



## Telephone intervention in self-care practices with the feet of patients with diabetes: a randomized clinical trial\*

Intervenção telefônica na prática de autocuidado com os pés em diabéticos: ensaio clínico randomizado

Intervención telefónica en la práctica del autocuidado con los pies en diabéticos: ensayo clínico aleatorizado

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### ABSTRACT

**Objective:** To assess the effect of a telephone intervention for self-care practices with the feet of people with type 2 diabetes mellitus. **Method:** This is a randomized clinical trial with two groups, control and intervention, carried out with 102 users with type 2 diabetes mellitus linked to four Basic Health Units in a municipality in the state of Piauí. For the intervention group, six telephone interventions were carried out in three months; and the control group received only conventional follow-up. For assessment, a form was applied before and after the intervention period. **Results:** In the intragroup analysis, when comparing self-care practices with the feet in the control group in the pre- and post-tests, there was no significant difference ( $p > 0.05$ ); in the intervention group, there was an increase in self-care practices in 70% of the items, with  $p < 0.001$  to 0.03. When analyzing the practice of intergroup self-care after the telephone intervention, the positive effect of the intervention was evidenced, obtaining statistically significant differences in 60% of the items, with a value of  $p < 0.001$  to 0.031. **Conclusion:** The telephone intervention promoted greater adherence to self-care practices with the feet of patients with type 2 diabetes mellitus. Brazilian Clinical Trials Registry: RBR-3pq5th.

### DESCRIPTORS

Health Education; Diabetic Foot; Diabetes Mellitus; Telephone; Self-care.

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## INTRODUCTION

“Diabetic foot is among the most frequent complications of diabetes mellitus (DM) and its consequences can be dramatic for an individual’s life, generating from chronic wounds and infections to lower limb amputations”<sup>(1)</sup>. “Complications of diabetic foot account for 40% to 70% of the total non-traumatic lower limb amputations in the general population and 85% of lower limb amputations in people with DM are preceded by ulcerations, the main risk factors being peripheral neuropathy, foot deformities and injuries”<sup>(1)</sup>.

Knowledge about proper foot care and self-care practices can reduce harmful changes that predispose ulcers and wounds, in addition to reducing most of the lower limb amputations<sup>(2)</sup>. Thus, it is necessary to develop health education activities to improve the knowledge of diabetic patients about foot care and encourage them to practice such care, in order to minimize or even prevent the occurrence of complications. Therefore, there is a need to use new approaches and support strategies to overcome limitations and assist conventional health education practices during nursing consultations.

In this innovative scenario, “the following stand out: telephone support for health care; free emergency telephone services; monitoring adherence to treatment; appointment reminders; health promotion actions; health education campaigns”, among others<sup>(3)</sup>. Although telephone support has been used in medicine for several years in several countries, it is still not widespread in nursing care in Brazil. “The use of the telephone emerges as a potential strategy for comprehensive care that translates into an expansion of health action, representing an evolution compared to traditional care”<sup>(4)</sup>.

Moreover, studies that used telephone intervention found improvement in self-care about food and physical exercise<sup>(5)</sup>, positive impact in reducing glycohemoglobin values and in insulin therapy<sup>(6-8)</sup>. It is noteworthy that this modality does not replace one-to-one care, as it is implemented as a support, a complementarity to conventional care.

Thus, it is assumed that using educational interventions by telephone calls to raise awareness of patients with DM2, carried out by nurses, will provide subsidies for an educational action that allows counseling and encouragement for greater adherence to self-care practices with the feet, aiming both at reducing complications of diabetic patients and preventing the appearance of future injuries and amputations. Thus, this study aimed to assess the effect of a telephone intervention to promote self-care practices with the feet of people with DM2 followed up in primary care.

## METHOD

### TYPE OF STUDY

This is an open randomized clinical trial conducted with two groups: Control Group (CG) and Intervention Group (IG).

## POPULATION

The study’s base population consisted of patients diagnosed with DM2 registered in primary care units. Users with a diagnosis of DM2 for at least two years, associated or not with hypertension, aged 18 years or older and with access to the phone or landline were included. Those who already had a previous diagnosis of diabetic foot, any cognitive, auditory or speech deficit, informed by participants/family member that prevented direct response to data collection instruments, who did not answer the calls after four consecutive attempts as well as those who changed phones during the study were excluded.

The sample was calculated from the formula for studies with comparison between groups<sup>(9)</sup>, placing a 10% margin for possible losses. Thus, it was found that 64 people would be needed in each group, totaling 128.

