Int J Cardiovasc Sci. 2022; 35(5), 635-642

ORIGINAL ARTICLE

Effectiveness of Telemedicine in Reducing Hospitalizations in Patients Discharged from the Hospital Due to Heart Failure: A Randomized Clinical Trial Protocol

Edmar Geraldo Ribeiro,[1] Luisa Brant,[1] Lilian Cristina Rezende,[1] Renato Azeredo Teixeira,[1] Laura Carvalho Parreiras,[1] Tulio Batista Franco,[2] Antônio Ribeiro,[1] Deborah Malta[1]

Universidade Federal de Minas Gerais,[1] Belo Horizonte, MG – Brazil
Universidade Federal Fluminense,[2] Niterói, RJ – Brazil

Abstract

Fundament: Telemedicine for follow-up in heart failure (HF) patients is effective in reducing hospitalizations, total and cardiovascular mortality. However, few studies were conducted in low and middle income, where lower access to technology and illiteracy could impact the results.

Objective: To assess the effectiveness of associating telemedicine strategies, when compared to usual care, in reducing hospitalizations related to HF in patients discharged from the hospital due to HF.

Methods: Controlled, randomized, multicenter, parallel-arm clinical trial, with an allocation ratio of 1:1, blinded to outcome evaluation, in which 340 patients who were discharged from public hospitals in Belo Horizonte due to HF will be randomized. Patients will be followed for 6 months and the intervention group will receive, in addition to the usual care, Structured Telephone Support (STS) from a nurse, a doctor, and an educational program. Counseling will be according to a clinical decision tree. The level of significance in the statistical analysis will be 5%.

Expected results: Reduction in the number of hospital readmissions and/or in hospitalization time, in addition to developing a software with a clinical decision tree for remote follow-up and patient education about HF adapted to local culture.

Conclusions: The intention of this study is to develop a telemedicine strategy and assess whether or not, in addition to the usual care, it is effective in reducing hospitalizations and mortality from HF. If effective, the aforementioned strategy could reduce costs and hospital needs in the Unified Health System (SUS, in Portuguese) for patients with HF. These results will be even more relevant considering the pandemic of COVID-19.Keywords: Heart Failure; Telemedicine; Telemonitoring; Hospitalization; Quality of Life.

Introduction

Heart Failure (HF) is a disease that affects more than 64.34 million people worldwide.[1] The survival rate after 5 years diagnosed can be of only 35%, higher in individuals of older ages. HF is the main cause of hospital admissions (50%) for the South American population.[2]

In the Brazilian context, in 2018, HF was the main cause of clinical hospitalizations related to the circulatory system, comprising 36% (222.394) of all admissions. Additionally, HF was responsible for 39% (R$348,832,330) of cardiovascular hospitalization costs in the Brazilian Unified Health System (SUS, in Portuguese).[3] It is important to note that at least one third of all HF hospitalized patients are readmitted 90 days after discharge.[4]

The *Brazilian Registry of Acute Heart Failure* (BREATHE) data showed that the main cause of hospital readmission is patient non adherence to prescribed therapy. Moreover, the registry revealed a high in-hospital mortality rate, ranking Brazil amongst countries with the highest rates in Western countries.[2] Other risk factors for decompensation identified by these records were: advanced age; infections;

Mailing Address: Edmar Ribeiro
Universidade Federal de Minas Gerais – Av. Alfredo Balena, 190. Postal code: 30130-100. Santa Efigênia, Belo Horizonte, MG – Brazil
E-mail: edmargribeiro@gmail.com

DOI: https://doi.org/10.36660/ijcs.20210131

Manuscript received May 20, 2021; revised manuscript December 27, 2021; accepted February 23, 2022.

nonadherence to nonpharmacological treatment, such as water and salt consumption; and cardiac arrythmias, especially atrial fibrillation.

Although HF treatment represents a challenge to health systems, the advances in technology has been creating alternative opportunities to aid HF patients, reducing their hospitalizations and improving their quality of life through the use of telemedicine strategies. These strategies can improve the self-care of HF patients, identify decompensation signs to provide timely and effective interventions, and optimize treatment recommended by guidelines to reduce hospital admissions.

