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ORIGINAL RESEARCH ARTICLE

Effectiveness of motivational interviewing on health-service use and mortality: a secondary outcome analysis of the MOTIVATE-HF trial

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Abstract

Aims Intense health-care service use and high mortality are common in heart failure (HF) patients. This secondary analysis of the MOTIVATE-HF trial investigates the effectiveness of motivational interviewing (MI) in reducing health-care service use (e.g. emergency service use and hospitalizations) and all-cause mortality.

Methods and results This study used a randomized controlled trial. Patients and caregivers were randomized to Arm 1 (MI for patients), Arm 2 (MI for patients and caregivers), or Arm 3 (control group). Data were collected at baseline and at 3, 6, 9, and 12 months. Face-to-face MI plus three telephone calls were performed in Arms 1 and 2. The sample consisted of 510 patient (median age 74 years, 58% male patients) and caregiver dyads (median age 55 years, 75% female patients). At 12 months, 16.1%, 17%, and 11.2% of patients used health-care services at least once in Arms 1, 2, and 3, respectively, without significant difference. At 3 months, 1.9%, 0.6%, and 5.1% of patients died in Arms 1, 2, and 3, respectively. Mortality was lower in Arm 2 vs. Arm 3 at 3 months [hazard ratio (HR) = 0.112, 95% CI: 0.014–0.882, P = 0.04]; no difference was found at subsequent follow-ups. Mortality was lower in Arm 1 vs. Arm 3 at 3 months but did not reach statistical significance (HR = 0.38, 95% CI: 0.104–1.414, P = 0.15).

Conclusion This study suggests that MI reduces mortality in patients with HF if caregivers are included in the intervention. Further studies with a stronger intervention and longer follow-up are needed to clarify the benefits of MI on health-care service use and mortality.

Keywords Health service use; Heart failure; Hospitalization; Mortality; Motivational interviewing; Randomized controlled trial

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Introduction

With over 23 million people affected worldwide, heart failure (HF) is currently considered a global pandemic.[1] In the United States, the prevalence of HF is approximately six million individuals,[2] whereas Europe has an additional burden of at least 15 million.[3] By 2030, the proportion of individuals suffering from HF is expected to increase by 46%,[4] accompanied by a rise in costs from the actual average of $30 to $50 billion.[5]

Greater health-care service use is common in patients with HF.[6] The physiopathology of the disease, which is characterized by many potential precipitating factors (e.g. acute decompensation, arrhythmia, renal impairment, infection, and hypertension),[6] leads to high emergency service use and hospitalizations. Over 650 000 presentations to the emergency department occur annually in the United States with about 80% of them ending up with a hospital admission.[7]

Another common problem in HF is the mortality rate. Although therapeutic progress has significantly improved

survival, HF still remains a major cause of death. Mortality is high in patients with HF and, although with regional differences, the rates reach 20–30% at 1 year after the diagnosis, with up to 50% mortality over 5 years of follow-up.[8]

To reduce health-care service use and mortality rates, individuals with HF are recommended to practice self-care, which also includes treatment adherence.[9] Self-care in HF was defined as the naturalistic decision-making process used by patients to maintain the stability of their disease (self-care maintenance), monitor HF signs and symptoms (symptom perception), and manage HF exacerbation (self-care management).[10] Evidence shows that HF self-care improves patient outcomes, such as health-care service use and mortality.[11]

Although its positive effects, patients with HF find it difficult to perform self-care,[12] and researchers are looking for interventions aimed at improving self-care; these interventions may also indirectly reduce health-care service use and mortality rates. One possible intervention is motivational interviewing (MI), which is a patient-centred counselling technique that has been used successfully in patients with chronic conditions.[13] MI evokes and enhances self-efficacy and intrinsic motivation, consequently reducing resistance and promoting a more sustainable health behaviour change.[14]

The *Motivational interviewing to improve self-care in heart failure patients* (MOTIVATE-HF) study[15] is a randomized controlled trial that demonstrated the effectiveness of MI in improving HF patient self-care. In the present study, consistent with the study protocol,[16] we evaluated if MI was effective in improving health-care service use (e.g. emergency service use and hospitalizations) and mortality rates at 3, 6, 9, and 12 months after patient enrolment.

