Official title: Effectiveness of video monitoring in care transition for heart failure patients (EVIT-HF): study protocol for a randomized clinical trial

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Abstract

Background: Real data on the impact of video monitoring on heart failure (HF) prognosis are limited and inconclusive. **Aims:** This article describes a randomized clinical trial protocol designed to assess the efficacy of a video monitoring and educational strategy for patients with heart failure with reduced ejection fraction (HFrEF). **Methods:** This is a randomized, parallel trial with blinded outcome assessment. During hospitalization, patients who meet the inclusion criteria will be invited to participate. Sociodemographic data, clinical variables, results of laboratory tests, current medications, and cardiovascular physical examination will be collected. Additionally, clinical congestion score, European HF self-care, HF knowledge, treatment adherence, quality of life, and cardiorespiratory fitness will be measured by validated instruments. The control group (CG) will receive usual care after discharge. In the intervention group (IG), the clinical discharge summary will be shared with the primary healthcare (nurse and physician) to discuss transitional care. IG participants will receive specialized cardiovascular nursing appointments through video monitoring (at 7, 30, 60, and 180 days). The primary outcome is the self-care score. Secondary outcomes include quality of life, HF knowledge, treatment adherence, cardiorespiratory fitness, death rates, and hospital readmissions. **Discussion:** Unlike strategies based on mobile devices or voice telemonitoring, video monitoring hypothetically generates greater trust between patients and professionals, improving measured outcomes. **Implication:** This study highlights the use of video monitoring in heart failure management, improving nurse-patient relationships, self-care, and treatment adherence. It emphasizes nurses' roles in transitional care and education, reducing readmissions and mortality. **Impact:** Video monitoring may enhance global nursing practices, improving outcomes and quality of life for heart failure patients. **Reporting Method:** This study has adhered to relevant EQUATOR guidelines using SPIRIT 2013 checklist. No Patient or Public Contribution.

Keywords: Educational interventions; heart failure; nursing; randomized clinical trial; video monitoring.

1 Introduction

Heart failure (HF) is a complex clinical syndrome, as it is the final pathway for several cardiovascular comorbidities associated with high mortality and hospitalization rates due to HF decompensation, with a high frequency of hospital admissions [1].

Due to clinical complexity and high mortality, the standards of treatment for HF with reduced ejection fraction (HFrEF) are still below the guideline recommendations [2]. There is low patient adherence to treatments proposed

in clinical protocols and guidelines, possibly due to the gap between patients and health services [3,4].

Patient monitoring after hospital discharge by a specialized nursing team using new technologies, such as telemonitoring, has demonstrated effectiveness in reducing deaths and hospital readmissions caused by decompensated HFrEF. The use of these technologies has sufficient levels of evidence to be incorporated into the main HFrEF guidelines around the world [5,2,6,7].

Despite this, there remains a number of areas of uncertainty about the impact of telemonitoring on the prognosis of patients with HF. Systematic reviews and meta-analyses have identified deficiencies in the use of educational interventions based on telemonitoring, mainly for outcomes such as knowledge about HF, self-efficacy, self-care and health-related quality of life, indicating the need for well-planned strategies that improve these facets of self-care [8,9].

Although most research is based on voice telemonitoring and structured telephone software for HF, strategies based on video monitoring are still scarce and inconclusive. A clinical trial did not show significant differences in outcomes such as self-care, quality of life, mortality, or readmission [10]. A clinical trial based on video monitoring is being conducted in Italy but without results thus far, and participants are still being recruited [11] .

A clinical follow-up model based on this model and health education provided by nurses may optimize clinical outcomes such as self-care, quality of life, cardiorespiratory fitness, knowledge about the disease, adherence to

self-care treatment, readmission and death in patients with HFrEF. The research protocol proposed in this study aims to test the efficacy of a video-based monitoring program that incorporates an educational program delivered by specialist cardiovascular nurses to patients with HFrEF after hospital discharge.

2 Methods/Design

2.1 Study design and centers

This a randomized, parallel trial with blinded outcome assessment, following the recommendations of SPIRIT statement (see Supplementary file 1). The study population comprises patients with a diagnosis of HFrEF defined by Brazilian Society of Cardiology who presented to hospital with HF decompensation. The study has been carried out at CLINICAL HOSPITAL OF UBERLANDIA, Brazil, and takes place at the Emergency Department or other inpatient units.

