ORIGINAL RESEARCH ARTICLE

Motivational interviewing to improve self-care in heart failure patients (MOTIVATE-HF): a randomized controlled trial

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Abstract

Aims   Self-care, an essential component of heart failure (HF) treatment, is inadequate in most patients. We evaluated if motivational interviewing (MI) (i) improves patient self-care maintenance (primary endpoint; e.g. taking medications), self-care management (e.g. responding to symptoms) and self-care confidence (or self-efficacy) 3 months after enrolment; (ii) changes self-care over 1 year, and (iii) augments patient self-care if informal caregivers are involved.
Methods and results   Parallel randomized controlled trial (1:1:1). A sample of 510 patients (median 74 years, 58% male) and caregivers (median 55 years, 75% female) was randomized to Arm 1 (MI only for patients), Arm 2 (MI for patients and caregivers), or Arm 3 (usual care). The intervention in Arms 1 and 2 consisted of one face-to-face MI session with three telephone contacts. Self-care was evaluated with the Self-Care of HF Index measuring self-care maintenance, management, and confidence. Scores on each scale range from 0 to 100 with higher scores indicating better self-care; ≥70 is considered adequate. At 3 months, self-care maintenance improved 6.99, 7.42 and 2.58 points in Arms 1, 2, and 3, respectively (*P* = 0.028). Self-care maintenance was adequate in 18.4%, 19.4%, and 9.2% of patients in Arms 1, 2 and 3, respectively (*P* = 0.016). Over 1 year, self-care maintenance, management, and confidence scores in Arms 1 and 2 were significantly higher than in Arm 3 in several follow-ups. Over 1 year, Arm 2 had the best scores in self-care management.
Conclusions   MI significantly improved self-care in HF patients. Including caregivers may potentiate the effect, especially in self-care management. ClinicalTrial.gov, identifier: NCT02894502.

Keywords   Motivational interviewing; Self-care; Heart failure; Caregivers

Received: 8 January 2020; Revised: 2 March 2020; Accepted: 3 April 2020
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Introduction

To improve heart failure (HF) outcomes (e.g. quality of life), it is essential that patients adopt self-care behaviours such as adhering to the medication, dietary, and physical activity regimen.[1] Self-care of HF is defined as those behaviours that keep HF stable (self-care maintenance), facilitate symptom perception, and control signs and symptoms (self-care management).[2] A metasynthesis of individual patient data demonstrated that HF self-care reduces mortality and hospitalization risk and improves quality of life.[3]

Despite the evidence supporting the benefits of HF self-care,[4] patients find it difficult to perform self-care, and self-care is often insufficient.[5–7] Investigators are struggling to find interventions that can effectively improve self-care. Recent trials of various interventions have had inconsistent results.[8,9] Authors of a systematic review exploring the mechanisms by which HF self-care interventions are effective recommended that effective interventions need a supportive relationship with the healthcare provider, an individualized approach, efforts to promote self-efficacy, practical information on how to perform self-care, and support from others

(e.g., informal caregivers).[10] All these principles are emphasized in motivational interviewing (MI).

MI is a goal-directed and client-centred counselling method[11] that helps people to change their behaviours by exploring and resolving ambivalence (e.g. understanding the importance of exercising but not doing so). The key elements of MI are expressing empathy, developing discrepancy, avoiding arguments, supporting self-efficacy, maintaining a focus on the client to develop a shared plan.[11] Several systematic reviews of trials have demonstrated that MI is effective for behaviour change.[12,13] MI has also been used to improve HF self-care, but trials conducted to date[14–16] have used small samples and had mixed results. Further, studies to date have not involved informal caregivers despite recent studies showing that caregivers have a key role in contributing to patient self-care.[17,18] None of the MI studies collected data on self-care over 12 weeks and evaluated if including informal caregivers in the MI intervention could improve HF patient outcomes. Therefore, the aims of this trial were to (i) evaluate if MI performed with patients improves their self-care maintenance (primary endpoint), self-care management, and self-care confidence at 3 months; (ii) evaluate changes in self-care over time (3, 6, 9, and 12 months); and (iii) evaluate if an MI intervention that included informal caregivers improves HF patient self-care over and above MI performed solely with patients.

