Study Protocol

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Improving Symptom Perception in Recently Discharged Patients with Heart Failure: Protocol for a Single-Centre Randomised Controlled Trial of a Nurse-Led Teach-Back Intervention

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Abstract

Introduction. Heart failure (HF) is a chronic condition associated with substantial symptom burden, frequent hospitalisations, and increased morbidity and mortality. Nurse-led informational–educational interventions, particularly those based on the teach-back method, may support patients in monitoring and interpreting HF-related symptoms, improving self-care behaviours and medication adherence, and potentially contributing to long-term clinical stability after discharge.

Objective. To evaluate the effectiveness of a face-to-face nurse-led informational–educational intervention using the teach-back method on patient-reported perception and severity of HF-related somatic symptoms at 3 months after the first outpatient cardiology follow-up visit in patients recently discharged with HF.

Trial design. Single-centre, open-label, parallel-group

randomised controlled trial with 1:1 allocation (intervention vs control).
Participants and Settings. Patients recently discharged from a cardiology unit with a diagnosis of HF will be enrolled and randomised at their first outpatient cardiology follow-up visit. Assessments will be conducted at baseline and at 3, 6, 9, and 12 months.
Interventions. The intervention consists of a 30-minute nurse-led face-to-face informational–educational session structured according to the teach-back method, focused on HF symptom monitoring, interpretation of worsening symptoms, and self-care behaviours. The session will be reinforced through a follow-up phone call. The control group will receive usual care.
Primary/Secondary Outcomes. The primary outcome is patient-reported symptom perception and severity of HF-related somatic symptoms at 3 months, measured using the Heart Failure Somatic Perception Scale (HFSPS). Secondary outcomes include self-care behaviours assessed with the Self-Care of Heart Failure Index (SCHFI v8.0), medication adherence measured using the General Medication Adherence Scale (GMAS), and clinical stability during follow-up. Disease-specific quality of life will be assessed exploratorily using the Kansas City Cardiomyopathy Questionnaire (KCCQ).
Ethical Considerations. Ethical approval has been obtained from the Comitato Etico Lombardia 1 (approval number CET 195-2025). The trial has been registered on ClinicalTrials.gov (identifier: NCT07280728).

Keywords: Heart Failure, Patient Education as Topic, Nursing Care, Self-Care, Medication Adherence, Teach-Back Communication

Introduction

Heart failure (HF) is a chronic, progressive syndrome characterised by the inability of the heart to meet the body's metabolic demands and represents the final stage of several cardiovascular conditions. It affects an increasing proportion of the adult population in Western countries, driven by ageing and improved survival after acute cardiac events (Authors/Task Force Members: et al., 2022; Virani et al., 2021). HF is associated with high morbidity and mortality, recurrent exacerbations, and significant healthcare utilisation. Patients frequently experience symptom burden, including dyspnoea, fatigue, palpitations, and peripheral oedema, which negatively affects their quality of life (QoL), functional capacity, and psychological well-being (Alpert et al., 2017; McGuinty et al., 2020). Rehospitalisations for acute decompensation remain common and markedly contribute to healthcare costs (Mentz et al., 2021; Virani et al., 2021).

Evidence shows that adverse outcomes can be mitigated when patients engage in effective self-care behaviours and adhere to prescribed therapies (Bernard et al., 2023; Cramer et al., 2008; Koirala et al., 2020; Riegel et al., 2016; Zhao et al., 2021). These behaviours include self-care maintenance, self-care monitoring, and self-care management, as conceptualised in the updated theory of heart failure self-care (Lee & Riegel, 2025; Riegel et al., 2016). However, many patients display suboptimal self-care and poor therapeutic adherence after hospital discharge, increasing the risk of deterioration and rehospitalisation (Jarab et al., 2023; Koirala et al., 2020).