Methods

Study design

The MOTIVATE-HF study is a three-arm, multicentre, parallel randomized controlled trial aimed at evaluating the effect of a MI intervention on HF patient self-care and caregiver contribution to self-care.[16] Data were collected in three Italian health-care centres between June 2014 and October 2018. Patients with HF and their caregivers were randomly assigned to one of the following arms: Arm 1, in which MI was performed only with patients; Arm 2, in which MI was performed with patients and caregivers; or Arm 3, standard of care.

Participants

Eligibility criteria for patients were as follows: (i) a diagnosis of HF; (ii) New York Heart Association (NYHA) functional class $\geq$ II; (iii) inadequate self-care (assessed with a score of 0, 1, or 2 in at least two items of the self-care maintenance or self-care management scales of the Self-Care Heart Failure Index)[17]; and (iv) willingness to participate in the study. Exclusion criteria for patients were as follows: (i) severe cognitive impairment (a score of 0–4 on the six-item screener[18]; (ii) acute coronary syndrome event within the last 3 months; (iii) living in a residential setting (e.g. nursing home); and (iv) caregiver not willing to participate in the study. Eligibility criteria for caregivers were as follows: (i) identification by the patient as the primary caregiver (e.g. the main unpaid individual who provides most of the informal care) and (ii) 18 years old of age or older.

Intervention and control

The intervention began with a face-to-face MI session of about 60 minutes, followed by three telephone calls to reinforce the first intervention. Both during the face-to-face intervention and the telephone calls, the interventionist applied MI principles,[19] to improve patient self-care (in Arms 1 and 2) and caregiver contribution to self-care (in Arm 2). Specifically, the interventionist developed discrepancy (e.g. helping the patient/caregiver to focus on the behaviours that would impede the ability to reach health goals), expressed empathy (e.g. with active listening and an attitude of acceptance), avoided arguing and direct confrontation (e.g. being respectful of patient/caregiver choices or preferences), rolled with resistance (e.g. avoiding confrontation while involving patient and caregiver in problem solving), and supported self-efficacy and optimism (e.g. by verbal persuasion and encouraging focus on past successes). The telephone calls were conducted within 2 months from enrolment, every 2 weeks. During these contacts, which lasted approximately 15 min, the interventionist continued to use an emphatic approach with the participants, particularly with those who reported critical obstacles during the behaviour change process. Patients and caregivers of all three arms were also given informational material on HF management that was consistent with the international guidelines. In Arm 3, the participants received standard care that consisted of medical check-ups every 6–12 months.

Procedures

The study was approved by the Institutional Review Board of the University of Rome Tor Vergata and conducted in line with Good Clinical Practice Guidelines and the Declaration of Helsinki. In the three centres where the participants were enrolled, the nurse research assistants approached potential participants, presented the study, and asked for their participation. In this phase of the study, both patients and their

caregivers had to agree in order to participate. If one member of the dyad did not agree, both patient and caregiver were excluded from the study. Afterwards, patients and caregivers were asked to sign the informed consent form. Patients were screened for self-care adequacy and cognitive impairment with the SCHFI v.6.2 and the six-item screener, respectively. If the self-care level and the cognitive impairment fell within the enrolment criteria, the research assistant administered the battery of the MOTIVATE-HF tools separately to patients and caregivers. After baseline data were collected, participants were randomized to study arms. Research assistants collecting data at baseline and follow-up (3, 6, 9, and 12 months from enrolment) were blinded to the study arm assignment but participants were not.