## DATA COLLECTION

The research was carried out with users of four Basic Health Units (BHU) in the municipality of Picos, state of Piauí, carried out by a nurse from December 2018 to July 2019. BHU were selected through the drawing via computational program and without replacement.

The study took place in three stages: 1) pre-intervention (before the start of the telephone intervention and randomization); 2) educational intervention; 3) post-intervention. In the first stage, through the application of a form in person, the first contact with BHU users was made. Data were collected on address and telephone number, and the sociodemographic variables sex, age, marital status, education, housing and family income; as well as the clinical variables weight, height, blood pressure (BP), body mass index (BMI), and self-care practices with the feet.

Weight was measured using a Techline® portable digital scale, with a maximum capacity of 150 kg, and height was verified using an anthropometric tape fixed to a flat vertical surface and without unevenness, with a scale between 1.0 cm and 2.0 m. BMI was obtained from the ratio between weight (kg) and the square of height (m). Specific parameters for adults were used, classifying them as low weight (< 18 kg/m<sup>2</sup>), normal weight (18.5 to 24.9 kg/m<sup>2</sup>) and overweight (25.0 to 29.0 kg/m<sup>2</sup>)<sup>(10)</sup>; and for older adults, classifying them as low weight (≤ 22 kg/m<sup>2</sup>), adequate or eutrophic (> 22 and < 27 kg/m<sup>2</sup>), and overweight (≥ 27 kg/m<sup>2</sup>)<sup>(11)</sup>.

Checking BP was performed with Welch Allyn Tycos<sup>ML</sup> aneroid sphygmomanometers and Littmann® binaural stethoscopes. Participants with systolic blood pressure (SBP) < 140 mmHg and diastolic blood pressure (DBP) < 90 mmHg were classified as normotensive<sup>(12)</sup>.

To assess self-care practices with the feet, an instrument was used, an adaptation of self-care knowledge and practice of patients with diabetes with regard to foot injury prevention, consisting of ten items, applied in pre- and post-intervention stages, namely: washing the feet at least once a day; drying the feet after bathing and drying between

the toes; moisturizing the feet with moisturizing creams or oils on the heels and soles (palm of the foot or bottom of the foot); wearing cotton socks; use of closed shoes and inspect (look) on the inside before putting them on; cutting the nails in a straight shape; using pointless scissors to cut them.

The outcome considered for this study was self-care practices with the feet of users with diabetes, measured using these ten items, in which, after the intervention, a difference of 25% of IG compared to CG was expected in more than 50% of items.

After the end of recruitment, participants were randomized to one of the groups (CG or IG), through Research Randomizer, by a statistical professional, generating truly comparable and proportional groups (1:1), in which the sample allocated in each group was proportionally adjusted, considering sex and time of diagnosis for DM.

The second stage, telephone intervention, called *Ligue-Pé* program, lasted three months, on guidelines for self-care with the feet, taking place in a systematic way with IG by the researcher. The intervention aimed to provide guidance, motivate and encourage individuals to practice self-care with their feet. The intervention occurred through telephone contacts that were made every 15 days, by a trained nurse, from March to May 2019. There were six telephone contacts per patient, with an average duration of seven minutes, carried out from Monday to Friday, in the morning, from 8 a.m. to 12 p.m., and in the afternoon, from 2 p.m. to 5 p.m.

It is noteworthy that telephone calls with guidance on foot care were made exclusively by the author of this study, who had access to participants' data records. Telephone interventions followed a previously prepared script, with content to be addressed in each contact (Chart 1). The contents were elaborated from information contained in the Diabetic Foot Manual<sup>(1)</sup> and in the International Consensus on the Diabetic Foot<sup>(13)</sup>.

**Chart 1** – Contents covered in the telephone intervention – Picos, PI, Brazil, 2019.

Telephone intervention (n = 6)	Intervention content
1 <sup>st</sup> contact	Inspection and self-examination of the feet
2 <sup>nd</sup> contact	Washing and drying feet
3 <sup>rd</sup> contact	Moisturizing and wearing socks
4 <sup>th</sup> contact	Use of footwear (type, format and material)
5 <sup>th</sup> contact	Nail and corn care
6 <sup>th</sup> contact	Physical activity and food

In the third stage, post-intervention, the post-test was applied 15 days after telephone interventions. In this stage, the reassessment of self-care practices was promoted through the application of the fifth part of

the form on self-care knowledge and practice of patients with diabetes regarding foot injury prevention through telephone contact.

