HOME BLOOD GLUCOSE MONITORING IN TYPE 1 DIABETES MELLITUS[1]

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Objective: To determine which of two simplified blood glucose monitoring schemes promotes better metabolic control in type1 diabetic patients during 12 months of participation in educational groups. Methods: A crossover clinical trial involving 21 patients divided into two groups was conducted. They were submitted to a two monitoring schemes:2 alternate daily preprandial measurements and 2 alternate daily pre-and postprandial measurements. The effectiveness of the schemes was evaluated based on HbA1c. Variations in mean HbA1c were analyzed by Friedman test. Results: The groups were homogenous in terms of sociodemographic and clinical variables (p>0.05). Mean HbA1c levels ranged from 8.48 (±1.00) to 7.37 (±0.99) over time in Group A and from 9.89 (±0.86) to 8.34 (±1.06) in Group B. The analysis of the HbA1c showed a significant reduction in the first and last 6 months and over the 12 months of the study in two groups (p<0.05). The preprandial scheme demonstrated the largest number and highest percentage of significant drops in HbA1c. Conclusions: The two monitoring improved the metabolic control and the preprandial scheme was more effective.

DESCRIPTORS: diabetes mellitus, type 1; blood glucose self-monitoring; nursing

MONITORIZACIÓN, EN EL DOMICILIO, DE LA GLUCEMIA EN PACIENTES CON DIABETES MELLITUS TIPO 1

Objetivo: Identificar cual de los dos esquemas de monitorización propuestos posibilita realizar un mejor control metabólico, en diabéticos del tipo1, durante los 12 meses de participación en grupos educativos. Método: Ensayo clínico cruzado con 21 pacientes divididos en dos grupos y sometidos a dos diferentes esquemas de monitorización. La efectividad de los esquemas fue evaluada por medio de la HbA1c. La variación de los promedios de HbA1c fue analizada con la prueba de Friedman. Resultados: Durante todo el estudio la variación de los promedios de HbA1c, para el grupo A, fue de 8,48(±1,00) la 7,37(±0,99) y de 9,89(±0,86) la 8,34(±1,06) para el grupo B. Los análisis de la variación de la HbA1c colocaron en evidencia una reducción significativa (p<0,05) en los dos grupos, en los 3 periodos evaluados: primeros y últimos 6 meses y durante los 12 meses de estudio. Conclusiones: Los dos esquemas mejoraron el control metabólico y el esquema antes de las comidas fue más efectivo.

DESCRIPTORES: diabetes mellitus tipo 1; automonitorización de la glucosa sanguínea; enfermería

MONITORIZAÇÃO DOMICILIAR DA GLICEMIA EM PACIENTES COM DIABETES MELLITUS DO TIPO 1

Objetivo: Identificar qual de dois esquemas simplificados de monitorização da glicemia viabiliza melhor controle metabólico, em pacientes com diabetes mellitus tipo 1, ao longo de 12 meses de participação em grupos educativos. Método: Ensaio clínico cruzado, com 21 pacientes divididos em dois grupos. Eles foram submetidos a dois esquemas de monitorização: duas medidas diárias pré-prandiais alternadas e duas medidas diárias pré e pós-prandiais alternadas. A efetividade dos esquemas foi avaliada pelos níveis de HbA1c. Para estudar a variação das médias das HbA1c aplicou-se o teste não paramétrico de Friedman. Resultados: Os grupos eram homogêneos ao início do estudo com relação às variáveis sócio-demográficas e clinicas(p>0,05). A variação das médias de HbA1c, ao longo do tempo para o grupo A foi de 8,48(±1,00) a 7,37(±0,99) e para o grupo B de 9,89(±0,86) a 8,34(±1,06). O resultado da análise da variação da HbA1c mostrou redução significativa nos dois grupos, nos primeiros e últimos 6 meses e ao longo dos 12 meses nos dois grupos (p<0,05). O Esquema de monitorizações pré-prandiais possibilitou o maior número e os maiores percentuais de quedas estatisticamente significativas nos níveis de hemoglobina glicada. Conclusões: Os dois esquemas melhoraram o controle metabólico e esquema pré-prandial foi mais efetivo.

