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RESEARCH ARTICLE

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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

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Abstract

In patients with heart failure (HF), self-care, and caregiver contribution to self-care (i.e., the daily management of the disease by patients and caregivers) are essential for improving patient outcomes. However, patients and caregivers are often inadequate in their self-care and contribution to self-care, respectively, and struggle to perform related tasks. Face-to-face motivational interviewing (MI) effectively improves self-care and caregiver contribution to self-care, but the evidence on remote MI is scarce and inconclusive. The aims of this randomized controlled trial will be to evaluate whether remote MI performed via video call in patients with HF: (1) is effective at improving self-care maintenance in patients (primary outcome); (2) is effective for the following secondary outcomes: (a) for patients: self-care management, self-care monitoring, and self-efficacy; HF symptoms; generic and

disease-specific quality of life; anxiety and depression; use of healthcare services; and mortality; and (b) for caregivers: contribution to self-care, self-efficacy, and preparedness. We will conduct a two-arm randomized controlled trial. We will enroll and randomize 432 dyads (patients and their informal caregivers) in Arm 1, in which patients and caregivers will receive MI or, in Arm 2, standard care. MI will be delivered seven times over 12 months. Outcomes will be assessed at baseline and 3 (primary outcome), 6, 9, and 12 months from enrollment. This trial will demonstrate whether an inexpensive and easily deliverable intervention can improve important HF outcomes. With the restrictions on in-person healthcare professional interventions imposed by the COVID-19 pandemic, it is essential to evaluate whether MI is also effective remotely.

KEYWORDS
heart failure, motivational interviewing, self-care, self-efficacy, telemedicine

1 | INTRODUCTION

Heart failure (HF) is a chronic syndrome that affects around 2% of the world's population (McDonagh et al., 2021; Tsao et al., 2022). HF prevalence is mounting, with a total predicted increase of 46% from 2012 to 2030 in adults over 18 years of age (Virani et al., 2021).

The impact of HF on patients, informal caregivers, and society is devastating. In patients, HF is associated with poorer quality of life (QoL) (McGuinty et al., 2020) and shorter survival (Virani et al., 2021). In informal caregivers, HF results in a burdening experience (Kim et al., 2020), which in turn, negatively impacts health-related QoL of both (Lahoz et al., 2021). Society is burdened by the high cost of recurrent HF hospitalizations and emergency services use (Mentz et al., 2021). Self-care behaviors adopted by patients and caregiver contribution to self-care may mitigate the above problems (Bidwell et al., 2017; Iovino et al., 2021; Rebora et al., 2021; Q. Zhao, Chen et al., 2021).

HF patient self-care is defined as those behaviors performed to maintain disease stability (self-care maintenance), monitor and perceive related symptoms (self-care monitoring and symptom perception), and respond to signs and symptoms of an HF exacerbation (self-care management (Riegel et al., 2022). Caregiver contributions to HF self-care is defined as "the process of recommending to (or substituting for) the patient to perform those behaviors that help (1) maintain the stability of HF conditions (caregiver contribution to self-care maintenance), (2) facilitate HF symptom monitoring and perception (caregiver contribution to symptom monitoring and perception), and (3) the management of signs and symptoms of an HF exacerbation when they occur (caregiver contribution to self-care management" (p 167) (Vellone et al., 2019). Therefore, caregiver contributions to self-care represent an important element in the process of HF care because the promotion of healthy behaviors and the support provided to monitor and manage signs and symptoms of the disease create the basis for better patient outcomes (Aggarwal et al., 2013; Wakabayashi et al., 2011). On the other hand, caregiving for a patient with a chronic illness may be both a burdensome (Kim et al., 2020) and a rewarding experience (Kang et al., 2011).

Both in patient self-care and caregiver contribution to self-care, self-efficacy plays a pivotal role. It has been consistently found that patient and caregiver self-efficacy are positively associated with self-care and caregiver contribution to self-care, respectively; for example, in patients, better self-efficacy promotes medication adherence (Cousin et al., 2020), whereas, in caregivers, better self-efficacy augments their support of health-promoting practices and symptom management (Sterling et al., 2022). Unfortunately, several studies have demonstrated that patient self-care and caregiver contributions to self-care (Kang et al., 2011) are often insufficient (Chen et al., 2017; Koirala et al., 2020; Ryou et al., 2021), with patients and caregivers generally struggling with both (Durante, Paturzo et al., 2019; Nordfonn et al., 2019). This issue has prompted investigators to design more efficient educational programs for promoting self-care and contributions to self-care.

Motivational interviewing (MI) is a well known strategy that can promote self-care. MI is a counseling technique that boosts motivation for behavior change (Miller & Rollnick, 2009). The principles underpinning this approach are avoiding arguments and direct confrontation, developing discrepancy, expressing empathy, rolling with resistance, and supporting self-efficacy (Miller & Rollnick, 2009). Two recent systematic reviews (Ghizzardi et al., 2021; Sokalski et al., 2020) demonstrated that MI improves self-care in patients with HF.