Outcome measures

The primary outcome of the trial was the level of self-care maintenance at 3 months after enrolment. A number of other outcome variables were measured at baseline and at each follow-up,[16] but for the aim of this study, we considered only patient health-care service use (e.g. emergency service use and hospitalizations) and all-cause mortality. These variables were collected at 3, 6, 9, and 12 months from enrolment by means of a telephone interview. Specifically, research assistants, blinded to study arm assignment, called the caregiver of each patient and asked questions related to patient use of health-care services (emergency services and hospitalizations) due to HF causes (e.g. for dyspnoea) in the preceding 3 months and if the patient had eventually died, regardless of cause. This method of collecting patient data from proxy responders was found to be accurate in prior studies, with higher levels of reliability in the event of non-spousal caregivers[20] and, generally, when the questions addressed objective outcomes (e.g. hospitalizations and use of preventative services).[21] Emergency services use related to other causes besides HF were not considered (e.g. use of emergency services for a bone fracture).

Randomization

Details on the randomizations have been reported elsewhere.[15,16] Briefly, we performed 1:1:1 randomization using a computer-generated randomization list with blocks of 15 patient and caregiver dyads. Three randomization lists with 400 random assignments per centre, sealed in envelopes, were prepared by a research assistant not involved in data collection and analysis. At each centre, each time a patient and caregiver dyad had been enrolled, a different research assistant opened an envelope to identify the assignment of the patient and caregiver dyad to one of the three arms. If the dyad was assigned to Arms 1 or 2, the research assistant notified the interventionist to perform MI and the subsequent telephone contacts with the patient (Arm 1) or with the patient and caregiver dyad (Arm 2). This second research assistant could not influence study arm assignment. The interventionist was not blinded to study arm assignment but did not collect any data.

Treatment fidelity

Treatment fidelity has been reported extensively in prior publications.[15,16] To evaluate whether the interventionists complied with the technical and relational components of MI, we used the Motivational Interviewing Treatment Integrity (MITI) scale, a behavioural coding scheme, that produces a score ranging from 1 to 5 (higher scores represent higher MI quality). For this purpose, we randomly audiotaped 48 face-to-face intervention sessions in Arm 1 and 97 sessions in Arm 2 (equivalent to 50 patient and 47 caregiver audiotapes). The mean technical component score was 2.4 (SD = 0.5), and the mean relational component score was 2.8 (SD = 0.8).[15] We also assessed the extent to which the interventionists were adherent to the protocol regarding the telephone calls. According to the checks performed, all telephone calls had been performed as planned.

Statistical analysis

Health-care service use (emergency service use and hospitalizations) and all-cause mortality among patients were summarized as absolute numbers and frequencies among the three study arms at each follow-up time (3, 6, 9, and 12 months from enrolment). Statistical differences among the three arms in health-care service use and all-cause mortality were assessed at each follow-up using Fisher's exact test.

A longitudinal generalized linear mixed model with logit link was applied to evaluate whether health-care service use was different among the three arms during follow-up to account for drop-out and missing values. The dependence of health-care service use among different visits on the same subject was accounted for by the inclusion of a random intercept and random slope in the models. The model included, as regressors, the visit number as a categorical variable (to account for non-linearity), the randomization arm, and the interaction between the study arm and visit number. Model-based estimates of frequency of use were also computed. The life-table approach was used to estimate survival, and the log-rank test was used to test the null hypothesis of no difference in survival among the three arms.

Unadjusted Cox proportional-hazards regression models were used for investigating the association between treatment arm and all-cause mortality. Proportionality of hazard was evaluated graphically and by Schoenfeld residuals. In

case of non-proportionality, time was split at follow-up time chosen by graphical evaluation in a time-dependent Cox model. Hazard ratios (HRs) with 95% confidence intervals (CIs) for each time interval were reported. SAS Version 9.4 was used for the analysis.