DESCRITORES: diabetes mellitus tipo 1; automonitorizacão da glicemia; enfermagem

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INTRODUCTION

One of the most significant studies to test the proposal that complications of Type 1 Diabetes Mellitus (DM1) are related to a chronic increase in blood glucose was the Diabetes Control and Complications Trial (DCCT)[1]. The DCCT showed that intensive insulin therapy to maintain glucose levels close to normal is certainly effective in minimizing the development and progression of complications of DM[1].

Many questions have been raised regarding the difficulties in implementing the rigid controls recommended by the DCCT and also regarding their implications in clinical practice, educational programs, self-monitoring, quality of life and treatment costs, especially at services where no resources or trained professionals are available. Alternative strategies for the control of DM that take into account individual limitations and deficits in the health system related to human and financial resources are necessary and are the main objective of the present study. The objective of the present study was to evaluate the effectiveness of two different home blood glucose monitoring schemes in improving glucose control in patients with DM1 undergoing a monthly therapeutic adjustment regimen over a period of 12 months of participation in educational groups.

PATIENTS AND METHODS

This randomized crossover study was carried out at the outpatient clinic of the "League of Diabetes", Discipline of Endocrinology, HC-FMUSP. The study population consisted of subjects with DM1 enrolled in the service who complied with the following inclusion criteria: age older than 2 years, motivation to monitor blood glucose twice a day for a period of 12 months, and the basic socioeconomic-cultural and cognitive conditions necessary to attend the educational groups and to participate in the activities developed. Excluded were patients with less than 2 years of the disease, patients sporadically or continuously using hyperglycemic drugs, patients with other DM-associated endocrinopathies, and subjects who did not agree to participate in the study. The sample consisted of 21 patients who already monitored blood glucose levels once a day and who fulfilled the criteria described above.

The patients were then randomly divided into two groups by drawing lots. Group A used Scheme 1 for monitoring blood glucose during the first 6 months of the study and Scheme 2 during the subsequent 6 months. Group B used Scheme 2 during the first 6 months of the study and Scheme 1 during the subsequent 6 months. In Scheme 1, the patients self-monitored capillary blood glucose levels twice a day at preprandial times (30 min before meals), at bedtime and at 3 am every 2 weeks over a period of 6 months. In Scheme 2, the patients self-monitored capillary blood glucose levels twice a day at preprandial (30 min before meals) and postprandial times (90 to 120 min after meals) and at 3 am every 2 weeks over a period of 6 months. The effectiveness of the monitoring schemes in promoting metabolic control was evaluated by the measurement of glycated hemoglobin (HbA1c) concentration and the results obtained during 12 months were compared to baseline values (November 2003). The patients and their caregivers participated in monthly educational group meetings with the multi-professional team. The meetings of groups A and B were held on different days. The insulin regimens used consisted of 2 to 4 daily applications (before breakfast, before lunch, before dinner, and at bedtime) of intermediate-acting (NPH) and ultrarapid-acting insulin (Lispro). Lispro insulin was applied 15 min before meals. In order to create objective criteria for the therapeutic adjustment of insulin, one week of intensive monitoring consisting of 8 daily pre- and postprandial measurements (run in) was performed at the beginning of the study to determine factors indicating insulin sensitivity and to calculate correction factors to be applied during the study when the number of glucose tests was reduced to twice a day. The same scheme was repeated at the time of inversion of the groups as wash-out. The project was approved by the Ethics Committee of HC-FMUSP (process No.521/01).

The data of this study were collected using seven different instruments containing data regarding identification, socio-demographic and clinical variables, insulin treatment regimen and adjustments, capillary blood glucose levels, daily problems, glucose profile, anthropometric measurements, and dietary record.

Blood was collected from patients of groups A and B for the measurement of HbA1c (HPLC, normal range: 4.1 to 6.5%) before (baseline values) and 2, 4, 6, 8, 10 and 12 months after the beginning of the study. As a control parameter, all patients had their HbA1c levels compared to baseline values. The patients were instructed regarding the correct technique for capillary blood glucose testing. Finger punctures were performed with Soft Touch Lancets and Advantage System strips were used for glucose testing (both from Boehringer Mannheim Corporation). The quality of the glucose measurements was determined according to the recommendations of the American Diabetes Association[2].

