

The Effectiveness of a Motivational Interviewing Intervention on Mutuality Between Patients With Heart Failure and Their Caregivers

A Secondary Outcome Analysis of the MOTIVATE-HF Randomized Controlled Trial

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Background: Mutuality, defined as “the positive quality of the relationship between a caregiver and a care receiver”, was found to be associated with self-care and caregiver contribution to self-care in heart failure (HF). However, no studies were conducted to evaluate whether motivational interviewing (MI) can improve mutuality in patients with HF and caregivers. **Objectives:** The aim of this study was to evaluate the effectiveness of MI on mutuality in HF patient–caregiver dyads. **Methods:** This is a secondary outcome analysis of the MOTIVATE-HF randomized controlled trial, the primary aim of which was to evaluate the effect of MI on improving self-care in patients with HF. Participants were randomized into 3 arms: (1) MI for patients only, (2) MI for both patients and caregivers, and (3) standard care. To assess the HF patients' and caregivers' mutuality, the Mutuality Scale was used in its patient and caregiver versions. **Results:** Patients with HF had a median age of 74 years, and there were more men (58%). Most patients were retired (76.2%). Caregivers had a median age of 55 years and were mostly women (75.5%). Most patients were in New York Heart Association class II (61.9%) and had an ischemic HF etiology (33.6%). The motivational interviews did not show any impact on changes in the patient and caregiver mutuality during the follow-up time (3, 6, 9, and 12 months from baseline). The condition of living together between the patient and the caregiver was significantly associated with better mutuality between the patient and the caregiver. **Conclusions:** Motivational interviewing performed by nurses

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was not effective in improving mutuality in patients with HF and caregivers, but the target variable of the intervention was patient self-care. Stronger effects of MI on mutuality were observed in patients with HF and caregivers who live together. Future studies should target mutuality to see whether MI is really effective.

KEY WORDS: caregiver, heart failure, motivational interviewing, mutuality, patient, trial

Heat failure (HF) is one of the most common cardiac conditions,¹ and its prevalence is growing because the population is aging.² Worldwide, 1% to 2% of people are affected by HF, and this rises to 10% or more among people 70 years and older.³ The mortality rate after a diagnosis of HF in the United States and Europe ranges between 10% and 40% during the first year after diagnosis.⁴

Despite improvements in treatment, the outcomes in patients with HF remain poor, and this has consequences not only for patients with HF but also for their caregivers. Indeed, people with HF experience physical symptoms such as breathlessness, fatigue, and poor appetite.⁵ Informal caregivers of patients also experience poor outcomes such as increased psychosocial distress and poor well-being,⁶ with a negative impact on their quality of life.

Outcomes in HF may be improved if patients engage in self-care behaviors. As described by the situation-specific theory of HF self-care, self-care is “the naturalistic decision-making process involving the choice of behaviors that maintain physiologic stability and the response to symptoms when they occur.”^{7(p515)} Self-care has a great impact on clinical outcomes and leads to improvements in quality of life.^{8,9} For example, Auld et al¹⁰ and Lee et al¹¹ studied the relationship between self-care and HF symptoms and observed that self-care moderated the relationship between physical symptoms of HF and emotional quality of life and depression. Considering the importance of self-care to improve HF outcomes, investigators around the world have put their effort into identifying variables influencing self-care, and mutuality was more recently identified as an important predictor of self-care.

Archbold et al¹² defined mutuality as “the positive quality of the relationship between a caregiver and a care receiver,” and several descriptive studies have found an association between better mutuality in patients with HF and caregivers and patient self-care and caregiver contribution to self-care.^{13–15} Regarding patients with HF, authors have shown that greater mutuality is associated with a reduced risk of HF patient mortality,¹⁶ lower anxiety and depression,¹⁷ and better health status. In caregivers, better mutuality was found to be associated with lower burden¹⁸ and less depressive symptoms.¹⁷ In other populations, such as patients who have had a stroke, authors observed that mutuality had a moderating role on the association between depression and quality of life.¹⁹ In the population with cancer, mutuality was associated with faster recovery,²⁰ whereas in patients with dementia, it was associated with decreased aggression.²¹

Aware of the association between mutuality and self-care and caregiver contribution to self-care, several authors have also started to develop interventions to improve patient and caregiver mutuality.^{22–24} However, to date, these interventions have been focused only on dementia care and have yielded conflicting results. For example, Kunik et al²³ showed that a program focused on pain recognition, enhancing communication, and making daily activities pleasant for patients with dementia and their caregivers improved both patient and caregiver mutuality. In another study, a technology-enabled personalized reminiscence intervention improved significantly patient but not caregiver mutuality.²² Finally, in another study, a program teaching resourcefulness to both patients and caregivers did not improve mutuality neither in patients nor in caregivers.²⁴ A principal limitation of the previously mentioned study was the small sample size,²² the quasi-experimental nature of the design,²² and the lack of a conceptual framework guiding the studies.^{22,23}