Methods

Trial design

We used a parallel randomized controlled trial with participants (patients and their caregivers) randomized to one of three arms: Arm 1, MI only for patients; Arm 2, MI for patients and caregivers; Arm 3, standard care. The complete protocol of this trial, entitled *Motivational interviewing to improve self-care in heart failure patients* (MOTIVATE-HF) has been published elsewhere.[19]

Participants

Participants included HF patients with insufficient self-care and their caregivers. Patients were eligible if they (i) had a diagnosis of HF[1] classified as New York Heart Association (NYHA) Class II–IV; (ii) had evidence of insufficient self-care determined with a score of 0, 1, or 2 on at least two items of the self-care maintenance or self-care management scales of the Self-Care of HF Index v.6.2 (SCHFI v.6.2)[20,21]; and (iii) were willing to sign the informed consent form. We excluded patients who had a myocardial infarction during the last 3 months, had severe cognitive dysfunction with a score between 0 and 4 on the Six-item Screener,[22]

lived in a residential facility where self-care was not expected, or had an informal caregiver who was not willing to participate in the study. Informal caregivers were eligible if they were designated by the patients as the primary caregiver. In cases where either the patient or the caregiver was not willing to participate in the study, both were excluded from enrolment; however, after enrolment, if one person dropped out, the other person continued in the study. Participants were enrolled at three centres in the Lazio region of Italy: one hospital, one outpatient, and one community setting.

Intervention and control

The intervention was delivered by 18 registered nurses, six in each centre, who attended a 40 h training course on MI and HF evidence-based care. These 18 registered nurses were 13 female and eight male nurses, 11 with a bachelor degree in nursing and nine with a nursing diploma. The mean age of the nurses was 38.33 (SD, 10.4; ranges, 25–59) years. Their experience working in cardiology was 5.7 years (SD, 3.5; ranges, 1–13). Six had a master's degree without a specialty in cardiology. The intervention consisted of a face-to-face MI intervention (about 60 min in length) followed by three telephone contacts (within 2 months from enrolment). During the MI session, the interventionists applied the principles of MI[11] with the patient (Arm 1) or the patient and caregiver (Arm 2). Specifically, the interventionist (i) developed a supportive and empathic relationship; (ii) developed discrepancy between the current and the desirable evidence-based behaviours needed to keep HF stable and respond to symptoms; (iii) were respectful of patient/caregiver preferences and avoided arguing or confrontation; (iv) involved the patient/caregiver in problem solving; and (v) stimulated patient/caregiver self-care self-efficacy.[11] During the telephone contacts included in the intervention, the interventionists used the same principles to further support HF evidence-based behaviour changes. In general, the interventionists continued to be emphatic with participants, especially with those expressing more difficulties in behaviour changes; complimented with participants even for small behaviour changes; and answered to questions related to HF and its treatment. These telephone contacts lasted on average 15 min. In Arm 2, MI and telephone contacts for patients and caregivers were performed separately. Patients and caregivers in the control group received standard care that consists of medical check-ups every 6–12 months depending on their HF condition and information given orally on HF and its treatment. The same standard care was also provided to patients and caregivers in Arms 1 and 2. All participants in the three arms received informational material focused on HF self-care.

Procedures

The study was approved by the Institutional Review Board of the University of Rome Tor Vergata. Research assistants, who were all registered nurses trained in the study protocol, approached potential participants at each centre, explained the study aims, and asked for consent to participate in the study. Both members of the dyad had to agree to participate in the study. After patients and caregivers signed the consent form, the research assistants screened the patients with the SCHFI v.6.2 and the Six-item Screener according to the study protocol. Then, when participants were found to qualify, the battery of instruments was administered to both patients and caregivers.[19] At baseline and follow-up, instruments were administered separately to patients and caregivers, and collaboration between them in completing the instruments was not allowed. Follow-up data collection was done by telephone at 3, 6, 9, and 12 months after enrolment.[19] At baseline and all follow-up intervals, research assistants were blinded to the study arms, as were the investigators. Participants were not blinded to study arm.

Outcomes

The primary endpoint of the study was the score on the self-care maintenance scale of the SCHFI v.6.2[20,21] 3 months after enrolment. The SCHFI v.6.2 is a psychometrically sound self-report instrument that measures HF self-care with three separate scales: self-care maintenance, self-care management, and self-care confidence. Each scale produces a standardized score ranging from 0 to 100 with higher scores indicating better self-care. The self-care management scale was completed only if the patient reported HF symptoms (e.g. dyspnoea) in the last month. On each scale, a score ≥70 indicates adequate self-care. Self-care management and self-care confidence were used as secondary outcomes.[19] Both primary endpoint and secondary endpoint were measured at 3, 6, 9, and 12 months from enrolment to evaluate change over time. Primary and secondary endpoints were not modified after trial commencement.

Sample size

A total sample of 240 patients (80 per each arm) was estimated to achieve 83% power to detect an 8% difference in self-care maintenance of patients at 3 months with the MI intervention (Arms 1 and 2) vs. patients in usual care (Arm 3). In order to account for an estimated 50% attrition rate, we planned to recruit 480 patients. In considering the evaluation of MI on caregivers (Arm 2), group sample sizes of 80 and 80 were estimated to achieve 71% power to detect a difference of 8 points of self-care with a standard deviation of 20 and a significance level of 0.05 using a two-sided two-sample t-test.

