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Evaluation of home visits for the empowerment of diabetes self-care

Avaliação da visita domiciliar para o empoderamento do autocuidado em diabetes

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Keywords

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Descritores

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Abstract

Objective: To evaluate the effect of home visits on adherence and empowerment of self-care practices in type 2 diabetes mellitus.

Methods: Cluster randomized clinical trial involving 145 users with type 2 diabetes *mellitus*, of which 34 in the intervention group and 111 in the control group. The diabetes self-care questionnaire and the Diabetes Empowerment Scale-Short Form were used for comparison between groups at baseline, and intragroup between before and after the study period. The level of significance was set at 0.05.

Results: The intervention group presented a statistically significant increase in the median score regarding adherence to diabetes self-care practices ($p=0.005$) and the empowerment scale ($p<0.001$).

Conclusion: The home visit promoted adherence to self-care practices of type 2 diabetes *mellitus*.

Resumo

Objetivo: Avaliar o efeito da visita domiciliar na adesão e empoderamento das práticas de autocuidado em diabetes *mellitus* tipo 2.

Métodos: Ensaio clínico randomizado por *clusters*, com a participação de 145 usuários com diabetes *mellitus* tipo 2, sendo 34 do Grupo intervenção e 111 do Grupo controle. Foram utilizados os questionários de Autocuidado com o diabetes e *Diabetes Empowerment Scale-Short Form* para comparação entre grupos na linha de base, assim como entre o antes e depois intragrupo. O nível de significância foi 0,05.

Resultados: O grupo intervenção apresentou aumento estatisticamente significativo do escore mediano referente à adesão às práticas de autocuidado em diabetes ($p=0,005$) e à escala de empoderamento ($p<0,001$).

Conclusão: A visita domiciliar promoveu a adesão às práticas de autocuidado com diabetes *mellitus* tipo 2.

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Introduction

Type 2 diabetes *mellitus* (DM) is a chronic health condition with low rates of adherence to treatment, since it imposes daily challenges for self-care practices associated with following a healthy food plan and practice of physical activity for control and prevention of complications arising from this chronic condition.⁽¹⁻⁴⁾

Different studies demonstrate the necessity to systematize educational strategies for improving adherence to diabetes self-care practices in order to meet users' needs by guiding, motivating and, above all, enabling them to effectively control diabetes.⁽²⁻⁵⁾ Home visits provide space for dialogue and qualified listening, since this educational strategy, as a way to empower users for diabetes self-care, allows an approximation to their life reality, and helps them making informed decisions.⁽⁵⁻⁷⁾

In this study, was used the empowerment approach in home visits. It is based on behavioral and psychosocial aspects inherent to users' autonomy and abilities to effectively take responsibility for their own care. Empowerment enables users to make healthy behavioral changes, take informed decisions about their treatment, and provides them with willingness to adhere to self-care practices.^(5,8,9)

The objective of this study was to evaluate the effect of home visits on the adherence and empowerment of users with type 2 diabetes *mellitus* for self-care practices.

Methods

Cluster randomized clinical trial formed by seven units of the Family Health Strategy (FHS) of a municipality in the state of Minas Gerais in the year 2015. Two of these units were allocated to the Intervention Group (IG) and the remaining five to the control group (CG). This study is part of a larger study in which three more units (FHS) were allocated to another type of intervention (operative groups).⁽⁴⁾

The sample size calculation was done for the larger study and considered the cluster effect.⁽¹⁰⁾ Previous studies with similar populations were used as reference,^(11,12) and the value of the intra-class correlation coefficient was estimated at $\rho = 0.008$. In the sample calculation were used the other following values: significance level $\alpha = 0.05$; test power $\omega = 0.90$; effect on the dependent variable (standardized) $d = 1$, average size of clusters $\bar{n} = 80.9$, total population $n = 1320$ and $k = 10$ clusters (total number of FHS units allocated). Thus, a number of 65 users was determined for each study group (CG and IG). Considering a friction rate of 35%, each group should begin the study with at least 100 users.