The MOTIVATE-HF trial was an randomized controlled trial (RCT) aimed to evaluate the effectiveness of motivational interviewing (MI) on self-care in patients with HF.²⁵ The analyses of the effect of the intervention on the primary end point showed that MI was effective to improve self-care.³⁰ Analyses on secondary end points showed that MI was effective to improve disease-specific quality of life, symptom burden, and mortality in patients, and self-efficacy in caregivers.

A planned secondary analysis of the MOTIVATE-HF study was to evaluate the influence of MI on patient and caregiver mutuality. For this specific analysis, Cilluffo et al²⁶ conceptual framework on mutuality was adopted (Figure 1). According to this conceptual framework, mutuality is influenced by caregiver (ie, previous experience, empathy, communication, and patient-centered care) and patient (ie, previous experience, communication, trust in others) factors. The outcomes of mutuality are both at the caregiver and patient levels and include satisfaction, better decision making, better responsibility, lower burden, and better quality of life for caregivers and better self-care, better quality of life, fewer complications, and fewer hospitalizations for patients. This conceptual framework fits well with the MI intervention adopted in the MOTIVATE-HF trial. In fact, MI is a counseling technique that improves communication, empathy, and trust in others and is focused on client needs. The literature does not report whether MI can improve mutuality in patients with HF and caregivers or in other patient and caregiver populations. Knowledge of whether MI can improve mutuality in

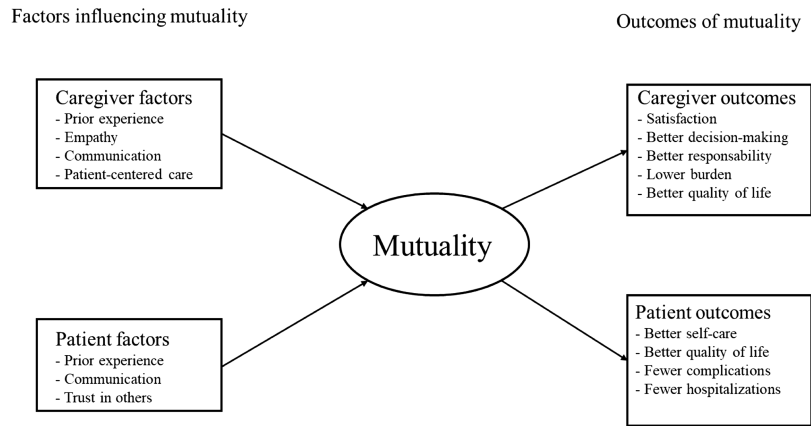


FIGURE 1. Conceptual framework of mutuality adopted.

HF patient–caregiver dyads is crucial because, as described previously, mutuality was found to be associated with better self-care and caregiver contribution to self-care,^{13–15} and other positive outcomes.^{16–21} Because it has increasingly been highlighted how important it is to include both the patient and caregiver in the care process,²⁷ studying the effect of MI on the patient–caregiver mutuality relationship is fundamental.

For these reasons, the aim of this secondary outcome analysis of the MOTIVATE-HF study was to evaluate the effectiveness of MI on mutuality in HF patient–caregiver dyads.

Methods

Trial Design

As reported previously, this is a secondary outcome analysis of the MOTIVATE-HF RCT,²⁵ whose primary aim was to evaluate the effect of MI on improving self-care in patients with HF. In this multicenter RCT, participants were randomized into 3 arms: (1) MI for patients only, (2) MI for both patients and caregivers, and (3) standard care.

Participants and Procedures

After the study protocol²⁵ received ethical approval, participants were recruited and signed the informed consent form. They were then screened through the Self-Care of HF Index (SCHFI) v.6.2 and the Six-item Screener,²⁸ to include only patients with insufficient self-care and exclude those with cognitive impairment. Data were collected at the baseline and at 3, 6, 9, and 12 months after enrolment, by research assistants blinded to the study arms.

The study²⁵ included patients with HF and their caregivers. The inclusion criteria for patients were as follows: (1) a diagnosis of HF with a New York Heart Association functional class of II to IV; (2) insufficient self-care, highlighted by a score of 0, 1, or 2 on at least

2 items of the self-care maintenance or self-care management scales of the SCHFI v.6.2; and (3) willingness to sign the informed consent form. Exclusion criteria for patients were as follows: (1) having had a heart attack in the previous 3 months; (2) having cognitive problems, with a score between 0 and 4 on the Six-item Screener; (3) living in residential care; and (4) having an informal caregiver who was not willing to participate in the study. Caregivers were included if they were recognized as the primary caregiver (ie, those providing most of the informal care) and were excluded if the patient was not willing to participate in the study.