Randomization

Randomization was done in a 1:1:1 ratio in the three arms of the study. To achieve a balance among the three arms, a block randomization scheme of 15 patient and caregiver dyads was generated with Microsoft Excel. These blocks were randomly placed into a list including 400 random assignments for each enrolling centre. Then, a research assistant prepared three containers, one for each centre, each of which included 400 envelopes. In each envelope, the research assistant placed one group assignment (i.e. Arm 1, Arm 2, or Arm 3). The three containers were given to another research assistant; the research assistant who prepared the containers was no longer involved in the study. Each time that a patient and caregiver dyad was enrolled, the second research assistant opened an envelope to identify the assignment arm. He then called the enrolling centre to inform the interventionist about which intervention to perform. If the dyad was assigned to Arm 3 (the control group), the research assistant did not call the interventionist. Blinding was successful because the first research assistant who prepared the envelopes for the three centres did not know any dyads; the second research assistant was not able to influence the group assignment; the interventionists did not collect any data; and the research assistants who collected the data did not know the group assignment.

Treatment fidelity

Treatment fidelity of the intervention (Arms 1 and 2) was evaluated at two levels. At the first level, we evaluated MI with the Motivational Interviewing Treatment Integrity (MITI) Scale.[23] The MITI is a behavioural coding system that evaluates the technical and relational components of MI using a score from 1 to 5, with a higher score indicating better MI quality. An ideal technical quality score is ≥3, and an ideal relational component score is ≥4. For this assessment, we evaluated 48 randomly selected audiotapes of Arm 1 and 97 audiotapes of Arm 2 (50 patient audiotapes and 47 caregiver audiotapes). The mean score for the technical component of all analysed MI interventions was 2.4 (SD, 0.5); the mean score of the relational component was 2.8 (SD, 0.8). At the second level, we checked if the three telephone calls had been done during the 2 month interval as planned. All the telephone calls had been done.

Statistical methods

Baseline characteristics were summarized by arm as medians and quartiles or as means and SDs for continuous

data and as absolute numbers and their frequencies for categorical data. The change in self-care scores during follow-up were reported as the difference/delta (Δ) of self-care score at each follow-up time (T1, T2, T3, and T4) minus the baseline self-care score (T0). The primary end-point was evaluated using a two-sample *t*-test comparing the delta of self-care score in Arms 1 and 2 with respect to the control Arm 3.

Changes over time (from baseline to T4) in self-care maintenance, management, and confidence were analysed with mixed models to account for drop-out and missing values including, as a response variable, the self-care maintenance, management, and confidence scores available from T0 to T4 for each patient in the study arm. The dependence between self-care maintenance, management, and confidence on the same subject was accounted for by the inclusion of a random