For cluster allocation to study groups, several combinations of the ten FHS units were formed and randomly assigned to two groups of five units each. Of the combinations in which groups met the criterion of homogeneity regarding age, glycated hemoglobin, and educational level, one was selected by lot. In the selected combination, one of the groups of five units was allocated randomly to receive the intervention, while the other was allocated to the control group. All this procedure was done using the R software.⁽¹³⁾

Subsequently, the intervention group was divided into two subgroups with three and two FSH units each. Considering home visits are an educational strategy operationally more expensive than that of operative groups, the subgroup with two FSH units was allocated to receive home visits.

The choice of the study through clustering allows randomization by groups of individuals. In the case of FHS units, it also reduces the chance of contamination by contact of control group users with intervention group users.⁽¹⁴⁾

One-hundred sixty-three users with type 2 diabetes *mellitus* were recruited at the beginning of the study, of which 41 were in the intervention group and 122 in to the control group. The inclusion criteria were age between 30 and 79 years, because type 2 diabetes is a chronic condition that usually begins at 30 years of age. This study selected adults and elderly with visual,

auditory and locomotor skills to participate in educational practices developed during home visits, and to perform self-care practices such as physical activity and diet. Other inclusion criteria were accepting the home visits and having a contact telephone number. Participating health units were allocated randomly to one of two study groups; two units were allocated to the intervention group and five to the control group, according to the CONSORT guidelines,⁽¹⁵⁾ as shown in figure 1.

Two hundred and thirty-eight home visits were held, since each user in the intervention group received seven visits. Each home visit had an average duration of two hours, which resulted in 14 hours of contact time distributed in three cycles (1, 2 and 3), three-month intervals between cycles, and the participation of two research nurses. Three meetings were held in cycle 1, one per week. In cycles 2 and 3, were held two visits with a 15-day interval between them.

The home visit was based on the Behavior Change Protocol in diabetes *mellitus*. It is composed of 31 questions divided into five steps: (1) identification of the problem; (2) identification and approach of feelings; (3) goal setting; (4) elaboration of the care plan to achieve the goals (My Intelligent Plan); and (5) assessment and experience of users about the care plan.⁽¹⁶⁾ These steps were addressed with support of interactive dynamics through dialogues between health professionals and users with the purpose to stimulate their reflection on the problems that prevented self-care, and thus develop possible goals to be achieved in their context of life by enabling better adherence and empowerment for self-care practices.

The themes discussed at the three-cycle home visits were self-care practices related to feelings and emotions about living with diabetes, healthy eating (food frequency, macro and micronutrients: carbohydrates, proteins, fats, vitamins and