During the COVID-19 pandemic, the use of HF telehealth interventions has seen a rapid expansion into clinical practice. This is not surprising as patients with HF are often older adults and exhibit a wide range of comorbid conditions, which in turn put them at additional risk for premature death. The use of telehealth seems to ensure the same effectiveness on outcomes that are typically

observed in the in-person healthcare settings. For example, Xu et al. (2022) found that HF telemedicine visits were as effective as in-person visits in reducing readmissions at 30 days. There is also evidence of positive experiences with telemedicine because, as a result of the virtual visits, patients perceive lower stress due to transportation and leaving their homes (Kerr et al., 2020; M. Zhao, Qin et al., 2021). A few recent analyses confirm significant HF-related cost savings compared to standard care (Jiménez-Marrero et al., 2020; Vestergaard et al., 2020).

Regrettably, robust evidence of the positive impact of remote MI-based interventions on HF self-care behaviors is lacking. Most trials, such as the MOTIVATE-HF (Vellone et al., 2017), demonstrated that the MI approach was effective to motivate the behaviors and improve patient self-care, symptoms, disease specific QoL, and mortality, but MI was performed face-to-face (Caggianelli et al., 2022; Iovino et al., 2021; Rebora et al., 2021; Vellone, Rebora et al., 2020). To the best of our knowledge, only three trials implemented remote MI in HF education (Dwinger et al., 2020; Härter et al., 2016; Sherwood et al., 2017). These trials had significant methodological problems, which hindered the generalization and validity of the results. Dwinger et al. (2020) and Härter et al. (2016), found that the arm that received the remote MI-based intervention had lower mortality, hospitalizations, and better physical activity. However, in both trials, the sample was randomized before seeking informed consent, resulting in a significant number of refusals (e.g., 57% in Harter's study), which raises concern for randomization bias. Sherwood et al. (2017) recruited a small sample ($n = 180$), and the nonsignificant effects of the intervention on self-care were possibly due to a lack of statistical power.

Even less well known is whether remote MI helps improve caregiver outcomes (e.g., caregiver contribution to self-care, preparedness). The trials mentioned above did not involve caregivers; thus, the role of caregivers remains unexplored. Since caring for a patient with HF can be a burdensome experience (Kim et al., 2020), we do not know yet whether an intervention aimed at increasing caregiver contribution to self-care might negatively affect caregiver QoL, anxiety, depression, and burden. Notably, a cross-sectional study Durante, Greco et al. (2019) found that caregiver contribution to HF self-care (CACHS) was not associated with caregiving burden. Although this result is important, more substantial evidence from RCTs is needed to establish whether this relationship actually exists and clarify the possible direction of causality.

Considering the limited evidence, it is reasonable to evaluate whether a remote MI intervention would be effective in improving self-care and other important patient and caregiver outcomes. The results of this trial would also be important in terms of sustainability and equity of care, since this intervention is expected to be less expensive than a face-to-face intervention, and the patients living far from HF centers would have the same opportunity to receive the same care as those who live closer.

The theoretical framework that guided the design of the present trial is the situation-specific theory of HF self-care (Riegel et al., 2022), which postulates that self-care behaviors are influenced by person, problem, and environmental factors. Self-care self-efficacy is a critical driver in the theory because it can mediate the relationship between such factors and self-care. The improvement in self-efficacy, which is transmitted via MI, improves patient self-care and this, in turn, improves intermediate (e.g., symptoms) and distal (e.g, mortality and use of healthcare services) outcomes. Another theory that informed the REMOTIVATE-HF study is the situation-specific theory of caregiver contributions to HF self-care (Vellone et al., 2019). In a very similar manner, it is postulated that self-efficacy can mediate the relationship between the factors influencing the caregiver contributions and the contributions themselves. Once again, MI targets self-efficacy, which leads to better contributions and better caregiver and patient outcomes.

Therefore, the aims of the REMOTIVATE-HF study will be to (1) evaluate the effect of an MI-based intervention performed via video call in improving self-care maintenance in patients at 3 months from enrollment (primary endpoint); and (2) evaluate the effect of an MI-based intervention performed via video call on the following secondary endpoints: (a) for patients: self-care management, self-care monitoring, and self-care self-efficacy; HF somatic symptom perception; generic and disease-specific QoL; anxiety and depression; use of healthcare services; and mortality; and (b) for caregivers: contribution to self-care, self-efficacy in contributing to self-care, and preparedness. We will also test the hypothesis that our intervention, in which we motivate caregivers to contribute more to patient self-care, will not affect caregiver QoL, anxiety, depression, or burden.