Figure 1 Participant flow. ITT, intention to treat.
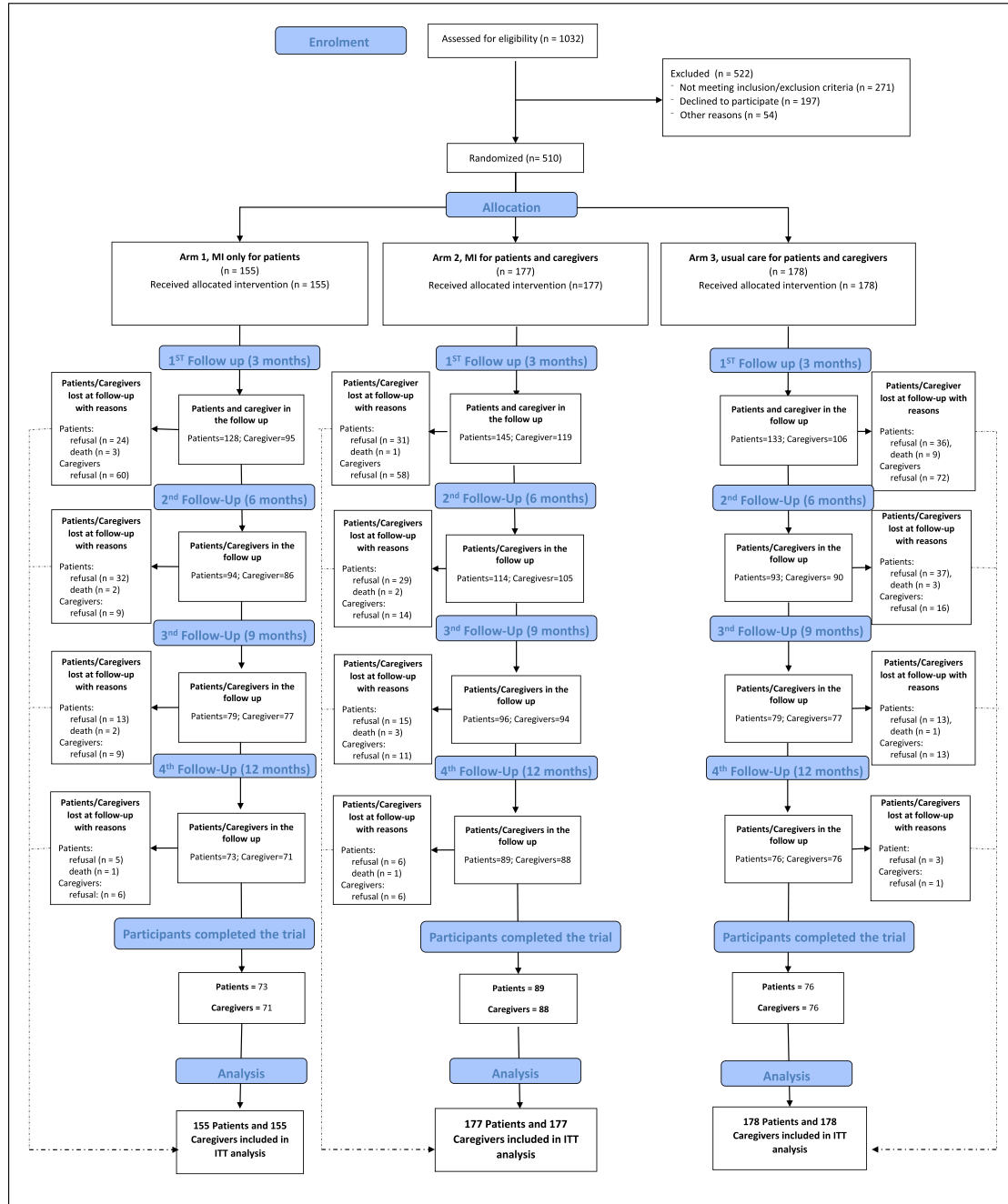
intercept in the models. The models included as regressors the visit number as a continuous variable, the randomization arm, the interaction between the arm, and visit number. The same models were also adjusted for patient age, sex, income, cohabitation with the caregiver, NYHA class, Charlson Comorbidity Index[24] and the Montreal Cognitive Assessment (MoCA)[25] scores, time since diagnosis, number of medications, and self-care confidence score at baseline to account for potential confounders. The percentage of patients with adequate self-care maintenance, management and confidence (scores ≥70) were evaluated using χ^2 test with one degree of freedom.

Results

Participant flow

Between June 2014 and October 2018, 1032 patients and caregiver dyads were assessed for eligibility. Of these, 522 dyads were excluded after assessment for the following reasons: n = 271 patient and caregiver dyads did meet the inclusion/exclusion criteria (n = 48 patients were in NYHA I; n = 28 patients did not have insufficient self-care; n = 47 patients had had a myocardial infarction during the preceding 3 months; n = 5 patients had severe cognitive impairment; n = 97 caregivers refused to participate although patients wanted to do so; n = 46 patients lived in residential settings); n = 197 patients declined to participate; n = 54 declined for other unknown reasons (*Figure 1*). All of the 510 enrolled and randomized HF patient and caregiver dyads were included in the intention-to-treat analyses (*Figures 1*). A total of 406 patients who completed T1 (3 months from enrolment) were used in the analysis of the primary endpoint. Attrition was 20.4% in patients and 37.2% in caregivers. Participants who completed the full 12 month trial included 238 HF patients and 235 caregivers (*Figure 1*).

Participants' characteristics

Patients' and caregivers' baseline characteristics, separated by study arm, are shown in *Table 1*. Patients had a median age of 74 years, with a prevalence of men (58%). Most of them were retired (76.2%). Caregivers had a median age of 55 years and were mostly women (75.5%). Most patients were in NYHA Class II (61.9%) and had an ischemic HF aetiology (33.6%). At baseline, self-care scale scores were inadequate; the mean self-care maintenance, management, and confidence scale scores were 45.55, 39.73, and 51.42, respectively (Supporting information, Figures *S1–S3*). Few had adequate self-care scores (5%, 6.5%, and 20.5% in self-care maintenance, management, and confidence, respectively; *Table 1*). Patient and caregiver characteristics and patient

self-care scores were not different among the three arms except for the variable 'caregiver living with patient'. In Arm 2, a higher percentage of caregivers were living with the patients. When Arms 1 and 2 were combined, this difference faded.