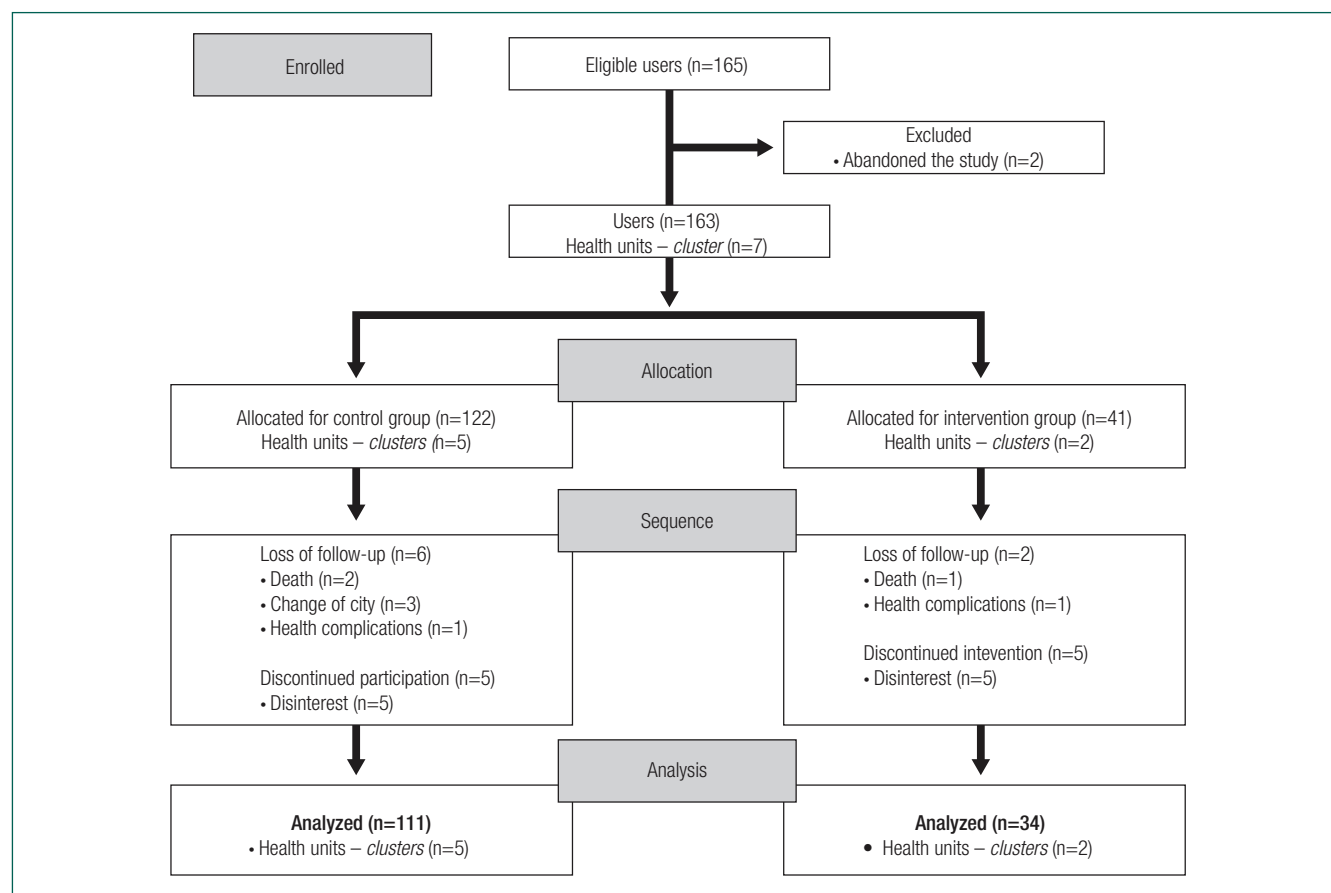


Figure 1. Diagram of the progress of clusters and users in the phases of the randomized trial

minerals, with emphasis on the importance of fiber intake and reduction of sugars). Covered topics included physical activity, prevention of complications of diabetes, and barriers identified by users that interfered with health care. At the end of each visit, the user was encouraged to set a goal to be achieved for solving the problem. In the intervals between the three cycles, users received a telephone call once a month with the purpose of guidance and encouragement regarding the goals.

Users of the control group participated in educational practices developed by the units of the Family Health teams to which they belong. They also maintained the conventional follow-up performed by these units through clinical care. In each cycle of this study, users of the control group received three telephone calls from the research nurses and informative pamphlets about the diabetes condition. Contact with the control group is justified by the need to maintain the bond with these users and decrease losses throughout the study.

In this study, the dependent variables were adherence to self-care practices related to physical activity and dietary reeducation; and the empowerment scale for DM self-care. The independent variable refers to the study group: intervention (home visit) and control.

For data collection, were used two validated instruments: Diabetes self-care questionnaire (ESM), and Diabetes Empowerment Scale-Short Form (DES-SF). The instruments were related to the variables of adherence and empowerment for self-care practices, respectively.

