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RESEARCH

Effects of supportive telephone counseling in the metabolic control of elderly people with diabetes mellitus

Efeitos do suporte telefônico no controle metabólico de idosos com diabetes mellitus

Efectos del soporte telefónico en el control metabólico de ancianos con diabetes mellitus

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ABSTRACT

Objective: the purpose of this study was to evaluate the efficacy of telephone-based support for the metabolic control of elderly patients with diabetes mellitus. **Method:** a pragmatic study was conducted in two groups, called G1 (n = 36) and G2 (n = 27), at a health unit from the countryside of São Paulo state. Patients in G1 group received telephone support over four months, through 16 telephone contacts with educational material; for the G2 group the educational material was mailed. **Results:** significant differences were found. The G1 group showed a reduction of the parameters of fasting glucose, as well as systolic and diastolic blood pressure. In G2 group a modest reduction was noted in some parameters, with no significant difference. **Conclusion:** telephone support was effective to deliver patient education to the diabetic elderly, leading to the reduction of fasting blood glucose. This, combined with other strategies, can contribute to reduce glycated hemoglobin (NCT 01972412).
Descriptors: Diabetes Mellitus, Telephone, Nursing, Old Age Assistance, Public Health Nurses.

RESUMO

Objetivo: avaliar a efetividade do suporte telefônico no controle metabólico de idosos com diabetes *mellitus*. **Método:** estudo pragmático com 63 participantes, alocados em dois grupos, denominados G1(n = 36) e G2(n = 27), em uma unidade de saúde do interior paulista. O suporte telefônico foi oferecido, durante quatro meses, para o G1, por meio de 16 ligações telefônicas com conteúdo educativo, e, para o G2, foram enviadas correspondências por via postal. **Resultados:** no G1 houve significância estatística na redução dos parâmetros das variáveis glicemia de jejum, pressão arterial sistólica e diastólica. No G2, houve redução discreta de algumas variáveis, mas sem significância estatística. **Conclusão:** o suporte telefônico foi considerado uma estratégia educativa efetiva para idosos com diabetes *mellitus* e favoreceu a redução da glicemia de jejum e, em conjunto com outras estratégias, pode agregar valor na redução da hemoglobina glicada (NCT 01972412).
Descritores: Diabetes *Mellitus;* Telefone; Enfermagem; Assistência a Idosos; Enfermeiras de Saúde Pública.

RESUMEN

Objetivo: evaluar la efectividad del soporte telefónico en el control metabólico de ancianos con diabetes mellitus. **Método**: estudio pragmático con 63 participantes, divididos en dos grupos denominados G1(n = 36) y G2(n = 27), en una unidad de salud del interior paulista. El soporte telefónico fue ofrecido durante cuatro meses para el G1, consistiendo en 16 llamadas telefónicas de contenido educativo, y para el G2, se realizaron envíos por vía postal. **Resultados**: en el G1 hubo significatividad estadística en la reducción de los parámetros de las variables glucemia en ayunas, presión arterial sistólica y diastólica. En el G2 hubo

discreta reducción en algunas variables, pero sin significatividad estadística. **Conclusión**: el soporte telefónico fue considerado como estrategia educativa efectiva para ancianos con diabetes mellitus y favoreció la reducción de la glucemia en ayunas. En conjunto con otras estrategias, puede agregar valor a la reducción de hemoglobina glicosilada (NCT 01972412).
Descriptores: Diabetes Mellitus; Teléfono; Enfermería; Asistencia a los Ancianos; Enfermeras de Salud Pública.

