









Effect of motivational interviewing on self-care of people with heart failure: a randomized clinical trial*

Efeito da entrevista motivacional no autocuidado de pessoas com insuficiência cardíaca: ensaio clínico randomizado

Efecto de la entrevista motivacional sobre el autocuidado de personas con insuficiencia cardíaca: ensayo clínico aleatorizado

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ABSTRACT

Objective: To analyze the effect of motivational interviewing on self-care for people with chronic heart failure. **Method:** A multicenter randomized clinical trial, which divided people into an intervention group (n=59) and a control group (n=59), followed for 60 days in centers of Brazil and Uruguay. The intervention group received three consultations per motivational interviewing, with an interval of 30 days, and the control group maintained conventional follow-up in specialized clinics. The data were assessed using the Self-Care of Heart Failure Index 6.2, before and after intervention in each of the centers. They were analyzed using the mean, median, t-test, correlation analysis using the Spearman coefficient and effect of the intervention by Cohen's d. **Results:** One hundred and eighteen people completed the study. In view of the assessment of the effect of the motivational interviewing on self-care, compared to conventional follow-up, a medium effect on maintenance and management (Cohen's d=0.6723; 0.5086) and high on self-care confidence (Cohen's d=0.9877). **Conclusion:** Motivational interviewing was effective in improving self-care in patients with heart failure, being a feasible strategy to be implemented in specialized clinics. Brazilian Registry of Clinical Trials (*Registro Brasileiro de Ensaio Clínicos*): RBR-6fp5qt.

DESCRIPTORS

Heart Failure; Motivational Interviewing; Self Care; Cardiovascular Nursing; Clinical Trial.

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INTRODUCTION

Cardiovascular diseases are the leading cause of deaths in the world⁽¹⁾. Among them, heart failure (HF) has been identified as an important health problem and considered as a new epidemic with high mortality and morbidity⁽²⁻³⁾.

In the United States, approximately 5.1 million individuals have the clinical manifestations of HF⁽⁴⁻⁵⁾. An American study indicated that between 2000 and 2009 there were about one million deaths per year in North America, followed by around 800,000 deaths in Latin America and about 7,500 in the non-Latin Caribbean⁽⁶⁾. In Brazil, between February 2018 and 2019, HF totaled 213,247 thousand cases of hospitalizations and 23,749 thousand deaths⁽⁷⁾. In Uruguay, in a survey conducted in a rural region, the prevalence of HF was 17.6/1,000 and the incidence, 4.6/1,000 cases per year⁽⁸⁾.

Studies indicate that the treatment of this syndrome is complex, as it requires severe changes in lifestyle, resulting in approximately 50% adherence⁽⁹⁾. HF clinics recommended by national and international consensus are considered beneficial and effective in reducing the number of hospitalizations and improving the quality of life through specialized multidisciplinary monitoring⁽¹⁰⁾.

Nurses, as part of the multidisciplinary team, work in these clinics, mainly in the orientation regarding self-care⁽¹¹⁾. Self-care is related to physical and psychological well-being, increased satisfaction and quality of life, reduced morbidity and mortality, associated with autonomy and responsibility in adhering to healthy behaviors⁽¹²⁾. Good prognosis is directly related to adherence with internationally established therapeutic measures related to pharmacological recommendations, such as low salt consumption, daily weight control, restriction of alcohol and tobacco use, recognition of decompensation signs and symptoms⁽¹²⁾.

Studies carried out in the United States of America (USA), Brazil and Uruguay also obtained low scores for self-care maintenance, management and confidence⁽¹³⁻¹⁵⁾, demonstrating the complexity of this problem. Self-care is a process that starts with the monitoring of therapy, involvement and motivation to adhere to the care plan, search for well-being and health, attendance to consultations and greater control of therapeutic measures. Improving self-care is a process that mainly requires behavioral change and the motivation of each person⁽¹⁶⁾, needing health interventions that assist the patient in this transition and maintenance of healthy life habits.

