# Original Article

# Effectiveness of nurse-led video monitoring for maintaining self-care in heart failure patients: study protocol for a randomized clinical trial

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Abstract: It is well established that video monitoring is effective in promoting self-care among patients with heart failure during the intervention period. However, its long-term impact on sustaining self-care behaviors after discontinuation remains unclear. This article describes a randomized clinical trial protocol designed to assess the effectiveness of a video monitoring strategy in maintaining self-care behaviors in patients with heart failure with reduced ejection fraction (HFrEF). This is a randomized, parallel trial with blinded outcome assessment. During hospitalization, eligible patients will be invited to participate. Data collection will include sociodemographic and clinical variables, laboratory test results, current medications, and cardiovascular physical examination. Validated instruments will measure clinical congestion, self-care (European HF Self-Care), HF knowledge, treatment adherence, quality of life, and cardiorespiratory fitness. The control group (CG) will receive standard care after discharge. In the intervention group (IG), the discharge summary will be shared with primary healthcare providers (nurse and physician) to facilitate transitional care. IG participants will receive structured video monitoring sessions with specialized cardiovascular nursing support at 7, 30, 60, 180, and 365 days post-discharge, focusing on self-care reinforcement. The primary outcome is the self-care score at one year. Secondary outcomes include quality of life, HF knowledge, treatment adherence, cardiorespiratory fitness, mortality, and hospital readmissions. Unlike mobilebased or voice telemonitoring strategies, video monitoring fosters a stronger connection between patients and healthcare professionals, which may enhance self-care maintenance over time. This approach aligns with personalized nursing interventions, reinforcing education and behavioral changes beyond the intervention period. This study highlights the role of video monitoring in sustaining self-care practices in heart failure management. By strengthening the nurse-patient relationship and promoting long-term adherence, it has the potential to reduce readmissions and mortality rates. Video monitoring may enhance global nursing practices, improving outcomes and quality of life for heart failure patients.

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

#### Introduction

Heart failure (HF) is a complex clinical syndrome, often representing the end stage of various cardiovascular diseases, and is associated with high rates of mortality and hospitalization due to decompensation, with frequent hospital readmissions [1].

Due to its clinical complexity and high mortality, the implementation of evidence-based therapies for heart failure with reduced ejection fraction (HFrEF) remains suboptimal, with many pa-tients not receiving the full spectrum of guideline-directed medical therapy [2]. This therapeutic gap may reflect multiple factors, including system-level barriers and clinical

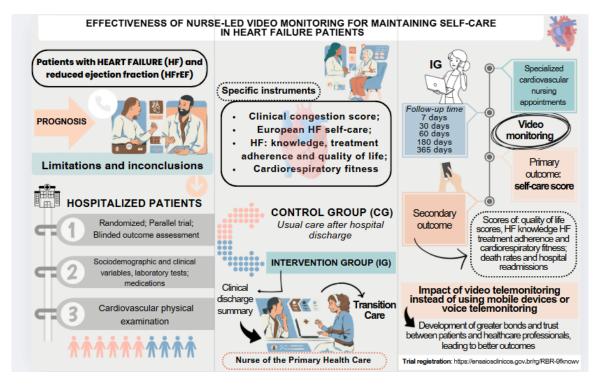


Figure 1. Graphical abstract: Maintenance of self-care by video monitoring in heart failure care.

inertia. Additionally, patient adherence to prescribed treatments is frequently low, potentially due to difficulties in accessing healthcare services and a lack of integration between patients and the care team [3, 4].

Patient monitoring after hospital discharge using new technologies, such as telemonitoring, has proven effective in reducing mortality and hospital readmissions caused by decompensated HFrEF. These technologies have sufficient evidence to be incorporated into global HFrEF guidelines [2, 5-7]. However, while the efficacy of telemonitoring has been established, uncertainties remain regarding its long-term impact, particularly on sustaining self-care behaviors once the intervention is completed.

Systematic reviews and meta-analyses have identified gaps in the use of telemonitoring-based educational interventions, particularly those relying on voice calls, for outcomes like HF knowledge, self-efficacy, self-care, and heal-th-related quality of life. These gaps highlight the need for well-planned strategies aimed at enhancing these self-care dimensions [6, 7].

Although most studies focus on voice telemonitoring, strategies based on video monitoring

are still limited and inconclusive. Some clinical trials have shown no significant differences in outcomes like self-care, quality of life, mortality, or readmission. A clinical trial currently underway in Italy is exploring video monitoring, though results are not yet available, and participant recruitment is ongoing [8].