2.2 Inclusion and exclusion criteria

The study includes patients aged 18 years or older, admitted for decompensated HFrEF from the emergency department or clinical admission of CLINICAL HOSPITAL OF UBERLANDIA with an ejection fraction less than 40% confirmed by echocardiogram performed in the last 3 months and who access to a mobile device with internet access. Patients on the heart transplant waiting list, who had undergone coronary artery bypass in the last 3 months who were in palliative care or who had a life expectancy of less than 1 year, as confirmed by a review of their medical records, will be excluded.

2.3 Ethical considerations

All procedures will be conducted according to ethical standards for research with human subjects established in the Declaration of Helsinki. Written informed consent must be obtained from all patients included in the study. The project was approved by the local Research Ethics Committee (registration number 5.568.868) and was registered (RBR-9fkncwv) in the Brazilian Registry of Clinical Trials (ReBEC). The coordinating center and steering committee of this study will be composed of nurses specializing in cardiovascular nursing, independent of the researchers. Monitoring meetings occur monthly.

2.4 Sample size

Assuming the ratio of self-care scores from previous studies at 180 days after clinical follow-up, a common standard deviation of 0.83 for the log ratio scale, a two-tailed hypothesis test with a significance level of 5% and a statistical power of 90%, a sample of 140 patients (70 patients for the intervention and control groups) will be sufficient to detect a 20% difference between the groups.

2.5 Interventions

The control group (CG) will receive usual care provided by CHU after hospital discharge. The intervention group (IG) will receive an educational nursing intervention supported by a printed booklet with information about the care of patients with HF based on the HF guidelines of the Brazilian Society of Cardiology. This information will be provided at the time of hospital discharge. The clinical discharge summary will be shared from hospital to nurse of primary health care unit to discuss the patient's clinical case and planning the transition and continuous care.

Additionally, this group will be followed up by specialized cardiovascular nurses through video monitoring in 7, 30, 60 and 180 days after discharge through WhatsApp video service. This video call will last 30 minutes to support patients in adhering to care plans using teaching back technique according to Brazilian Society of Cardiology guidelines for HC care. The calls will cover the following topics, sodium and fluid intake, medication adherence, cardiovascular rehabilitation in HF, and the detection of warning signs of HF decompensation.

The video consultations will be conducted using the motivational interview, a counseling technique that focuses on the individual, helping to awaken and strengthen personal motivation for change. At the end of each video consultation, researchers will use the teach-back learning method, which is a technique that aims to improve patients' understanding of health education.

2.6 Study protocol

During hospitalization, patients who meet the inclusion criteria will be invited to participate. Sociodemographic data, clinical variables, laboratory test results (sodium, urea, creatinine, potassium and complete blood count), current medications and cardiovascular physical examination data will be collected. Moreover, Clinical congestion score, European HF self-care, HF knowledge, HF treatment adherence, HF quality of life and Cardiorespiratory Fitness data will be collected by specific instruments [12-16]. After this step, participants will be randomized in CG or IG.

At hospital discharge, the IG will receive educational material in booklet form, containing a checklist of important information about cardiovascular care in HFrEF, based on the HF guidelines of the Brazilian Society of Cardiology, including warning signs and symptoms for decompensated HFrEF. Researchers will reinforce with the patient, family, and caregivers the commitment of reading the booklet and will read the booklet to patients and caregivers who cannot read it.

Furthermore, in the first week after hospital discharge, the discharge summary will be shared with the nurse of the primary health care unit of the patient to discuss the patient's clinical case to plan the transition and continuous HF cardiovascular care.

The IG participants will receive specialized cardiovascular nursing appointments through video monitoring (at 7 days, 30 days, 60 days, and 180 days). Firstly, researchers will determine the participants' status in relation to the adherence to the booklet's guidelines, clarify doubts, and teach them the best way to follow the recommendations. The video monitoring sessions will be conducted using motivational interviewing techniques, and at the end of each video consultation, the teach-back technique will be applied to reinforce understanding and adherence to the guidelines. At the end of each video appointment, the instruments will be collected: clinical congestion score, European HF self-care scale, HF knowledge questionnaire, HF treatment adherence questionnaire, HF quality of life questionnaire, and cardiorespiratory fitness. In order to promote participant retention and complete follow-up, researchers will schedule all monitoring sessions and update the register of patients in the virtual system.