HF guidelines emphasise the importance of structured, multidisciplinary educational approaches to support patients in developing adequate self-care (Authors/Task Force Members: et al., 2022; Heidenreich et al., 2022). Among available educational approaches, nurse-led interventions have demonstrated positive effects on HF knowledge, self-care, and, in some cases, hospital utilisation (Bernard et al., 2023; Bulto & Hendriks, 2024; Ghizzardi et al., 2022). The teach-back method, in particular, has shown promise in enhancing patient comprehension, self-care behaviours, and medication adherence, with potential benefits for quality of life and healthcare utilisation (Bodenheimer, 2018; Centrella-Nigro & Alexander, 2017; Zare-Kaseb et al., 2024).

However, current evidence on teach-back in HF is fragmented, as studies differ in content, timing, setting, and outcome measures, and most involve small samples and short-term follow-up (Bodenheimer, 2018; Centrella-Nigro & Alexander, 2017; Talevski et al., 2020). Critically, no existing Randomised Controlled Trials (RCTs) have evaluated teach-back as a strategy to improve HF symptom perception or to support long-term clinical stability.

Within the clinical care journey of a patient with HF, the first post-discharge outpatient cardiology visit represents a critical transition point, during which many patients still struggle to manage their new condition, develop adequate symptom awareness, and maintain medication adherence. In the Italian healthcare landscape, this pattern is frequently observed in clinical practice, including in regional healthcare settings. In the local context of ASST Lodi (Northern Italy), clinical experience indicates that many patients present at this visit with insufficient understanding of HF and its self-management requirements, which manifests as low self-care engagement, limited attention to HF-related somatic symptoms, and suboptimal adherence to pharmacological therapy. These factors, taken together, increase their vulnerability to clinical worsening in the months ahead. A structured, nurse-led informational-educational intervention delivered using the teach-back method at this first visit may support patients in monitoring and interpreting HF-related symptoms, while also promoting self-care behaviours and medication adherence.

This single-centre RCT was designed to assess the effectiveness of a face-to-face nurse-led informational-educational intervention on HF symptom perception at 3 months (primary outcome), and on clinical stability, self-care, and medication adherence over 12 months (secondary outcomes).

Objectives

Primary aim:

To assess the effectiveness of a face-to-face nurse-led informational-educational intervention on patient-reported perception and severity of HF-related somatic symptoms, measured with the Heart Failure Somatic Perception Scale (Pucciarelli et al., 2019), at 3 months after the first outpatient cardiology visit.

Secondary aims:

- To assess the long-term effectiveness of a face-to-face nurse-led informational-educational intervention on disease clinical stability at 6, 9, and 12 months after the first outpatient cardiology visit.
- To measure at 3, 6, 9, and 12 months after the first outpatient cardiology visit:
  a. Levels of self-care
  b. Adherence to pharmacological therapy

Endpoints

Primary endpoint:

The primary endpoint will be measured using the HF Somatic Perception Scale (HFSPS) (Pucciarelli et al., 2019). The HFSPS will be used as a patient-reported measure of the perception and severity of HF-related somatic symptoms. Although the intervention is expected to support patients in monitoring and interpreting symptoms, the HFSPS does not directly measure early symptom recognition or decision-making in response to symptoms. Therefore, the primary endpoint will be interpreted as a change in perceived HF-related symptom burden/severity. A between-group difference of at least 7 points in HFSPS scores at 3 months after the first outpatient cardiology visit (in favour of the intervention group) will be used as the target effect size for sample size estimation. The rationale for this threshold is reported in the sample size section.

Secondary endpoints:

- Proportion of patients classified as clinically

stable at 6, 9, and 12 months after the first outpatient cardiology visit, according to the predefined composite criteria described below.

1. Self-care: Between-group differences in mean standardised scores on the Self-Care of Heart Failure Index (SCHFI) version 8.0 (self-care maintenance, self-care monitoring, and self-care management scales) (Lee & Riegel, 2025), expected to be higher in the intervention group, assessed at 3, 6, 9, and 12 months after the first outpatient cardiology visit.
2. Between-group differences in mean total scores on the Italian version of the General Medication Adherence Scale (GMAS) (Napolitano et al., 2025), expected to be higher in the intervention group, assessed at 3, 6, 9, and 12 months after the first outpatient cardiology visit.

