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Impact of telephone monitoring on patients with heart failure: a randomized clinical trial

Impacto do monitoramento telefônico em pacientes com insuficiência cardíaca: ensaio clínico randomizado

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Keywords

Heart failure; Monitoring; Telephone; Continuity of patient care

Descritores

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Abstract

Objective: To analyze self-care and knowledge in patients with heart failure who were monitored telephonically, and to analyze the correlation of knowledge with self-care.

Methods: It was a randomized clinical trial, performed in a specialized clinic from April of 2015 to December of 2015. Thirty-six patients were monitored and randomized, with 17 in the control group and 19 in the intervention group. Both groups participated in the conventional monitoring, which included three visits (initial, second and fourth month); the intervention group was associated with telephone support by means of a standardized guide. The Knowledge and Self-Care Questionnaires were used to evaluate the primary and secondary outcomes.

Results: Difference in knowledge (12.7 ± 1.7 vs. 10.8 ± 2.2 , $p=0.009$) and self-care (25.4 ± 6.6 vs. 29.5 ± 4.8 , $p=0.04$) were identified in the fourth month; and there was a negative correlation between knowledge and self-care scores in the second month ($r=-0.48$; $p=0.03$).

Conclusion: The conventional management combined with telephone monitoring was effective in the 4th month with improved knowledge and self-care of patients with heart failure and a significant correlation of these outcomes in the second month.

Resumo

Objetivo: Analisar o autocuidado e o conhecimento em pacientes com insuficiência cardíaca monitorados por contato telefônico e analisar a correlação do conhecimento com o autocuidado.

Métodos: Ensaio clínico randomizado, realizado em uma clínica especializada, no período de abril de 2015 a dezembro de 2015. Foram monitorados e randomizados 36 pacientes no Grupo Controle (17) ou no Grupo Intervenção (19). Ambos os grupos participaram do monitoramento convencional, compreendendo três atendimentos (Basal; 2º mês; 4º mês); no Grupo Intervenção houve associação do monitoramento telefônico por meio de um guia padronizado. Foram utilizados os Questionários de Conhecimento e de Autocuidado para avaliação dos desfechos primários e secundários.

Resultados: Houve diferença no conhecimento ($12,7 \pm 1,7$ vs. $10,8 \pm 2,2$; $p=0,009$) e autocuidado ($25,4 \pm 6,6$ vs. $29,5 \pm 4,8$; $p=0,04$) no 4º mês; correlação negativa entre os escores do conhecimento e autocuidado no 2º mês ($r=-0,48$; $p=0,03$).

Conclusão: O monitoramento convencional combinado ao monitoramento telefônico mostra-se eficaz no 4º mês com a melhoria do conhecimento e autocuidado de pacientes com insuficiência cardíaca e correlação significativa desses desfechos no 2º mês.

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Conflicts of interest: there are no conflicts of interest to declare.

Introduction

Heart failure (HF) is considered a public health problem with high morbidity and mortality, prevalent in 5.1 million individuals in the United States between 2007-2012, with an expected increase of 46% between 2012 and 2030.

⁽¹⁾ The BREATHE study (Brazilian Registry of Heart Failure - Clinical Aspects, Care Quality and Hospitalization Outcomes) identified an in-hospital mortality rate of 12.6% in 1245 patients assessed, involving 51 public and private hospitals, and these results are related to several causes, such as the low percentage of medical orientation at hospital discharge.⁽²⁾

A systematic review of randomized studies found a 25% reduction in the total number of readmissions with HF decompensation for multidisciplinary treatments, such as health education and telephone-based monitoring or telemonitoring. Studies published in the last five years were selected to develop the methodology of this research.⁽³⁾

Health education is a widely used practice in the outpatient and in the hospital settings, whose strategies show beneficial effects on health promotion for the treatment of diseases, especially chronic diseases.⁽⁴⁾ Health education is an influential factor, directly related to the outcomes of positive patient care, aiming to teach people how to live life as healthily as possible to reach their maximum health potential.⁽⁵⁾ Dialogic education encourages autonomy in health care practice, and the participation of the individual in the control and supervision of the health service.⁽⁶⁾