It is noteworthy that IG continued to receive routine care at BHU, whereas CG received only routine care at BHU, with guidelines that are offered during nursing and medical consultations. In order to apply the post-test, even though CG did not receive any telephone intervention, the intervention time of IG was respected. The post-test application in the CG also occurred through telephone contact.

As this is an educational intervention study, it was not possible to blind the researcher responsible for the intervention, as it was necessary to contact participants by telephone to carry out the intervention; therefore, this is an open trial. To ensure reliability in measuring the outcome, nurses and other BHU professionals were not informed which patients were part of IG or CG. Data analysis, in turn, was carried out by a statistical professional; it was also not informed for the group in which patients had been allocated.

## DATA ANALYSIS AND TREATMENT

To perform the data statistical analysis, the software R version 3.5.3 was used for chi-square tests of homogeneity, and the Statistical Package for the Social Sciences (SPSS) version 20 was used to perform the McNemar and Student's t test. For qualitative variables, absolute (n) and relative (%) frequencies were used; for quantitative variables, mean and standard deviation were used.

To compare self-care practices with feet of patients with diabetes before and after the intervention, in the intragroup analysis, the McNemar test was used due to paired sampling. In intergroup comparisons, the chi-square test of homogeneity was used to compare proportions. For continuous variables, Student's t test was used for independent samples with equal variances; to test homogeneity of variances, the Levene test was used. For all analyzes, a significance level of 0.05 was considered.

## ETHICAL ASPECTS

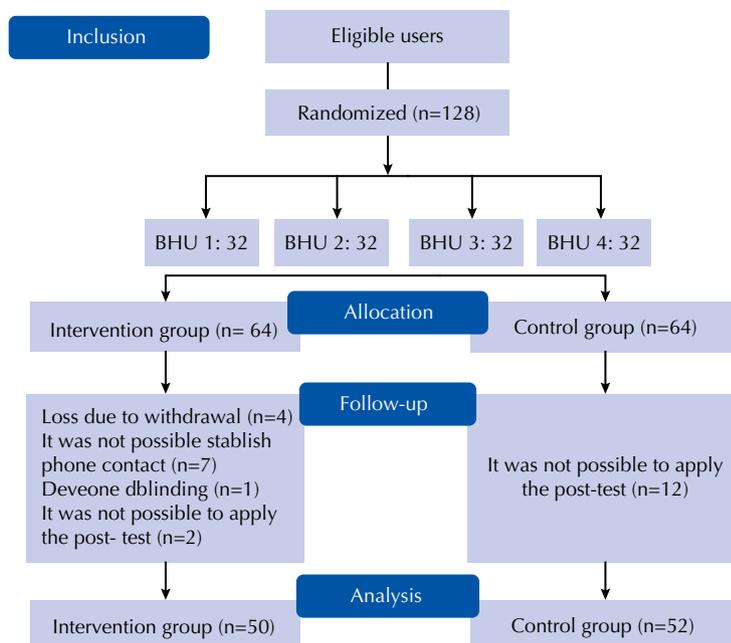
The study was developed meeting the standards of research ethics involving human beings according to Resolution N. 466/2012 of the Brazilian National Health Council<sup>(14)</sup>. The research was approved by the Research Ethics Committee (REC) of *Universidade Federal do Piauí* (UFPI) in 2018, under Opinion 3.018.155/2018. The research is registered in the RBR-3pq5th Brazilian Clinical Trials Registry Platform and UTN identification number U1111-1218-1886.

Patients were approached in the BHU, and when they entered the unit for consultations, receiving medications and scheduling tests, they were also referred to a room made available for collection. Then, the objective of the study was explained and patients were asked about their interest in participating in the study. All users who agreed to participate signed an Informed Consent Form (ICF) in two copies.

## RESULTS

Of the total of 128 users in the sample, in IG, in the first telephone contact, four reported withdrawal; it was not possible to establish telephone contact during the telephone intervention with seven (telephone number did not exist

or did not answer calls) and one developed blindness; in the final phase, it was not possible to apply the post-test to two participants. In CG, it was not possible to apply the post-test to 12 participants. Thus, the final sample of the study consisted of 102 users, 50 belonging to IG and 52 to CG (Figure 1).