In this perspective, motivational interviewing (MI) aims to assist the individual in the behavioral change process, boosting commitment through a convincing and encouraging approach. It is a relatively simple and low-cost technique, based on cognitive principles such as understanding problems and emotional reactions to them. It aims to establish alternatives for modifying thought patterns, implementing solutions and proposing individualized therapeutic interventions to increase treatment adherence⁽¹⁷⁾.

The need for behavioral change in people with HF in relation to the pharmacological and non-pharmacological treatment inspired MI testing as a nursing intervention in the face of self-care in specialized HF clinics in two countries in South America (Brazil and Uruguay).

Several studies that used MI have shown positive results for smokers⁽¹⁸⁾, alcohol consumers⁽¹⁹⁾ and the obese⁽²⁰⁾. Studies conducted in the USA have also demonstrated effective results of MI as an approach to be used in individuals with HF to improve the implementation of physical activity⁽²⁰⁻²¹⁾, the transition from hospital to home⁽²²⁻²³⁾ and the decreased hospital readmission⁽²³⁻²⁴⁾.

Despite this, the effectiveness of MI in self-care has not yet been tested in clinics specialized in HF in Brazil and Uruguay. Thus, this study aimed to analyze the effect of MI on self-care for people with chronic HF.

METHOD

STUDY DESIGN

It is a multicentric randomized clinical trial (RCT), in which the control group received conventional follow-up (carried out by nurses, physicians, nutritionists, physiotherapists, psychologists, physical educators, pedagogues, and social workers). The intervention group received three consultations, with an interval of 30 days (in addition to conventional follow-up), for a period of 60 days in each of the centers, respecting the same research protocol.

DEFINITION OF SAMPLE

It is a simple random probabilistic sample, without stratification. The sample was calculated using the WinPepi 11.65 program, based on a pilot study⁽¹⁵⁾, through the outcome 'maintenance of self-care', related to the control group (CG) and intervention group (IG). The following values were used: before intervention (CG=48.3 ± 19.0; GI=43.2 ± 11.4) and after intervention (CG=49.7 ± 14.9; GI=60.8 ± 10.4). The final sample was 29 patients for each subgroup, with 9 points of difference between groups, 95% confidence, 20% loss and 80% power. A researcher external to the intervention organized a list with sequential numbering and patient names and performed a randomization by simple sequence through the website www.randomization.com.

DATA COLLECTION

In Brazil, data collection was performed at a clinic specialized in HF based in Niterói, Rio de Janeiro state. The physical space is properly air-conditioned, has four offices, one for meetings and a waiting room. Conventional follow-up is performed by nurses, physicians, nutritionists, physiotherapists, psychologists, physical educators, pedagogues and social workers. Education and monitoring strategies include multi-professional face-to-face

consultations, telephone consultations, home visits and support groups.

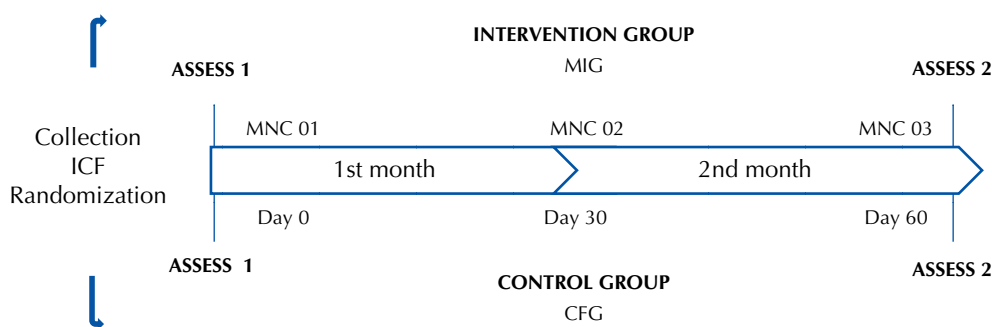
In Uruguay, data collection was performed at a specialized HF clinic located in Montevideo, Uruguay. The physical space has six offices, a meeting room and a waiting room. Conventional follow-up is carried out by nurses, physicians, nutritionists, psychologists and social workers. Education and monitoring strategies include multi-professional face-to-face consultations and telephone consultations.

