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The Effects of Therapeutic Education on Self-care in Patients with Heart Failure and an Implantable Cardioverter Defibrillator: Study Protocol for a Randomised Controlled Trial

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Background

Heart failure (HF) is a clinical syndrome caused by an abnormality of the cardiac structure or function, leading to the heart's failure to deliver oxygen at a rate commensurate with the requirements of the metabolizing tissues, despite normal filling pressures (or only at the expense of increased filling pressures).¹ It is estimated that there are 23,000,000 people affected by HF worldwide, with approximately 2-3% in the European population.² HF is a condition that increases in prevalence with age, and affects more than 25% of the population aged >84 years old. It has been predicted that by 2030 there will be an increase of 25% in the number of people with HF.³ In Italy, where this study will be conducted, the prevalence of HF is between 1.1% and 1.4% of the general population.^{4,5} Mortality due to HF is high after diagnosis: the 30-day, 1-year and 4-year mortality rates are 12.1%, 28.8% and 61.4%, respectively.⁹

To reduce the burden of HF, self-care is considered a cornerstone in HF treatment.⁶⁻²² In fact, it was shown in previous studies that HF patients who perform adequate self-care may have fewer hospitalizations, better QOL and even lower mortality.⁷⁻⁸ However, patients struggle to perform adequate self-care and it was found not at adequate levels in several studies.^{25,28}

One of the main causes of death in patients with HF is sudden cardiac arrest due to ventricular arrhythmia.¹⁰⁻¹¹ To prevent this problem, international guidelines suggest the implantation of an implantable cardiac defibrillator (ICD) in HF patients who are more exposed to sudden cardiac death: ICD therapy is associated with significant reduction in mortality compared with antiarrhythmic drug therapy.¹²⁻¹⁶

While an ICD implantation can lead to important clinical benefits (e.g., the 20% reduction of deaths), this procedure can also determine new clinical issues in HF patients and greater need of self-care behaviors.^{17,19} Since it has been already found that self-care is poor in HF patients,²⁷ it is important that HF patients with ICD undergo educational intervention to improve their level of self-care.²⁰⁻²¹

Study Objectives

The primary objective of this study will be to examine whether a nursing educational intervention based on therapeutic education

can improve self-care in HF patients with recent implantations of ICD. The secondary objective will be to evaluate if a nursing educational intervention will improve quality of life in HF patients with ICD.

Methods / Design

Design of the study

This is a multicenter, single blind, parallel-group study, which will involve two cardiovascular centers in northern Italy. The participant flowchart for the study is illustrated in Figure 1.

This study received formal ethical approval from both participating centers, ASLTO1 (Prot. 0123113) and ASLTO3 (Prot. 0006237 and Prot. 0008168).

Participants

The participants will be enrolled according to the following inclusion and exclusion criteria.

Inclusion criteria:

- Patients affected by HF according to the international guidelines, following elective hospitalization during which an ICD is implanted on an arrhythmic and/or ischemic basis.^{13,14,15}
- Patients who provide written consent for this study.

Exclusion criteria:

- Patients with compromised cognitive state with a diagnosis of dementia or Alzheimer disease.
- Minors: under the age of 18.

Instruments

HF patient self-care will be measured using the Self-Care of Heart Failure Index (SCHFI) version 6.2. This instrument consists of 3 scales: self-care maintenance, self-care management and self-care confidence. The self-care maintenance scale has 10 items, and measures how often the HF patient evaluates his/her symptoms (e.g., ankle swelling) and adheres to treatments (e.g., taking medications regularly). The self-care management scale has six items, and evaluates patient's ability to recognize and evaluate the symptoms of HF exacerbation, implement a remedy to reduce symptoms (e.g., reducing fluid intake) and evaluate the effectiveness of the remedy if implemented. The self-care confi-