Self-care maintenance (primary endpoint), management, and confidence at T1

At 3 months after enrolment (T1), the improvement in the self-care maintenance scores (primary endpoint) from baseline was higher in Arms 1 and 2 than in Arm 3 (*Table 2*).

Specifically, the improvement was 6.99 (95% CI, 3.3; 10.6), 7.42 (95% CI, 3.9; 10.9), and 2.58 points in Arms 1, 2, and 3, respectively (P = 0.0282; *Table 2, Figure S1*). Moreover, at T1, 18.4% and 19.4% of patients in Arms 1 and 2, respectively, had adequate self-care maintenance scores (score ≥70), while in Arm 3, only 9.2% of patients had adequate self-care maintenance (P = 0.0162). At T1, also the self-care management scores improved significantly (*Table 3 and Figure S2*). Specifically, Arm 1 improved 12.33 points (95% CI, 7.7; 16.9), Arm 2 improved 15.25 points (95% CI, 10.9; 19.6), and Arm 3 improved only 7.72 points. The improvements in self-care maintenance and self-care management score can be considered clinically significant. No significant improvement was observed regarding self-care confidence scores at T1.

Changes in self-care maintenance, management, and confidence over time

Self-care maintenance, management, and confidence scale scores during follow-up are reported in *Figures S1–S3*. We generally found a higher improvement in self-care maintenance scale scores in Arms 1 and 2 with respect to Arm 3 (*Table 2*). Also, the percentage of patients with adequate self-care maintenance (scores ≥70) was significantly higher in Arms 1 and 2 than Arm 3 at each follow-up time, with, on average, 10% more patients with adequate self-care maintenance at each follow-up interval (*Table 2*).

The improvement in self-care management scale scores in the three arms was significantly higher in Arms 1 and 2 than Arm 3 at T1 and T2 (P = 0.028 and P = 0.0076, respectively) but not at T3 and T4. An average of 10% more patients reported self-care management adequacy in Arms 1 and 2 with respect of Arm 3, but the difference was significant only at T2 (*Table 3*).

Regarding changes in self-care confidence scale scores, no significant differences were observed in the three arms at T1 and T4, however, at T2 and T3, patients in Arms 1 and 2 had better improvement in self-care confidence than patients in Arm 3 (P = 0.037 and 0.031, respectively). A similar pattern was observed in the number of patients who became

Table 1 HF patients' and caregivers' characteristics at baseline (*n* = 510)

Characteristics	Arm 1: MI only for patients (*n* = 155)				Arm 2: MI for patients and caregivers (*n* = 177)				Arm 3: Usual care for patients and caregivers (*n* = 178)			
	Patients		Caregivers		Patients		Caregivers		Patients		Caregivers	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Age	74	65–82	54	44–64	73	64–81	57	44–68	75	64–83	53	42–64
Time with HF (months)	36	24–72	—	—	36	15–84	—	—	48	20–96	—	—
N. of medications	6	4–8	—	—	7	5–9	—	—	6	4–8	—	—
CCI scores	2	2–4	—	—	2	2–4	—	—	2	1–4	—	—
MoCA Scores	25	21–27	—	—	26	19–28	—	—	24	18–27	—	—
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Self-care maintenance scores	45.72	15.23	—	—	45.98	16.35	—	—	44.98	14.61	—	—
Self-care management scores[a]	41.75	17.94	—	—	37.62	18.43	—	—	40.32	16.40	—	—
Self-care confidence scores	51.51	20.94	—	—	52.09	21.24	—	—	50.66	22.56	—	—
N. of medications	6.39	2.66	—	—	7.04	2.91	—	—	6.47	3.07	—	—
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Patients adequate in self-care[b]												
Self-care maintenance	5	3.2	—	—	12	6.8	—	—	8	4.5	—	—
Self-care management[a]	9	9.0	—	—	6	4.6	—	—	8	6.5	—	—
Self-care confidence	29	18.7	—	—	37	21.0	—	—	38	21.4	—	—
Sex (male)	80	51.6	36	24.0	107	60.5	42	23.9	109	61.2	45	25.4
Marital status												
Married	81	52.3	108	72.5	123	69.5	124	70.5	112	62.9	129	72.9
Widower	55	35.5	6	4.0	44	24.9	3	1.7	51	28.7	3	1.7
Divorced	10	6.5	10	6.7	4	2.3	14	8.0	6	3.4	12	6.8
Single	9	5.8	25	16.8	6	3.4	35	19.9	9	5.1	33	18.6
Education (high schools or higher)	41	26.4	90	59.6	44	24.8	86	49.4	47	26.4	99	56.2
Employment (retired)	119	76.8	33	22.0	137	77.8	50	28.4	131	74.0	52	29.4
Income												
Not the necessary to live	7	4.5	—	—	7	4.0	—	—	8	4.5	—	—
The necessary to live	131	84.5	—	—	138	78.0	—	—	141	79.2	—	—
More than the necessary to live	17	11.0	—	—	32	18.1	—	—	29	16.3	—	—
Caregiver living with patient	—	—	76	51.0	—	—	126	71.6	—	—	104	58.8
NYHA Class												
II	98	63.2	—	—	108	61.7	—	—	107	60.8	—	—
III	49	31.6	—	—	55	31.4	—	—	56	31.8	—	—
IV	8	5.2	—	—	12	6.9	—	—	13	7.4	—	—