The ESM measures adherence to self-care practices of users with diabetes. The total score is 8 points, and it covers issues related to self-care activities related to food and physical activity in the previous seven days. To indicate improvement in adherence to self-care practices, a minimum score of 5 points should be reached.⁽¹⁷⁾

The DES-SF instrument was applied to assess users' empowerment for self-care with diabetes *mellitus*. This instrument is a short version adapted from the original instrument called Di-

abetes Empowerment Scale (DES).⁽¹⁸⁾ In Brazil, the DES-SF translated version and adapted to Portuguese is titled Self-efficacy Scale in Diabetes - short version (EAD-VC/Escala de Autoeficácia em Diabetes - versão curta).⁽¹⁹⁾ However, the DES-SF acronym was kept because the empowerment variable is the basis of the hypothesis of this study and known internationally. DES-SF has domains that consider the psychosocial aspects of diabetes; management of dissatisfaction and readiness to change; and setting and achieving goals. It has eight closed questions answered with help of a 5-point Likert scale ranging from 'strongly disagree' to 'strongly agree'. Scores range from 1 to 5 for each question, and the overall score is calculated by the average score of each of the eight items. The higher the total score value the higher the level of user empowerment. A score of 3.8-5.0 is considered high, values between 2.4-3.7 are considered medium, and a score of 1-2.3 is considered low.^(18,19)

ESM and DES-SF were applied before the start of cycle 1 and at the end of cycle 3 by means of telephone contact. Each call had an average duration of 15 minutes, and responses were recorded in the eSurv online tool.

Data analysis was performed with use of the STATA (STATA Corp., College Station, Texas, USA) statistical software, version 11.1. Descriptive analysis was performed with calculation of frequencies and measures of central tendency and dispersion. In addition, the Shapiro-Wilk test was applied to verify the normality assumption for the distribution of continuous quantitative variables.

Mean and median of independent groups were compared using the Student's t and Mann-Whitney tests, respectively. Proportions were compared using the Pearson's chi-square test. The evaluation of the intervention's effectiveness was performed through the paired Student's t test or the Wilcoxon test to compare means and medians respectively.

For variables of self-care and empowerment, the effect of the experiment was defined as the difference between its value in the final period

and initial period (Δ), divided by the initial value. The effect values were multiplied by 100 to transform them into percentage variations. For all analyzes, was used a confidence level of 95% ($p < 0.05$).

The study was approved by the Research Ethics Committee of the Universidade Federal de Minas Gerais, Brazil, under protocol number 426.968/2013. Participants signed an Informed Consent form. The registration number is NCT02132338 in the international registry of clinical trials, and RBR-92j38t in the national registry.

Results

The sample consisted of 163 users with type 2 diabetes. After distribution of the health units, 41 users were allocated to the intervention group and 122 to the control group. There were losses throughout the study, and 145 users (34 of the intervention group and 111 of the control) had their data analyzed at the end.

The losses were considered random. There was no statistically significant difference in relation to variables of age, sex and educational level ($p > 0.05$) between users who left the study (losses) and those who remained in the study. The main reasons for losses were: lack of interest in continuing in the study, deaths, health complications related to other diseases, and two users of the control group moved to other cities.

The groups were considered homogeneous at baseline in relation to the following variables: sociodemographic data, sex, educational level, marital status and occupation (Table 1).

The analysis of sociodemographic characteristics demonstrated that the majority of users in the intervention group (76.5%) and in the control group (65.8%) were female. The mean age in the intervention group was 56.1 years, and 57.5 years in the control group. Regarding marital status, most users in the intervention group (82.3%) and control group (78.4%) lived with a partner. With regard to occupation, half of users in the intervention group and 50.5% of users of the control group declared

Table 1. Distribution of sociodemographic variables of users with type 2 diabetes *mellitus*