The data were analyzed under the supervision of a statistician, using SPSS for Windows, version 10.0. Results presenting a p value < 0.05 were considered significant. The following tests were applied to determine the homogeneity of the groups at the beginning of the study: nonparametric Mann-Whitney test for HbA1c, family income, household members, Student *t*-test for age and BMI, and Fisher's test for gender, educational level and housing conditions. Along the study, all other analyses consisted of the interpretation of intragroup data. The nonparametric Friedman test was applied to study the variation in HbA1c and mean glucose levels between the different periods and over time. These analyses were performed separately for each group during the course of the two schemes. When a significant difference in HbA1c concentration was detected, Bonferroni multiple comparisons were performed to identify between which two months the difference occurred. The Wilcoxon test was used for intragroup comparisons of two schemes.

RESULTS

The characteristics of groups A and B are shown in Table 1.

Table 1 - Characteristics of groups A and B

Characteristics (n = 21)	Group A	Group B	p-value	Characteristics (n = 21)	Group A	Group B	p-value
Age in years				Family income in R$			
Mean (SD)	11.82 (3.19)	9.40 (2.8)	0.082*	Mean (SD)	1200.00 (512.08)	1075.00 (973.21)	
Gender				Median	1100.00	500.00	
Male	4 (36.4%)	3 (30.0%)		Range	500-2000	350-2900	0.221***
Female	7 (63.6%)	7 (70.0%)	0.999**	No.of household members			
Educational level				Mean (SD)	3.80 (0.63)	4.14 (1.57)	
Incomplete primary school	5 (50.0%)	7 (100.0%)		Median	4.00	4.00	
Complete primary school	1 (10.0%)			Range	3-5	2-6	0.719***
Incomplete middle school	2 (20.0%)			Baseline HbA1c			
Complete middle school	2 (20.0%)		0.233**	Mean (SD)	8.51 (1.26)	8.92 (1.83)	0.548***
No.of rooms in the dwelling				Chronic complications			
Mean	4.10	4.00		Yes			
Median	4.00	5.00		No	11 (100.00%)	10 (100.00)	
Range	1.10	1.63	0.920**	BMI			
				Mean (SD)	19.79 (3.92)	17.58 (1.80)	
				Range	15.3-26.7	15.5-21.4	0.129*

SD: standard deviation; BMI: body mass index; * Student t-test; ** Fisher's exact test; *** Mann-Whitney test.

The Mann-Whitney test confirmed the homogeneity of the sample in terms of HbA1c levels at baseline (p=0.548).These values were used as a control parameter for the subsequent analyses. With respect to the glycemic profiles, mean pre- and postprandial glycemic levels and glycemic variation were higher than desired in the two groups over time and no significant difference was observed over time in either group or between periods (nonparametric Friedman test, p>0.05).

Table 2. Variation in HbA1c concentration over time in group A

	Mean	SD	25th Percentile	Median	75th Percentile	Count
HbA1c/Nov03	8.20#	1.04	7.15	8.30	9.05	9
HbA1c/Jan04	8.39*	.58	7.80	8.60	8.90	9
HbA1c/March04	7.50*	.73	7.05	7.40	8.20	9
HbA1c/May04	7.37*	.99	6.80	7.30	8.20	9
HbA1c/July04	8.48**	1.00	7.65	8.20	9.35	9
HbA1c/Sept04	7.47**	1.31	6.35	7.40	8.55	9
HbA1c/Nov04	7.56**	.82	7.00	7.40	8.20	9

#baseline; *scheme 1; **scheme2; Friedman test: p<0.001

The lowest mean was obtained during the last measurement in Scheme 1 and the poorest mean was observed when the patients changed to Scheme 2. The nonparametric Friedman test showed a significant decrease of mean HbA1c levels in group A over time.

Table 3. Variation in HbA1c concentration over time in group B

	Mean	SD	25th Percentile	Median	75th Percentile	Count
HbA1c/Nov03	8.93#	1.94	7.10	8.90	10.55	9
HbA1c/Jan04	9.89*	.86	9.35	10.00	10.55	9
HbA1c/March04	9.06*	1.14	8.60	9.10	10.05	9
HbA1c/May04	8.81*	1.20	7.80	9.00	9.65	9
HbA1c/July04	9.11**	1.35	8.50	8.90	10.05	9
HbA1c/Sept04	8.34**	1.06	7.90	8.50	8.80	9
HbA1c/Nov04	8.51**	1.16	7.90	8.60	9.25	9

#baseline; *scheme 2; ** scheme1; Friedman test: p=0.002

A significant decline in mean HbA1c levels over time was also observed in group B.