MI, Motivational Interviewing; IQR, interquartile range; HF, heart failure; CCI, Charlson Comorbidity Index; MoCA, Montreal Cognitive Assessment; All patient and caregiver characteristics were not statistically different among the three Arms as well as between the composite group (Arms 1 and 2) and the control group (Arm 3).
[a]Self-care management score can be computed only if patients have had HF symptoms in the last month (n = 354): symptomatic patients were n = 100 in Arm 1, n = 130 in Arm 2, and n = 124 in Arm 3; all percentages in the line are referred to the number of symptomatic participants per each Arm.
[b]Patients adequate in self-care were those with a score ≥70 at self-care maintenance, self-care management and self-care confidence scales.

adequate in self-care confidence during the follow-up period (*Table 4*).

Model-based trends over time (from baseline to T4) in self-care maintenance, management, and confidence scale scores are shown in *Figure 2* All arms improved their scores in self-care maintenance, management, and confidence, with Arms 1 and 2 having generally a higher slope than Arm 3. Specifically, over the year of the observation, in self-care maintenance, Arm 1 improved significantly more than Arm 3 (*P* = 0.0464), and the difference between Arms 2 and 3 improved on the edge of statistical significance than Arm 3 (*P* = 0.0557). In self-care management, Arm 1 did not improve significantly when compared with Arm 3 (*P* = 0.0934), but Arm 2 improved significantly more that Arm 3 (*P* = 0.0047). Finally, for self-care confidence, Arms 1 and 2 did not differ in their

improvement when compared with Arm 3 (*P* = 0.1728 and *P* = 0.2894, respectively). Results of these models were consistent even after adjusting for other variables (patient age, sex, income, cohabitation with caregiver, NYHA class, Charlson Comorbidity Index and MoCA score, time since diagnosis, number of medications, and self-care confidence scale score at baseline).

Discussion

In this study, we demonstrated that MI was effective in improving not only self-care maintenance after 3 months from enrolment (primary endpoint) but also self-care management. Also, improvements in self-care maintenance, management,

Table 2 Self-care maintenance changes and self-care maintenance adequacy during follow-up

Variable	N	Arm 1: MI only for patients	Arm 2: MI for patients and caregivers	Arm 3: Standard of care	Difference (95% CI)[a]	P value
Δ in Self-care maintenance scores[b]		Mean (SD)	Mean (SD)	Mean (SD)		
T1	363	6.99 (19.62)	7.42 (20.17)	2.58 (18.26)	4.63 (0.5;8.76)	0.0282
T2	293	9.6 (18.94)	10.15 (22.25)	4.69 (21.73)	5.21 (−0.13;10.55)	0.0558
T3	252	13.84 (16.5)	15.96 (16.92)	7.81 (20.96)	7.18 (1.88;12.49)	0.0083
T4	238	21.19 (16.71)	18.84 (20.74)	14.65 (18.89)	5.25 (0.05;10.45)	0.0480
Patients adequate in self-care maintenance (score ≥70)[c]		N (%)	N (%)	N (%)		
T1	363	21 (18.4)	25 (19.4)	11 (9.2)	9.8 (2.6;16.9)	0.0162
T2	293	20 (22)	23 (20.7)	9 (9.9)	11.4 (3.1;19.7)	0.0181
T3	252	15 (19)	20 (21.3)	6 (7.6)	12.6 (4.3;21)	0.0117
T4	238	24 (32.9)	31 (34.8)	14 (18.4)	15.5 (4.2;26.9)	0.0138

CI, confidence interval; MI, motivational interviewing; SD, standard deviation.
[a]The difference is between Arms 1 and Arm 2 vs. Arm 3.
[b]Δ Self-care maintenance scores. The columns for each arm report the delta (Δ) of the self-care maintenance score computed subtracting the self-care maintenance score at baseline from the self-care maintenance score at each follow-up time (T1, T2, T3, and T4).
[c]In each column is reported the number and percentage of patients with adequate self-care maintenance (scores ≥70) at each follow-up time (T1, T2, T3, and T4). Comparisons between Arms 1 and 2 regarding self-care maintenance scores and self-care maintenance adequacy were not statistically significant.