Telephone-based monitoring, or telephone support, has been used by nurses as a strategy for educational process, for identification of signs of HF decompensation, and for guidance: The instructions provided to patients with HF, by telephone, are part of nursing education strategies, and are effective for health promotion, with a consequent improvement in knowledge and self-care.^(7,8)

Several studies demonstrate efficacy in telemonitoring, however, many of them do not present

a systematized approach for a telephone protocol or clear process in terms of which patient questions were addressed, or the possible interventions based on the answers presented. The relevance of this study is related in the use of an efficient and standardized approach, using a proper standardized guide for conducting telephone support, showing how this process occurred: what was asked, what is included in HF education, self-care skills, contact follow-up, and finally, how it is conducted. We believe that the standardization of telephone calls can significantly improve both knowledge and self-caring in HF that is, providing better conventional monitoring for the patient.

From this perspective, the main objective of this research was to verify the effect of telephonic monitoring on self-care and knowledge of HF patients. A secondary objective was to analyze the correlation of knowledge with self-care during the observation period.

Methods

This was a randomized clinical trial, conducted at the heart failure clinic of Pedro Ernesto University Hospital (Hospital Universitário Pedro Ernesto - HUPE), a large university institution located in the city of Rio de Janeiro, dedicated to the care of different pathologies. The collection and monitoring of patients occurred from April of 2015 to December of 2015.

The inclusion criteria were patients: with HF who were hospitalized and/or who were in emergency care in the last three months due to decompensated HF; of both sexes; age group ≥ 18 years; New York Heart Association (NYHA) Functional Classification;⁽⁹⁾ without functional problems that prevented them from speaking, writing or interfering with cognition; assessed and indicated by the physician; with residential or cellular telephone contact; and who were available for monitoring. Patients with very advanced HF with a short life expectancy (≤ 6 months), and/or other end-stage comorbidities that may interfere with the evaluation were excluded.

The sample calculation was performed by G*Power 3.1.5 software (Universitat Dusseldorf, Dusseldorf, Germany). G*Power provides the sample calculation based on the distribution of the study design, as well as on the type of statistical test and the power analysis type. Therefore, since the statistical test was the repeated measures ANOVA with group-time interactions, the power for the n-sample analysis was a priori (sample size calculated as a function of the $1-\beta$ power level, significance level α and effect size). Hence, G*Power provided a total sample size of 36 participants, a mean effect size $f=0.25$, level $\alpha=$ (err prob 0.05), sampling power ($1-\beta=0.90$), number of groups=2, number of measurements (0, 2 and 4 months), nonspherical correction ($\epsilon=1$). Considering potential losses, the total sample was increased by 20% ($n=44$): 22 participants allocated in two groups.

After eligibility, participants attending the HF clinic were automatically randomized to either the control group (CG) or intervention group (IG). Randomization occurred using simple randomization, with a random number table, sequentially identified as CG or IG.

The patients from the CG and IG were monitored by a nurse at the HF clinic at three times: on the day of the recruitment, during the second and fourth months after the first nursing care. Each appointment lasted approximately 40 minutes, with administration of the following questionnaires and data worksheet:

1. Outpatient Contact Form (plus nursing consultation at the first contact), including information on changes in body weight, hospitalization since last visit, change in medication use and prescription, and main difficulties found for adherence.

2. HF Knowledge Questionnaire: Validated for Brazil, it was applied to patients with HF ($n=153$) during outpatient follow-up (two years) with the multidisciplinary team of a university hospital, indicating that it is an adequate tool to evaluate knowledge of Brazilian HF patients. The 14-question instrument includes questions related

to food, liquids, weight, general information on HF, medication, physical activity, actions that improve HF, and, reasons for readmission. To evaluate this questionnaire, the knowledge score is determined by the sum of the number of correct answers. Considering that the adapted instrument contains 14 questions, and that for the correct answer the patient receives 1 point, the score of correct answers ranges from 0-14 points; at least 7 points are necessary to be considered with good knowledge.⁽¹⁰⁾