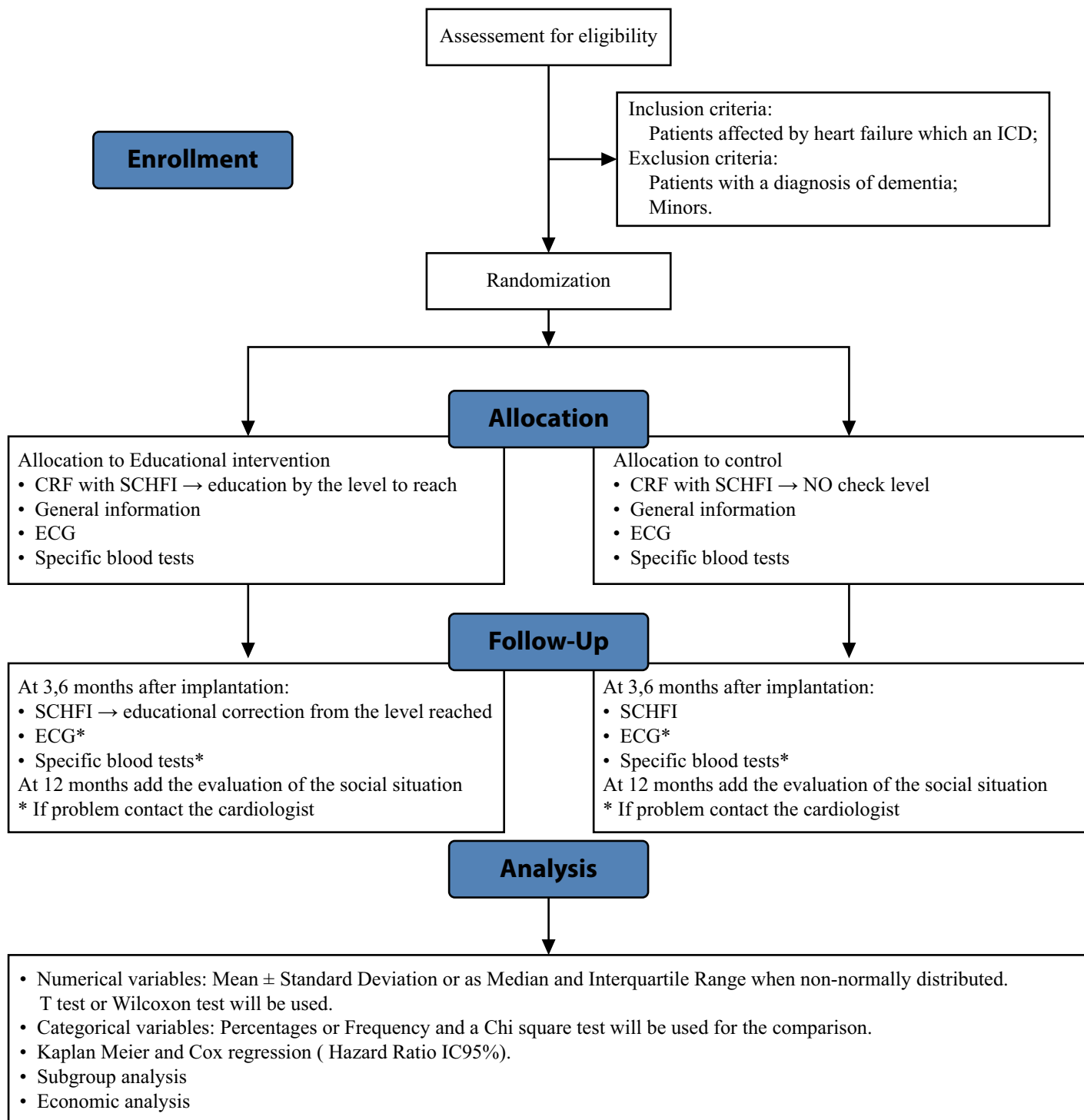


Figure 1. Flow Diagram of the Study.

dence scale has six items, and measures patient’s self-efficacy in all the self-care processes. Each scale uses a 4-point Likert scale for responses from “never or rarely” (1 point) to “every day or always” (4 points). The psychometric characteristics of the Italian version of the SCHFI v. 6.2 have been previously tested.^{28,29,31} Specifically, the instrument showed supportive fit indices at confirmatory factor analysis, and was able to discriminate patients educated in self-care versus those who were not. The test-retest reliability was also supportive, as was the internal consistency reliability. In all three SCHFI scales, a standardized score from 0 to 100 can be obtained, with a higher score meaning better self-care. A score of 70 or more is adequate self-care.^{7,30}

Perceived quality of life in HF patients will be evaluated with a visual analogic scale (VAS). VASs are instruments with good validity and reliability to measure several variables including QOL. The VAS that we will use consists of score from 0 to 100. The use is recommended in clinical trials to assess the global quality of life.³²

For all the included patients, also the following data will be collected: socio-demographics (gender, age, educational level, marital status and country of birth), and clinical information (New York Heart Association (NYHA) functional classification, the implantation date, type of ICD, laboratory tests, ECG results and their changes at each follow-up and number of perceived



shocks).³³ The information on the patients' diagnoses and possible associated diseases will be obtained through the analysis of clinical documentation, and will be collected in accordance with the International Statistical Classification of Diseases and Related Health Problems, 9th Revision (ICD-IX). Before any data collection, participants will be fully informed about the study and will be asked to sign the informed consent form.