and confidence were evident in the two active intervention groups over time. These findings are important because modifying self-care behaviours is not easy in HF, and a previous study found an improvement in self-care maintenance at 3 months only after adjusting for confounding variables.[14]

At T1, we observed a statistically significant improvement in self-care maintenance and management that was also clinically significant. In fact, the developers of the SCHFI v.6.2[26] defined half SD as a clinically significant improvement on the SCHFI v.6.2 scales. In our study, half SD was 7.6 points for self-care maintenance and 8.8 points for self-care management. Considering these values, we obtained a clinically significant effect for self-care maintenance, which improved

on average 6.99 and 7.42 points in Arms 1 and 2 respectively, and a clinically significant effect for self-care management, which improved 12.33 and 15.2 points in Arms 1 and 2, respectively.

In this study, we evaluated the effect of MI over a 1 year interval. Unexpectedly, we observed a mixed and long-lasting effect of MI on self-care maintenance, management, and confidence. For example, MI had a significant effect on self-care maintenance at all follow-up intervals, a significant effect on self-care management at T2, and a significant effect at T2 and T3 on self-care confidence. These results were partially confirmed when we applied the mixed model analysis from baseline to T4 in which we controlled

Table 3 Self-care management changes and self-care management adequacy during follow-up

Variable	N	Arm 1: MI only for patients	Arm 2: MI for patients and caregivers	Arm 3: Standard of care	Difference (95% CI)	P value
Δ in Self-care management scores[a]		Mean (SD)	Mean (SD)	Mean (SD)		
T1	152	12.33 (15.29)	15.25 (16.94)	7.72 (15.87)	6.29 (0.68;11.9)	0.0284
T2	110	13.53 (23.18)	18.86 (24.13)	4.84 (18.69)	11.69 (3.21;20.18)	0.0076
T3	90	24.14 (23.11)	21.91 (22.16)	14.44 (16.54)	8.49 (−0.01;16.99)	0.0503
T4	89	18.17 (19.59)	26.72 (23.16)	15 (18.76)	7.58 (−1.52;16.69)	0.1009
Patients adequate in self-care management (scores ≥ 70)[b]		N (%)	N (%)	N (%)		
T1	176	15 (29.4)	16 (22.5)	8 (14.8)	10.6 (−1.6;22.8)	0.1186
T2	145	13 (28.3)	13 (23.6)	3 (6.8)	18.9 (7.6;30.2)	0.0088
T3	126	17 (41.5)	12 (26.7)	8 (20)	13.7 (−2.2;29.6)	0.1154
T4	113	11 (29.7)	12 (30.8)	6 (16.2)	14 (−1.7;29.8)	0.1086

CI, confidence interval; MI, motivational interviewing; SD, standard deviation.
[a]Δ Self-care management scores. The columns for each arm report the delta (Δ) of the self-care management score computed subtracting the self-care management score at baseline from the self-care management score at each follow-up time (T1,T2,T3, and T4).
[b]In each column is reported the number and percentage of patients with adequate self-care management (scores ≥70) at each follow-up time (T1, T2, T3, and T4). Comparisons between Arm 1 and Arm 2 regarding self-care management scores and self-care management adequacy were not statistically significant.

Table 4 Self-care confidence changes and self-care confidence adequacy during follow-up

Variable	n	Arm 1: MI only for patients	Arm 2: MI for patients and caregivers	Arm 3: Standard of care	Difference (95%CI)	P value
Δ Self-care confidence scores[a]						
T1	363	6.49 (21.59)	5.82 (24.11)	3.43 (19.98)	2.7 (−1.91;7.32)	0.2495
T2	292	7.39 (23.58)	6.62 (28.66)	0.06 (25.93)	6.91 (0.41;13.41)	0.0374
T3	251	17.45 (24.02)	16.02 (22.92)	9.85 (22.94)	6.83 (0.63;13.02)	0.031
T4	237	17.67 (20.73)	15.48 (27.28)	12.51 (27.56)	3.96 (−3.36;11.29)	0.2865
Patients adequate in self-care confidence (scores ≥ 70)[b]		N (%)	N (%)	N (%)		
T1	364	34 (29.8)	37 (28.5)	27 (22.5)	6.6 (−2.8;16)	0.1821
T2	293	23 (25.3)	32 (28.8)	13 (14.3)	12.9 (3.5;22.4)	0.0152
T3	252	25 (31.6)	34 (36.2)	15 (19)	15.1 (3.9;26.3)	0.0145
T4	238	31 (42.5)	35 (39.3)	23 (30.3)	10.5 (−2.3;23.3)	0.1194

