation of the region for insulin application; and in the fourth contact, on the correct way to dispose of the materials used.

The third phase was the application of the post-test in both groups, fifteen days after the last approach to the subject, via telephone intervention. To guarantee the reliability of the data measurement, professionals from the Municipal Health Department were blinded. The data analysis, in turn, was performed by a statistical professional, also blind to the group in which the user had been allocated.

In the statistical analysis of the data, the software R, version 3.5.3, and the Statistical Package for the Social Sciences, version 20 were used. For qualitative variables, absolute (n) and relative (%) frequencies were adopted; and for quantitative: age (years) and family income (R$), mean and standard deviation.

The correct answers of the responses on the insulin delivery technique were compared between and within the groups at the beginning and at the end of the study. In the intragroup analysis, the McNemar test was applied, in the intergroup comparisons, the chi-square test was adopted, both with 0.05 significance level.

The study complied with national and international standards of ethics in research with human beings, according to Resolution 466/12, and was approved by the Ethics and Research Committee of the Universidade Federal do Piauí, Brazil, according to opinion No. 3,018,168/2018 and Brazilian Registry of Clinical Essays No. U1111-1228-3200.

Results

From the initial sample of 84 recruited users, after losses due to discontinuity in the IG, 76 users remained, being 37 in the IG and 42 in the CG (Figure 1).
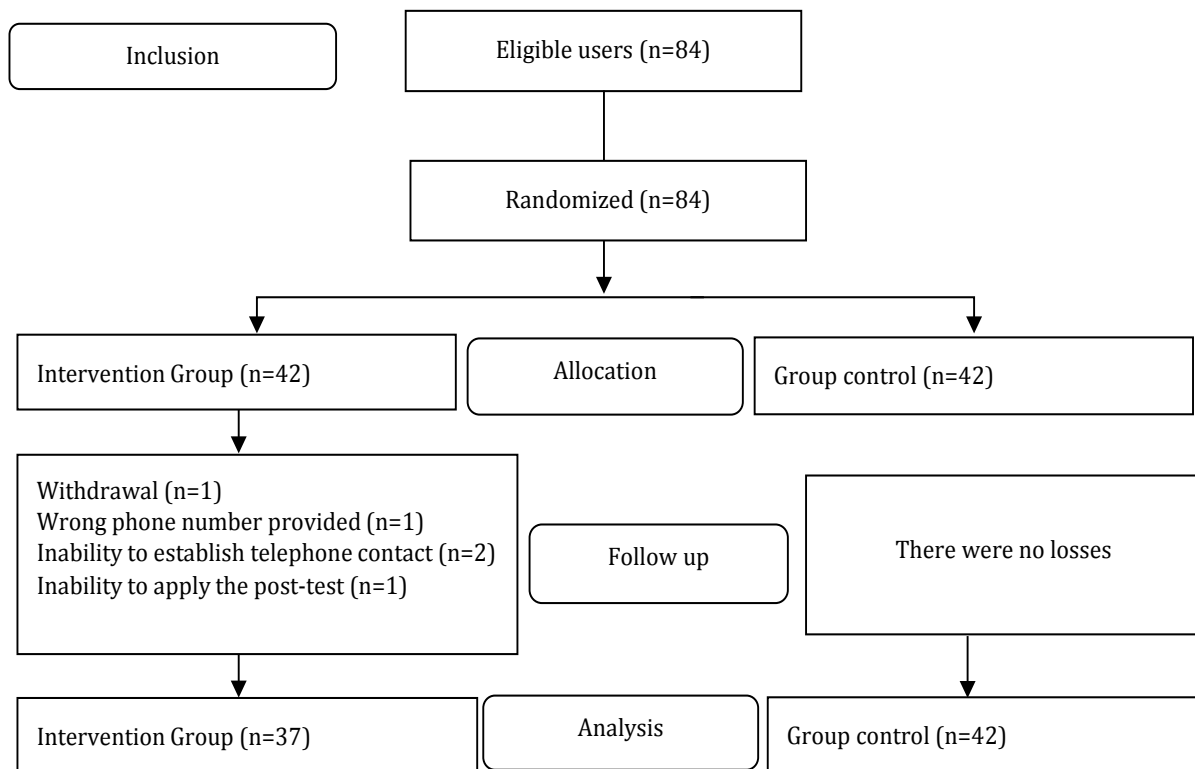
Figure 1 – Flowchart showing the sample's constitution. Picos, PI, Brazil, 2019