Results

A sample of 1032 of patients and their caregivers was assessed for eligibility, and 510 were enrolled and randomized to the intervention (Arm 1 = MI for patients only; Arm 2 = MI for patients and caregivers) or control group (Arm 3). Baseline characteristics and participants' attrition at each follow-up are presented in the primary study.[15] Briefly, patients (median age = 74 years) were mostly male (58%), retired (76.2%), NYHA Class II (61.9%), and had ischemic HF (33.6%). Caregivers (median age = 55 years) were mostly female (75.5%), not retired (73.5%), and resided with the patient (60%). Among the three arms, participants had comparable sociodemographic and clinical characteristics at baseline, as well as self-care levels. At 3, 6, 9, and 12 months from enrolment, there were 406, 301, 254, and 238 patients in all three arms, respectively. Reasons for loss at each follow-up were due to refusal to continue the study or death.[15]

During the observation period, in total, 25 (16.1%) patients in Arm 1, 30 (17.0%) patients in Arm 2, and 20 (11.2%) patients in Arm 3 used health-care services (emergency service use and hospitalizations) at least once during follow-up. *Table 1* reports data regarding health-care service use among patients in each follow-up visit. Health-care service use ranged from 7.5% to 16.7% with no clear trend in time and no statistical difference among the three arms (P = 0.836 from interaction between arm and visit number in the mixed model). Results of the model are reported in *Table S1*. Model-based estimates of health-care service use among patients are shown in *Figure 1*.

In total, 28 patients died during the 12 months of the study. At T1 (3 months from enrolment), three (1.9%) patients, one (0.6%) patient, and nine (5.1%) patients had died in Arms 1, 2, and 3, respectively (Fisher test P = 0.026). The survival curve in the year of follow-up is shown in *Figure 2*. Survival estimates were lower in the control arm (Arm 3) with respect to the other arms (Arms 1 and 2), but the log-rank test considering the whole follow-up was not statistically different among the three study arms (P = 0.2886). As the hazard proportionality among the three arms was not respected (global Schoenfeld test P = 0.042), we split time at 3 months in a time-dependent Cox model. By the Cox model, we found that mortality was much lower in Arm 2 with respect to Arm 3 in the first 3 months (HR = 0.112, 95% CI: 0.014–0.882, P = 0.038), while there was no difference in the following months (P = 0.699). A suggestion of lower mortality in Arm 1 with respect to Arm 3 was also present in the first 3 months, without reaching statistical significance (HR = 0.383, 95% CI: 0.104–1.414, P = 0.155, *Table 2*).

Discussion

The aim of this secondary outcome analysis was to determine if a MI intervention, which was found to be effective in improving self-care in patients with HF, was also effective in reducing health-care service use and patient mortality. We found that MI had no effect on health-care service use, whereas a significant effect on mortality was detected. This finding is noteworthy because it supports the use of strategies other than medical treatments to improve survival in HF.

We believe that the substantial reduction of mortality in patients with HF at 3 months may be attributable to improvements in self-care behaviours. In our primary study,[15] we found that self-care maintenance (primary outcome) improved significantly at 3 months after enrolment, and this improvement was also sustained at the remaining follow-ups (at 6, 9, and 12 months, respectively).