2 | METHODS

2.1 | Study design

This is a two-arm randomized controlled trial (Figure 1). The study protocol has been approved by the Ethical Committee of the University of Rome Tor Vergata (approval # 263/21) and registered at ClinicalTrials.gov (Identifier: NCT05205018).

2.2 | Recruitment and eligibility assessment of study participants

Patients and caregivers will be enrolled in eight HF clinics located across Italy. Inclusion criteria for patients will be: (1) a diagnosis of HF (McDonagh et al., 2021), (2) Class II, III, or IV HF according to the New York Heart Association (NYHA) functional classes, (3) poor self-care, defined as a score of 0, 1, or 2 on at least two items of the self-care heart failure index 7.2 (SCHFI 7.2) (Vellone, De Maria et al., 2020), (4) age ≥18 years, and (5) having Internet access or mobile phone data to allow the video calls. Patients will be excluded in cases of: (1) severe cognitive dysfunction, with a score of 0–4 on the six-item screener (Callahan et al., 2002; Xue et al., 2018), (2) acute coronary event(s) in the past 3 months, (3) living in

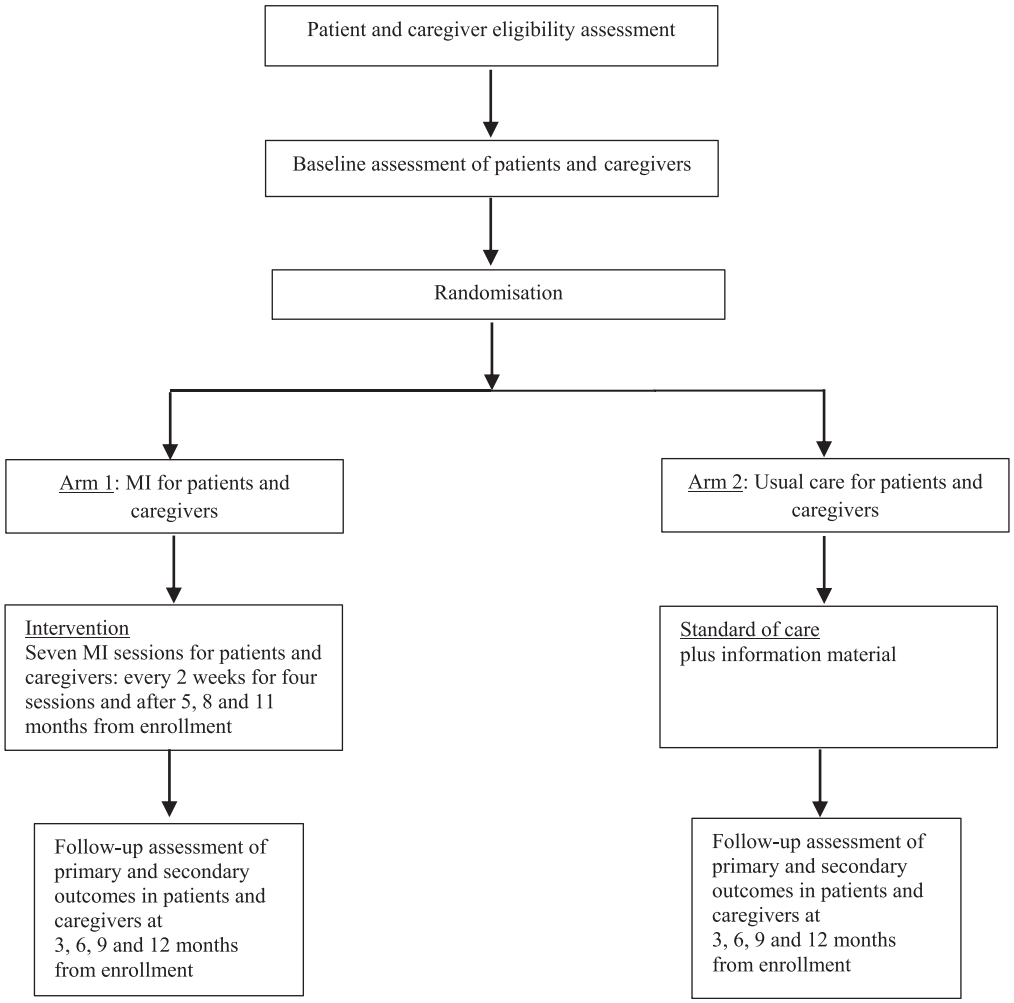

FIGURE 1 Flow-chart of the study. MI, motivational interviewing.

residential settings where self-care may be biased due to contact with providers, or (4) if their caregivers are not willing to participate in the study.