Methods and Materials

Study Design

Single-centre, open-label, randomised controlled trial with a 1:1 allocation ratio.

Eligibility Criteria

Inclusion criteria for patients will be:

1. Age ≥ 18 years;
2. Discharged from the Cardiology Unit of the Hospital of Lodi;
3. Diagnosis of HF according to international guidelines (NYHA functional class II-IV assigned at discharge);
4. First outpatient cardiology visit scheduled 30 (±15) days after discharge;
5. Willingness to sign the informed consent form.

Exclusion criteria will include patients with:

1. Severe cognitive impairment, defined as a score of 0–3 on the Six Item Screener (20);
2. Discharge from units other than the Cardiology Unit of the Hospital of Lodi;
3. NYHA class I;
4. First outpatient cardiology visit scheduled less than 30 or more than 45 days after discharge;
5. Previous management in any HF Outpatient Clinic;
6. Acute coronary event within the last three months.

Based on the above criteria, enrolled participants will exclusively be patients attending their first outpatient visit for HF following a recent hospitalisation in the Cardiology Unit. These will therefore be considered incident cases. Patients already known to the outpatient clinic or referred from other clinics (i.e., prevalent cases) will be excluded from the study.

Study procedures

All patients who meet the eligibility criteria at screening will be included in the study and randomly assigned to one of two arms (intervention vs control).

Intervention arm:

Patients in the intervention arm will receive a 30-minute face-to-face nurse-led informational and educational intervention at 30 (±15) days post-discharge, coinciding with their first outpatient cardiology visit. The intervention will be structured as follows.

1. Assessment of perceived symptoms, disease-specific QoL, therapeutic adherence, and self-care levels (T0);
2. Health information (provision of informational material from Penn Nursing Science – see subparagraph "Instruments" – explained using the teach-back method) (T0);
3. Provision of a daily diary for recording parameters (blood pressure, heart rate, weight) with instructions on how to fill it out (T0);
4. Reinforcement phone call for the informational intervention, including parameter assessment, at 30 (±5) days after the nurse consultation;
5. First follow-up data collection at 3 months after outpatient visit (T1)
6. Second follow-up data collection at 6 months after the outpatient visit; the informational-educational intervention will be repeated using the teach-back method (T2).
7. Third follow-up data collection at 9 months after outpatient visit (T3)

8. Fourth (and last) follow-up data collection at 12 months after outpatient visit (T4)

To ensure consistency across nurses, the intervention will be delivered using a structured intervention checklist covering the core educational components: HF symptom monitoring, recognition of worsening symptoms, medication adherence, daily weight and vital parameter monitoring, physical activity, and barriers to self-care. The checklist will also include the teach-back steps to be completed during each session. Completion of the checklist will be documented after each intervention session.

Control arm:

At T0, the same baseline data collection as the intervention arm will be conducted. Patients in the control arm will receive standard care. As part of routine clinical management at ASST Lodi, they will also receive a brief post-discharge telephone check one week after the first cardiology visit, during which vital signs are collected.

For both groups, follow-up calls will be conducted monthly up to 12 months after enrollment. These calls will be limited to the collection of vital parameters and safety monitoring using a standardised script. No structured education, counselling, teach-back reinforcement, or self-care coaching will be provided during these calls, except for referral to the responsible cardiologist if predefined signs of clinical instability are detected. This approach was chosen to ensure participant safety while minimising contamination between groups.

Timepoints

The study will include five data collection timepoints: at enrollment (T0), and at 3 (T1), 6 (T2), 9 (T3), and 12 (T4) months.