Analysis of the variation in HbA1c concentration over time by the Friedman test showed a significant difference in the first (p=0.0004) and last 6 months (p=0.002) and along the 12 months (p<0.001) of the study in group A, and a significant difference in the first (p=0.028) and last 6 months (p=0.006) and along the 12 months (p=0.002) of the study in group B, irrespective of the current scheme.

Tables 4 and 5 show basal, intra-and interscheme comparisons of mean HbA1c concentration between the different months over the 12 months of the study. Comparisons of basal/Scheme 1 and intrascheme 1 showed that this scheme promoted three nonsignificant increases of HbA1c levels in groups A and B and nine declines, four of them being significant. The same comparison for Scheme 2 also showed three nonsignificant increases and nine declines, one of them significant. Interscheme comparisons revealed six increases, two of them significant and three declines, one of them significant when changing from Scheme 1 to Scheme 2 (Table 4).When changing from Scheme 2 to Scheme 1, the comparisons showed seven declines, two of them significant, and two nonsignificant increases (Table 5). Schemes 1 and 2 were compared within each group by the nonparametric Wilcoxon test for paired samples. The results showed no significant difference in mean HbA1c levels between schemes in group A (p=0.79), whereas in group B Scheme 1 significantly improved glycemic levels (p=0.021).

Table 4. Multiple comparisons of mean HbA1c in group A

Multiple comparison	Difference	p-value	Multiple comparison	Difference	p-value
Comparison basal X Scheme 1			Intrascheme 2 comparison		
Nov 03 X Jan 04	-0.189	> 0.999	July 04 X Sept 04	1.011	0.097
Nov 03 X March 04	0.700	0.080	July 04 X Nov 04	0.922	0.001*
Nov 03 X May 04	0.833	0.049*	Sept 04 X Nov 04	-0.089	>0.999
Intrascheme 1 comparison			Interscheme comparison**		
Jan 04 X March 04	0.889	0.008*	Jan 04 X July 04	-0.089	>0.999
Jan 04 X May 04	1.022	0.017*	Jan 04 X Sept 04	0.922	0.238
March 04 X May 04	0.133	>0.999	Jan 04 X Nov 04	0.833	0.049*
Comparison basal X Scheme 2			March 04 X July 04	-0.978	0.041*
Nov 03 X July 04	0.278	> 0.999	March 04 X Sept 04	0.033	>0.999
Nov 03 X Sept 04	0.733	0.937	March 04 X Nov 04	-0.056	>0.999
Nov 03 X Nov 04	0.644	0.219	May 04 X July 04	-1.111	0.008*
			May 04 X Sept 04	-0.100	>0.999
			May 04 X Nov 04	-0.189	>0.999

* Statistically significant; ** Change from Scheme 1 to Scheme 2

Table 5. Multiple comparisons of mean HbA1c in group B

Multiple comparison	Difference	p-value	Multiple comparison	Difference	p-value
Comparison basal X Scheme 1			Intrascheme 2 comparison		
Nov 03 X July 04	-0.178	>0.999	Jan 04 X March 04	0.833	0.191
Nov 03 X Sept 04	0.589	>0.999	Jan 04 X May 04	1.078	0.522
Nov 03 X Nov 04	0.422	>0.999	Interscheme comparison**		
Intrascheme 1 comparison			Jan 04 X July 04	0.778	>0.999
July 04 X Sept 04	0.767	0.024*	Jan 04 X Sept 04	1.544	0.011*
July 04 X Nov 04	0.600	0.881	Jan 04 X Nov 04	1.378	0.006*
Sept 04 X Nov 04	-0.167	>0.999	March 04 X July 04	-0.056	>0.999
Comparison basal X Scheme 2			March 04 X Sept 04	0.711	0.186
Nov 03 X Jan 04	-0.956	>0.999	March 04 X Nov 04	0.544	>0.999
Nov 03 X March 04	-0.122	>0.999	May 04 X July 04	-0.300	>0.999
Nov 03 X May 04	0.122	>0.999	May 04 X Sept 04	0.467	>0.999
			May 04 X Nov 04	0.300	>0.999