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INTRODUCTION

Non-transmissible diseases accounted for 38 million deaths worldwide in 2012. At least 40% of these were considered as premature, affecting people under 70, and in their majority were classified as avoidable[1]. One of the principal diseases involved in this condition is diabetes mellitus (DM). Currently it is estimated that 387 million people have DM and that their number is expected to reach 471 million by 2035 due to the rapid demographic transition, with higher relative weight, toward adults and elderly people. Therefore, because DM is a chronic disease with severe complications that require continuous care, it turns into an onerous disease for these individuals, their families, and the healthcare system[2]. Taking into account the described demographic and epidemiological changes, it is up to researchers to improve the management of self-care of diabetes in the elderly. Along this line, a study concerning the application of communication technologies in the treatment of the elderly with chronic pain has shown the potential to improve access, quality, and efficiency of support, which has proven to be particularly useful for the care of older persons with chronic and acute illnesses[3].

The main efforts in developing strategies to manage type 2 diabetes mellitus (DM2) have focused on patient education, either by individual appointment or by a group approach. Even though satisfactory results have been obtained, there is still a need to widen specific strategies such as telephone, smartphone, and the Internet, as well as cellular text messages (Short Messaging System – SMS)[4]. Among these strategies, the use of smartphones has attained prominence as an aid to the adequate home-based administration of medicaments and to the enhancement of the communication with health professionals, reducing the feeling of isolation and favoring effective results in the care of the elderly[5]. In Brazil, two studies demonstrated that telephone support is a promising strategy for the management of DM. The first study was carried out with 26 DM participants before and after telephone support consisting of four calls while in the process of insulin application. This study showed that this type of intervention strategy is effective in providing better knowledge about the application of insulin[6]. A second study was designed to verify the effect of telephone support as a strategy to favor physical activity. A total of 26 participants with DM from the same Family Health unit were divided in two groups. Participants in the first group were subjected to weekly face-to-face meetings for two months and telephone calls for four months, while the second group only received telephone calls. Results demonstrated the effectiveness of telephone intervention for the improvement of physical activity of DM patients[7].

In view of the observations, despite the successful results, it is still necessary to augment the study of intervention in elderly DM patients due to the particularities and singularities of this age, which will consequently lead to the reduction of acute and chronic complications associated with bad management of the disease[8].

The objective of this study consists therefore in the evaluation of the efficacy of educative telephone-based support in the metabolic control of elderly DM patients. This study is expected to contribute in the valuation of strategies used in the health education of elderly people with DM.

METHODS

Ethical aspects

This study was performed in accordance with the ethical standards in research, and approved by the Ethics Committee of Research from the University of São Paulo at Ribeirão Preto College of Nursing. This study was also registered in the database of clinical research in humans known as Clinical Trials.gov, under protocol number NCT01972412.

Study design, setting, and period

This is a pragmatic clinical assay[9] developed in 2013 at a district health unit from the western region, a large inner county of the São Paulo state. This health unit was selected because of its favorable conditions for the development of assistance, education, and research in attention to the local health system.

Population

The subjects under study were chosen from an automated diabetes registry provided by the pharmacy information system called FARMANET, which includes the patient's name, the birth date, telephone contact number, and prescriptions for the insulin used. The database of diabetes patients enrolled 9,482 from five municipal regions of the health service. This system is responsible for the management of the distribution (demand) of inputs, specifically for DM patients who take insulin, and use glucose monitoring devices and reagent stripes.

Inclusion and exclusion criteria

The criteria established for the inclusion of data samples were: having DM2; being part of FARMANET; older than 60 years of age; and having a residential telephone line. After, pre-processing the data, 5,278 patients were excluded. The reasons for exclusions were the following: 2,388 patients with repeated name; 350 who were deceased; 1,408 did not have a phone; 182 who had a telephone only for messages; 749 who only had mobile phones; and 201 who were younger than 60. These criteria resulted in 4,204 acceptable patients. Among these, 1,298 were registered in the western district, 978 in the east, 588 in the south, 915 in the north, and 425 were registered in the central region. The remaining 1,298 patients that formed part of the sample for this

study were registered in the western district and were allocated to two groups, defined via a simple random sampling method implemented via the SPSS software. Initially 649 patients were assigned to group 1 (G1) and group 2 (G2). The interventions for G1 consisted of 16 telephone calls, and for G2 the results of the laboratory tests were sent by mail.