3. European Heart Failure Behavior Scale (EHFScBS) questionnaire: In order to evaluate the self-care of patients with HF, this instrument was based on the theoretical assumptions of Orem's Self-Care Theory. This instrument was adapted for use in Brazil in 2012, and 124 patients with HF, 62.3 ± 12 years old, were included in the cross-cultural adaptation. The internal consistency of the questions presented a Cronbach's alpha of 0.70, and the reproducibility evaluated by the intraclass correlation coefficient was 0.87, assuring validity and reliability of the adapted instrument. The instrument has a single domain that is related to self-care behavior. The answers for each item range from: one = "fully agree" to five = "strongly disagree", according to a five-point Likert scale. The total score is obtained by the sum of all the answers, which can range from 12 to 60. Lower values indicate better self-care.⁽¹¹⁾

The questionnaires were completed by the nurse; immediately thereafter, a physical education session on HF and self-care in the disease was conducted, and an explanatory booklet on the main care in HF was provided.

In addition to outpatient monitoring, the IG also received telephone calls ($n=12$). The calls were made at the HF clinic, on a day and time agreed between patient and researcher, beginning the week following the first appointment, weekly during the first two months (eight telephone calls), and biweekly in the following two months (four telephone calls). In the telephone-based approach conducted by the research nurse, completing the instrument named the Standardized

Guide for Telephone-based Monitoring, an guiding instrument for conducting telephone calls (Annex 1), developed on the basis of the updated Brazilian Guideline III.⁽⁹⁾

The patient's main difficulties in pharmacological and non-pharmacological adherence to HF treatment were identified in the telephone calls, and specific and general information about the disease and self-care were provided.

The number of and interval between the phone calls stipulated in this study were based on prior research protocols. However, each study showed different outcomes, as they were different in terms of the educational approach, face-to-face appointment intervals, and on the emphasis on the phone calls in the first two months after HF decompensation, as this research proposed to perform.

After four months, 36 participants completed the follow-up: 19 in IG and 17 in CG. A total of eight participants were lost, due to death (n=2), hospitalization (n=3), treatment abandonment (n=1), and difficulties making telephone contact (n=2). Data were analyzed for participants who received at least seven phone calls during the four months (three in the first two months, and four in the two following months).

For data analysis, continuous variables are expressed as mean \pm standard deviation; categorical variables are expressed in percentages, when the normality was confirmed by the Shapiro-Wilk test. To test the differences in the sample characteristics, the Student's t-test was used for independent samples to compare the continuous variables, and the chi-square test to compare the categorical variables. The repeated measures analysis of variance (ANOVA) (2 X 3- groups X observation times) was used to evaluate the possible differences between groups (IG vs. CG), with the outcomes of the HF knowledge and self-care scores. To verify the homogeneity of the variance and sphericity of the data, the Muchly's test and the Greenhouse-Geiser correction were performed, when necessary. In the case of statistically significant F-critical values, ANOVAs were complemented by Fisher's post hoc analysis.

To analyze the correlation between knowledge and self-care scores, the Pearson correlation test was used, categorized by r-values from -1 to +1 (strong negative/positive correlation with values of -1/+1, and weak correlation for scores values next to 0). In all cases, a value of $p \leq 0.05$ was adopted as the significance level. Statistical calculations were performed using the Statistical Package for the Social Sciences, version 20.0 (SPSS Inc TM, Chicago, IL, USA).

The study was registered in the Brazil Platform, Certificate of Presentation for Ethical Appreciation (CAAE) number 38268514.8.0000.5259, and was approved by the Research Ethics Committee of the institution (CEP-HUPE), protocol nº 963.111. All patients signed the Terms of Free and Informed Consent form, according to Resolution 466/12, which provides guidelines and regulatory norms for research involving human beings.⁽¹²⁾ This clinical trial was registered in the Brazilian Clinical Trials Registry (ReBEC RBR-8m8tmq), and followed the guidelines of the CONSORT 2010 checklist.

Results

Table 1 shows data with the characteristics of the sample participants, with sociodemographic and clinical profile. In the same table, we can observe that no significant difference between the groups were identified.