In both centers, people with medical diagnosis of HF regardless of etiology, preserved or decreased ejection fraction, over 18 years of age, with functional classes I-III New York Heart Association (NYHA) and at least one face-to-face consultation with multidisciplinary teams in specialized clinics participated in the research. People with self-reported or identified cognitive neurological sequelae during the multidisciplinary consultation were excluded, as were patients

who did not attend one of the proposed interventions or assessments.

In both centers, the research teams were divided as follows: Group 1 – Collection and Assessment: composed of a nurse (only blind group); Group 2 – Randomization: composed of a nurse for both centers; Group 3 – Intervention (Motivational Interviewing Group – MIG): composed of a nurse, the same for both centers; Group 4 – Control (Conventional Follow-Up Group – CFG): composed of the multidisciplinary team.

In both centers, eligible individuals were invited to participate in the research. Those who agreed, signed the Informed Consent Form (ICF), duly appropriate for each center. After randomization, the first assessment (ASSESS1) was performed for both groups. After 60 days, MIG and CFG survey participants were re-assessed for the same outcomes in the second assessment (ASSESS2), as shown in Figure 1.



ICF: Informed Consent Form; ASSESS1: first assessment; MNC: motivational nursing consultations; ASSESS2: second assessment.

Figure 1 – RCT protocol

In the IG, in addition to the conventional follow-up, three face-to-face nursing consultations were performed using IM as an approach, with an interval of 30 days between consultations, as shown in figure 01. Consultations with MI lasted about 30 minutes, performed in individual, comfortable and air-conditioned offices in both centers. MI was carried out by the same professional at the two centers, who received three trainings by MI experts to apply the intervention, being fluent in Portuguese and Spanish. Data collection in Brazil (January to July 2017) preceded data collection in Uruguay (August to December 2017), one sequentially the other. The professional who performed the intervention, when arriving in Uruguay, followed the clinic routine for 15 days before starting the intervention, to recognize the routines, as well as cultural and idiomatic characteristics of the population.

MI started with the OARS scheme. ‘O’ from Open questions, ‘A’ from Affirmation, ‘R’ from Reflection and ‘S’ from Summary. In the case of participants resistant to changes, consultation continued using the DARNC scheme (desire,

ability, reasons, need, and commitment), to favor behavior change. For participants who have already decided to change their behavior, the CATS technique (commitment, activation, taking steps) was used⁽¹⁷⁻²⁴⁾.

The outcome of this study was self-care, assessed using the Self-care of Heart Failure Index questionnaire, version 6.2⁽¹⁵⁾. In Brazil, the 2012 translated and validated version was used, in which the internal consistency of the questions was 0.70, Cronbach’s alpha and the reproducibility assessed by the intraclass correlation coefficient was 0.87⁽¹³⁾. In Uruguay, the same questionnaire was cross-culturally adapted by this research team⁽¹⁵⁾, according to the guideline proposed by the Institute for Work & Health⁽²⁵⁾.

ANALYSIS AND TREATMENT OF DATA

The collected data were organized and analyzed using the Statistical Package for the Social Sciences/IBM (SPSS), version 22.0. The descriptive analysis was based on frequency distributions, mean, median, standard deviation, interquartile range. The comparison of two independent groups was made using the Student’s t-test. The effect size

calculation was performed by Cohen's $d^{(26)}$. Correlation analysis was performed using Spearman's correlation coefficient. All discussions were conducted considering a maximum significance level of 5%.