A total of 589 patients were excluded from G1 and 611 from G2, as described in Chart 1.

Chart 1 – Reasons for the exclusions of patients from Group 1 and Group 2

Reason for the exclusion	G1	G2
Patients were not contacted because of missing telephone number, wrong registered number, or deprogrammed telephone number	302	123
Refused to be part of the study	14	162
Did not answer the telephone during any of three calls	151	114
Had difficulty in participating within the stipulated period for the development of the study	40	30
Participation was confirmed but patient did not show up during the activities	78	154
Death	1	15
Traveling	2	10
Patient did not have a diagnosis of diabetes *mellitus*	1	3
Total	589	611

Note: G1 – Group 1; G2 – Group 2.

The study was conducted with a sample formed by 98 elderly patients with DM. Taking into account the type of study (intervention), its objective (evaluate the efficacy of supportive telephonebased education on the management of metabolic control of elderly DM patients), and the sample size (98 older), according the methodology used to evaluate healthcare programs, the study's reach was calculated. This tool is useful to evaluate the effective representation of the sample to the population. Our sample is characterized by a 11.5% reach index; thus, it is considered to be representative of the target population[11].

Study protocol

In order to collect the necessary data, a survey was applied containing 10 questions related to clinical and sociodemographic variables such as gender, age, education, time of diagnosis, treatment to control of DM, and comorbidity. Another survey with 13 questions was applied in order to record variables such as height, weight, body mass index (BMI), systolic arterial pressure (SAP) and diastolic arterial pressure (DAP), waist circumference (WC), fasting blood glucose, low density lipoprotein (CLDL), high density lipoprotein (CHDL), triglycerides, total cholesterol level, and glycosylated hemoglobin (HbA). A pilot study was conducted from March to April in 2013, with five patients receiving medical care from another medical unit, in order to train the researchers beforehand. Study outcomes were collected at the beginning (called P0) and at four months following (P4). Of the 98 elderly participants, 63 completed both phases of the program, 36 from G1 and 27 from G2. The reasons for the reduction in participants in G1 were: 20 patients did not attend to collecting blood after three consecutive contact attempts (P0), and four withdrew from the study. In G2, 11 older patients did not attend the appointments for blood collection (P4) (Figure1).