Figure 1 shows the comparison of the HF knowledge and the self-care score on HF between the IG vs. CG, during four months in three different moments (base, second and fourth months, respectively)

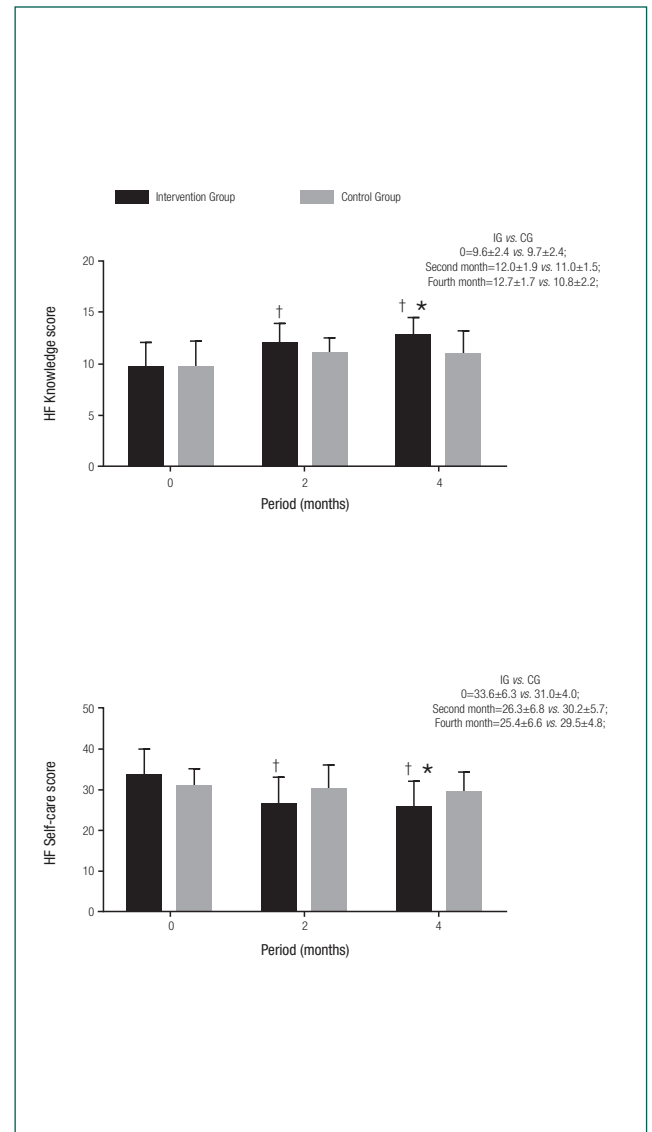
Considering the HF knowledge score, a significant difference between the groups were found (group effect *time: $f = 2.96$, $p < 0.05$), and significantly different in the fourth month ($p = 0.009$). In addition, a significant increase in knowledge in the IG was verified when compared to the second and fourth months with the base score ($p = 0.001$), which was uncharacterized analysis for CG.

Table 1. Sociodemographic and clinical characteristics of the sample

Variables	Intervention Group n=19	Control Group n=17	p-value
Age (years)	60.5±12.3	60.0±10.9	0.89 [*]
Weight (Kg)	77.5±21.0	70.2±14.5	0.29 [*]
Body mass index (kg/m ²)	29.6±7.8	25.5±9.1	0.15 [*]
Abdominal circumference (cm)	100.3±14.9	97.7±12.8	0.58 [*]
Systolic blood pressure (mmHg)	108.6±21.1	114.7±16.4	0.34 [*]
Diastolic blood pressure (mmHg)	72.7±16.6	73.2±8.5	0.91 [*]
Mean blood pressure (mmHg)	84.7±17.3	87.0±9.5	0.62 [*]
Heart rate (Bpm)	77.7±13.4	71.2±15.7	0.19 [*]
Ejection fraction (%)	36.3±14.1	26.8±16.9	0.91 [*]
NYHA (%)			
I	10.5	11.8	0.94 ^{**}
II	36.8	41.2	
III	52.6	47.1	
Comorbidities (%)			
Systemic arterial hypertension	42.1	23.5	0.42 ^{**}
Diabetes mellitus	0	5.9	
Acute myocardial infarction	10.5	5.9	
More than one comorbidity	47.4	64.7	
Sex (%)			
Male	52.6	47.4	0.49 ^{**}
Female	41.2	58.8	
Marital status (%)			
Single	10.5	29.4	0.38 ^{**}
Married	73.7	47.1	
Divorced	5.2	5.9	
Widow(er)	10.5	17.6	
Etiology of heart failure (%)			
Ischemic cardiomyopathy	36.8	29.4	0.82 ^{**}
Hypertensive cardiomyopathy	31.6	29.4	
Others	31.6	41.2	
Level of education (%)			
Illiterate	0	17.6	0.22 ^{**}
1 - 4 years	36.8	35.5	
> 4 years	63.2	47.1	
Outpatient time (%)			
< 6 months	36.8	17.6	0.34 ^{**}
6 - 12 months	15.8	11.8	
> 12 months	47.4	70.6	