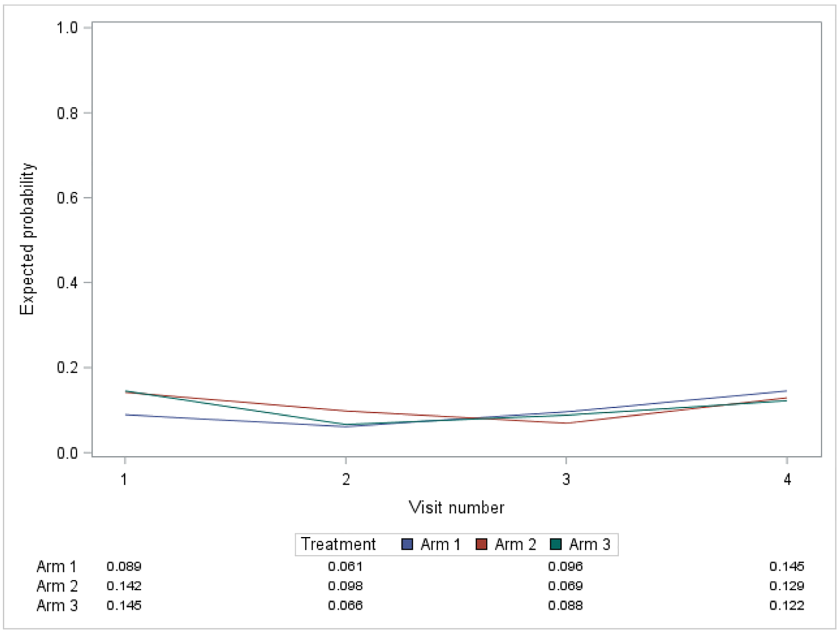
Indeed, the association between better self-care and improved mortality is not new in the literature.[11] However, there is a general lack of evidence on the impact of MI on HF mortality. To the best of our knowledge, the only study investigating this relationship is the trial by Vaillant-Roussel *et al.*[22] who found a lower number of deaths in the intervention group compared with those in the control group, but this difference was not statistically significant. The remaining evidence is found in reviews and meta-analyses,[23,24] which

Table 1 Health-care service use among patients with heart failure at each follow-up

	Arm 1			Arm 2			Arm 3			
Follow-up	Number of patients with available information	Number of health-care services	%	Number of patients with available information	Number of health-care services	%	Number of patients with available information	Number of health-care services	%	Fisher's exact test
1	86	9	10.5	103	17	16.5	90	15	16.7	0.4097
2	80	6	7.5	91	11	12.1	77	7	9.1	0.6136
3	73	8	11.1	83	7	8.4	68	8	11.8	0.7614
4	62	10	16.1	73	11	15.1	62	10	16.1	1

Follow-up numbers 1, 2, 3, and 4 correspond to 3, 6, 9, and 12 months from enrolment, respectively. Arm 1 = motivational interviewing (MI) only for patients; Arm 2 = MI for patients and caregivers; and Arm 3 = standard of care.

Figure 1 Expected probabilities of health-care service use among patients with HF by treatment arm. Note. Visits number 1, 2, 3 and 4 correspond to 3, 6, 9, and 12 months from enrolment, respectively. Arm 1 = motivational interviewing (MI) only for patients; Arm 2 = MI for patients and caregivers; and Arm 3 = standard of care.



agree on the positive effect of educational interventions on mortality; however, the trials adopted approaches that are substantially different from MI.