Based on previous studies of the efficacy of the telemedicine associated telemonitoring showed a reduction in hospitalizations due to all-causes (OR 0.82, 95% CI, 0.73-0.91), hospitalizations due to heart disease (OR 0.83, 95% CI, 0.72-0.95), and a reduction in all-cause mortality (OR 0.75, 95% CI, 0.62-0.90).[5] Mortality by all causes (grouped OR = 0.80, 95% CI, 0.71-0.91, p<0.001), HF related admission rate (grouped OR = 0.63, 95% CI, 0.53-0.76, p<0.001), and length of stay in the hospital related to HF (standardized difference grouped into means = -0.37, 95% CI, -0.72 to -0.02, p = 0.041) were significantly lower in the telemedicine group (remote transmission and telephone support).[6]

The results of another meta-analysis indicated that non-invasive telemonitoring reduced all-cause mortality (RR 0.80, 95% CI, 0.68-0.94) and HF related hospitalizations (RR 0.71, 95% CI, 0.60-0.83). The structured telephone support reduced all-cause mortality (RR 0.87, 95% CI, 0.77-0.98), and HF related hospitalizations (RR 0.85, 95% CI, 0.77-0.93).[7]

Despite the result of meta-analyses, the telemedicine approach was not recommended by guidelines from such organizations as the European Society of Cardiology (ESC) and the American Heart Association, due to the negative result of large trials, mainly in low and middle income countries.[8]

The aim of the present study is to test whether or not adding telemedicine strategies to usual care can in fact further reduce HF-related hospitalizations of patients recently discharged from hospital, when compared to usual care. Through STS, allied with an educational program, we intend to promote self-care, as well as improve the quality of treatment and patient adherence to it, which could generate benefits to patients' quality of life and reduce unfavorable outcomes.

Methods

This study will be a multicenter, controlled, randomized clinical trial, in two parallel arms with an allocation ratio of 1:1 and blinded for outcome assessments. This study was logged under the Universal Trial Number (UTN): U1111-1263-9802, Brazilian Clinical Trials Registry (ReBEC) RBR-10znr9xn (https://ensaiosclinicos.gov.br/rg/RBR-10znr9xn).

Participants (trial environment and eligibility)

We will include patients hospitalized for HF (CID10 I50) who are close to being discharged from the public hospitals in Belo Horizonte. Hospital Metropolitano Odilon Behrens (HOB), Santa Casa de Misericórdia de Belo Horizonte, Hospital Risoleta Tolentino Neves (HRTN), Hospital Metropolitano Dr. Célio de Castro (HMDCC), Hospital das Clínicas da UFMG/EBSERH (HC) and Hospital Julia Kubitschek of FHEMIG (HJK) were selected because, together, they were responsible for 72.8% of the HF hospitalizations in SUS in Belo Horizonte, Brazil. in 2018.[3]

The uptake of patients will be carried out by undergraduate students, Scientific Initiation scholarship holders, who have been previously trained and who will invite eligible participants for the study. These activities will be coordinated by the study's management team, made up of two nurses and a doctor.

The inclusion criteria are: patients living in Belo Horizonte and its metropolitan region, older than 30 years of age, using diuretics regularly (Functional Class II/III/IV, according to *The New York Heart Association*), defined as continuous use prior to admission or use upon hospital discharge, and who agreed to participate and signed the Informed Consent Form. The exclusion criteria are patients with diseases that reduce life expectancy to less than six months after their inclusion in this study (patients in palliative care described in medical records); patients in renal replacement therapy; pregnant patients; patients with difficulties or that are unable to complete the interview or to use the telemonitoring devices, defined as patients with dementia or cognitive alterations described in medical records; illiterate patients (those unable to read and/or write) with no responsible caregiver who agrees to help; patients with some condition that could limit the conformity with the study procedures (i.e. known alcohol or other drug abuse); patients that are participating in other HF intervention studies.