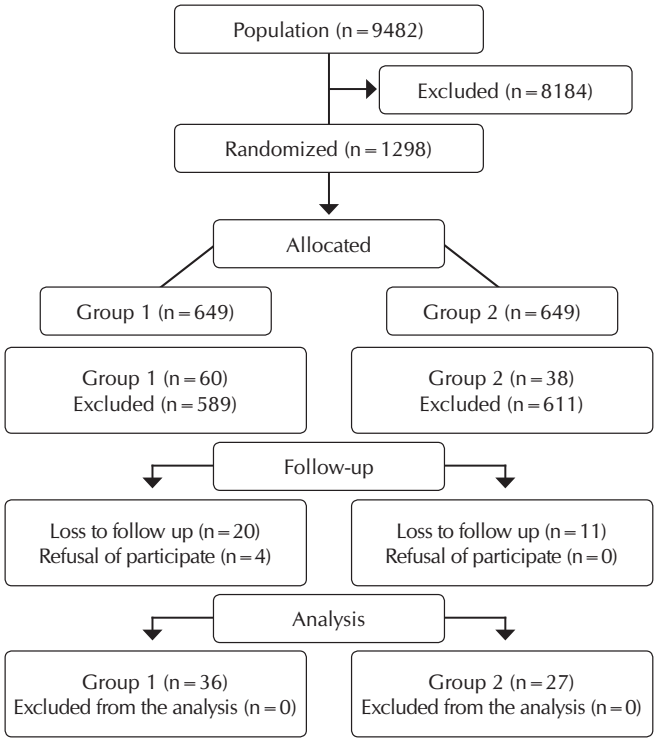
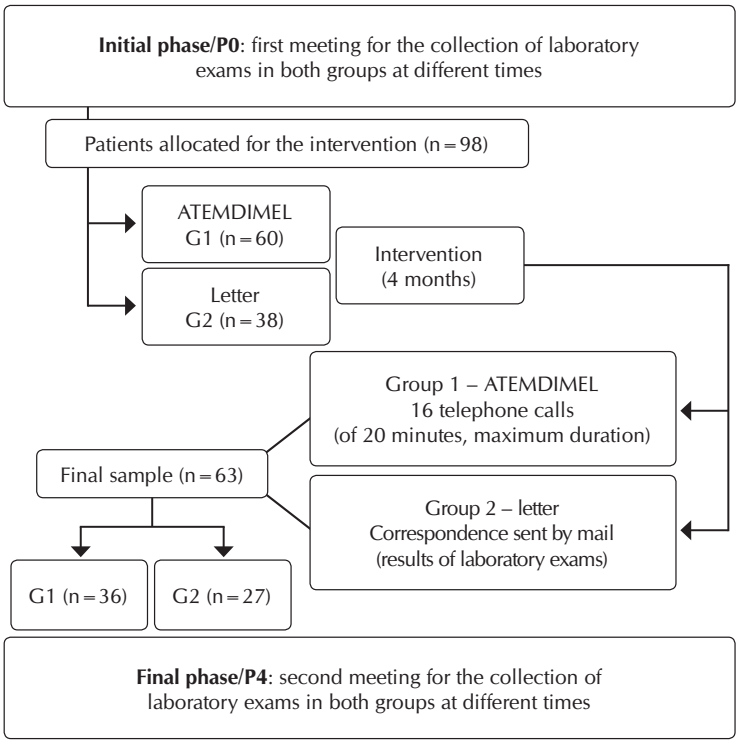


Figure 1 – Flow diagram of the study

The intervention consisted of supportive telephone calls based on national[6-7] and international studies[12-14]. The education program was elaborated according to support for self-care[15] and the cognitive behavioral approach[16], and also followed the guidelines of the Brazilian Diabetic Society[17]. To guarantee the homogeneity of the interventions in P0, an intervention manual was adopted[6]. The content of the educational program was organized into four topics: general definitions of DM; drug treatment and special situations; food planning; and physical activities. To initiate the educational program, 16 telephone calls were made (four calls for each topic) of a maximum duration of 20 minutes each, regarding national[6-7] and international[12-14] studies. By following the recommendation of the manual, the first topic approached was the general definition of DM. The subsequent sequence of themes to be approached were the evaluation of the needs of diabetes patients identified by the research and validated by the patients, and the results of laboratory exams (Figure 2). All of the interventions were registered using Microsoft Excel software, including the patient's name, telephone contact number, data and time of telephone calls, the interventions done, the goals, and the outcomes. Patients received telephone support Monday through

Friday between 8h0012h00 and 14h0018h00, after scheduling on PCtel software. The intervention that included scheduled telephone support, called ATEMDIMEL, was conducted by three nurses and a nutritionist and physical educator, who accompanied the patients over the four-month intervention period. At the end of the telephone call, the researcher stated the goals of the next intervention. Weekly meetings were conducted to clarify questions regarding the most complex cases, among the researchers. The intervention for G2 was made by mailing the laboratory results based on the concept of one of the five Patient Assessment Chronic Illness Care (PACIC) domains, called Setting Goals/Adaptation[18]. This dimension refers to evaluating the overall care quality received by the patient with one or more chronic conditions in the last six months. In addition to receiving the exam results, the DM patients were oriented to take these results to their next medical appointment at their reference unit (Figure 2).