The total sample consisted of 79 participants, of whom 27 (34.2%) were participants who applied insulin to patients with diabetes and 52 (65.8%) were self-administered diabetics. The mean age was 53.37 years, with a standard deviation of 13.9, with the majority being female (60.8%), married (53.2%) and without work (62.0%). Most users had complete or incomplete primary education (36.7%), lived with a partner (58.2%), had children (81.0%) and were in economic class C1 (41.8%). With regard to the average monthly income of patients who self-administered insulin, this was R$ 1,439.7 reals, with a standard deviation of R$ 1,068.1 reals. Regarding the type of Diabetes Mellitus, there was a predominance of Type 2 (83.5%) and use of insulin between one and five years (48.5%).

Of the total, 59.6% cited visual problems, mainly cataracts and impaired visual acuity. The 76 said they had another chronic disease, mainly hypertension, hyperthyroidism and dyslipidemia. In the pre- and post-test intragroup analysis, in the CG, there was no significant difference (p>0.05), except for the item: introduces the needle perpendicular to the skin (p=0.004). However, in GI, there was an improvement in the technique of insulin application in 80.0% of the items evaluated, with p<0.021 (Table 1).

In the pre-test intergroup comparison, there was no statistical difference, indicating homogeneity in the description of the application technique between the groups. In the intergroup comparison, post-test, there was a positive effect of the intervention, with statistically significant differences in 70.0% of the items (Table 2).

Table 1 – Intragroup comparison of the described technique of insulin application, in the pre and post-test. Picos, PI, Brazil, 2019

Items	Group control			Intervention group		
	Pre n (%)	Post n (%)	p*	Pre n (%)	Post n (%)	p
Holds the syringe like a pencil	41 (97.6)	41 (97.6)	1.000	37 (100.0)	36 (97.3)	1.000
Cleans the skin with cotton and alcohol	30 (71.4)	32 (76.2)	0.500	25 (67.6)	37 (100)	<0.001
Uses region of the outer and upper arms	27 (64.3)	28 (66.7)	1.000	17 (45.9)	25 (67.6)	0.021
Uses abdominal region	30 (71.4)	32 (76.2)	0.500	28 (75.7)	36 (97.3)	0.008
Uses the front and sides of the thighs	16 (38.1)	17 (40.5)	1.000	20 (54.1)	33 (89.2)	0.001
Uses gluteal region	4 (9.5)	6 (14.3)	0.500	4 (10.8)	13 (35.1)	0.004
Makes a skin fold holding the subcutaneous tissue with the thumb and middle fingers	34 (81.0)	37 (88.1)	0.453	33 (89.2)	37(100.0)	0.125
Insert the needle perpendicular to the skin	32 (76.2)	41 (97.6)	0.004	27 (73.0)	37(100.0)	0.002
When finishing the application, remove the needle and apply light pressure on the area with cotton, without massaging	15 (35.7)	14 (33.3)	1.000	19 (51.4)	36 (97.3)	<0.001
After using the material, throw it in the trash inside polyethylene terephthalate (soda) bottles	15 (35.7)	18 (42.9)	0.375	10 (27.0)	36 (97.3)	<0.001

*McNemar's exact test

Table 2 – Pre-and post-test intergroup comparison of the description of the insulin delivery technique. Picos, PI, Brazil, 2019