The CG will receive the usual care provided by Clinical hospital of Uberlandia-Brazil, after hospital discharge and a telephone call to collect the same instruments used for the IG 30, 60 and 180 days after discharge. The SPIRIT flowchart of the participant recruitment process is shown in Figure 1.

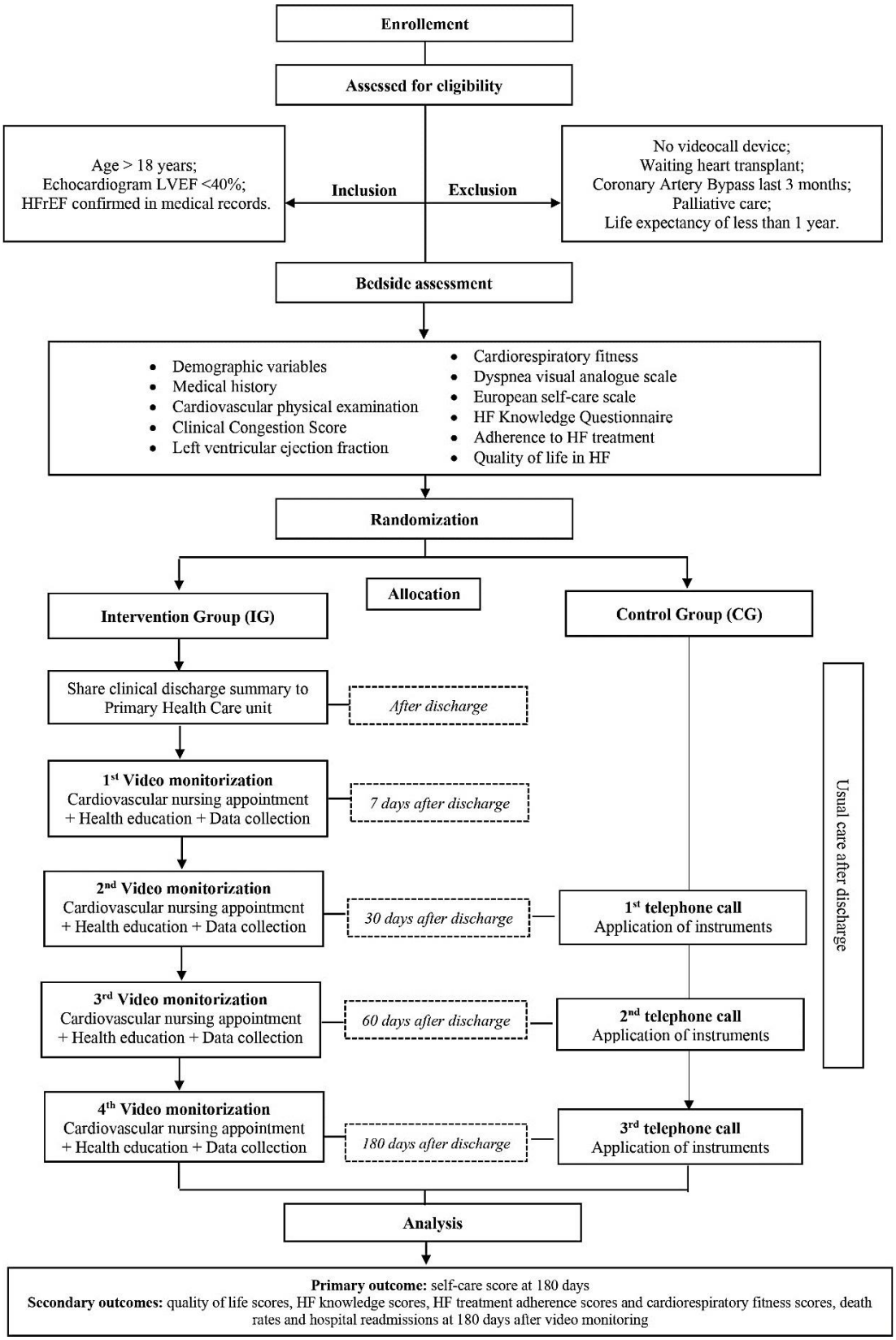

Figure 1. Flowchart of study participation and interventions.