Educational intervention

After randomization, all patients in the intervention group will undergo an educational intervention program, which will be delivered through a 30-minute talk given by the outpatient nurse during the first follow-up (7 ± 3 days from ICD implantation).²³ The further educational interventions (3, 6 and 12 months) will be based on the SCHFI score obtained at the first follow-up. Specifically, a practical guide focused on HF self-care (e.g., recommending exercise) will be used with emphasis on the care of the surgical site where the ICD was implanted.^{34,35} The patients in the control group will receive the standard of care that is normally provided to HF patients after an ICD implantation.

Study outcomes and outcome measurements

The primary outcome of this study will include the self-care levels and their modifications measured using the SCHFI v. 6.2.^{24,26} The secondary outcomes will include the QOL. Also, we will evaluate the number of visits in the emergency department and hospitalization. All cause mortality 6 month after ICD implantation and the infection rate on the ICD device pocket.

The nurse at the outpatient clinic, in which the educational intervention will be conducted, will be able to consult the patient's chart and research dossier. At the first follow-up, the nurse will proceed to gather socio-demographic and clinical data. During the first and subsequent follow-ups (at 7 ± 3 days and 3, 6 and 12 months), the self-care skills of the patients will be assessed using the SCHFI scale, and any changes in the previous data will be collected.

At the first follow-up visit and, if necessary, after 3 months, the nurse will assess the inflammatory signs and symptoms of the ICD pocket; if the signs increase, the patient will be asked to contact the hospital. The nurse will also assess the patient's emergency department visits, hospitalizations, and the time spent by the patients and their companions; these will be checked at 3, 6 and 12 months. The research team will then investigate the databases of the clinical centers involved in this study, to gather information regarding hospitalizations and visits to the ED that occurred in the period between ICD implantation and the 12-month follow-up, as reported in the data collection files.

Sample size

The primary aim of this study was to examine the effects of a nursing educational intervention to improve the level of self-care, as measured through the SCHFI. A change in these scores is clinically relevant when the change is greater than half of one standard deviation from the mean;³⁰ therefore, 128 patients (64 per group) with ICD implantations will be randomly assigned to the treatment or control groups. The sample size calculation was performed using Query Advisor software version 5.0, with a power of 80%.

Randomization

The "First Generator" software (available online at www.randomization.com) will be used to generate a randomization list, making it possible to assign participant to the intervention or control group.

Data analysis

The numerical variables will be reported as the mean \pm standard deviation, or as the median and interquartile range when non-normally distributed. The t-test or non-parametric Wilcoxon test will be used, when appropriate, for the between-group comparisons. Normal distribution will be tested with the Kolmogorov Smirnov test, and through the evaluation of the plot (plot of the data and q-q plot). The categorical variables will be expressed as a percentage or frequency, and a chi square test will be used for the comparison. The survival analysis will be evaluated through the Kaplan Meier analysis, and compared by the Log-Rank test. This solution involves conducting an intention-to-treat analysis. Furthermore, a Cox proportional hazards model will be implemented to assess the independent prognostic value of the educational program, adjusted for the variables significant in the univariable analysis. A hazard ratio (IC 95%) will be presented. In addition, the effects of the educational levels will be examined with regard to the perception of the quality of life in the different patient groups, according to specific characteristics (gender, age, NYHA class and level of education). For all of the statistical analyses, the significance will be set at $p < 0.05$. All of the analyses will be performed using the SAS 9.3 statistical package (SAS Institute Inc., Cary, NC, USA) and IBM SPSS Statistics version 22.

Discussion

The aim of this study will be to evaluate the effects of a nursing educational intervention on improving self-care in HF patients with recent ICD implantations. HF patients with ICDs are a growing and frail population that needs special attention from healthcare providers. Few studies have been conducted on self-care in HF patients with ICD, and we expect that because of the psychological problems experienced by this specific population, self-care will be poorer. Consequently, an intervention aimed at improving self-care will be particularly helpful for this specific population, and we anticipate that our study will improve self-care in HF patients with ICD. The participants in this study are expected to be compliant with the intervention and therapeutic education.

The majority of the medical demands today are concerned with chronic disease, and the health care providers can provide support to their patients with their life choices, and in helping them to improve the bio-psycho-social aspects of their health. In this regard, therapeutic education helps the patient to learn and develop numerous competencies, to adapt behaviors and improve different health parameters, including the bio-markers and quality of life. We also anticipate that therapeutic education in the intervention group will have an impact on costs. As demonstrated in the general HF population, patient education can be effective in reducing emergency department visits and hospitalizations.^{37,38,39} Consequently, we hypothesize that healthcare costs will decrease by the effect of the intervention.³⁹

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