* Statistically significant; ****** Change from Scheme 2 to Scheme 1

DISCUSSION

Although analysis of glycemic profiles did not reveal significant improvement, metabolic control improved in the two groups studied irrespective of the scheme used. Although mean glycated hemoglobin concentration remained above the upper limit of the method, which is 6.5%, disagreeing with the patterns recommended in the literature, which classifies values of up to 10% above the upper limit of the method as satisfactory[1], analysis of HbA1c variation showed a significant reduction in the first and last 6 months and along the 12 months of the study in the two groups. It is possible that the therapeutic adjustments the team performed monthly based on individual glycemic profiles improved glycemic levels at times not contemplated in the schemes proposed, an improvement reflected in HbA1c levels. The fact that this improvement occurred irrespective of the scheme used suggests that the two monitoring strategies contributed to this improvement. As demonstrated in other studies, these results confirm that, when a monitoring program is encouraged[3-5] or when glycemic values are used to understand the interaction between insulin therapy, diet, physical activity and complications and to guide treatment, blood glucose monitoring effectively improves metabolic control and treatment compliance increases both among young patients and among those above the age of 60[5-7].

It has been well documented in the literature that, the larger the number of glucose tests performed, the greater the opportunities for insulin adjustment and the better the glycemic control[3,7-9]. In a study evaluating the effect of an insulin therapy regimen on metabolic control in 229 children, it was demonstrated that an increase in the frequency of blood glucose monitoring (1 to 6 times per day) was correlated with lower HbA1c (r=-0.15, p=0.006), with each additional daily monitoring resulting in a 0.4% decrease in HbA1c concentration, and that the number of insulin types and applications was correlated with increased HbA1c (r=0.2, p=0.02), with each additional insulin dose resulting in a 0.46% increase in HbA1c concentration[10]. Other studies have also demonstrated a correlation between lower HbA1c and the frequency of daily tests for blood glucose monitoring[8-12]. Some studies found no association between the frequency of blood glucose monitoring and better metabolic control[4,13].In a population study, data on the frequency of daily monitoring were obtained by questionnaires and the aim of that study was not to use blood glucose testing as a therapeutic strategy but only to investigate its relationship with HbA1c concentration[13]. Another study was conducted on 60 patients with DM1 who participated in an encouraged long-term self-monitoring program. High compliance with the program was observed during the first 6 months, with a frequency of about four daily monitorings, but only 50% of the subjects continued in the program for more than 3 years. During a critical period of the study, comprising the 8th to 11th semester, a higher frequency of daily monitoring was correlated with glycemic levels higher than 180 mg/dl and poor HbA1c values[4].The authors concluded that the worsening of metabolic control demonstrated by the increased HbA1c and capillary glucose tends to increase the frequency of monitoring. We agree with this conclusion.

When no intensive or ideal glucose monitoring is possible, which is the case for most health services in developing countries, alternative and less expensive strategies for blood glucose monitoring such as that proposed here can be adopted. Although not ideal, the present proposal permitted to improve the condition of the participants, with two daily glucose tests. Improvement of metabolic control with two daily monitorings on average has also been documented in a long-term follow-up study after the 12th semester and after a period of deterioration of glycemic control, when the participants readjusted to the requirements of the program[4].We found no studies in the literature reporting glycemic profiles obtained with the application of simplified monitoring strategies in patients with DM1. Many of the investigations mention such strategies but the study is focused on other variables. An interesting study evaluating glycemic profiles was conducted on 150 patients with stable type 2 diabetes in order to determine the effectiveness of once- and twice-daily self-monitored blood glucose testing strategies in detecting hyperglycemia and hypoglycemia. The pre-breakfast and pre-lunch measurements detected the largest proportion (63.6%) of hypoglycemic readings, pre-dinner and bedtime measurements detected the largest proportion (66.2%) of hyperglycemic readings, and pre-lunch and pre-dinner measurements detected the largest proportion (57.7%) of all hypoglycemic and hyperglycemic readings[14].These data support our intention to continue investigating and adopting simplified monitoring strategies in low-income populations.