ETHICAL ASPECTS

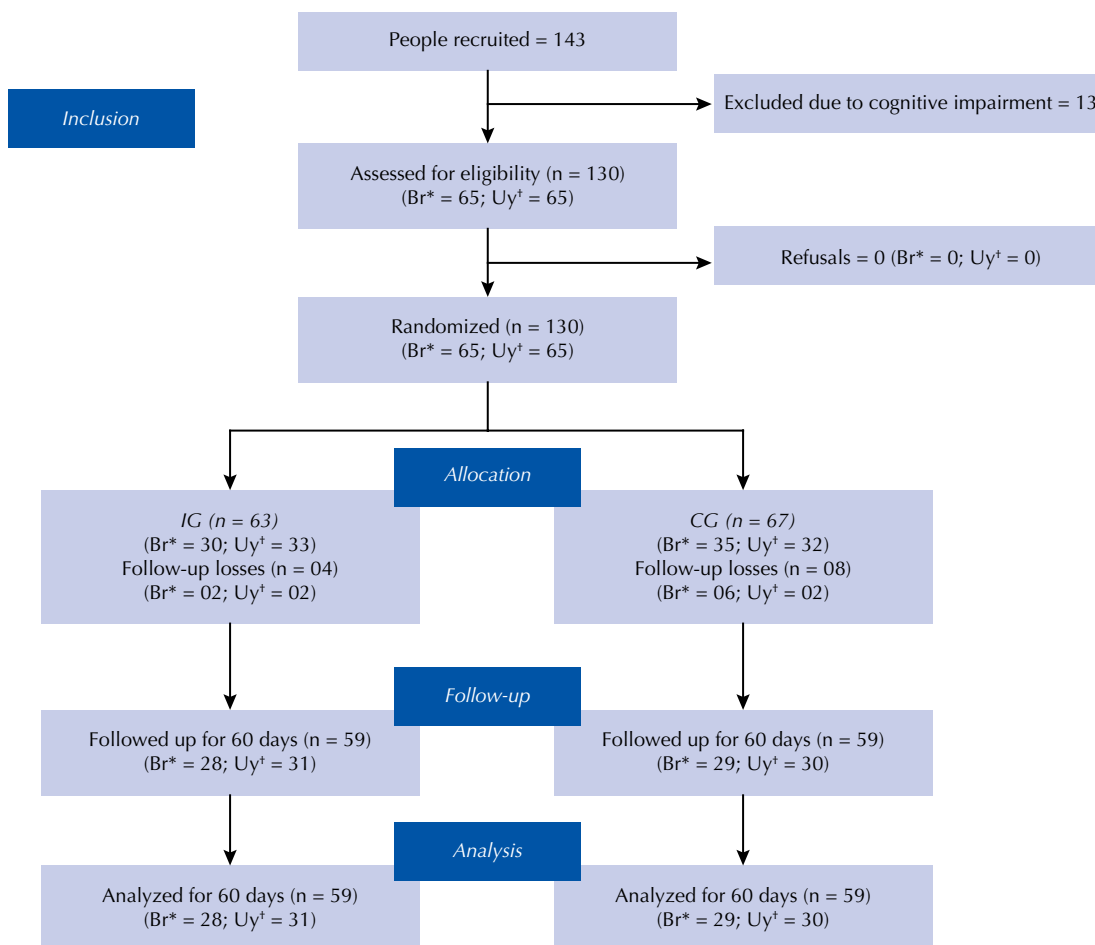
This research guarantees the maintenance of the secrecy, confidentiality and privacy of the subjects' data, according to Resolution 466/12 of the Brazilian National Health Council. The Research Ethics Committee of Hospital Universitário Antônio Pedro, Universidade Federal Fluminense, Brazil, approved the research on May 8, 2015, under Opinion 1.055.465. It was also approved by the National Research Ethics Commission on February 27, 2018, under Opinion 2.404.683 and by the Brazilian Registry of Clinical Trials (*Registro Brasileiro de Ensaios Clínicos*) (RBR-6fp5qt), updated on November 16, 2017, according to the precepts of Resolution CNS/MS 466/12. The Research Ethics Committee of Hospital de Clínicas Manuel Quintela, Universidad de la Republica, Uruguay, approved the study on May 17, 2017.

RESULTS

Figure 2 shows the flowchart for inclusion, allocation, follow-up and analysis for the RCT. One hundred forty-three people with HF were recruited, however, 13 were excluded for cognitive impairment and 130 were assessed for eligibility, with 65 patients randomized to Brazil and 65 to Uruguay.

In the IG, considering both countries, 63 patients were allocated (Brazil=30 and Uruguay=33). Two follow-up losses were accounted for in each country, leaving 59 patients to monitor and implement the intervention (Brazil=28 and Uruguay=31). These same patients completed the study, reaching the data analysis phase, maintaining this sample number ($n=59$), 28 in Brazil and 31 in Uruguay.