Variable	Mean \pm SD or Median (Minimum - Maximum)		p-value*
	IG(n=34)	CG(n=111)	
Age, mean \pm SD	56.1 \pm 10.6	57.5 \pm 9.7	0.228
Female, n (%)	26(76.5)	73(65.8)	0.224
Educational level, n (%)			
Up to incomplete primary school	25(73.53)	73(65.8)	0.128
Complete primary school until post-graduation	9(26.47)	38(34.2)	
Marital status, n (%)			
With partner	28(82.3)	87(78.4)	0.617
Without partner	6(17.7)	24(21.6)	
Occupation, n (%)			
Active	17(50.0)	55(49.6)	0.963
Inactive	17(50.0)	56(50.5)	
Time of diabetes diagnosis, n (%)			
≤ 5 years	19(55.9)	21(18.9)	0.001
> 5 years	15(44.1)	90(81.1)	

*Student's t test. IG - intervention group; CG - control group; SD - standard deviation

themselves as inactive, that is, they did not perform any paid activity.

Most users had incomplete primary school; 73.5% of the intervention group and 65.8% of the control group. About the time since the illness diagnosis, a little more than half of users of the intervention group (55.9%) claimed having a chronic condition for up to 5 years, while a great part in the control group (81.1%) reported having diabetes for more than 5 years.

The study groups were considered homogeneous at the baseline for adherence to self-care practices ($p=0.894$), but not for the empowerment score ($p<0.001$; Table 2).

Regarding adherence to self-care practices, the comparison between pre and post-education periods in the group with home visits showed a statistically significant increase in the median score ($p<0.05$). However, among users of the control group, the same did not happen. In the comparison between intervention and control groups (Table 3), the effect on the score of the diabetes self-care (Δ ESM) in the intervention group was considered statistically different from the control group ($p<0.001$).

Finally, regarding empowerment measured by the DES-SF, there was a statistically significant increase of the median score in both groups ($p<0.05$; Table 2). However, this increase was not considered statistically different between the two groups ($p=0.607$; Table 3).

Table 2. Intragroup comparison of self-care measurements with diabetes (ESM) and empowerment (DES-SF), before and after the intervention, and at baseline

Variables	Intervention Group		p-value*	Control Group		p-value*	Intervention Group - Control Group p-value**
	Initial time	Final time		Initial time	Final time		
	Median (Minimum-Maximum)	Median (Minimum-Maximum)		Median (Minimum-Maximum)	Median (Minimum-Maximum)		
ESM	3.0(2.0-6.0)	5.0(2.7-6.2)	<0.001	3.2(1.0-6.8)	3.0(1.2-6.1)	0.970	0.894
DES-SF	4.0(2.5-4.7)	4.2(3.5-4.9)	0.005	3.6(2.7-4.7)	4.0(2.5-4.9)	<0.001	<0.001

*Wilcoxon test for intragroup comparison (before and after the study period); **Mann-Whitney test for comparison between groups at baseline. ESM - Diabetes self-care questionnaire; DES-SF - Diabetes Empowerment Scale-Short Form

Table 3. Intergroup comparison for self-care with diabetes (Δ) and empowerment (Δ)

Variables	Intervention Group	Control Group	Intervention Group - Control Group p-value*
	Median Δ (Minimum-Maximum)	Median Δ (Minimum-Maximum)	
ESM	43.22(-35.29 - 179.23)	0(-61.54 - 435)	<0.001
DES-SF	4.70(-20 - 55)	9.27(-42.66 - 59.09)	0.607

*Mann-Whitney test for intergroup comparison. Δ - percentage variation of the measurement between the beginning and end of the study. ESM - Diabetes self-care questionnaire; DES-SF - Diabetes Empowerment Scale-Short Form

Discussion

The characterization of sociodemographic data revealed the average age of users was 56.8 years old, the majority were women with low educational level, living with partners, inactive in the labor market and with an average time of diabetes diagnosis of up to five years. This information is similar to the literature data that indicate an increase in adults with diabetes aged 40 years or older, the majority over 50 years old, predominantly women, with low educational level and inactive.^(11,20-22)

The prevalence of women in this study is similar to that obtained by Vigitel,⁽²³⁾ in which the frequency of self-reported diabetes diagnosis in 2012 was 8.1% in women and 6.5% in men. The higher prevalence among women has been reported in other studies in Brazil.^(3,24)