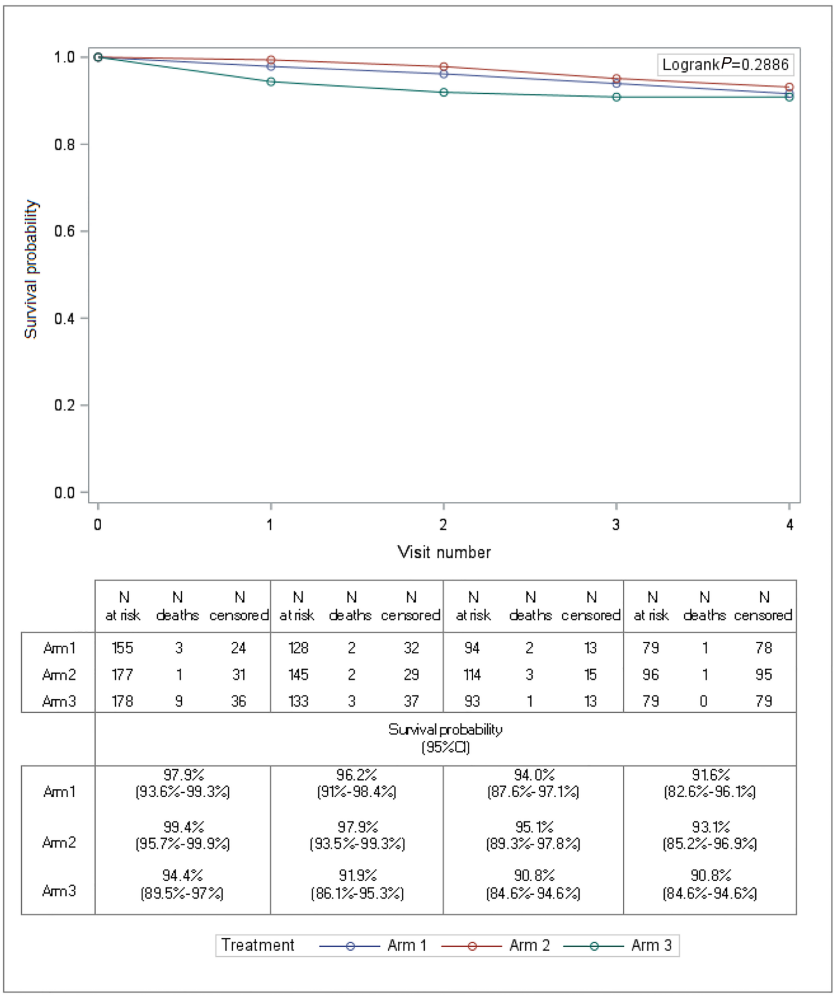
Taken together, the experimental arms of our study had lower mortality rates, but this reduction was statistically significant only in the group in which both patients and caregivers received the intervention. This finding is important because it means that this intervention might be more effective if performed in dyads than in patients alone. The presence of the caregivers may act as a protective factor towards the patients. We hypothesize three logically consecutive steps: (i) MI might have increased the level of the caregiver contributions to self-care; (ii) the higher caregiver contributions might have had an additive effect (above and beyond MI itself) on improving the patients' behaviours, and (iii) improvements in self-care behaviours might have lowered the mortality rate. Although the magnitude of this finding is small, it bodes well for a novel and promising beneficial mechanism. Thereby, we recommend that authors of future trials harness the involvement of the caregivers to make sure of getting the most out of MI interventions.

Interestingly, in our primary study, the study arm with both patients and caregivers had the best self-care level at 3 months, which might explain why patients had a significantly lower death rate in this group. Self-care also improved consistently across the two intervention arms over time, although we observed an improvement in mortality only at 3 months after the intervention. An explanation could be that MI improves survival not only via self-care but also via other variables, which may be particularly sensitive to MI, such as anxiety and depression.[25] At 3 months after the intervention, the effect on these other variables may have faded due to a deteriorating effect of MI, and self-care alone might have been insufficient to reduce mortality. Future secondary analyses are warranted to investigate the possible trend of these MI-sensitive variables across follow-ups. One more reason for the absence of any effect at successive follow-ups might be the small number of events and the increasingly drop-out over time, which in turn probably decreased the statistical power of the analyses.

We also found that our MI intervention was not effective in reducing emergency service use or hospitalizations. The literature supports the beneficial effects of HF self-care interventions on health-care service use,[26] but studies investigating the efficacy of MI on this outcome are absent, except for two studies.[22,27] Riegel *et al.*[27] administered one MI dose to patients during a home visit followed by up to four follow-up phone calls and found a significant reduction in all-cause readmissions at 3 months. Contrastingly, the study by Vaillant-Roussel *et al.*[22] administered a 2 day educational programme, which also used MI, but did not detect any significant reduction in hospitalizations, although they performed the analyses after 19 months of follow-up.

In our study, the fact that we did not detect any influence on hospitalizations might be linked to our use of a composite all-cause hospitalization outcome. This choice was

Figure 2 Life-table survival estimate of patients with HF in the three arms. Note. Visits number 1, 2, 3, and 4 correspond to 3, 6, 9, and 12 months from enrolment, respectively. Arm 1 = motivational interviewing (MI) only for patients; Arm 2 = MI for patients and caregivers; and Arm 3 = standard of care.