Inclusion criteria for caregivers are being identified as the patient's principal informal caregiver (i.e., the person who provides the patient with the majority of their informal care) and age ≥18 years. We will exclude caregivers from the study if the patient is not willing to participate in the study. After initial enrollment, if caregivers want to leave the study, the patient can remain in the study; however, if the patient wants to leave the study, the caregiver will be excluded from the study as well.

2.3 | Intervention

The intervention, which will be delived to patient and caregiver together, consists of two parts: a first and more intensive part in which four MI-based educational sessions will be performed within 2 months; and a second and less intensive part in which the sessions will be performed at 5, 8, and 11 months from enrollment. We decided on these two parts of the intervention because in our prior experience with face-to-face MI (Vellone et al., 2020), four sessions in 2 months were successful in improving patient self-care maintenance at 3 months from enrollment and because a recent Delphi survey involving several stakeholders (patients, clinicians, and policymakers) suggested that the best approach for an HF self-care intervention would be one with more intense sessions for the first 2–3 months, followed by less intense sessions over time (Whittal et al., 2021). Conducting a study over 1 year might affect the retention of participants. However in another longitudinal study we are conducting (De Maria et al., 2019), we have found that when data collectors remain the same for the same dyads, attrition is significantly reduced. All the remote sessions will be performed using commonly accessible video call platforms, such as WhatsApp, FaceTime, and Zoom.

The intervention will be delivered at each enrolling center by nurses trained in HF self-care and MI. In each session, the intervention will be delivered both to patients and caregivers. The interventionists, guided by the principles of MI, will develop discrepancy (e.g., helping the patient/caregiver to reason how their

current behaviors could impede reaching their health goals); will deal with and adapt to resistance (e.g., by involving the patient/caregiver to self-identify solutions to poor self-care); will avoid direct confrontation and arguing (e.g., listening to patient/caregiver preferences and being respectful of their choices); will express empathy (e.g., show an attitude of acceptance); and will support self-efficacy (e.g., by encouraging a focus on past successes and by verbal persuasion).

In terms of contents, before starting each MI-based session, the interventionist will ask the patient and the caregiver to complete the self-care of HF index 7.2 and the caregiver contribution to self-care of HF index 2 (CC-SCHFI), respectively. Depending on the responses to each specific item, the interventionist will tailor the intervention. In each session, the interventionist will address both patient and caregiver deficit in self-care and caregiver contribution to self-care. Each session will last for about 1 h.

2.4 | Control group

In Arm 2 (the control group), patients and caregivers will receive usual care, consisting of face-to-face verbal information on HF and its treatment and management during routine check-ups, which are generally performed every 6–12 months by cardiologists and nurses (not belonging to the study team), depending on the specific patient's situation. During these check-ups, patients are generally accompanied by their caregivers.

Patients and caregivers from both arms will receive informational material on HF management based on international guidelines (McDonagh et al., 2021).

2.5 | Treatment fidelity

Treatment fidelity will be monitored by checking if all MI-based educational sessions have been performed as planned for each patient/caregiver dyad by asking for a brief report to each interventionist after each session, and by evaluating the MI skills of the interventionists before they are involved in the study. Specifically, the psychologists training the interventionists will evaluate the MI skills of the interventionists at the end of their training and will evaluate the video recordings of the first three interventions with patients not included in the study, against the Motivational Interviewing Treatment Integrity Coding Manual 4.1. (Moyers et al., 2014). According to this manual, MI's technical and relational components should score at least 3 and 4, respectively, out of the maximum score of 5. In the case that an interventionist scores lower, they will be retrained. If their skills do not improve, they will not be involved in the study. Also, to further guarantee treatment fidelity, the psychologists training the interventionists will randomly monitor the 20% of the MI sessions throughout the study.

To assure treatment fidelity for the control group, the staff who cares for these patients will be instructed not to deliver any educational activity that substantially deviates from the study protocol. However, this possibility cannot entirely be excluded due to the unique patient needs and the multisite nature of the study. Also, any possible protocol drift will be documented and assessed by a trained investigator who will supervise the adherence to the study protocol. In case a study site is not adherent to the study protocol, data from that site will be excluded from the analyses.

2.6 | Assessment at baseline and follow-ups

Patients and caregivers will be assessed in-person at baseline after enrollment (T0) and at each follow-up performed at 3 (T1), 6 (T2), 9 (T3), and 12 (T4) months. At baseline, patients will be assessed for sociodemographic and clinical characteristics. Patients will be evaluated for their NYHA functional class and comorbidities using the Charlson comorbidity index (Charlson et al., 2022), while caregivers will be assessed for their sociodemographic and caregiving characteristics. At baseline, patients and caregivers will also be evaluated for their mutuality using the mutuality scale (Dellafiore et al., 2018) (patient and caregiver version), which measures the quality of the relationship between the caregiver and the care-receiver. All instruments used at baseline and follow-ups are reported in Table 1. Each assessment will be performed by research assistants (clinic staff), who will be trained on the study protocols, will be blinded to arm assignment and will not be the interventionists performing MI. Each baseline and follow-up assessment will require the patient and caregiver to complete the questionnaires either autonomously or with the support of the research assistant. Based on our previous experience (Vellone, Rebora et al., 2020), the set of questionnaires pertaining to the present trial will take approximately 30 min to complete.