Note: P0 – start of data collection; ATEMDIMEL – telephone support program to manage diabetes mellitus; G1- group 1; G2 – group 2; P4 final data collection after four months

Figure 2 – Study design

Analysis of results and statistics

Descriptive analyses were conducted for the metabolic control data. T-tests were applied to compare two means of non-paired samples. To apply this test it is necessary to test whether both groups had the same variance and also whether they are normally distributed. These conclusions were made by using the PROC TTEST procedure implemented in SAS® 9.0. Linear mixed effects models were used in the analysis of the HbA1c data[19]. The individual patient samples were considered as the random effects, whereas the time periods and their interactions were considered as the fixed effect component of the model. This model was adjusted via the PROC MIXED procedure in SAS® 9.0. The telephone support was used as a strategy to evaluate the effectiveness of the educational intervention. The use of HbA1c for the mixed effects model allows visualization of the effectiveness of this tool in metabolic control and therefore aids in the prevention of acute and chronic complications in DM. It is expected that the HbA1c values should be smaller at the end of the intervention that at the initial condition. The statistical significance adopted throughout was of 5% (p-value <0.05).

RESULTS

Of 63 (100%) elderly patients with DM, 36 (57.14%) were allocated to G1 and 27 (42.85%) to G2. The mean age for both groups was 63 years (sd +/-7.85 for G1 and +/-11.38 for G2). Women were predominant, at 20 (55.56%) in G1 and 17 (62.96%) in G2. In regard to schooling, the G1 group had a mean of seven years of study while G2 had six. In terms of the DM treatment, the non-medicated patients represented by those subjected to an alimentary and physical activity plan were only 39.68% in the G1 group and 19.04% in G2. Therefore, medical treatment, represented by the application of insulin (96.82%) and oral antidiabetics (69.84%), was the most commonly used strategy by participants of both groups. It was also noticed that 69.44% of G1 were declared to by hypertensive and 72.4% in G2. These findings show statistical significance for the PAS, PAD, and fasting blood glucose variables for the participants of the G1 group. This group also showed discrete reductions in the values of IMC, PAS, PAD, fasting blood glucose, total cholesterol, triglycerides, and HbA1c; however, these were of little statistical significance (p-value >0.05). While not statistically significant (p-value >0.05), the G2 group also showed a discrete diminution for the values of IMC, PAS, PAD, fasting blood glucose, LDL-C, total cholesterol, and triglycerides. In the analysis between G1 and G2, it was also observed that the G2 group had a larger GA value of CA throughout the study. The comparison of the effects before and after the intervention in each group separately showed a discrete variation in CA, with an increment of 0.25cm in G1 and 0.89cm in G2. These results were, however, not statistically significant (Table 1). The analysis between the groups of the LDL-C variable showed an increment for the data in G1 (1.07 mg/dl) and a diminution in the G2 group (7.11 mg/dl) (Table 1).

The effects of the intervention between the G1 and G2 groups referring to the fasting food glucose level did not show any statistically significant change. It is worth mentioning that, prior to the telephonic support, the mean value for the fasting food glucose level in G1 was 34.09 mg/ml higher than the mean of G2. There was only a statistically significant difference in G1, because this group presented a decrease of 35.97 mg/ml (p-value = 0.035; Table 1). The effect of the

intervention between groups revealed that there is a difference in the period prior to the intervention only for HbA1c (p-value = 0.0042). Inter-group analysis showed that G1 had a reduction of 0.49% in HbA1c. However, the G2 group presented a discrete rise of 0.54% (Table 2).

Among other documents, this report discusses the gap between the recommendations based upon evidence and the clinical practice in the services, prevention, and treatment of chronic conditions. This interference is caused by the rigidity of the inclusion criteria that exclude many patients[20].