A clinical follow-up model using video monitoring, combined with health education delivered by specialized cardiovascular nurses, has the potential to optimize clinical outcomes such as self-care, quality of life, cardiorespiratory fitness, knowledge about the disease, adherence to self-care treatments, readmissions, and mortality in patients with HFrEF. The protocol proposed in this study aims to evaluate the efficacy of a video monitoring program that includes an educational component delivered by cardiovascular nurses to support patients with HFrEF after hospital discharge. The Graphical abstract is shown in Figure 1.

#### Methods/design

Study design and centers

This is a randomized, parallel trial with blinded outcome assessment, following the reco-

mendations of the SPIRIT statement (<u>Supplementary File</u>). The study population comprises patients with a diagnosis of HFrEF as defined by Brazilian Society of Cardiology who presented to the hospital with HF decompensation. The study has been carried out at the Clinical Hospital of Uberlandia, Brazil, and takes place at the Emergency Department or other inpatient units.

#### Inclusion and exclusion criteria

The study includes patients aged 18 years or older, admitted for decompensated HFrEF from the emergency department or clinical admission at the Clinical Hospital of Uberlandia, Brazil, with an ejection fraction less than 40% confirmed by an echocardiogram performed in the last 3 months and who have access to a mobile device with internet access. Patients on the heart transplant waiting list, who had undergone coronary artery bypass surgery 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.

#### Ethical considerations

All procedures will be conducted according to the ethical standards for research with human subjects established in the Declaration of Helsinki. Written informed consent will 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 in ClinicalTrials. gov (NCT06731166), at the link https://clinicaltrials.gov/study/NCT06731166.

The coordinating center and steering committee of this study will be composed of nurses specializing in cardiovascular nursing, independent from the researchers. Monitoring meetings will occur monthly.

#### Sample size

Assuming the ratio of self-care scores from previous studies at 365 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 per group) will be sufficient to detect a 20% difference between the groups.

#### Interventions

The control group (CG) will receive the usual care provided by the CHU after hospital discharge, which consists of outpatient consultations scheduled only upon patient request, without proactive follow-up or structured clinical monitoring.

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 the hospital to the nurse of the primary health care unit to discuss the patient's clinical case and plan the transition and continuous care.

Additionally, this group will be followed up by specialized cardiovascular nurses through video monitoring at 7, 30, 60, 180, and 365 days after discharge through the WhatsApp video service.

In addition to the scheduled video consultations, patients in the intervention group will be informed that they can contact the research team via WhatsApp messages or voice calls during business hours if they experience any warning signs or health concerns. Trained cardiovascular nurses will assess these situations and provide guidance or refer the patient to the appropriate healthcare service when necessary, ensuring timely clinical responses and safety.

This video call will last for 30 minutes to support patients in adhering to care plans using the teach-back technique according to Brazilian Society of Cardiology guidelines for HF 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 motivational interviewing, 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.

The researchers will conduct the final intervention at 6 months, and the patients will be reassessed at 1 year to evaluate the long-term effects of the video monitoring intervention.

### 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 selfcare scale, HF knowledge, HF treatment adherence, HF quality of life, and cardiorespiratory fitness data will be collected by specific instruments [10-15]. After this step, participants will be randomized into 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 to 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 and 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, 180, and 365 days). Firstly, researchers will determine the participants' status in relation to their 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 followup, researchers will schedule all monitoring sessions and update the register of patients in the virtual system.

The researchers will conduct the final intervention at 6 months, and the patients will be reassessed at 1 year to evaluate the long-term effects of the video monitoring intervention.

The CG will receive the usual care provided by the Clinical Hospital of Uberlandia after hospital discharge and a telephone call to collect the same instruments used for the IG at 30, 60, 180, and 365 days after discharge. The flow-chart of the participant recruitment process is shown in **Figure 2**.

#### Randomization

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

#### Blinding

The patients will be blinded according to group allocation. Data analysts will also be blinded to group allocation.