2.7 | Randomization and blinding

After enrollment and collection of the baseline data, patients and caregivers will be randomized (1:1) to the study arms. We will perform block randomizations of six patient/caregiver dyads per block to guarantee the same number of dyads in the two arms. We will perform as many blocks as necessary to reach the predetermined sample size. Afterward, the randomization blocks will be randomly assigned to the enrolling centers by a research assistant who will then not be involved in other aspects of the study. In this way each center has its own randomly assigned bocks of participants. Only research assistants blinded to study arm will collect data.

2.8 | Outcome measures

2.8.1 | Primary endpoint

The primary outcome will be patient self-care maintenance measured using the self-care maintenance scale of the self-care of hf index

TABLE 1 Variables and instruments

Variable	Instrument	# items	Administered to	Score range	Validity	Reliability
General						
Sociodemographic and clinical characteristics	Sociodemographic and clinical questionnaire	14 for P 10 for C	P–C	NA	NA	NA
Comorbidity	CCI	19	P	0–33	Concurrent, incremental and predictive	Intraclass correlation coefficient 0.80; Cohen Kappa 0.93[a]
Cognitive impairment (exclusion criterion)	Six-item screener	6	P	0–6	Construct	Cronbach's α: 0.70[2]
Primary endpoint: patient						
Self-care maintenance	SCHFI v.7.2	10	P	0–100 for each scale	Structural and construct	Cronbach's α: 0.73; Composite reliability: 0.89; intraclass correlation coefficient: 0.80[b]
Secondary endpoints: patient						
Self-care monitoring and management	SCHFI v.7.2	19	P	0–100 for each scale	Structural and construct	Cronbach's α: 0.80–0.83; composite reliability: 0.89; intraclass correlation coefficient: 0.73–0.91[c]
Self-care self-efficacy	Self-care self-efficacy scale	10	P	0– 100	Structural	Cronbach's α: 0.92[d]
HF symptom burden	HFSPS	18	P	0–90	Structural and criterion-related	Factor score determinacy: 0.87–0.96; Model-based internal consistency: 0.91[e]
HF specific QoL	KCCQ	23	P	0–100	Construct	Cronbach's α: 0.62–0.90[f]
Secondary endpoints: caregivers						
Caregiver contribution to HF self-care	CC-SCHFI 2	22	C	0–100	Structural and construct	Cronbach's α: 0.81–0.83; Global reliability: 0.79–0.86; intraclass correlation coefficient: 0.72–0.91[g]
Caregiver contribution to HF self-care	CACHS	20	C		Structural	Cronbach's α: 0.93[h]
Caregiver self-efficacy	Caregiver self-efficacy scale	10	C	0–100	Structural and construct	Composite reliability coefficient: 0.90–0.95; factor score determinacy: 0.93–0.97; global reliability: 0.92; Cronbach's α: 0.94[i]
Caregiver preparedness	CPS	8	C	0–4	Structural and construct	Cronbach's α of 0.91[j]
Caregiver burden	CBI	24	C	0–100	Structural and construct	Cronbach's α: 0.88–0.96[k]
Healthcare service use	Questionnaire		C			
Mortality	Questionnaire		C			

TABLE 1 (Continued)

Variable	Instrument	# items	Administered to	Score range	Validity	Reliability
Secondary endpoints: dyad						
Generic QoL	SF-12	12	P–C	0–100	Structural and construct	Cronbach's α: 0.75–0.85[l,m]
Anxiety/depression	HADS	14	P–C	0–21	Structural and construct	Cronbach's α: 0.82–0.87[n]
Contextual factors influencing self-care decision	Self-care decision inventory (patient and caregiver version)	27	P–C	27–135	Content, structural and construct	Multidimensional reliability: 0.86[o]
Mutuality	MS	15	P–C	0–4	Content, structural and construct	Cronbach's α and model-based internal consistency: 0.72–0.94[p]

Note: All instruments reported in the table are administered at baseline and 3, 6, 9, and 12 months from enrollment except for the sociodemographic and clinical questionnaire and the mutuality scale which are administered only at baseline, and the mortality and healthcare service use questionnaires, which are administered at 3, 6, 9, and 12 months from enrollment.