NYHA - New York Heart Association. Continuous variables were expressed as mean ± standard deviation, and categorical variables were presented as percentages. *Independent T-test; **Chi-square test

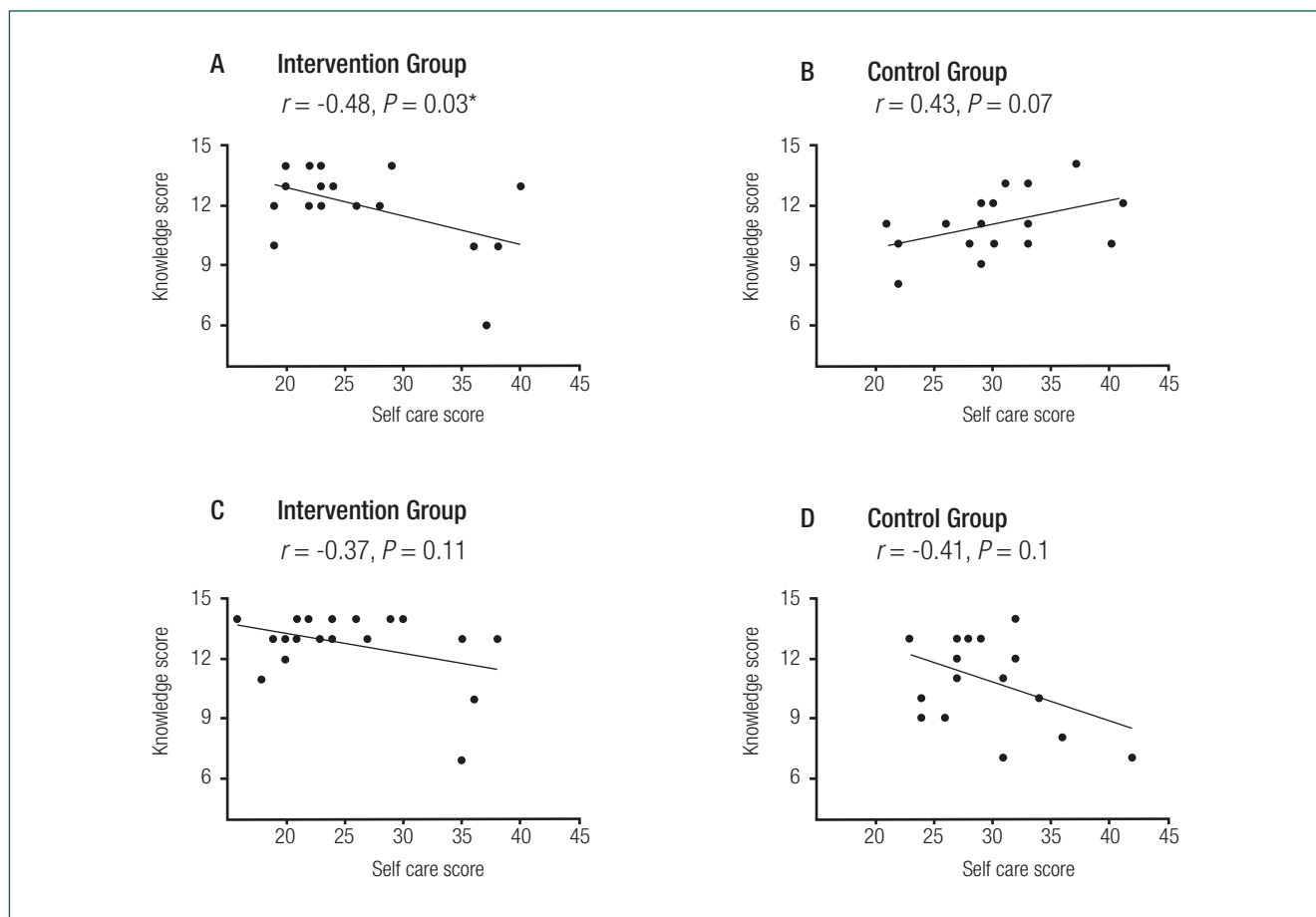
Comparing the self-care scores, differences can be observed between the IG vs. CG (group effect *time: $f = 7.32$, $p = 0.001$), and significantly in the fourth month ($p = 0.04$), considering the score per period. In addition, a significant improvement in HF self-care in the IG was verified during the period, when compared to the second and fourth months with base data ($p = 0.001$), which was not expressed in the CG.