Instruments

Screening

To assess cognitive status, patients will complete the Six-Item Screener (Callahan et al., 2002). This tool evaluates temporal orientation and short-term memory through six items: three orientation questions and three recall tasks. Scores range from 0 to 6, with 0–3 indicating probable cognitive impairment and 4–6 indicating preserved or non-significantly impaired mental function.

Intervention

Patients meeting the eligibility criteria and providing informed consent will be enrolled and randomly assigned to the intervention or control arm. At enrollment (T0), baseline data (perceived symptoms, disease-specific QoL, therapeutic adherence, and self-care levels) will be collected before the nurse-led informational-educational intervention.

a) Assessment tools:

- Perceived symptoms: The Italian version of the HF Somatic Perception Scale (HFSPS), validated by Pucciarelli et al. (Pucciarelli et al., 2019), will be used. This 18-item instrument assesses the subjective perception and severity of HF-related somatic symptoms, including dyspnoea, palpitations, fatigue, peripheral oedema. Items are scored on a 0–4 Likert scale (0 = "not at all", 4 = "extremely"), with higher scores indicating greater perceived symptom burden. In this study, the HFSPS will not be interpreted as a direct measure of early symptom recognition, but rather as a patient-reported measure of perceived somatic symptom burden/severity.
- QoL: The Italian version of the Kansas City Cardiomyopathy Questionnaire (KCCQ), validated by Miani et al. (Miani et al., 2003), will be used to assess HF-specific QoL and functional status. The 23-item instrument generates multiple domain scores and an overall summary score, with higher scores reflecting better QoL. QoL will be assessed as a descriptive and exploratory outcome and will not be included among the primary or key secondary endpoints.
- Therapeutic adherence and self-care: Medication adherence will be assessed using the Italian version of the GMAS (Napolitano et al., 2025). The GMAS consists of 11 items covering three adherence domains (patient behaviour, comorbidity/pill burden, and cost-related adherence), rated on a 1–4 Likert scale. Total scores range from 11 to 44, with higher scores indicating better adherence

to medication. Self-care will be assessed using the updated SCHFI 8.0 (Lee & Riegel, 2025), which is grounded in an expanded theoretical framework and assesses self-care maintenance, monitoring, and management. The Italian translation of the SCHFI 8.0 is currently undergoing psychometric validation. As with previous versions, each scale is standardised from 0 to 100, with scores ≥70 indicating adequate self-care (Lee & Riegel, 2025).

- Health information: The information provided to patients will be based on on publicly available educational materials developed by Penn Nursing.(Penn Nursing University of Pennsylvania, s.d.). Specifically, the following materials will be provided and explained using the teach-back method: "Overcoming Barriers," "Overcoming Barriers to Self-Care", "Managing HF Symptoms", and "Staying Active to Help the Heart". Patients who experience a new hospitalisation due to HF exacerbation or present to the emergency department for the same reason will be considered clinically unstable and classified as having adverse outcomes for the secondary endpoint. These events will not automatically result in study exclusion unless the participant withdraws consent or becomes unreachable for follow-up. In cases of withdrawal or loss to follow-up, data collected up to the time of the event will still be analysed according to the intention-to-treat principle.

Randomisation and Blinding

After enrollment and baseline data collection, patients will be randomised (1:1) into the two study arms using block randomisation. Multiple randomisation blocks will be performed as needed to reach the predetermined sample size. A research assistant, who will not be involved in the study beyond performing the randomisation blocks, will carry out this process. The allocation of patients will be communicated by an external researcher to the HF Outpatient Clinic, who will not be directly involved in patient enrollment. Due to the nature of the intervention, blinding of participants and nurses is not possible, as they will be aware of the assigned study arm. However, outcome assessment will be blinded, as data analysis will be conducted by a statistician who will not be able to distinguish between participants in the intervention and control groups. Blinding will also be maintained during data entry. As the primary outcome is patient-reported, the study may be exposed to expectancy and reporting bias. To minimise these risks, both groups will complete the same outcome measures at the same timepoints, using standardised instructions. Follow-up assessments will be conducted using predefined data collection forms, and participants will not be encouraged to report improvement. The statistician will remain blinded to group allocation until the primary analysis has been completed.