Interventions

Patients included in this study will be randomized and allocated either to the control group (CG), which will receive usual care from the SUS unit where they are referred to, or to the intervention group (IG), for which STS and case management by a nurse, linked to a consultant physician (cardiologist), in parallel with a remote educational program, will be added to the usual care. For both groups, a booklet containing information and counselling about HF itself and about self-care will be offered[9] in addition to an echocardiogram for those patients who have not done this exam in the month prior to their inclusion in this study.

The IG group will receive weekly STS with the same nurse – the case manager. Each call will last around 20 minutes, including the 5 following approaches: i) measuring of daily weight, blood pressure, and heart rate monitoring; ii) investigation of signs and symptoms of decompensation; iii) assessment of pharmacological therapy adherence and barriers to achieve it; iv) educational approach of the disease – signs and symptoms, treatment, and healthy habits; and v) questions & answers.

Weekly, the case manager will meet with the consulting physician to discuss the clinical condition and progress of patients, particularly those who present non-urgent signs and symptoms of early decompensation or that required elective treatment optimization, according to predefined protocols based on the current guidelines. If needed, elective teleconsultations can take place via telephone or videocall. In addition, the case manager will be able to contact an on-call cardiologist (24/7) and, according to predefined protocols, discuss and request an urgent teleconsultation.

Subjects in the intervention group will also receive WhatsApp unidirectional educational messages twice a week, with self-management strategies, counselling about the subject's disease, according to the respective week's topic and to the subject's characteristics (diabetics, non-diabetics, smokers, and/or non-smokers), and reminders about their scheduled medical visits. Table 1 shows examples of messages to be sent to each participant from the intervention group according to each topic.

Participants in the intervention group will have access to a WhatsApp queries channel on office hours and a 24/7 medical on-call service available for guidance in urgent situations (Figure 1).

Table 1 – Examples of messages sent to the intervention group

Main topic of discussion	Message example
HF Understanding	Heart failure is the main cause of clinical hospitalization in Brazil. We need to take care of you together so that we can avoid another hospitalization. We're counting on you!
Medication	The treatment of heart failure with medication aims to reduce or delay the onset of symptoms, such as tiredness (fatigue), shortness of breath (dyspnea) and swelling (edema). Take your medications every day, as per the prescription.
Signs and Symptoms of Decompesation	Do you know when to contact the health team to avoid hospitalization? Please contact us: worsening shortness of breath, worsening swelling and weight gain greater than 2 kilos in 3 days. A simple orientation or adjustment of medications can solve it!
Diet	One of the pillars of cardiovascular disease prevention is healthy eating. Try to eat natural foods and avoid processed foods, which in general have a lot of salt and preservatives.
Lifestyle changes	One of the best things you can do for the success of your treatment is to have a healthy lifestyle. A balanced diet, regular physical activity, and getting enough sleep and rest are essential. Ask health team professionals for guidance.
Caregiver involvement	Ask someone you like to help you remember medication times and to accompany you during appointments. It is always good to have support!
Smoking	Quitting smoking is the most important action that a smoker can take to improve his health. Have you thought about it? Ask a professional for help and believe in yourself!
Diabetes Mellitus	Test your capillary blood glucose as directed by your healthcare team. Values that are too high (> 200 mg / dl) or too low (<60 mg / dl) are warning signs and should be reported to the healthcare team.