2.7 Randomization

The randomization will be performed through a simple sequential randomization plan generated online using the www.randomization.com website.

2.8 Blinding

The patients will be blinded according to group allocation. All researchers who will conduct video monitoring appointments will also be blinded to group allocation.

2.9 Variables in the study

Demographic variables

A structured questionnaire will be administered to all participants for the collection of sociodemographic characteristics (age, sex, ethnicity) and educational data.

Medical history

Data on the etiology of HF, history of present illness, past medical history, comorbidities and current medications will be collected from patient records.

Cardiovascular physical examination

The cardiovascular physical examination will be based on the variables weight, height, blood pressure, heart rate and cardiac auscultation.

Clinical Congestion Score

The clinical congestion score is an instrument composed of seven questions designed to assess signs and symptoms of congestion, including the presence of pulmonary crackles, third heart sounds, jugular venous distension, peripheral edema, hepatojugular reflux, orthopnea, paroxysmal nocturnal dyspnea, and the New York Heart Association functional class. This score ranges from 1 to 22 points, with higher scores being directly indicative of worse congestion [17].

Left ventricular ejection fraction

The left ventricular ejection fraction will be assessed by means of echocardiography, using the Teichholz method or, if available, the Simpson method.

Dyspnea visual analog scale

The visual analog scale consists of a subjective scale for measuring the patient's dyspnea, which ranges from 0 to 10, where 0 means no dyspnea and 10 means the patient's maximum dyspnea.

Laboratory variables

Blood samples will be collected by a trained professional at the time of study enrollment at hospital discharge. Blood analysis will include urea, serum creatinine, plasma sodium and potassium.

European Self-Care Scale

The European self-care scale consists of 12 questions with a single domain related to self-care behavior. Responses to each item range from 1, “I completely agree”, to 5, “I completely disagree”, following a five-point Likert scale. The total score is obtained by summing all the responses, which can range from 12 to 60. Low values indicate better self-care. The items concern the various self-care behaviors of patients with heart failure, such as checking daily weight (item 1), rest (items 2 and 7), seeking help from the healthcare team (items 3, 4, 5 and 8), fluid restriction (item 6), diet (item 9), medication adherence (item 10), flu vaccination (item 11) and exercise (item 12) [15].

HF Knowledge Questionnaire

The HF knowledge questionnaire consists of 14 questions related to domains such as knowledge of the appropriate diet in HF, knowledge about the amount of fluids ingested and weight control, knowledge about pharmacological and nonpharmacological treatment of HF and general knowledge about the disease. The knowledge score is determined by the sum of the number of correct answers: for the correct question, the patient gains one point, and for each incorrect answer, the patient loses one point. In this way, the score ranges from 0 to 14 [18].

Adherence to HF treatment

Adherence to HF treatment will be assessed by an instrument with 10 questions related to the use of prescribed medications, daily weight checks, salt intake, water intake and attendance at scheduled appointments and exams.

Each question has 3 to 4 alternatives; for questions with 4 alternatives, the score varied from 0 to 4 points, and for questions with 3 alternatives, the score varied from 0 to 3 points. Therefore, the general adherence score could vary from 0 to 26 points. A minimum score of 18 points will be considered a cutoff point for patients adhering to treatment, corresponding to 70% adherence [12].

Quality of life in HF patients

The quality of life of patients with HF will be assessed by the Minnesota Living with Heart Failure Questionnaire (MLHFQ), a disease-specific questionnaire for patients with HF, comprising 21 items rated on six-point Likert scales representing different degrees of impact of HF on quality of life, from 0 (none) to 5 (very much). It provides a total score (range 0–105, from best to worst quality of life), as well as scores for two dimensions, physical (8 items, range 0–40) and emotional (5 items, range 0–25). The other eight items (a total of 21) are considered only for the calculation of the total score [14].