#### 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

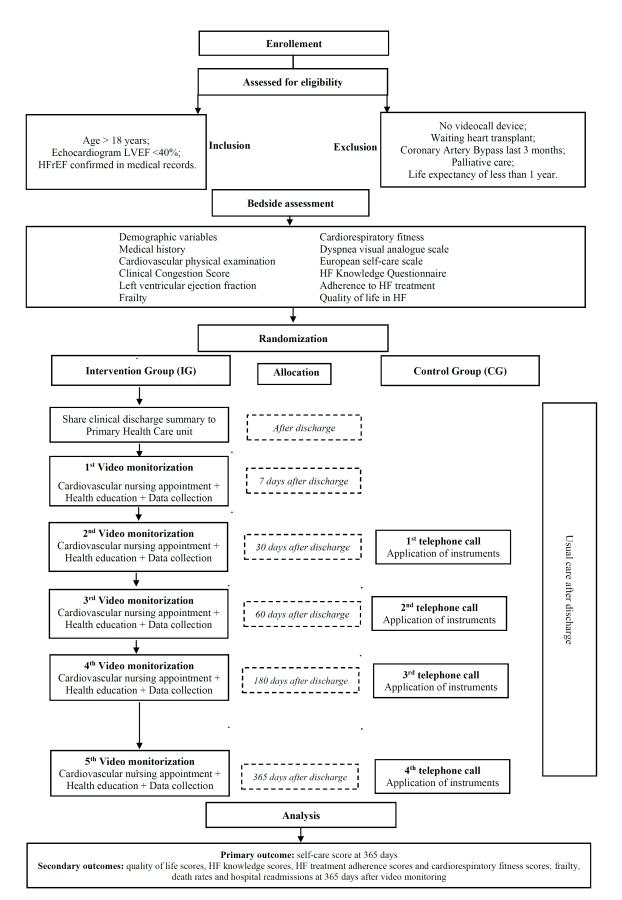


Figure 2. Flowchart of study participation and interventions.

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 [9].

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 selfcare 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) [10].

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 non-pharmacological 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 incor-

rect answer, the patient loses one point. In this way, the score ranges from 0 to 14 [11].

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 [13].

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 [14].

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 [15].

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 [16].

#### Primary outcome

The primary outcome consists of the selfcare score at 365 days after clinical video monitoring.

#### Secondary outcomes

The secondary outcomes will be quality of life scores, HF knowledge scores, HF treatment adherence scores, cardiorespiratory fitness scores, general cardiovascular death rates and hospital readmissions at 365 days after video monitoring.

## Statistical analyses

The data will be treated using double data entry. The effect of the intervention between

the IG and CG will be carried out using an unpaired test for independent samples of self-care scores at 365 days in relation to the baseline score. To identify significant differences in self-care scores throughout the follow-up (30, 60, 180, and 365 days), the paired t-test will be used if the sample distribution is normal, or the Wilcoxon test will be used 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 of <0.05 (two-tailed) shall be considered to indicate statistical significance.

#### Trial status

This study protocol is in its first version, registered at (https://clinicaltrials.gov/study/N-CT06731166). Recruitment will start in August 2025, and the approximate date of its completion is August 2026. Any necessary changes to this protocol will be reported 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 kept confidential before, during, and after the trial.

#### Results and discussion

Considering the scarcity of studies in South America evaluating structured interventions in the transition of care for heart failure patients, we believe that this clinical trial can offer relevant evidence to support the integration of specialized nursing follow-up into public health policies.

Although several studies have demonstrated positive outcomes for heart failure (HF) patients under the care of specialized nursing teams [17-20], well-designed clinical trials evaluating the effectiveness of care transition and follow-up strategies between tertiary and primary care, based on established theoretical models, remain scarce [21, 22].

The use of video monitoring, combined with educational strategies such as teach-back and

motivational interviewing, may represent a practical and cost-effective alternative for countries with limited resources.

From our perspective, the added value of this intervention lies not only in its technological component, but also in its ability to humanize remote care, promote health literacy, and strengthen the link between patients and the healthcare system-factors that are often neglected in conventional follow-up models.

The use of telemonitoring via audio calls as a technological care tool is already widely implemented worldwide, particularly in developed countries [23-25]. However, video consultations remain rare and are not commonly guided by teach-back techniques or motivational interviewing conducted by nurses [26, 27].

A high-sensitivity database search identified only one registered clinical trial protocol titled "Remote motivational interviewing to improve patient self-care and caregiver contribution to self-care in heart failure (REMOTIVATE-HF): Rationale, design, and methodology for a multicentre randomized controlled trial". This study, led by researchers at the University of Rome Tor Vergata, uses video monitoring but focuses on caregivers of HF patients [8].

In Brazil, no studies of this design have been identified that test the effectiveness of video monitoring technologies in the care transition of these patients.

The primary outcome proposed in this clinical trial protocol is self-care. Secondary outcomes include treatment adherence for HF, quality of life in HF, disease knowledge, cardiorespiratory fitness, frailty, HF-related mortality, and HF rehospitalization. These outcomes are the focus of this clinical trial protocol.

International guidelines consider self-care essential for the effective management of HF and recommend patient self-management strategies to reduce the risk of hospitalization and mortality. Measures to improve self-care should be integral to HF management programs [25].