In this study, the time of diabetes diagnosis was up to five years among the majority of users who received home visits, unlike the control group, in which the majority claimed to have diabetes for more than five years. The time of diagnosis should be considered, since it can be difficult to determine the exact duration of diabetes time given the asymptomatic period before the diagnosis period.^(1,25) This chronic health condition may remain asymp-

tomatic for a long time, and its clinical detection is commonly performed by its risk factors.⁽¹⁾

The results of the present study also showed that home visits were effective for adherence to diabetes self-care practices, since there was a change in the ESM median score in the group that received the visits and was considered statistically different among users of the two study groups. A similar result was found in a study in which the assessed outcome was improvement of self-care practices in patients followed for six months (intervention), compared to the conventional follow-up of health services (control), confirming the beneficial effect of this educational strategy.⁽⁷⁾

These results are important for glycemic control and consequently, for the prevention of complications of type 2 diabetes, because self-care practices such as healthy eating and regular practice of physical exercise help in the metabolic control of this chronic health condition.⁽⁴⁾ Complementarily, the home environment enabled the assistance to users regarding appropriate decision making for meeting goals in face of their specific needs and social context, which positively influenced self-care practices.^(7,24) Corroborating evidence from the literature, home visits facilitate users' understanding on self-care with diet, physical exercise and weight control by improving their diabetes management continuously.^(6,7,24)

It is noteworthy that home visits as an educational strategy for adherence to diabetes self-care practices allows monitoring the performance of the care executed by users and predicting the factors interfering in the development of care for diabetes control.⁽¹⁷⁾

Regarding empowerment for self-care practices, the results revealed an increase in the median score

both in the control and intervention groups after the study. However, this increase was not statistically different between the two groups.

The users who participated in home visits increased confidence hence, improved their ability of making informed decisions and developing skills to improve self-care behaviors. In addition, they learned to manage their chronic condition more efficiently and to find solutions that allowed overcoming the barriers for development of self-care.⁽¹⁹⁾ Therefore, the results demonstrate the empowerment approach has the potential to help users with solving daily problems related to social, psychological and clinical aspects, because it influences on adherence to healthy behaviors by increasing their autonomy and capacity to care for their own health.^(4,19)

In the intervention group, there were also changes in positive behaviors related to dietary re-education and physical activity. Gradually, users with home visits realized they were able to care for themselves, as they felt able to change habits. The greater the users' ability for self-care of their chronic health condition the closer to empowerment they are by taking over the abilities to be responsible for their own health care.⁽¹⁹⁾

Note that most of the population in this study was over 55 years of age. According to the literature, young people tend to seek more information and are more willing to adhere to healthier behaviors to control diabetes.⁽⁵⁾ That is, the time users live with diabetes may affect their willingness to engage in self-care practices through the empowerment approach.

Experimental studies using the empowerment scale also find positive results in adherence to self-care practices when addressing empowerment.^{(4,26-}

²⁸⁾ The educational strategy of home visits allowed the problematization (together with users) of the necessary knowledge and skills for adherence to self-care practices.

The results of the present study indicate that home visits improved the skills for adherence and empowerment of self-care practices with type 2 diabetes *mellitus* of users, and may also influence important clinical outcomes that deserve to be studied in other opportunities.

This study presents some limitations, such as the time of development of the educational strategy of home visits, which, as discussed in the literature, should be greater than 12 months and not only ten months.^(8,26-29)

Conclusion

The home visit promoted adherence to self-care practices of type 2 diabetes *mellitus*.

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Collaborations

Souza DAS collaborated with the project design, planning, analysis and interpretation of data, and writing of the article. Reis IA contributed with analysis and interpretation of data and relevant critical review of intellectual content, and final approval of the version to be published. Cortez DN collaborated with the project design and relevant critical review of intellectual content, and final approval of the version to be published. Afonso GS collaborated with the project design. Torres HC collaborated with the project design, planning, analysis and interpretation of data and writing of the article, relevant critical review of intellectual content, and final approval of the version to be published.

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