*Significant difference between groups in the fourth month ($p < 0.05$);
† significant difference in IG compared to baseline time ($p < 0.001$)

Figure 1. Comparison of HF knowledge scores and self-care between IG vs. CG

The analysis of the secondary objective, as demonstrated in figure 2, shows the negative correlation between the score of the HF knowledge questionnaire and the score of the HF self-care questionnaire on during the observation periods of the second and fourth months in both groups. Thus, we observed a significant negative correlation in the IG in the second month of evaluation ($r = -0.48$, $p = 0.03$), and a tendency to remain in the fourth month ($r = -0.37$, $p = 0.11$), which was not identified in the CG period.



*Pearson correlation between HF knowledge and self-care scores A and B second month. C and D fourth month

Figure 2. Analysis of the association of the knowledge scores and self-care of HF

Discussion

This study had, as a limitation, a reduction for telephone calls from 12 to the minimum of seven, because it was not possible to complete the telephone contact in the proposed time. The difficulty in encountering them was due to inadequate contact information.

The main results of this research reveal the efficacy of health education by means of the telephone-based nursing approach on the HF/HUPE clinic, which was demonstrated when the IG was compared to the CG. A significant improvement was identified in the HF knowledge and self-care scores in the fourth month of observation, and concomitantly a significant evolution in the IG in both scores, when analyzed by time measurement (baseline vs. second and fourth months); and a

significant negative correlation of HF knowledge scores with self-care in the IG in the second month, and a similar trend in the fourth month was demonstrated.

Before discussing the findings cited above, some considerations were paramount to lessen the possible biases of this study. There was no significant difference in the sample characteristics, which was an interesting consequence of the randomization. The loss of eight participants throughout the study was planned for previously, by recruiting 20% above the sample estimate ($n=36$). Although this study did not select only participants with an ejection fraction $<50\%$, all subjects presented results $\leq 50\%$ for this variable, diversified level of education, and a higher representation of NYHA classes II and III, where greater risk for decompensation, emergency services, readmission and death can occur.

The most commonly used strategies in health education for patients with HF are: individual discussion, written material (booklets, posters, instructions guide), CD-ROM, video, web page usage, telephone conversation, and a guidance group. The most valued intervention is the individual discussion associated with play activities that facilitate the learning.⁽⁸⁾ Most of the studies did not address only one strategy, often integrating two or three of them.⁽¹³⁻¹⁶⁾ This research corroborates this data, considering the individual reality, and emphasizing the patient's commitment to self-care, as well as associating the telephone-based approach with the use of explanatory booklets.