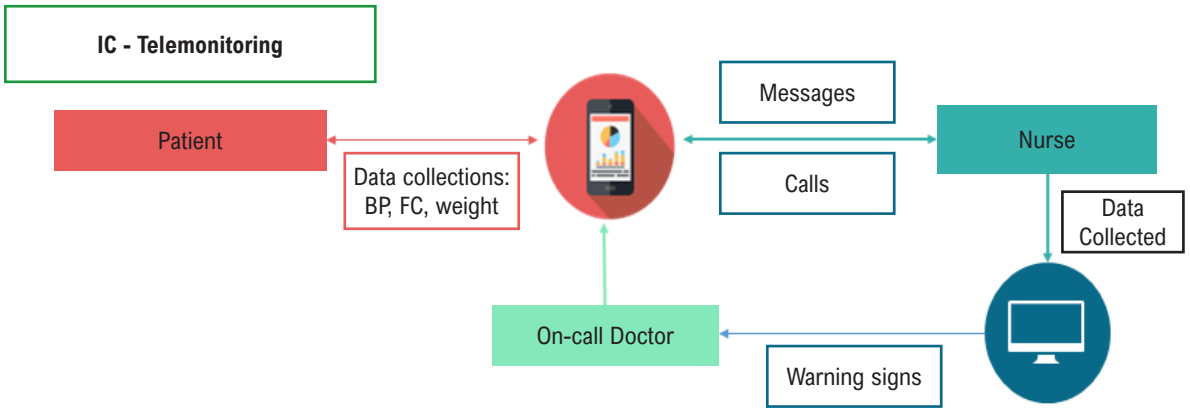

Figure 1 – Scheme of the technological telemedicine intervention proposed for the Clinical Trial, GI, 2021.

Outcomes

The primary outcome will be unplanned HF-related hospitalizations in six months, defined as those with CID-10 I50 or with diseases that may be related to HF decompensation (Ex. arrhythmias, exacerbated chronic kidney disease, dehydration, electrolyte imbalance), evaluated by an adjudication committee consisting of two physicians, based on discharge notes.

The secondary outcomes will be the evaluation of all-cause death; cardiovascular death (CID-10, Chapter IX); readmission by all causes (≥24h length of stay, unplanned); readmission due to HF (CID-10 I50, ≥24h length of stay, unplanned); sought emergency health services, including ambulances (<24h); lost days for unplanned hospitalization or death by all causes in six months; lost days for unplanned hospitalization in six months; change in quality of life of HF patients, assessed through quality of life scores: Minnesota Living with Heart Failure Questionnaire (MLHFQ),[10] HF self-knowledge,[11] and 12-Item Health Survey (SF-12).[12]

The outcome events will be registered for both groups, either through structured telephone calls every 45 days made by trained research team members or through identified mortality and hospital admission data from Belo Horizonte. Data collected through telephone calls will be checked by videocall in 180 days ± 15 after hospital discharge.

Sample Size

To determine the study's sample size, the following formula will be used:

$$2N = \frac{2\{Z_\alpha\sqrt{\bar{p}(1-\bar{p})} + Z_\beta\sqrt{\overline{p_c}(1-\overline{p_c}) + \overline{p_i}(1-\overline{p_i})}\}^2}{(p_c - p_i)^2}$$

The following parameters were used:

- Outcome: readmission ratio
- Control group ratio (pc)=0.386
- Intervention group ratio (pi)=0.26
- Type II Error (β) =0.20
- Type I Error (α) =0.05

The reference for case and control parameters in hospitalization outcome were taken from "Oscalices MIL, Okuno MFP, Lopes MCBT, Campanharo CRV, Batista REA. Discharge guidance and telephone follow-up on heart failure therapeutic adherence: randomized clinical trial. Rev Lat Am Nursing, 2019".[13] Although in the mentioned study the telemedicine intervention has been less intensive than that proposed herein, we chose to use this study data because the target population is similar and, as the present study intervention is more robust and intensive, we might overestimate the sample.

Considering a loss ratio of 25%, after this correction the study generated a sample of 340 randomized patients randomly assigned to two groups (1:1).[14] The patient who does not follow the intervention or answer the calls will be considered a loss in the sample.

The planned total duration of the study is 10 months, with an inclusion time (4 months) and a follow-up time (6 months).