Cardiorespiratory fitness

Cardiorespiratory fitness will be assessed by the Veterans Specific Activity Questionnaire (VSAQ), a brief questionnaire that consists of a list of activities presented in a progressive order according to metabolic equivalents (METs). Participants are instructed to determine which activities would cause fatigue, shortness of breath, chest discomfort, or necessity of stopping due to exhaustion if performed for a few minutes. The VSAQ was scored as a whole number (1 to 13 METs) directly from the subject's response. The VSAQ score will be adjusted by age and METs following a regression equation to predict aerobic fitness: METs = 4.7 + 0.97 × VSAQ − 0.06 × age [16].

Motivational Interviewing

The approach to IG patients via video consultation will be grounded in Motivational Interviewing (MI), a counseling technique that focuses on the individual, helping to evoke and strengthen personal motivation for change through a collaborative and evocative strategy that values the patient's autonomy in fostering their own motivation for health-related behavior change. MI is considered the opposite of offering unsolicited advice. It works by exploring and resolving ambivalence in people’s behaviors, such as a patient who acknowledges the

importance of exercise but does not engage in it, or one who understands the need to reduce salt intake but continues to use it excessively, aiming to promote intrinsic motivation for change. The principles of MI include demonstrating empathy, avoiding direct confrontation, managing resistance, and fostering self-efficacy and optimism[19].

Teach-back

At the end of each video consultation, researchers will use the Teach-back method, a technique aimed at improving patients' understanding of health education. This method involves the following steps: the researcher provides clinical information to the patient about heart failure (HF); the patient then repeats the information in their own words; if the patient's explanation does not fully capture all the information provided, the researcher will offer further clarification and ask the patient to restate the information again, continuing this process until the patient correctly understands the information. This technique offers insights into the patient's actual health literacy, and throughout the video monitoring sessions, it is expected to contribute to better knowledge retention by the patient regarding HF[20].

2.10 Primary outcome

The primary outcome consists of the self-care score at 180 days after clinical video monitoring.

2.11 Secondary outcomes

The secondary outcomes will be quality of life scores, HF knowledge scores, HF treatment adherence scores, cardiorespiratory fitness scores, death rates and hospital readmissions at 180 days after video monitoring.

2.12 Statistical analyses

The data will be treated in double entry. The effect of the intervention between the IG and CG will be carried out using an unpaired test for an independent sample of self-care scores at 180 days in relation to the baseline score. To identify significant differences in self-care scores throughout the follow-up (30, 60 and 180 days), the paired t test will be used in the case of a normal sample distribution or the Wilcoxon test otherwise. Quantitative secondary outcomes will be compared between groups using the t- test or Mann–Whitney–Wilcoxon nonparametric test. Categorical secondary outcomes will be compared between groups using Fisher's exact test or the chi-square test. Deaths and hospital readmission rates will be measured using logistic regression. A P value <0.05 (two-tailed) shall be considered to indicate statistical significance.

3 Trial status

This study protocol is in its first version, registered in the Brazilian Registry of Clinical Trials. Recruitment will start in December 2024, and the approximate date of its completion is December 2025. Any necessary changes to this protocol will be informed to the local Research Ethics Committee. All authors will have access to the final trial dataset. Personal information about potential and enrolled participants will be collected in redcap forms, shared only with researchers, and confidentiality before, during, and after the trial

4 Results and Discussion

European Self-Care Scale

HF Knowledge Questionnaire

Adherence to HF treatment

Quality of life in HF patients

Cardiorespiratory fitness

Mortality

Hospitalization

Motivational Interviewing

Teach-back

The proposed multifaceted strategy has the potential to optimize the outcomes assessed in the IG compared to the CG, as well as to generate technological innovation in cardiovascular health for the Brazilian public health system. Hypothetically, video monitoring is a strategy capable of fostering a stronger bond and trust between patients and healthcare professionals compared to other telehealth approaches, potentially leading to improved measured outcomes. This study also aims, indirectly, to strengthen the relationships between different healthcare models, as primary care professionals will receive the patient's hospital discharge summary, enabling them to design strategies for the promotion and prevention of the patient's individual needs.

5 Conclusions

Unlike strategies already widely discussed in the literature (which are based on structured mobile devices or voice telemonitoring), the protocol of this study is based on video monitoring. The consultations will be guided by the

techniques of motivational interviewing and the teach-back method, both of which are widely validated in clinical practice for promoting behavior change in health and enhancing health literacy, respectively.

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