Setting and Nurse Training

Nurses working at the HF Outpatient Clinic of ASST Lodi will be involved in the study. The Clinic, located within the Codogno Hospital of ASST Lodi, registers approximately 100 new first-visit patients per year. The nursing team includes four full-time nurses with ten years of experience in caring for HF patients. The medical staff consists of three cardiologists with an average of 10 years of experience; outpatient cardiology visits are scheduled weekly on three different days.

Before the study begins, all nurses involved in the intervention will undergo a standardised two-hour remote training session on the teach-back method, conducted by an expert researcher. The training will cover the theoretical principles of teach-back, and nurses will also be trained to use the intervention checklist and educational materials.

To promote intervention fidelity, nurses will receive a written intervention guide including the core contents to be addressed, suggested teach-back prompts, and documentation procedures. Before enrolling participants, nurses will complete at least one simulated teach-back session, discussed with the expert researcher. During the study, fidelity will be monitored through completion of the intervention checklist and periodic team meetings to discuss implementation issues and ensure consistency across nurses.

Teach-Back Principles

The teach-back method will be applied using three core principles (Bonaldo & Maso, s.d.;

Centrella-Nigro & Alexander, 2017):

1. Information delivery: nurses will provide essential information in small units, using plain language and focusing on the most relevant self-care behaviours for HF management.
2. Checking understanding: after each key message, nurses will ask patients to explain the information in their own words using non-judgemental prompts, such as "I want to make sure I explained this clearly; can you tell me how you will monitor your weight at home?" or "What would you do if your breathlessness or ankle swelling worsened?"
3. Closing the loop: if the patient is unable to explain the information correctly, the nurse will rephrase the message and ask the patient to repeat it until adequate understanding is achieved. The same teach-back structure will be used across all intervention sessions and reinforced during the 6-month educational session.

Sample Size and Statistical Considerations

The sample size was estimated using TTestIndPower from the statsmodels Python package (version 0.14.2) (Josef Perktold et al., 2024). The formula used was: [n = 2 \times \left[\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{\delta / \sigma} \right]^2], where (Z_{1-\alpha/2} = 1.96) (critical value for a two-sided α = 0.05), (Z_{1-\beta} = 0.84) (for 80% statistical power), (\delta = 7) (clinically relevant difference), and (\sigma = 12.8) (standard deviation). Applying the formula yields a sample of 106 patients. Considering a 10% dropout rate at 3 months, the total planned sample size is 118 patients (59 per arm, with a 1:1 allocation ratio). The values used to define the clinically relevant difference and the corresponding standard deviation were derived from the literature. Specifically, Jurgens et al. reported a standard deviation of 12.8 for HFSPS responses in a study of 378 HF patients (Jurgens et al., 2017). The minimal clinically significant difference (delta) on the HFSPS was set at 7 points in accordance with the half-standard deviation rule (0.5 SD rule), a well-established criterion for identifying meaningful changes in symptom assessment tools (20). Furthermore, studies on similar HF instruments suggest that changes between 5 and 10 points are clinically relevant (Spertus & Jones, 2015). The value of 7 represents approximately 8% of the total HFSPS range (0–90) and is assumed to correspond to a clinically perceivable change in symptom severity.

All statistical analyses will be conducted according to the intention-to-treat principle, whereby all randomised participants will be included in the analyses in the groups to which they were initially assigned, regardless of adherence to the intervention or withdrawal. Descriptive statistics will be used to summarise baseline characteristics and outcome measures. Categorical variables will be presented as frequencies and percentages, while continuous variables will be reported as means and standard deviations, or medians with interquartile ranges, depending on their distribution.