Table 1 – Mean values of metabolic control variables from Group 1 and Group 2, before and after the telephone-based intervention support, Ribeirão Preto, São Paulo, Brazil, 2014

Metabolic control variables	Group 1 (n = 36)			Group 2 (n = 27)		
	Before Mean (SD)*	After Mean (SD)	*p* value	Before Mean (SD)	After Mean (SD)	*p* value
Body mass index	31.52 (5.51)	31.07 (4.88)	0.7355	32.67 (6.31)	32.66 (6.19)	0.9924
Waist circumference	105.64 (11.61)	105.89 (10.93)	0.9289	108.07 (13.23)	108.96 (11.93)	0.7834
SAP mean**	146.17 (21.53)	134.50 (16.16)	0.0079	146.89 (17.56)	137.78 (17.15)	0.0704
DAP mean***	77.53 (11.78)	72.89 (8.55)	0.0377	79.93 (8.15)	75.81 (7.76)	0.1095
Fasting blood glucose	162.61 (96.31)	126.64 (48.23)	0.0345	128.52 (55.40)	112.33 (72.27)	0.4064
C-LDL****	86.36 (39.79)	87.43 (36.20)	0.9028	102.96 (35.96)	95.85 (33.86)	0.4784
C -HDL*****	42.00 (9.60)	39.47 (11.05)	0.4329	44.85 (20.07)	41.33 (13.43)	0.3448
Total cholesterol	174.17 (45.85)	168.44 (42.36)	0.5829	179.67 (47.97)	166 (39.69)	0.2570
Triglycerides	212.75 (184.81)	201.67 (180.02)	0.7476	145.04 (79.75)	144.15 (61.35)	0.9822
Glycosylated hemoglobin	9.36 (2.13)	8.87 (1.38)	0.2558	8.01 (1.87)	8.55 (1.78)	0.2768

*Note: *standard deviation; **systolic arterial pressure; ***diastolic arterial pressure; ****low density lipoprotein; *****high density lipoprotein*

Table 2 – Comparison and analysis of mixed effect models for the glycated hemoglobin variable, before and after intervention in Group 1 and Group 2, Ribeirão Preto, São Paulo, Brazil, 2014

Comparisons inter and between groups	Glicated Hemoglobina			
	Mean (SD)*	CI 95%**		*p* value
Before (Group 1–Group 2)	9.36 (2.13) 8.01 (1.87)	0.4304	2.2511	0.0042***
After (Group 1–Group 2)	8.87 (1.38) 8.55 (1.78)	-0.5928	1.2280	0.4911
Group 1 (Before–After)	9.36 (2.13) 8.87 (1.38)	-0.3567	1.3290	0.2558
Group 2 (Before–After)	8.01 (1.87) 8.55 (1.78)	-1.5103	0.4362	0.2768

*Note: *SD: standard deviation; **CI 95%: 95% confidence interval; ***statistically significant (P-value < 0.05).*

DISCUSSION

Studies concerning chronic health conditions in a determined life context, including the structure of the related services, face methodological challenges due to human nature and to the variables relative to the occurring disease and the environment. The pragmatic clinical trial option was discussed by the "Crossing the Quality Chasm" report published by the Committee on Quality of Health Care in America, USA[20].

Therefore, it is recommended to include an ample and representative sample via the recruitment of a great variety of scenarios proper to common clinical practice. In contrast, the majority of previous studies consider rigorous selection criteria which often do not consider the comorbidities associated with the chronic disease[21].

These difficulties were also found during the process of selecting participants through the FARMANET system list; nevertheless, this constituted the only access to the population under the study. This limitation failed to include the totality of the target population because of the exclusion of people without a telephone and those with missing data. The selection criteria included 11.5% of the initial participants.

In Brazil, studies[6-7] that used telephone support managed to reach out to 13.61% and 16.45% of the participants respectively. The reach, as one of the parameters considered by the RE-AIM model, is defined as the absolute number, proportionately and representatively, of the individuals who are willing to participate in a given initiative when compared to those that desist or those who are potentially eligible[9-10].

Our results show that there is a discrete reduction in the values of some of the clinic variables used in the metabolic control of DM in both groups; however, these changes were not statistically significant except for the fasting blood glucose levels in the G1 group subjected to telephonic support as an educative strategy.