In the CG, 67 patients were allocated in both countries (Brazil=35 and Uruguay=32). There were eight follow-up losses, six in Brazil and two in Uruguay, leaving 59 patients for the CG (Brazil=29 and Uruguay=30). The same patients remained until the data analysis phase ($n=59$), 29 in Brazil and 30 in Uruguay.



Caption: Br – Brazil^{*}; Uy[†] – Uruguay.

Figure 2 – Consort Flowchart

The final sample consisted of 118 people with HF in the two centers, with 59 patients in the IG (motivational interviewing) and 59 in the CG (conventional follow-up). Table 1 shows the socio-demographic and

clinical characterization of these people and shows that the groups are homogeneous in the two centers, except for the etiology, which does not change the study outcome.

Table 1 – Sociodemographic and clinical characterization of patients with chronic HF followed up in specialized clinics in Brazil and Uruguay – Niterói, RJ, Brazil/Montevideo, Uruguay, 2017.

Variables	Brazil = 57			Uruguay = 61		
	Intervention (n=28)	Control (n=29)	P value	Intervention (n=31)	Control (n=30)	P value
Sex. Female [†]	18(64.3)	11(37.9)	0.047	14(45.2)	13(43.3)	0.886
Age [‡]	68(59-74.5)	59(51-64)		65(56-72)	64(57-72)	
Retired [†]	15(53.6)	10(34.5)	0.697	13(41.9)	13(43.3)	0.472
Elementary School [†]	6(21.4)	6(20.7)	0.083	14(45.2)	13(43.3)	0.217
Married [†]	17(60.7)	21(72.4)	0.120	16(51.6)	13(43.3)	0.228
LV EF [†]	55(40-71)	57(34-67)	0.552	30(28-35)	35(30-43)	0.057
NYHA II* [†]	17 (60.7)	17(58.6)	0.697	19(61.3)	12(40.0)	0.248
Non-ischemic ^{c*}	13(46.4)	8(27.6)	0.012	25(80.6)	20(66.7)	0.380
Smoking [†]	2(7.1)	2(6.9)	1.000	3(9.7)	5(16.7)	0.709
Alcoholism [†]	5(17.9)	2(6.9)	0.253	3(9.7)	2(6.7)	0.611
Self-care scores‡						
Maintenance	48.3±19.0	43.2±11.4	0.220	62.9±14.5	63.9±15.2	0.796
Manegement	45.8±24.4	46.3±19.3	0.953	41.4±23.6	46±20.1	0.624
Confidence	51.8±22.2	58.2±20.7	0.282	67.6±17.5	63.6±21.8	0.427

[†]n (%); [‡] median (interquartile range 25-75); [‡] mean ± standard deviation.

Left ventricular ejection fraction (LV / EF); New York Heart Association (NYHA) Functional Class; Non-ischemic (Etiology).

Note: (n=118).

When assessing the samples from the perspective of each country, in Brazil, 57 people completed the study, with 18 females (64.3%) in the IG and 11 (37.9%) in the CG. Regarding age, the intervention subgroups are older than the CG, with medians 68 (59-74.5) and 59 (51-64), respectively.

In Uruguay, 61 people completed the study, and 34 (55.7%) were male. The difference between these proportions was not statistically significant (p value=0.443), that is, it can be said that the proportion of men and women in

the Uruguay sample is the same and that the predominance of cases in male group is not significant.

When assessing the global sample (Brazil + Uruguay), from the perspective of the IG and CG, Table 2 shows the comparison of self-care maintenance, management and confidence scores before and after MI intervention or conventional follow-up. It also presents the measure of effect in the study sample in the following proportions: Self-care maintenance (75%), self-care management (69%) and self-care confidence (84%), considering Cohen's d values.

Table 2 – Comparison between the CG and IG in self-care skills and verification of the magnitude of the effect in the two centers in the pre- and post-assessments – Niterói, RJ, Brazil/Montevideo, Uruguay, 2017.