	N at risk	N deaths	N censored	N at risk	N deaths	N censored	N at risk	N deaths	N censored	N at risk	N deaths	N censored
Arm1	155	3	24	128	2	32	94	2	13	79	1	78
Arm2	177	1	31	145	2	29	114	3	15	96	1	95
Arm3	178	9	36	133	3	37	93	1	13	79	0	79

	Survival probability (95%CI)			
Arm1	97.9% (93.6%-99.3%)	96.2% (91%-98.4%)	94.0% (87.6%-97.1%)	91.6% (82.6%-96.1%)
Arm2	99.4% (95.7%-99.9%)	97.9% (93.5%-99.3%)	95.1% (89.3%-97.8%)	93.1% (85.2%-96.9%)
Arm3	94.4% (89.5%-97%)	91.9% (86.1%-95.3%)	90.8% (84.6%-94.6%)	90.8% (84.6%-94.6%)

Table 2 Hazard ratios of all-cause mortality within (T0–T1) and over (T1–T4) 3 months after enrolment

Time interval	Arm	HR	HR (95% CI)	*P*
0–3 months	Arm 1 vs. Arm 3	0.383	(0.104–1.414)	0.1498
0–3 months	Arm 2 vs. Arm 3	0.112	(0.014–0.882)	**0.0376**
3–12 months	Arm 1 vs. Arm 3	1.268	(0.340–4.721)	0.7237
3–12 months	Arm 2 vs. Arm 3	1.294	(0.365–4.587)	0.6896

Arm 1 = motivational interviewing (MI) only for patients; Arm 2 = MI for patients and caregivers; Arm 3 = standard of care; Significant *P* values are in bold.
CI, confidence interval; HR, hazard ratio; *P*, *P* value.

unavoidable because there were few readmissions and emergency services visits during follow-up. Although composite outcomes are used to enhance the rates of events and increase statistical power, the sensitiveness of each outcome may be dissimilar. This may have masked the statistical significance of our composite outcome.[28]

Limitations and strengths

This trial also has limitations. Despite performing an appropriate power analysis to estimate the effect on the primary outcome, no specific calculations were performed for the secondary outcomes. In addition, the general drop-out rate

of patients was high (about 20% at T1 and more than 45% at T4). The frequencies of readmissions and emergency services visits were lower than expected, and although we performed a mixed model analysis to compensate for this and the high drop-out rate, combining these two outcomes may have lowered the likelihood of detecting significant effects. Second, although we adopted broad eligibility criteria, we enrolled predominately patients in NYHA class II and III. Hence, our findings might not apply to populations with greater disease severity. Lastly, we cannot ignore that, during the study period, the participants had other visits above and beyond those planned for the trial. Any consequent contact with the providers and/or nurses during these visits might have reduced the rate of health-care service use for all participants.

This trial also has several strengths. First, it is the first of its kind to use such a large sample size; most recent MI studies involved no more than 100 participants.[29,30] Second, we recruited a sample with characteristics that are similar to the general non-institutionalized HF population (i.e. a typically old, multimorbid, and fragile individuals cared for by a caregiver), which enhances the external validity of this trial. Third, we assessed treatment fidelity constantly throughout the trial, giving further credibility to our results.

Conclusion

This secondary outcome analysis of the MOTIVATE-HF trial adds promising evidence that a MI programme administered by trained nurses may be an effective strategy in reducing mortality of patients with HF if their caregivers are included in the intervention. However, studies that adopt a stronger and more reliable intervention and longer follow-up are needed to better understand the benefits of MI on health-care service use and mortality.

Conflict of interest

No conflict of interest has been declared by the authors.

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Author contributions

All authors have agreed on the final version and meet at least one of the following criteria:

- Substantial contributions to conception and design, acquisition of data or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content.

Supporting information

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

Table S1. Longitudinal generalized linear mixed model results on health-care service use.

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