The primary analysis will focus on the between-group difference in patient-reported perception and severity of HF symptoms at 3 months, as measured by the HFSPS. This comparison will be performed using an analysis of covariance (ANCOVA), adjusting for baseline HFSPS scores. This approach provides a more precise estimate of the intervention effect by accounting for individual differences at baseline. Results will be expressed as adjusted mean differences with corresponding 95% confidence intervals.

For secondary outcomes, the proportion of patients classified as clinically stable at 6, 9, and 12 months will be compared between groups using the Chi-square test or Fisher's exact test, as appropriate, for the composite measure of clinical stability. Additionally, a multivariable logistic regression analysis will be conducted to estimate the adjusted odds of clinical stability associated with the intervention, providing effect estimates along with 95% confidence intervals.

For self-care (SCHFI 8.0) and medication adherence (GMAS) scores, which are collected repeatedly over the 12-month follow-up period, changes over time and differences between groups will be analysed using linear mixed-effects models. Group, time, and group-by-time interaction terms will be included as fixed effects, with random intercepts specified for individual participants. Missing data will be handled under the assumption that the missing values are missing at random. Linear mixed-effects models will be used for repeated measures, as they can accommodate incomplete follow-up data. If necessary, sensitivity analyses using multiple imputation will be conducted

to assess the robustness of the results. KCCQ scores will be analysed descriptively at each timepoint and explored longitudinally using the same repeated-measures approach adopted for self-care and medication adherence, if data distribution and completeness allow. These analyses will be considered exploratory and hypothesis-generating; therefore, no formal sample size calculation was based on KCCQ outcomes. All statistical tests will be two-tailed, with a significance threshold set at $p < 0.05$. Data will be analysed using IBM SPSS Statistics version 31.0.1.0 (IBM Corp., Armonk, NY, USA).

Study Duration and Completion

The total expected study duration is 36 months (24 months for enrollment and 12 months to complete follow-up for the last enrolled patient). The enrollment period is scheduled to take place between February 2026 and January 2028. Data processing and reporting are anticipated between March and May 2028.

Ethical considerations, data protection, and administrative aspects

The study will be conducted in accordance with the Declaration of Helsinki, European Union Good Clinical Practice principles, and applicable national and European regulations on personal data protection. Ethical approval has been obtained from the Comitato Etico Lombardia 1 (approval number CET 195-2025), and the trial has been registered on ClinicalTrials.gov (NCT07280728). All participants will provide written informed consent before enrolment.

Data will be collected by authorised study personnel and processed only for study-related purposes. Study data will be pseudonymised during data collection and analysis and reported only in aggregate form. Essential study documents, including informed consent forms and data collection sheets, will be stored securely in accordance with institutional procedures. No additional costs will be charged to participants, and no compensation is planned for healthcare professionals or the facility. The study will be conducted within the institution's existing organisational and insurance framework for clinical research.

Limitations

This study has some limitations. First, due to the behavioural and educational nature of the intervention, blinding of participants and nurses is not feasible. As the primary outcome is patient-reported, expectancy and reporting bias cannot be fully excluded. However, standardised data collection procedures, identical assessment timepoints in both groups, blinded data entry, and blinded statistical analysis will be used to reduce this risk. Second, monthly follow-up calls are planned for both groups to monitor safety and collect vital parameters. Although these calls will not include structured education or counselling, they may increase patients' attention to symptoms and self-care behaviours, potentially attenuating between-group differences. Third, the single-centre design may limit the generalisability of the findings to other organisational contexts.

Conclusions

The conduct of this study will allow the evaluation of the effectiveness of a nurse-led, teach-back-delivered informational-educational intervention for the initial management of patients with HF. Practical health information provided at the start of the patients' care pathway can serve as a solid foundation to promote a lifestyle that helps slow the progression of HF. This approach could have a positive impact on both life expectancy and QoL for patients and their families. It could provide a basis for implementing systematic interventions in the outpatient cardiology setting.

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