Assignment/allocation and blinding

The present study will have a two-form randomization, simple and stratified. The simple randomization ensures total randomness in assigning participants to each group. This will be applied in a complete and random manner to the first patient, and subsequently each patient will be evaluated in order to avoid disbalancing between the two groups at the end of participant inclusion phase. This means that for every randomized patient, the next one will have the probability of being assigned to each recalculated group. To this end, the algorithm below will be used:

```
#nc: number of cases
#ni: number of interventions
loop
n=nc+ni
intervention=ni/n
if
rand= randomization (0 a 1)> intervention returns "CASE" otherwise "INTERVENTION"
    if rand = "CASE" returns nc-1 otherwise nc-1
#End
```

On the other hand, knowing that subject's profile may differ according to the hospital in which one was hospitalized (for example: sociodemographic or severity profile); thus, the randomization will be stratified by hospital. The stratification will be conducted through separated randomization blocks for each hospital. After the assignment of subjects to a hospital pack, the simple randomization is applied inside each pack. The randomization system will be centralized, applied by a software after the inclusion of subject's baseline data, in previously created packs for each hospital. The allocation is confidential, preventing researchers from predicting the distribution order.

This is an open study because of its intervention nature and, as such, the treatment allocation will not be blinded either to researchers or to the participant. The outcomes will be collected by blinded researchers for the participant group and endorsed by a blinded adjudication committee.

Data collection methods

The data collection will be made using a designed and dedicated software, via tablet, with automatic data transfer to the center, and will be carried out in four steps, according to the flowchart presented in **Figure 2.**

Data managing and monitoring

Participants will be registered through codes, ensuring confidentiality. Each patient will have an electronic chart where data collected will be registered in eachg step. Access to a data managing system will be authorized via personal and non-transferable password, and the forms will be signed electronically, guaranteeing data confidentiality.

Group data analysis and monitoring team will be responsible for registered data. Data input will happen via WEB: "website" with user management, identification, and password. Systematic verifications of data consistency will be done periodically. The general responsibility for the study will be of the steering committee, along with the responsibility for decisions to improve the study monitoring.

Considering the intervention nature that does not expose participants to additional risks to their health, there are no pre-defined conditions to withdraw the study before the planned period.

Statistical analysis

The main data analysis will be performed after finishing the inclusion of participants estimated in sample planning. During the participant's' inclusion period, the composition of each sample will be evaluated by descriptive analysis to assure homogeneity.

Four months after the beginning of data collection, the first partial results will be presented, showing the descriptive analysis of the participants' baseline sociodemographic and clinical variables.

The final report will be comprised of a primary analysis, following the "intention to treat" principle. As a sensitivity analysis, we will also analyze data per protocol. Statistical tests will be applied to compare groups and the 95% confidence intervals of group variables will be estimated. Moreover, a secondary analysis will be drafted using logistic regression models to estimate the odds ratio according to the comparison group. Chi-square tests (categorical variables) and the Student t mean comparison tests, paired and unpaired, will be applied, as well as the accepted normality test, will be performed. Otherwise, non-parametric tests will be applied (Mann-Whitney, Wilcoxon, McNemar, Sign-Test, Kruskal-Wallis, among others, if necessary). The level of significance adopted in the statistical analysis will be 5%.