Abbreviations: C, caregiver; CACHS, caregiver contribution to HF self-care; CBI, Caregiver burden inventory; CCI, Charlson comorbidity index; CC-SCHFI, caregiver contribution to self-care of HF index; CPS, caregiver preparedness scale; HADS, hospital anxiety and depression scale; HF, heart failure; HFSPS, heart failure somatic perception scale; KCCQ, Kansas city cardiomyopathy questionnaire; MS, mutuality scale; NA, not applicable; P, patient; QoL, quality of life; SCHFI, self-care of heart failure index; SF-12, short form 12.

[a]Charlson et al. (2022).

[b]Xue et al. (2018).

[c]Vellone, De Maria et al. (2020).

[d]Yu et al. (2021).

[e]Pucciarelli et al. (2019).

[f]Green et al. (2000).

[g]Vellone, Barbaranelli et al. (2020).

[h]Ali et al. (2022).

[i]De Maria et al. (2021).

[j]Petruzzo et al. (2017).

[k]Greco et al. (2017).

[l]Kathe, et al. (2018).

[m]Shah et al. (2018).

[n]Christensen et al. (2020).

[o]Page et al. (2022).

[p]Dellafiore et al. (2018).

version 7.2 (SCHFI 7.2). The SCHFI 7.2 measures patient self-care in the dimensions of self-care maintenance (i.e., behaviors to maintain HF stability), symptom perception (i.e., behaviors aimed at monitoring HF signs and symptoms), and self-care management (i.e., responses to signs and symptoms of exacerbations). Each SCHFI 7.2 scale has a standardized 0–100 score, with higher scores indicating better self-care. A score ≥70 is considered adequate self-care (Riegel et al., 2019). An increase of 8 points in each SCHFI 7.2 scale (including the self-care maintenance scale) is considered a clinically meaningful change (Vellone, De Maria et al., 2020). The tool was tested on a sample of 280 Italian patients with HF and yielded satisfactory reliability indexes (i.e., Cronbach's α and composite reliability indexes between 0.73 and 0.88) (Vellone, De Maria et al., 2020).

The self-care maintenance scale score will be evaluated at 3 months after enrollment. In addition, we will assess patient self-care maintenance scores at each follow-up over the year of the study.

2.8.2 | Secondary endpoints

Several secondary endpoints will be evaluated at the patient-, caregiver,- and dyad level, using a battery of tools, all with established validity and reliability (Table 1). Specifically, in patients, we will use: the self-care monitoring and self-care management scales of the SCHFI 7.2 (Vellone, De Maria et al., 2020) to measure symptom monitoring and the responses to signs and symptoms of HF exacerbation; the self-care self-efficacy scales (Yu et al., 2021), which measure patient confidence in dealing with self-care; the HF somatic perception scale (Pucciarelli et al., 2019) to measure the burden of symptoms; and the Kansas city cardiomyopathy questionnaire (Green et al., 2000; Nassif et al., 2022) to measure HF-specific QoL.

In caregivers, we will use: the CC-SCHFI 2 (Vellone, Barbaranelli et al., 2020) and the CACHS (Buck et al., 2017) which investigate the extent to which caregivers recommend patients to perform self-care or perform self-care on behalf of the patients if they are unable to do so; the caregiver self-efficacy scale (De Maria et al., 2021), which measures the extent to which caregivers feel confident in contributing to patient self-care; the caregiver preparedness scale (Vellone, Barbaranelli et al., 2020), which assesses the extent to which caregivers feel prepared to take care of the person they care for; and the caregiver burden inventory (Greco et al., 2017), which evaluates the physical and psychological burden of caregivers. All these scales have satisfactory psychometric properties (Table 1). Also, using an investigator-developed questionnaire, we will ask caregivers to report patient use of healthcare services (e.g., how many times the patient was hospitalized during the last 3 months) and patient mortality if this occurred.

For both patients and caregivers, we will use the short form 12 (Gandek et al., 1998), which measures the generic QoL in its physical and mental dimensions; the hospital anxiety and depression scale (Zigmond & Snaith, 1983), which measures anxiety and depression; and the self-care decision inventory (Page et al., 2022), which evaluates contextual factors influencing decision making by patients and caregivers in cases where patients have symptoms (Table 1).

2.9 | Statistical analysis

2.9.1 | Sample size

A total sample of 216 patients (108 per arm) would achieve 90% power to detect an eight-point difference in self-care maintenance (Vellone, De Maria et al., 2020) improvement at 3 months in patients under MI intervention versus those in standard care. This difference will be detected using a two-sided *t*-test with a 0.05 significance level. The eight-point difference corresponds to an effect size of 0.44 by assuming a common standard deviation of 18 within each arm.

The sample will also provide 83% power to detect an eight-point difference in patient self-care management and self-care self-efficacy improvement at 3 months among the two arms, assuming a standard deviation of 20. Based on the available literature and to account for an estimated 50% attrition rate (Vellone, Rebora et al., 2020), 432 dyads (432 patients and 432 caregivers) will be recruited.