Deterioration of metabolic control was observed in the two groups when changing from one scheme to the other (July), a finding indicating an adaptive phase during the new scheme. We believe that blood glucose monitoring consisting of two daily tests was not the only factor responsible for the improved metabolic control of the participants in this study. Monthly participation in the educational group, individual nutritional care and the bond established with the team surely contributed to this finding, since significant reductions in glycated hemoglobin were already observed at the end of the first 6 months (May) in the two groups and during the last 6 months of the two schemes (November).

The importance of education and comprehensive therapeutic support of patients with chronic diseases has been reported in some studies[13,15-16].The requirements for self-care and the psychosocial aspects involved in the daily management of diabetes are a source of stress, which might be minimized by personal engagement in the development of knowledge and adequate behaviors to cope with these situations[17].The role of the healthcare team in training and education programs is to adopt strategies to improve the way diabetic patients cope with daily situations and complications[17].In this respect, there was constant concern on the part of the professionals involved in the educational groups and individual meetings to enable and provide specific support to the participants in order to make decisions regarding diet, exercise, insulin adjustment, and management of hypoglycemia and other complications. The patients and their relatives were encouraged to understand the glycemic profiles and to discuss procedures with the team and could freely express their opinion and difficulties. Submissive behaviors were discouraged. The bond established between patients, relatives and the team was maintained throughout the 12 months, including telephone contact. We believe that the knowledge acquired and the approach established in educational practice substantially contributed to the improved metabolic control observed in the two groups.

The importance of this type of understanding approach objectively directed at solving daily problems related to the lack of glycemic control has been well described in a study involving 842 diabetic adults treated with insulin. The authors emphasized that blood glucose monitoring is not sufficient but that the patients should be able to manage the lack of glycemic control with the help of the team, which plays a fundamental role in the teaching and correction of judgment errors related to disease management[6]. The findings of an American multicenter study including 3567 adult patients with type 2 diabetes suggest that home blood glucose self-monitoring plays an important role in metabolic control only if it is an integral part of educational strategies aimed at promoting patient autonomy[13]. Although the present study involved children and adolescents, we believe that favoring autonomy is a fundamental aspect of treatment compliance in chronic diseases, especially in adolescents.

In order to better understand the behavior of the groups regarding the two different monitoring strategies proposed here, multiple comparisons of mean HbA1c concentration were performed between the different months (Tables 4 and 5). Basal and intrascheme comparisons demonstrated a superiority of Scheme 1 in terms of improving metabolic control in the two groups, since four statistically significant declines were observed during the course of this scheme versus only one significant decline during Scheme 2. The greater effectiveness of Scheme 1 was demonstrated by the significant reduction of glycated hemoglobin levels in group B (Table 5). Interscheme comparisons revealed worsening of metabolic control when changing from Scheme 1 to Scheme 2, with six increases in HbA1c, two of them significant (Table 4).When changing from Scheme 2 to Scheme 1, HbA1c levels improved as confirmed by the observation of seven declines, two of them significant (Table 5).The higher effectiveness of Scheme 1 can also be demonstrated when comparing the percentage reduction in HbA1c concentration between the beginning and end of the schemes. During Scheme 1, a 0.83% reduction was observed in group A during the first 6 months and a 0.30% reduction was noted in group B during the last 6 months. During Scheme 2, HbA1c concentration declined by 0.12% in group B during the first 6 months and increased by 0.19% in group A during the last 6 months. Since, during Scheme 1, the patients only adjusted preprandial insulin doses, the possibility of adjustments was greater, a fact that certainly contributed to the higher effectiveness of this strategy. Thus, in the present study, in which preprandial adjustment was used, it is possible to affirm that Scheme 1 was more effective than Scheme 2 in promoting metabolic control.

CONCLUSIONS

The two monitoring schemes permitted therapeutic adjustments that promoted significant improvement of metabolic control in the two groups as measured by HbA1c levels. This improvement seems to be related to an increased number of opportunities for therapeutic adjustment provided by the monthly meetings, monitoring and the educational program developed. Scheme 1 consisting of preprandial monitoring of blood glucose associated with the adjustment of insulin doses before meals was more effective in promoting metabolic control since it permitted a larger number of significant declines in HbA1c.The percentage of these declines was also higher during this scheme. Group A presented less variability and better HbA1c indices throughout the study, but there was no statistical explanation for the better performance of this group. It is possible that some intrinsic characteristics of this group not evaluated in the present study influenced the results, such as greater interest, compliance and participation.

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