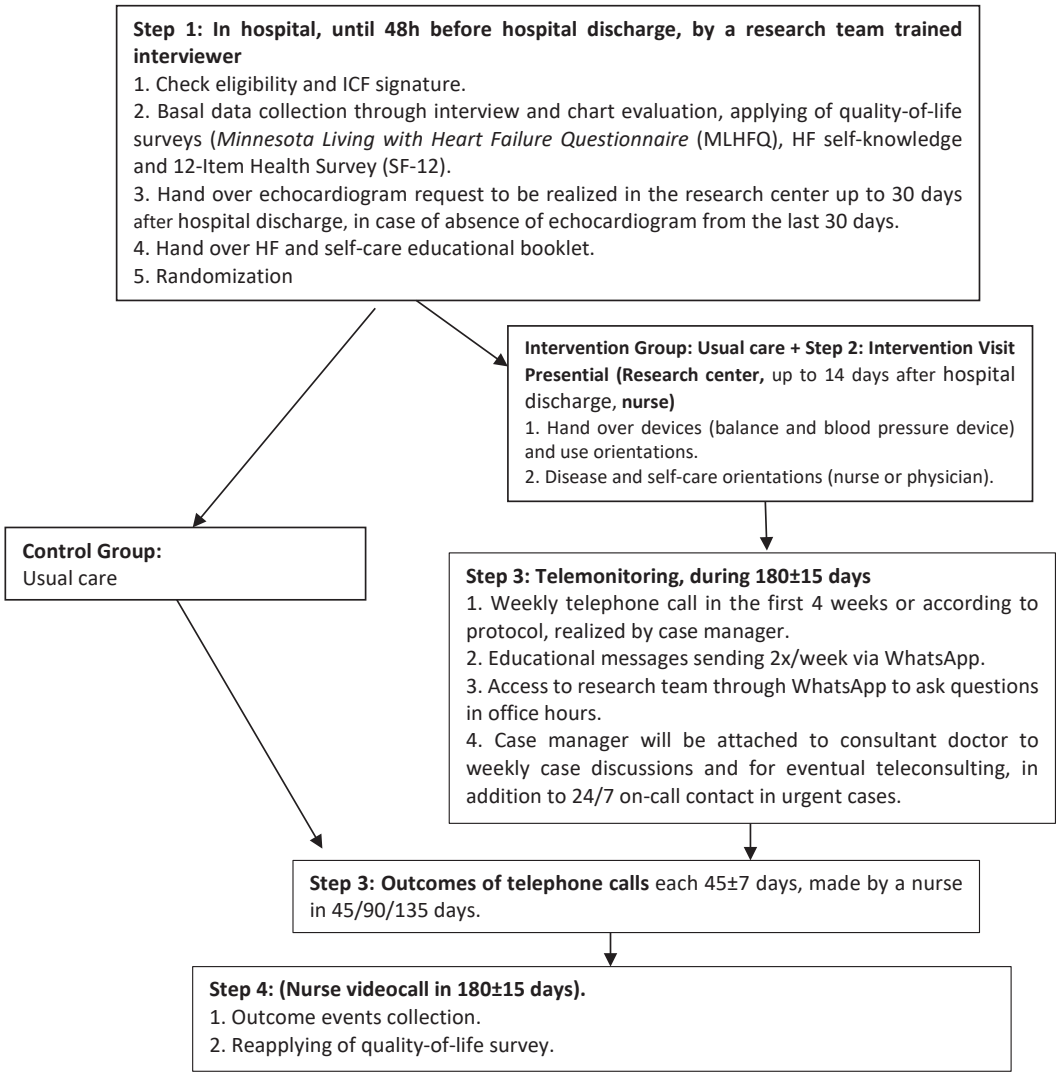

Figure 2 – Data collection flow chart

Participants that die during the 180 days of follow-up will be considered in the analysis of days lost by hospitalization until the day of death.

The pre-specified subgroup analysis will include:

- Sex
- Age (stratified at 60 years)
- Literacy (incomplete elementary education vs. others)
- HF cause (ischemic vs. others)
- NYHA II vs. III and IV
- LVEF < 40%, > 50%
- Center

It is important to emphasize that all project planning was defined using information gathered prior to the COVID-19 pandemic. The study planning estimated the mean period of hospitalization so that the project would be developed in the stipulated time. However, different scenarios can be observed and, consequently, adaptations and alterations can be made. For example, the data collection process was elaborated to include the last patient until the end of the 6th month. If the partial analysis shows that this projection is not feasible, the inclusion period could be extended as a way to maintain the study's statistical power for the comparison group regarding outcomes.

Ethics and promotion

This research was approved by the Research Ethics Committee (REC) of Fluminense Federal University (FFU), CAAE: 38594020.0.1001.5243. It will follow the Regulatory Norms and Guidelines involving Human Beings, established by Resolution 466/12 of the National Health Council and Tripartite Harmonized Manual of Harmonization International Conference (HIC) for Good Clinical Practice (GCP).