Self-care subscales	Multicentric – Pre (n=118)			Multicentric – Post (n=118)			Effect Cohen' d
	Control [†] (n=59)	Intervention [†] (n=59)	P value [†]	Control [†] (n=59)	Intervention [†] (n=59)	P value [†]	
Maintenance	56.30 ±18.78	53.08 ±16.1	0.322	56.97 ±17.2	69.02 ±13.9	<0.001	0.6723
Manegement [‡]	45.86 ±22.1	44.00 ±21.1	0.756	63.88 ±21.9	74.00 ±17.0	0.187	0.5086
Confidence	57.73 ±22.6	63.1 ±19.9	0.172	54.93 ±22.1	73.31 ±16.8	<0.001	0.9807

[†]Mean ± standard deviation; [‡] T-Student test; [‡] pre- (control n=23 and intervention=30) and post-management (control n=09 and intervention=20)

Note: (n=118).

DISCUSSION

The results point out for the first time the effect of MI on self-care for people with HF followed at two specialized centers in South America (Brazil and Uruguay). When compared to the CG, there was a significant increase in maintenance scores ($p < 0.001$) and confidence ($p < 0.001$) in the IG self-care.

A systematic review carried out in Canada identified that achieving self-care was seen as a challenge for the patient/caregiver binomial due to the difficulty in identifying the most important self-care behaviors (self-care maintenance), as well as managing the symptoms of decompensation (self-care management)⁽²⁷⁾.

In patients who received consultations with a MI, the average total score for post-intervention self-care behaviors was significantly increased compared to that in the pre-intervention phase.

A descriptive study published in 2014⁽²⁸⁾ carried out four sessions with a brief MI approach. The patient's frustration related to hospitalization was discussed, specifically with possible ways of addressing problems in self-care behaviors. Using this approach, the patient reported an increase in his/her motivation and ability to change and develop a plan to incorporate self-care behaviors into his/her daily routine⁽²⁸⁾.

The present study showed that MI improved self-care in the two specialized centers, possibly due to the individual character of this approach, respecting the limitations, weaknesses and pre-dispositions for these people to change. On the other hand, a major challenge is to assist these people in making decisions for behavioral changes. These people have physiological, spiritual, social and psychological needs affected, which can reduce their intrinsic motivation, even knowing what self-care measures they should incorporate.

One study tested MI effectiveness through home visits and telephone consultations in the self-care of 67 patients with HF and had a moderate effect on maintaining self-care (Cohen's $d = 0.44$)⁽²²⁾. The present study corroborates this result, as it had a moderate effect (Cohen's $d = 0.6723$; $p < 0.001$), in the same outcome, however, with a different strategy to approach the MI.

An American study published in 2016 tested the effectiveness of MI in decreasing hospital readmissions for 100 patients with HF and found that after 3 months, 34 participants had at least one hospital readmission. The proportion of hospital readmission for a condition not related to HF was lower in the IG (7.1%) compared to the control group (30%, p value = 0.003). Significant predictors of a 'non-HF' readmission in the IG were: age, diabetes and hemoglobin. Together, these variables explained 35% of the variance in multimorbidity readmissions⁽²⁴⁾.

Self-care confidence is related to the interpretation and response to symptoms⁽²⁹⁾. Thus, an intervention that is capable of producing adequate levels of self-care confidence becomes an important strategy in care. In this regard, changing behavior or ability for self-care implies more than providing health education. Although studies indicate that the self-care of people with HF is inadequate⁽¹¹⁻¹⁴⁾ and that self-management educational programs have better results in this ability⁽²²⁾, the present study highlights the need to improve the self-care of patients through individualized care models. For this, MI is an important tool to insert them in the planning of self-care.

The present study points to results that corroborate self-efficacy improvement mechanisms (confidence that a person has in himself/herself to perform specific tasks, in this study, assessed through self-care confidence), because it used in its MI intervention protocol steps for affirmation, reflection and synthesis, positive conversation for change and personalized problem solving. These implications prove that these mechanisms for MI have shown good responses in HF, and may be a choice for better health results in the face of the challenge of self-care.