Regarding secondary endpoints, a final sample of 108 dyads per arm with complete follow-up evaluation would allow the detection of an effect size of at least 0.38, with a minimum power of 79%. To test the hypothesis that our intervention will not affect caregiver QoL, anxiety, depression, or burden, the final sample will achieve 71% power to detect non-inferiority using a one-sided, two-sample *t*-test with a non-inferiority margin of 0.3 (effect size).

2.9.2 | Description of patient and caregiver characteristics

Measures of central tendency (e.g., means, medians) and variability (e.g., standard deviation, interquatile ranges) will be used to describe HF patient and caregiver characteristics and the outcome measure scores at each follow-up point.

2.9.3 | Evaluation of the intervention on the primary endpoint (aim 1)

A two-sample *t*-test will be used to compare self-care maintenance improvement (from baseline to month 3 and from baseline to month 6, 9, and 12) of participants in Arm 1 versus Arm 2. A longitudinal linear mixed regression model will be applied with self-care maintenance scale score as dependent variable, and visit time, randomization arm, and their interaction as independent variables and including the patient as random effect. The efficacy of the MI-based intervention will be tested by the interaction between time and treatment arm (at 3 months and subsequent time points) with an intention-to-treat approach. Adjusted models including demographic, socioeconomic, and clinical variables on the patient and eventually

unbalanced baseline covariates, will be also fitted. The amount and the mechanism of missing data will be evaluated; primary analysis using linear mixed models on all available data will adopt the missing at random assumption (Molenberghs, 2004). If more than 10% of randomized patients drop out before the primary endpoint evaluation, sensitivity analyses will be also performed by setting up extreme scenarios and by the joint modeling of response and drop-out. To assess the impact of the MI-based intervention on the percentage of patients with adequate SCHFI v.7.2 score (≥70) (Riegel et al., 2019), the χ^2 test will be used.

2.9.4 | Evaluation of the intervention on the secondary endpoints (aim 2)

For the secondary endpoints, the impact of the intervention on the other dimensions of the SCHFI 7.2 instrument and on somatic perception scale and the Kansas city cardiomyopathy questionnaire will be evaluated by the interaction term between time and treatment arm in linear mixed regression models on patients. Mortality will be estimated using Kaplan–Meier curves and compared between the two arms using the log-rank test. The differences in healthcare service use between the two arms will be summarized by counting the number of accesses to emergency departments and the number of hospitalizations occurring between follow-ups. This comparison will be performed with a Poisson model. Mixed longitudinal linear regression models will be also used to assess the impact of the MI-based intervention on the caregiver contribution to self-care of HF index, the short form 12 QoL scale, the hospital anxiety and depression scale, and the self-care decision inventory of both patient and caregivers. In case of imbalances between baseline variables, these will be included in the models as covariates. The 95% confidence intervals of the difference between the improvements in the two arms will be used to assess the non-inferiority of the caregiver burden, QoL, and anxiety/depression in Arm 1 with respect to Arm 2.

3 | DISCUSSION

This protocol describes the design of a RCT aiming to assess the impact of a remote MI-based intervention on the self-care of patients with HF and the caregiver contribution to self-care. We also expect that the trial will improve important distal outcomes, such as survival in patients and preparedness in their caregivers. A further important assumption embedded in the trial is that an intervention focused on encouraging the caregivers to contribute more to self-care would not worsen their QoL, anxiety, depression, and burden. The central tenet of this hypothesis lies in the potential of MI to improve caregiver self-efficacy, which act as a protective factor against several psychological issues (Cheng et al., 2013; Grano et al., 2017). Given that the caregiver contribution to self-care significantly improves patient outcomes (Bidwell et al., 2017) and that caregiver psychological stressors are often related to lower frequency and quality of informal care support (Cooney et al., 2006), shedding light on whether MI preserves the mental health of the caregivers is paramount.

A big novelty of the REMOTIVATE-HF trial lies in the method of intervention administration. First, the sessions will be conducted remotely, with a series of advantages, such as extended access to care and higher flexibility in case of a need for frequent visits with healthcare professionals (Alvarez et al., 2021; Nardo et al., 2021). We opted for videoconferencing as this approach most closely resembles classic face-to-face visits. This choice, however, calls for further considerations; first, although the effectiveness of remote MI-based education on patient outcomes is well established (Härter et al., 2016; Palacio et al., 2015; Sherwood et al., 2017), the adoption of videoconferencing remains scarce in the care of HF. Tang et al. (2021) suggest that compared to the phone modality, videoconferencing leads the participants to become more engaged on behavior change (Tang et al., 2021); moreover, the interventionists may offer more elements to build better connection and trust with the patients. These positive aspects can be justified by the improvement in digital empathy conveyed by nonverbal communication (Nguyen & Canny, 2009), which, in contrast to phone calls, is preserved in videoconferencing. Notably, attention to nonverbal cues is essential for ensuring high-quality and effective MI sessions (Rosengren, 2017). Second, it seems that at least regarding MI, videoconferencing shows a higher acceptability rate than phone calls (Baca & Manuel, 2007; Tang et al., 2021).