**Figure 1** – CONSORT diagram: User allocation process in the clinical trial phases – Picos, PI, Brazil, 2019.

Regarding sociodemographic data, the mean age in the 102 participants (100%) in both groups was over 60 years (CG = 65, IG = 61,  $p = 0.079$ ). Most were female (CG = 73%, IG = 68%,  $p = 0.574$ ), retired (CG = 67.3%, IG = 44%,  $p = 0.019$ ) and married (CG = 58%, IG = 66%,  $p = 0.388$ ). Although most of the users of IG have completed elementary school (48%) and the majority in CG were illiterate (49%), there was no statistical association ( $p < 0.05$ ). With regard to the mean monthly income, in CG, it was R\$ 1,679.7 (BRL Brazilian *Reais*) and in IG, it

was R\$ 1,624.9, with no significant difference ( $p = 0.759$ ). Thus, groups are homogeneous according to sociodemographic variables, except for occupation.

Regarding the clinical data, both groups had an mean diagnosis time of more or less eight years, an average BMI of 26.4 (CG) and 27 (IG)  $\text{kg/m}^2$ ; DBP values of 77.6 (IG) and 78.1 (CG) mmHg; SBP values of 127.2 (IG) and 130.8 (CG) mmHg. As shown in Table 1, it is possible to verify that the groups are homogeneous according to clinical variables ( $p > 0.05$ ).

**Table 1** – Clinical characteristics of the research participants – Picos, PI, Brazil, 2019.

Clinical variables	CG (n = 52)	IG (n = 50)	P value*
	Mean (standard deviation)	Mean (standard deviation)	
BMI ( $\text{kg/m}^2$ )	26.4 (4.7)	27 (4.8)	0.560
DM time (years)	8.33 (6.76)	8.5 (8.3)	0.909
Diastolic Blood Pressure	78.1 (10.5)	77.6 (10.8)	0.821
Systolic Blood Pressure	130.8 (17.7)	127.2 (16.2)	0.291

Note: \*Student's t test for independent samples.

Regarding the intragroup analysis in CG, it was observed that there was no significant difference ( $p > 0.05$ ) in self-care practices with the feet by patients with diabetes between the pre and post-tests. When comparing self-care practices with feet, in IG, in the pre and post-tests, it was noted that after the intervention there

was greater adherence to self-care practices in 70% of the items assessed, obtaining a value of  $p < 0.001$  to 0.031. It is noteworthy that washing the feet was already consolidated among participants (100%), so there was no room for improvement in the post-test (Table 2).

**Table 2** – Intragroup self-care practice with feet in the pre- and post-tests – Picos, PI, Brazil, 2019.

Variables	Control Group			Intervention Group		
	Pre-test %	Post-test %	p **	Pre-test %	Post-test %	p **
<b>Self-care practice with the feet</b>						
Wash the feet at least once a day	100.0	100.0	1.000	100.0	100.0	1.000
Dry the feet after bathing	75.0	75.0	1.000	74.0	88.0	<b>0.020</b>
After the bath dry between the toes	40.4	40.4	1.000	34.0	84.0	<b>&lt; 0.001</b>
Moisturize the feet with moisturizing creams or oils on the heels	59.6	69.2	0.060	58.0	98.0	<b>&lt; 0.001</b>
Moisturize the sole of the feet (palm or bottom of the foot)	34.6	21.2	0.092	44.0	64.0	<b>0.002</b>
Use cotton socks	26.9	28.8	1.000	36.0	32.0	0.625
Wear closed shoes	48.1	48.1	1.000	44.0	40.0	0.625
Inspect (look) the inside every day before putting it on	40.4	38.5	1.000	48.0	82.0	<b>&lt; 0.001</b>
Always cut nails straight	25.0	23.1	1.000	20.0	72.0	<b>&lt; 0.001</b>
Cut nails with pointless scissors	3.8	1.9	1.000	4.0	16.0	<b>0.031</b>

Note: \*\*McNemar test; % - percentage.

Regarding the intergroup comparison, in the pre-test, on self-care practices with the feet, it can be observed that there was no statistical difference indicating homogeneity in self-care practices between the groups. Among the items practiced by more than 50% of those surveyed, in the pre-test, in both groups, there were only three, namely: washing the feet at least

once a day; drying the feet after bathing; moisturizing the feet with moisturizing creams or oils on the heels. Regarding the intergroup comparison after the telephone intervention, in the post-test, the positive effect of the intervention is noted, since statistically significant differences were obtained in 60% of the items, with a p value  $< 0.001$  to 0.031 (Table 3).