The focus areas for HF patients in health education are: knowledge about the disease, monitoring of signs and symptoms of decompensation, and education for adherence to pharmacological and non-pharmacological treatment.⁽¹⁷⁾ The assessment of knowledge on HF is still growing, mainly by nurses, in terms of monitoring of HF,^(13,14) as well as the effectiveness of the telephone-based approach, as shown by a recent meta-analysis.⁽¹⁸⁾

In a randomized clinical trial (RCT) that used telephone-based education and monitoring (weekly in the first month/fortnightly for three months), a significant improvement in knowledge scores and self-care was demonstrated, independent of telephone contact. The absence of significantly better results in the intervention group can be explained, by the fact that 29% of the participants received only one or two telephone contacts during the whole monitoring period, reducing the number of health education sessions.⁽¹⁴⁾ A telephone intervention on an every two week basis, over a period of three months, found in another RCT, showed that self-care scores were higher in the intervention group than in the control group throughout the observation period.⁽¹⁵⁾ In the present study, at least seven telephone calls were performed (three in the first two months, and four in the following two months), making possible a greater number of weekly approaches in the first two months post HF decompensation, increasing the number of health education sessions and orientations in a period so critical for hospital readmission.

In another study, the follow-up time was nine months: first three months with health education, three months followed with telephone monitoring (connecting every three to four weeks), and last three months without any type of monitoring. There were positive results regarding self-care, quality of life, and knowledge about HF, as well as meta-memory (peoples' knowledge of their own memory and all that is relevant to the retention, storage and retrieval of information). The evaluation of meta-memory in studies that have HF knowledge as their outcome seems to offer promising results that should be better elucidated in future research.⁽¹⁹⁾

Despite different outcomes in the monitoring of HF patients, as in the previously mentioned studies, the number and frequency of telephone calls and the teaching-learning strategies used must be considered. The studies do not usually provide detail about how the telephonic-based approach occurs, considering all recommendations for improving knowledge and self-care.⁽⁴⁻¹⁵⁾ The disclosure of the way in which the telephone-based approach has occurred can contribute to the ability of HF clinics to monitor their patients in an standardized manner, and the scientific community must have access to these previously tested instruments, for future validation.

Self-care in HF is a crucial factor for successful treatment. A recent study identified an association between self-care and the number of hospitalizations of patients admitted for acutely decompensated HF.⁽²⁰⁾

A survey showed that forgetting to check daily weight, and lack of a scale at home, were the main barriers to adherence to self-monitoring, and that the higher the level of education, and the lower the number of comorbidities, the more the patient perceives the benefits of self-monitoring.⁽²¹⁾ Other research shows that younger patients with more years of education presented better results in self-care.⁽¹⁷⁾ This study did not identify significant differences in the level of education of the participants.

Studies report that the improvement in knowledge about the disease favors self-care, however, the research used in the present study did not demonstrate statistically significant results for this correla-

tion. In this study, a correlation of approximately 50% between the HF knowledge score and the self-care scores from the second month, and a tendency for this association in the fourth month, which was not observed in the CG in any of the visits. This data represents valuable information, revealing that already in the second month of health education via telephone-based monitoring, the participants were influenced by a beneficial teaching-learning stimulus.

The knowledge and self-care in HF questionnaires used in this study have been used for several monitoring strategies, such as home visit, telehealth, and telephone-based approach, presenting satisfactory outcomes regarding their confidence and relevance.^(13,22,23)

Studies detailing how the telephonic-basic approach, and the teaching-learning process used, must be conducted, correlating the possible effects of knowledge and self-care of HF with clinical outcomes, such as re-hospitalization and death rates. More RCTs, which are scarce in Brazil, must be performed, for identification of knowledge outcomes and self-care.

Conclusion

Conventional monitoring, combined with the Standardized Guide for Telephone-based Monitoring, was effective in the fourth month, with improvement of knowledge and self-care in the IG, and a significant negative correlation between knowledge and self-care was already evident in the second month of observation.

Collaborations

Oliveira JA, Cordeiro RG, Rocha RG, Guimarães TCF and Albuquerque DC contributed to the study design, analysis and data interpretation, relevant critical review of the intellectual content, and final approval of the version to be published.

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ANEX 1. Standardized Guide to Telephone Monitoring

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