To our knowledge, this is the first clinical trial in which the SCHFI 7.2, CC-SCHFI 2, and CACHS will be used. This will be important to provide information on score modification of these measures after an intervention for future comparisons. The SCHFI 7.2 and CC-SCHFI 2 have been improved in reference to their prior versions, with the addition of items regarding self-care maintenance and management scales and, more importantly, the addition of the caregiver contribution to symptom perception scale. Symptom perception is an important determinant of self-care management, since patients can only respond promptly to symptoms and avoid deterioration of their HF if they perceive the symptoms (and caregivers help them to do so). With this trial, we can evaluate whether MI-based education is effective at improving caregiver contribution to symptom perception. Also, we will use the CACHS, which measures caregiver contribution to self-care from a different perspective than the CC-SCHFI 2. In fact, while the CC-SCHFI 2 has the same items as the SCHFI 7.2, and was developed from a patient perspective, the CACHS was developed from a caregiver perspective with qualitative interviews. In the MOTIVATE-HF study, we did not observe any significant effect of the intervention on caregiver contribution to self-care, which was measured using the CC-SCHFI (Locatelli et al., 2022). It is possible that the CACHS is more sensitive to interventions, but this remains to be demonstrated since no trial has been conducted to date using the CACHS, and no study has investigated whether CACHS scores are associated with caregiver and patient outcomes.

The main strength of this study is that for the first time in a trial involving patients with HF and caregivers, the intervention sessions

are planned to be delivered over 1 year. By opting for this timing, we expect a more consistent and durable improvement in outcomes, given that the likelihood of an effect seems to rise as the number of MI encounters increases (Rubak et al., 2005). Conducting the the study over 1 year has the potential issue of high attrition rates. However, we expect our retention strategies to keep attrition to a minimum.

We also foresee some limitations. MI is a complex intervention. Although we will provide the interventionists with regular coaching and feedback throughout the trial, the learned skills may tend to wear off as time elapses, which may lead to lower treatment fidelity. However, the psychologists training the interventionists will randomly monitor the 20% of the MI sessions throughout the study to monitor this issue. One more limit may be regarding the self-care measures as primary outcomes: since self-care identifies an array of behaviors and given that the patient will work on one or a limited set of behaviors (depending on deficits detected by the surveys' responses), this might not accurately reflect the overall MI success. However, prespecifying self-defined goals with the interventionist should, at least partially, counterbalance this shortcoming. Finally, the likelihood of selection bias cannot be excluded; indeed, some participants might not be able to participate due to absence of Internet connectivity. However, this issue can be mitigated by the use of WhatsApp, which does not necessarily require connectivity to perform a video call (i.e., this function can be covered by using mobile phone data only).

3.1 | Progress to date

The protocol described has proven to be feasible based on our first enrollments. To date, we have collected data on 10 patient-caregiver dyads over nearly 2 months. There have not been delays due to the COVID-19 pandemic. We have noticed a high participation rate, and patients in the intervention arms have been enthusiastic about this new form of education.

3.2 | Lessons learned

During the MI training and in the early phases of this trial, we learned some lessons that will help future work. At the end of the MI training, in which each interventionist performed the intervention with "real" patients and caregivers (not included in the study), we experienced common positive feedback from patients, caregivers, and interventionists. Patients shared pleasant feelings of empathy and intimacy with the nurse interventionists, whereas the caregivers reported feelings of relief and support because their caregiving responsibilities had been shared with the interventionist. Finally, the interventionists felt enthusiastic after noticing that the patients were more receptive and compliant after the sessions. With the first 10 patients enrolled, we have found that the study protocol works well, and we have not needed to modify the protocol. We have not experienced any issues with scheduling and conducting the intervention via video calls with participants. Both patients and caregivers were able to manage the video calls and were satisfied with this form of care, maybe because most of them had become familiar with video calls during COVID-19 pandemic.

4 | CONCLUSION

The prevalence of HF is increasing worldwide, and healthcare systems struggle to provide the necessary care to affected people and their families. With the aging of the population, these costs are certain to increase. Since self-care and caregiver contribution to self-care can improve patient outcomes, interventions aimed at improving self-care represent a priority. Face-to-face MI-based education effectively improves self-care, but there is currently no evidence regarding whether it also works via remote technology. We seek to provide an answer with this new trial.

AUTHOR CONTRIBUTIONS

All authors have substantially contributed to the conception and design of the work, have drafted and critically revised the manuscript, have approved the final version to be published, and agreed to be accountable for all aspects of the work.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data will be available by contacting the corresponding author.

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