CI, confidence interval; MI, motivational interviewing; SD, standard deviation.
[a]Δ Self-care confidence scores. The columns for each arm report the delta (Δ) of the self-care confidence score computed subtracting the self-care confidence score at baseline from the self-care confidence score at each follow-up time (T1, T2, T3, and T4).
[b]In each column is reported the number and percentage of patients with adequate self-care confidence (scores ≥70) at each follow-up time (T1, T2, T3, and T4). Comparisons between Arms 1 and 2 regarding self-care confidence scores and self-care confidence adequacy were not statistically significant.

for missing data and confounding variables. This analysis showed that, over 1 year, our intervention effectively improved patient self-care maintenance even if the caregiver in the same dyad did not receive the intervention (Arm 1). But, for self-care management, MI was only effective if it was also performed with caregivers (Arm 2). This finding reinforces our belief that HF self-care management is more complex than self-care maintenance and is facilitated by others.[2] Prior studies that used MI to improve self-care in HF patients found only an improvement in self-care maintenance, management, and confidence[15] at 12 and 8 weeks after enrolment. We demonstrated that MI can affect self-care up to 1 year from the enrolment.

Several potential sources of bias were identified in this study. First, at T1, the patient attrition was 20.4% and this roll to 46.7% at T4. Although high, our attrition rate at T1 was better than similar studies (33%).[14] By T4, when attrition was highest, we compensated for drop-outs and confounders, using a mixed model analysis that confirmed the efficacy of MI on self-care maintenance and management in Arms 1 and 2, respectively. Another source of bias

could be MI quality scores that were lower than desired for the technical and relational components. In spite of this, the MI intervention was effective. Had the intervention quality been better and the dose been higher, we anticipate that the improvement in self-care maintenance, management, and confidence would have been even better. Another potential limitation is that MI is a personalized, tailored approach that is difficult to standardize. Consistent with the method, our interventionists let the patients decide which self-care behaviour to address during the intervention (e.g. physical activity and diet). In spite of these limitations, as we recruited patients from different healthcare settings and our inclusion and exclusion criteria were not strict, the results of this study may have good external validity.

We believe that this study has important clinical implications. Because the MI approach was useful in improving self-care and self-care can improve patient outcomes, MI could become an inexpensive tool to improve HF patient outcomes. However, we discovered that MI is not easy to perform with adequate technical and relational skills. In the

Figure 2 Model-based self-care maintenance (A), self-care management (B), and self-care confidence (C) scale scores by follow-up time.
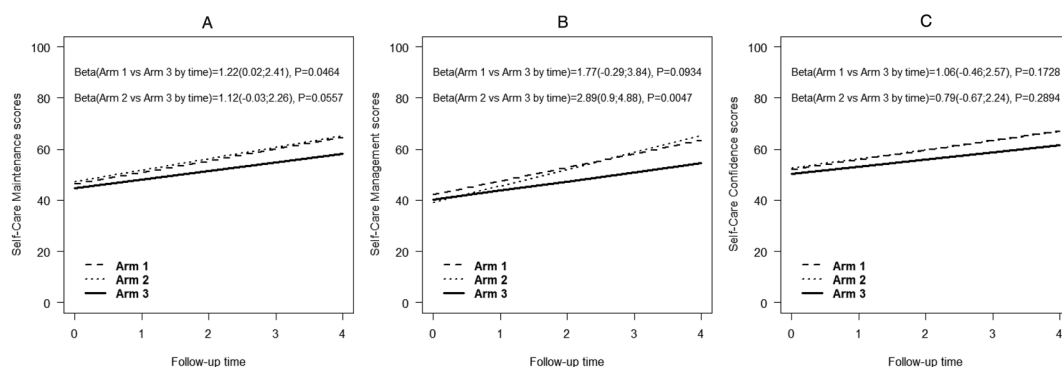
future, we recommend further studies in which interventionists performing MI are trained for longer periods and their MI skills are evaluated before they are allowed to perform the intervention.

In conclusion, we demonstrated that MI performed by a general population of trained nurses was effective in significantly improving self-care of adults with HF. Including caregivers may augment the effectiveness of an MI intervention in this population, especially in self-care management.

Acknowledgements

Conflict of interest

None declared.

Funding

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Box-plot on Self-Care maintenance scale scores (randomized set with available data).
Figure S2. Box-plot on Self-Care management scale scores (randomized set with available data).
Figure S3. Box-plot on Self-Care management scale scores (randomized set with available data).

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