It is well established that self-care in HF is directly influenced by telemonitoring. A previously published study utilized remote monitoring through software and non-invasive devices to monitor HF patients at home. In this study, self-care scores in the intervention group increased by 6 points over 12 months, compared to a 1-point increase in the control group [28].

Another recent clinical trial using text messages as a remote monitoring tool showed a significant increase in self-care scores in the intervention group compared to the standard care group (score difference at 465 days of -2.08 points, P<0.01) [29].

Regarding treatment adherence, research has shown that patients in the telemonitoring intervention group demonstrated better adherence to actions such as taking prescribed medications (P=0.014), weighing themselves daily (P=0.001), and attending scheduled appointments (P=0.008), indicating a positive effect of telemonitoring on HF treatment adherence [30].

Although HF knowledge is an outcome directly linked to telemonitoring interventions, few studies have addressed this outcome. A systematic review showed a statistically significant improvement in HF knowledge in the telemonitoring intervention group compared to the control group at 6-month follow-up (P<0.00001), with no heterogeneity among studies (I²=0%). Similarly, an improvement in quality of life was observed (P=0.03), with low heterogeneity between studies (I²=20%) after 6 months of telemonitoring intervention [31].

Several studies have also investigated the effects of remote monitoring programs on cardiovascular mortality and HF rehospitalization outcomes. Among various telemonitoring systems, one study showed a significant 16% reduction in HF mortality compared to standard care (OR: 0.84; 95% CI: 0.77-0.93). The effect was more pronounced with non-invasive systems (15% reduction), while invasive systems (15% reduction), while invasive systems showed no statistically significant impact on mortality. Regarding rehospitalization, telemonitoring reduced the risk of first HF hospitalization by 19% (OR: 0.81; 95% CI: 0.74-0.88) and total HF-related hospitalizations by 15% (IRR: 0.85; 95% CI: 0.76-0.96) [32].

A systematic review evaluating data from 2,390 HF patients, 1,260 in the remote monitoring group and 1,130 in the control group, showed that remote monitoring significantly reduced

the risk of hospitalization in the intervention group compared to the control group (RR 0.32, CI 0.04-2.46; P=0.27), as well as significantly reducing the risk of HF-related hospitalization (RR 0.83, CI 0.74-0.93; P=0.002) [33].

The same study reported that telemonitoring significantly reduced emergency department admissions and hospitalizations due to HF. Emergency department admissions decreased from 100 to 34 (66%; P<0.001), HF hospitalizations decreased from 71 to 23 (68%; P<0.001), and hospitalization days were reduced from 692 to 178 (75%; P<0.001) [33].

No studies were found that measured the effect of telemonitoring on cardiorespiratory fitness. Therefore, the protocol proposed here has the potential to investigate and address this gap, as improvements in metabolic equivalents in HF are important predictors of survival and positive clinical outcomes.

This study protocol is grounded in a solid theoretical framework, as the proposed interventions (nurse-led video monitoring and care transition between health networks) are guided by teach-back techniques and motivational interviewing.

Teach-back in HF is a patient-centered educational strategy for conveying complex health information. This method assesses patients' understanding of the health information received. After education, patients are asked to rephrase the information in their own words. This teaching method has shown positive associations with clinical outcomes in cardiac patients [34].

Combined with teach-back, motivational interviewing is another strategy to guide cardiovascular health interventions. It encourages a collaborative and non-directive conversation between the patient and the professional. The professional facilitates and guides the conversation to establish goals and motivation for change, having a direct and positive impact on self-efficacy [15].

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.

In our view, video monitoring represents not only a technological innovation, but also a paradigm shift in the delivery of post-discharge care for heart failure patients within the Brazilian public health system. By strengthening the nurse-patient bond, encouraging patient empowerment, and bridging the gap between hospital and primary care, this intervention has the potential to reduce clinical inertia and promote more patient-centered care. We believe that the proposed protocol responds to systemic gaps, particularly the lack of structured transitional care and the absence of proactive follow-up for chronic conditions such as HF. Moreover, by incorporating motivational interviewing and teach-back strategies, the intervention fosters behavioral change and autonomy, rather than passive compliance. These elements, in our opinion, are essential for sustainable improvements in chronic disease management.

# Conclusions

Unlike strategies widely discussed in the literature - such as those based on structured mobile devices or voice telemonitoring - this study protocol is centered on video monitoring. The consultations will be guided by motivational interviewing and the teach-back method, both extensively validated in clinical practice for promoting health behavior change and enhancing health literacy, respectively.

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#### Disclosure of conflict of interest

None.

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