**Table 3** – Comparison of self-care practice with feet, intergroup, between CG and IG in the pre and post-test – Picos, PI, Brazil, 2019.

Variables	Pre-test			Post-test		
	CG %	IG %	p ***	CG %	IG %	p ***
<b>Self-care practice with the feet</b>						
Wash the feet at least once a day	100	100	1.000	100.0	100.0	1.000
Dry the feet after bathing	75	74	1.000	75.0	88.0	0.152
After the bath dry between the toes	40	34	0.644	40.4	84.0	<b>&lt; 0.001</b>
Moisturize the feet with moisturizing creams or oils on the heels	60	58	1.000	69.2	98.0	<b>&lt; 0.001</b>
Moisturize the sole of the feet (palm or bottom of the foot)	35	44	0.443	21.2	64.0	<b>&lt; 0.001</b>
Use cotton socks	27	36	0.439	28.8	32.0	0.896
Wear closed shoes	48	44	0.830	48.1	40.0	0.534
Inspect (look) the inside every day before putting it on	40	48	0.565	38.5	82.0	<b>&lt; 0.001</b>
Always cut nails straight	25	20	0.714	23.1	72.0	<b>&lt; 0.001</b>
Cut nails with pointless scissors	4	4	1.000	1.9	16.0	<b>0.031</b>

Note: \*\*\*Chi-square test for proportion.

## DISCUSSION

This study assessed the effect of an educational intervention via telephone, focusing on guidelines related to self-care with the feet. The study obtained as a result a positive effect of the intervention, as users who received the telephone intervention showed greater adherence to self-care practices with their feet compared to CG.

Regarding the participants' profile, corroborating the findings of other studies conducted with users with DM2 in BHU, the results demonstrate that most patients are female and have a partner and are, on average, over 60 years old<sup>(15-18)</sup>. The average time of diagnosis found was greater than eight years in both groups, representing, therefore, an aggravating potential for the possible complications of DM2, presenting a normal BMI for older adults<sup>(15,19)</sup>.

International studies focused on the use of telephone intervention for the prevention and self-care of the feet of patients with diabetes have approached as technology, unlike the present study, the use of cell phone text messages to reinforce the learning and practice of foot care of users with diabetes. As in this study, those who received the intervention had better results in adhering to the practice of this care<sup>(20-21)</sup>.

Other studies carried out with diabetic patients show satisfactory results with the use of telephone intervention. The general self-care scores in the intervention groups were significantly higher than in CG<sup>(22)</sup>, in adherence to diet, exercise, foot care, blood glucose monitoring and medication use<sup>(23-24)</sup>.

Regarding the Brazilian studies that used telephone intervention with patients with diabetes, it was observed that they were not aimed at reinforcing foot care; however, they approached the telephone intervention as capable of promoting an effective form of communication by professionals and people with DM2, since the telephone calls allow dialogue, reflection and greater co-responsibility of people with a chronic condition in relation to their own health<sup>(16,25)</sup>.

Most of studies that used telephone intervention with diabetic users obtained satisfactory results. Participants who received interventions showed better results in adhering to healthy eating<sup>(25)</sup>, promoting self-care related to physical activity and following an eating plan<sup>(16)</sup>, reducing cardiovascular risk factors and improving health-related quality of life<sup>(26)</sup>. Through the calls it is possible to make recommendations about food, physical activity, correct use of medicines, foot care and even teach how to identify symptoms of hyperglycemia and hypoglycemia<sup>(27)</sup>.

Furthermore, an observational study, when assessing telephone support as a strategy for monitoring DM, was able to identify great satisfaction on the part of users with telephone calls, having their expectations met<sup>(28)</sup>. It is also noteworthy

that "the use of the telephone is considered an effective method to approach the user in his home or community, at flexible times, in addition to optimizing the time"<sup>(16)</sup>.

Thus, telemedicine can be an important complement in the treatment of users with DM2, improving patient education and knowledge about the disease. "In addition, it can help the health system, alleviating the burden in specialized care settings and supporting the role of primary care administrator"<sup>(29)</sup>.

It is observed that the follow-up with the use of a user-centered approach, encouraging them to have autonomy in carrying out self-care practices, contributed to improve foot care practices among IG users. Therefore, telephone contact proved to be a viable and effective communication option for monitoring users with DM2, as it is simple, comfortable, fast and low cost. The telephone shortens physical and socio-cultural distances, strengthening the bond and facilitating listening and understanding, especially when it comes to Primary Care<sup>(30)</sup>.