Items	Pre-test			Post-test		
	Group control n (%)	Intervention group n (%)	p*	Group control n (%)	Intervention group n (%)	p
Holds the syringe like a pencil	41(97.6)	37 (100.0)	0.345	41(97.6)	36(97.3)	1.000
Cleans the skin with cotton and alcohol	30(71.4)	25 (67.6)	0.710	32(76.2)	37 (100.0)	0.020
Uses region of the outer and upper arms	27(64.3)	17 (45.9)	0.102	28(66.7)	25 (67.6)	0.932
Uses abdominal region	30(71.4)	28 (75.7)	0.670	32(76.2)	36 (97.3)	0.007
Uses the front and side of the thighs	16(38.1)	20 (54.1)	0.155	17(40.5)	33(89.2)	<0.001
Uses gluteal region	4(9.5)	4 (10.8)	0.850	6 (14.3)	13(35.1)	0.030
Makes a skin fold holding the subcutaneous tissue with the thumb and middle fingers	34(81.0)	33 (89.2)	0.309	37(88.1)	37 (100.0)	0.030
Insert the needle perpendicular to the skin	32 (76.2)	27 (73.0)	0.743	41(97.6)	37 (100.0)	0.345
When finishing the application, remove the needle and apply light pressure on the area with cotton, without massaging	15 (35.7)	19 (51.4)	0.161	14(33.3)	36(97.3)	<0.001
After using the material, throw it in the trash inside polyethylene terephthalate (soda) bottles	15 (35.7)	10 (27.0)	0.407	18(42.9)	36(97.3)	<0.001

*Chi-square test

Discussion

This study has limitations as the short follow-up period, as it is a clinical trial conducted in four months, in addition to the inhomogeneity of the target audience, the lack of blinding of the researcher, as the performance of the interventions required that he knew who composed each group. Despite this, the study presents contributions, such as the ease of providing access to information to the patient; the new possibility of action for nurses, which can be a complementary strategy in nursing care; and strengthening the bond between professional and patient.

Thus, this study corroborates research that applied telephone intervention with diabetics, which obtained satisfactory results, showing that the participants showed improvements in knowledge, in the practice of self-care and satisfaction with the calls, with the expectations met[15-17].

In contrast, a study with people with type 2 Diabetes Mellitus, monitored for four months by phone, found no improvement in the glycemic profile, but considered this technology a good option for monitoring and monitoring people with Diabetes Mellitus, bringing users and the health team closer, improving self-care to prevent possible damage related to Diabetes Mellitus and insulin therapy[16].

In a study aimed at evaluating the effect of telephone support on the metabolic control of elderly people with Diabetes Mellitus, small changes were observed in the results of patients who received these calls, comparing them with those who did not receive any intervention. However, a significant increase was noted when the fasting blood glucose variable was assessed[18].

A study that analyzed the effect of telephone interventions on the self-care of diabetic people, in line with the findings of this study, showed that educational interventions with this type of strategy are an effective alternative to inform patients about diabetes care, assist in the decrease or maintenance of HbA1c levels and other parameters for metabolic function[8].

Another study analyzed the effect of personalized nursing, face-to-face and telephone counseling on cardiovascular risk factors for seven months, and found that women showed a significant increase in the components of mental and physical health, weight loss, abdominal circumference, total cholesterol and lipoprotein cholesterol, making this intervention an effective strategy for controlling three cardiovascular factors and improving quality of life[19].

Similar intervention to the present study, three connections were made with guidance on exclusive breastfeeding to mothers in postpartum and observed similar results in the two groups up to 15 days after delivery, however, it showed a difference in the duration of breastfeeding of the two groups after four months of this practice, being higher in the group that received guidance by telephone[20].

Given the above, it is observed that telephone intervention is an effective educational resource that reaches several audiences, since most studies that used this strategy obtained satisfactory and convergent results. From the results of this study, it is observed that the follow-up with the use of telephone calls in users with Diabetes Mellitus, encouraging them to perform the appropriate practices, contributed to improving the description of the appropriate technique of insulin application in the users of the IG. In addition, telephone contact is a viable and effective communication option for monitoring, as it is simple and low cost.

Conclusion

The educational telephone intervention promoted a positive effect on the description of the insulin delivery technique, with better values in the intervention group, compared to the control group, showing an effect on improving the description of the insulin delivery technique by patients with Diabetes Mellitus and their caregivers.

Acknowledgments

Collaborations

Moura TVC, Silva AFR, Machado ALG, Carvalho GCN and Silva ARV contributed to the project design, data analysis, relevant critical review of the intellectual content and approval of the final version to be published.

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