While analyzing the values for HbA1c and fasting blood glucose for P0, it was found that the G1 group presented worse metabolic control when compared to G2. However, after the intervention via phone, a distinctive reduction was observed in G1. G2 also presented a reduction but this was less remarkable. Analysis of HbA1c should be made frequently as

part of the treatment of DM, due to its highly predictive value for the complications inherent to the disease. Measurement every three months determines whether the glycemic target has been reached or maintained[17]. Thus, the HbA1c was considered as an important predictor to evaluate the educative intervention via telephone support, realized during the four months of this study. The diminution of HbA1c is of great clinical relevance to the metabolic control of people with DM[22]. A study in 2014 described a reduction of 9.38% mg/ml in the fasting blood glucose level and 0.02% of HbA1c in a group that underwent telephone support during eight encounters per week. A group that only received telephone support during four months experienced a reduction of 6.38 mg/dl in the fasting blood glucose and 0.1% in HbA1c[7].

In the present study, the results indicate that the use of telephone support seemed to meet the individual objectives of elderly people with DM, because when added to the usual care it further offers the possibility of a periodic analysis of additional interventions and reassessments. This study also considered the submission of a letter, which had positive repercussions in the metabolic control of elderly people with DM.

The regular follow-up of a person with a chronic health condition is a major gap in health services, with DM clearly standing out[8]. This follows because the quality of the assistance for the treatment of DM is complicated day after day by the associated comorbidities and by the supplies involved such as the blood glucose monitoring equipment, infusion pumps, injection pens, and medications. This poses a challenge to the DM patients and to home-care providers, resulting in a high demand for health services dedicated to this chronic condition[23]. The focus of DM treatment is to empower patients and relatives in the management of their self-care with the objective to achieve metabolic control[8,17].

One possible way to achieve this goal is through health education and the supervision of regular patients via telephone support, according to a study that investigated the impact of education and telephone support on self-care and metabolic control in people with DM. This experimental study was carried out in Turkey with 88 people with DM divided into two groups (44 control and 44 in the intervention group). People in the intervention group were subjected to telephone intervention for three months. The results showed that, in this group, where 47% of the sample was more than 58 years old, there was a reduction in the values for some metabolic control variables including HbA1c, total cholesterol, triglycerides, C-LDL, and systolic blood pressure. An increase in the self-care scoring scale was also observed. In view of these results and according to the authors, healthcare education via telephone support is a strong partner to the health professional, who can better assist people with DM to maintain their self-care behavior[24].

A study of systematic revision within the elderly population evaluated the benefits of the intervention via communication technology, which also included telephone support. A total of 8,666 cases were analyzed, the majority of which were concentrated in persons with DM (31%) or cardiac insufficiency (29%). Based upon the analyzed evidence, the interventions via telephone support seem to be more related to the monitoring of vital signals and to the accompaniment of the clinical conditions by the nurse in order to reduce the demand for health services[25]. This has been discussed in several other studies[6-7,22] and is a matter of concern among health-care managers, most markedly in developing countries such as Brazil[8,17,20-21].

Limitations of the study

Future studies with a representative sample of the elderly population with DM are needed to prove the effectiveness of telephone support as a tool in diabetes education with a view to generalizing the results.

Contributions to the area of nursing, health or public policy

The use of telephone support is an innovative tool that can add value to the strategies used by the nurse in diabetes education and increase health care services for the elderly with DM.

CONCLUSION

After four months of telephone support intervention as an educational strategy, a significant reduction in fasting blood glucose levels was obtained, as well as clinically relevant results in relation to HbA1c values in elderly people with DM. It is expected that the results presented here will lead future investigations. What is needed is a reflection on the necessity of further planning and the implementation of educational interventions for innovative strategies to treat the elderly with DM that can be relayed in the context of health by the use of the telephone.

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