Failure to perform multivariate analysis, stratification by sex and not blinding for intervention, as the patients who received MI knew that they had been allocated to the IG, as well as the nurse who performed the consultation with MI knew which group it was constitute limitations of this study. However, randomization, allocation, outcome assessment and statistical analysis were blinded. Moreover, the study was carried out in two specialized clinics, one in Brazil and the other in Uruguay, which may limit the generalization of results to other regions in both countries, despite the fact that specific factors of geographical influences have not emerged in the intervention.

The need for a large team to maintain the precepts of an RCT in two centers, for a professional fluent in the second language, besides training and improvement on the intervention and cost of the study are among the main difficulties to carry out this study. Although the study obtained assistance for internationalization, it was largely funded by the main researcher.

Multicentric studies in other regions and countries should be carried out for the construction of evidence by meta-analyzes and incorporation of nursing intervention with MI in guidelines.

CONCLUSION

MI was effective in improving self-care for patients with chronic HF from specialized clinics in Brazil and Uruguay. It is recommended to incorporate this strategy in specialized clinics in both countries and other regions with a similar sociodemographic and cultural profile.

RESUMO

Objetivo: Analisar o efeito da entrevista motivacional no autocuidado de pessoas com insuficiência cardíaca crônica. **Método:** Ensaio clínico randomizado, multicêntrico, dividindo as pessoas em grupo intervenção ($n = 59$) e grupo controle ($n = 59$), acompanhadas por 60 dias nos centros do Brasil e Uruguai. O grupo intervenção recebeu três consultas por entrevista motivacional, com intervalo de 30 dias,

e o grupo controle manteve o acompanhamento convencional nas clínicas especializadas. Os dados foram avaliados através do *Self-Care of Heart Failure Index 6.2*, antes e após a intervenção, em cada um dos centros e analisados através de média, mediana, teste-t, análise de correlação pelo coeficiente de Spearman e efeito da intervenção pelo *d de Cohen*. **Resultados:** 118 pessoas concluíram o estudo. Diante da avaliação do efeito da entrevista motivacional no autocuidado, comparando-se ao acompanhamento convencional, foi identificado efeito médio na manutenção e manejo (Cohen-d=0,6723; 0,5086) e alto na confiança do autocuidado (Cohen-d=0,9877). **Conclusão:** A entrevista motivacional foi efetiva na melhora do autocuidado dos pacientes com insuficiência cardíaca, sendo uma estratégia factível a ser implementada em clínicas especializadas. Registro Brasileiro de Ensaios Clínicos: RBR-6fp5qt.

DESCRITORES

Insuficiência Cardíaca; Entrevista Motivacional; Autocuidado; Enfermagem Cardiovascular; Ensaio Clínico.

RESUMEN

Objetivo: Analizar el efecto de las entrevistas motivacionales en el autocuidado de personas con insuficiencia cardíaca crónica. **Método:** Ensayo clínico aleatorizado, multicéntrico, que divide a las personas en un grupo de intervención (n=59) y un grupo de control (n=59), seguidos durante 60 días en centros de Brasil y Uruguay. El grupo de intervención recibió tres consultas por entrevista motivacional, con un intervalo de 30 días, y el grupo de control mantuvo el monitoreo convencional en clínicas especializadas. Los datos se evaluaron utilizando el *Self-Care of Heart Failure Index 6.2*, antes y después de la intervención, en cada uno de los centros y se analizaron utilizando la media, la mediana, la prueba t, el análisis de correlación utilizando el coeficiente de Spearman y el efecto de la intervención por el *d de Cohen*. **Resultados:** 118 personas completaron el estudio. En vista de la evaluación del efecto de la entrevista motivacional sobre el autocuidado, en comparación con el seguimiento convencional, un efecto medio en el mantenimiento y el manejo (Cohen-d=0.6723; 0.5086) y alto en la confianza en el autocuidado (Cohen-d=0,9877). **Conclusión:** La entrevista motivacional fue efectiva para mejorar el autocuidado de pacientes con insuficiencia cardíaca, siendo una estrategia factible para ser implementada en clínicas especializadas. Registro brasileño de ensayos clínicos: RBR-6fp5qt.

DESCRIPTORES

Insuficiencia Cardíaca; Entrevista Motivacional; Autocuidado; Enfermería Cardiovascular; Ensayo Clínico.

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