This study was registered in the Brazilian Clinical Trials Registry (ReBEC), RBR-10znr9xn, logged under UTN number: U1111-1263-9802 and followed Consolidated Standards of Reporting Trials 2010 (CONSORT 2010) recommendations.

The adverse events that may occur during the study period will be registered and informed to the attending physician or to participants of the Health Center management via e-mail, fax, or telephone calls and forwarded on the partial reports. The following will be registered:

- Nature of events, its beginning and ending dates, its severity;
- The introduction of treatment, if applicable, including adjustment of HF pharmacological therapy or patient counselling conducts, such as recommendations to search for medical assistance, urgently or not;
- Event results and its relation with the allocated study intervention, evaluated by the researcher.

The actions that will follow an adverse event identified by telemonitoring will be defined by pre-defined protocols.

An adverse event is defined as any adverse medical occurrence in a patient or clinical trial subject that does not necessarily have a cause relation with the treatment.[15]

Expected results

The expected result is to answer if telemedicine by STS follow-up of HF patients will reduce the need for re-hospitalization or the amount of time that they spend in the hospital, in comparison to usual care, in our country.

The secondary outcomes will be cardiovascular death, readmission for HF; search for emergency services, such as Emergency Care Units, Hospital Emergency Service, or SAMU; and days lost due to unplanned hospitalization. It is expected that this study can contribute to improvements in the quality of life and functional class of patients with HF upon hospital discharge. In addition, software is being developed to record patient data and the compilation of results after six months of follow-up. The use of assisted technologies, such as telemedicine, to assist HF patients has the potential to reduce hospital admission and disease mortality rates through improved understanding and self-care; individualized counselling on diets, especially water and salt restrictions; and the practice of physical activity, as well as stimulus for regular medication use, the fast optimization of current guideline based treatments, and the early detection of decompensation signs and symptoms.[7,16,17]

Hospitalizations are associated with the worsening of health-related quality of life and with an increasing risk of death, and are responsible for most health costs in the treatment of individuals living with severe chronic conditions.[7,16,18,19] Considering COVID-19 concomitance, these outcomes could be worsened. In this context, testing new evidence in the field of telemedicine could support health care.

Conclusion

In conclusion, this study aims to provide information by means of controlled randomized data as to whether or not telemedicine interventions are effective in reducing re-hospitalizations due to HF.

Importantly, the telemedicine and STS apparatus developed for this study, such as software and applications, may be used afterwards, even in patients who live in areas where the access to specialized medical care is scarce. If the expected results of the present study are confirmed, the trial may serve as a reference to the implementation of similar strategies in a wider context in the scope of SUS, reducing HF hospitalization in Brazil.

Acknowledgments

We wish to thank the National Health Fund / Health Ministry for their funding. We would like to acknowledge Kênia Lara, Alzira Jorge, Pedro Cisalpino, Rayssa Guimaraes, Valéria Augusto, Regina Bernal, and Liliane Mendes for their significant contribution in creating this protocol.

Author contributions

Conception and design of the research: Edmar Geraldo Ribeiro, Luisa Brant, Lilian Cristina Rezende, Renato Azeredo Teixeira, Laura Carvalho Parreiras, Tulio Batista Franco, Antônio Ribeiro, Deborah Carvalho Malta. Statistical analysis: Renato Azeredo Teixeira. Obtaining financing: Tulio Batista Franco. Writing of the manuscript: Edmar Geraldo Ribeiro, Luisa Brant, Lilian Cristina Rezende, Laura Carvalho Parreiras, Deborah Carvalho Malta. Critical revision of the manuscript for intellectual content: Luisa Brant, Deborah Carvalho Malta.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

This study was funded by National Health Fund.

Study Association

This article is part of the thesis of Doctoral submitted by Edmar Geraldo Ribeiro, from Federal University of Minas Gerais.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Ethics Committee on Animal Experiments of the Research Ethics Committee (REC) of Fluminense Federal University (FFU) under the protocol number CAAE: 38594020.0.1001.5243. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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