During the planning and execution of this research, some aspects that could influence the positive effect of the telephone intervention were considered, such as the calls being made by only one nurse, standardization of language and quality of the information provided. In view of this, a script was designed to guide calls and organize the days and times of calls to ensure successful contact.

Nonetheless, some limitations should be noted. Among them are short follow-up period, lack of analysis of some clinical variables, such as capillary glycemia and glycohemoglobin, the impossibility of blinding the study participants and the difference in occupation between groups. However, these limitations do not invalidate the findings of this study and may result in further studies.

## CONCLUSION

The performance of telephone intervention as an educational strategy, performed with users with DM2 followed up in primary care, showed greater adherence to self-care practices with feet in IG compared to CG. One emphasizes the importance of using this type of strategy to be continuous in order to maintain this satisfactory result as well as to expand self-care.

The results of this research show the benefits of telephone intervention as an innovative strategy that can help improve self-care practices with feet in patients with DM2. With this, it is expected that this study will have future developments, being able to implement the telephone intervention as a support to conventional treatment (consultations) used in Primary Care services. It is believed that the trend is to add several educational strategies aimed at encouraging adherence to self-care practices in DM2 and that these strategies can be assessed as to their contribution, especially in foot care.

## RESUMO

**Objetivo:** Avaliar o efeito de uma intervenção telefônica para a prática de autocuidado com os pés em pessoas com diabetes mellitus tipo 2. **Método:** Ensaio clínico randomizado com dois grupos, controle e intervenção, realizado com 102 usuários com diabetes mellitus tipo 2, vinculados a quatro Unidades Básicas de Saúde de um município do Piauí. Para o grupo intervenção, foram realizadas seis

intervenções telefônicas em três meses, e o grupo controle recebeu somente o acompanhamento convencional. Para a avaliação, aplicou-se um formulário antes e após o período das intervenções. **Resultados:** Na análise intragrupo, ao comparar a prática de autocuidado com os pés no grupo controle, no pré e pós-teste, não houve diferença significativa ( $p > 0,05$ ); já no grupo intervenção, houve aumento da prática de autocuidado em 70% dos itens, obtendo-se  $p < 0,001$  a  $0,03$ . Ao analisar a prática de autocuidado intergrupar após a intervenção telefônica, evidenciou-se o efeito positivo da intervenção, obtendo diferenças estatisticamente significativas em 60% dos itens, com valor de  $p < 0,001$  a  $0,031$ . **Conclusão:** A intervenção telefônica promoveu maior adesão à prática de autocuidado com os pés dos pacientes com diabetes mellitus tipo 2. Registro Brasileiro de Ensaios Clínicos: RBR-3pq5th.

## DESCRITORES

Educação em Saúde; Pé Diabético; Diabetes Mellitus; Telefone; Autocuidado.

## RESUMEN

**Objetivo:** Evaluar el efecto de una intervención telefónica para la práctica del autocuidado con los pies en personas con diabetes mellitus tipo 2. **Método:** Ensayo clínico aleatorizado con dos grupos, control e intervención, realizado con 102 usuarios con diabetes mellitus tipo 2, vinculado a cuatro Unidades Básicas de Salud en un municipio de Piauí. Para el grupo de intervención, se llevaron a cabo seis intervenciones telefónicas en tres meses y el grupo de control recibió solo un seguimiento convencional. Para la evaluación se aplicó un formulario antes y después del período de intervención. **Resultados:** En el análisis intragrupo, al comparar la práctica del autocuidado con los pies en el grupo control, en el pre y post test, no hubo diferencia significativa ( $p > 0,05$ ); en el grupo de intervención, hubo un incremento en la práctica del autocuidado en el 70% de los ítems, obteniendo  $p < 0,001$  a  $0,03$ . Al analizar la práctica del autocuidado intergrupar posterior a la intervención telefónica, se evidenció el efecto positivo de la intervención, obteniendo diferencias estadísticamente significativas en el 60% de los ítems, con un valor de  $p < 0,001$  a  $0,031$ . **Conclusión:** La intervención telefónica promovió una mayor adherencia a la práctica del autocuidado con los pies de los pacientes con diabetes mellitus tipo 2. Registro Brasileño de Ensayos Clínicos: RBR-3pq5th.

## DESCRIPTORES

Educación en Salud; Pie Diabético; Diabetes Mellitus; Teléfono; Autocuidado.

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