Intervention and Control

Motivational interviewing was implemented by 18 nurses who had previously completed a 40-hour training course on MI and HF evidence-based care. The intervention in arm 1 (delivered to patients only) and arm 2 (delivered to both patients and caregivers) consisted of 1 face-to-face MI session (lasting approximately 60 minutes) and 3 telephone follow-up contacts within 2 months. The principles of MI consisted of developing an empathetic relationship, showing discrepancies between current behaviors and evidence-based recommended behaviors, supporting self-efficacy, developing problem-solving abilities, respecting patients' and caregivers' choices, and avoiding contrasts. Standard care provided to participants in arm 3 was also provided to patients and caregivers in arms 1 and 2.

Outcomes

The MOTIVATE-HF trial²⁵ investigated the effect of MI on several variables, among which self-care maintenance was the primary outcome. The present planned secondary outcome analysis focuses on the effect of MI on mutuality in both patients and caregivers. The Mutuality Scale that was adopted was the one developed by Archbold et al¹² and translated into Italian by Pucciarelli et al,²⁹ which has been shown to be valid

and reliable for patients with HF and caregivers by Dellafiore et al.³⁰ The Mutuality Scale consists of 15 items divided into 4 dimensions: love and affection, shared pleasurable activities, shared values, and reciprocity. Each item is assessed on a 5-point Likert scale ranging from 0 (“not at all”) to 4 (“a great deal”), with higher scores indicating higher mutuality. The patient and caregiver versions of the Mutuality Scale were administered to patients and caregivers, respectively.

Sample Size

The sample size was calculated for the primary outcome of the MOTIVATE-HF trial,²⁵ namely, self-care maintenance in patients with HF. It was estimated that a total sample of 240 patients would achieve 83% power to detect an 8% difference in self-care maintenance at 3 months in patients receiving the MI intervention (arms 1 and 2) compared with patients receiving usual care (arm 3). To account for an estimated 50% attrition rate, 480 participants were ultimately planned to enroll for the study.

Randomization

A block randomization scheme of 15 patient-caregiver dyads was generated and followed a 1:1:1 ratio in the 3 arms of the study. Each enrolling center received a list with 400 random assignments and a container with 400 opaque envelopes each containing 1 assignment to a group (arm 1, 2, or 3), prepared by a research assistant “A.” Every time a patient-caregiver dyad was enrolled, a research assistant “B” opened an envelope, assigned a treatment arm, and contacted the interventionist to perform MI. Research assistants who collected the data were blinded to the study arm assignment. More details on the randomization process can be found elsewhere.^{25,31}

Statistical Method

Baseline characteristics were summarized by arm as medians and quartiles (Q1–Q3) or as means and SDs for continuous data and as absolute numbers and their frequencies (%) for categorical data. The changes in mutuality scores (MSs) during follow-up were reported as the difference/delta (Δ) between the MS at each follow-up time (T1, T2, T3, and T4) and the baseline MS (T0). Two-sample *t* tests were applied to compare the difference in each of these scores in arms 1 and 2 with respect to the control arm 3 (for patients), or in arm 2 with respect to arms 1 and 3 separately (for caregivers). Multilevel modeling was used to analyze data at the level of the patient-and-caregiver dyad to control for interdependencies in the data. A longitudinal dyad model was tested for each MS domain (ie, love and affection, shared pleasurable activities, shared values, and reciprocity) and for the total score. This was a lin-

ear model of MS within dyads over time, which estimates the population averages of the MS for both patients and caregivers (fixed effects), the interdependence between the MS of the members of the patient-caregiver dyad (τ correlations), and the variability around the average trajectories of the MS for both members (random effects). The model included the treatment arm (MI only for patients, MI for patients and caregivers, and standard care), and its interaction with the visit number and the patient-caregiver living together condition as covariates, for both patients and caregivers.

Results

Participants' Characteristics

The patients' and caregivers' baseline characteristics, separated by study arm, are shown in Table 1. The patients had a median age of 74 years, and there was a prevalence of men (58%). Most patients were retired (76.2%). Caregivers had a median age of 55 years and were mostly women (75.5%). Most patients were in New York Heart Association class II (61.9%) and had an ischemic HF etiology (33.6%). At baseline, the mean (SD) MSs (love and affection, shared pleasurable activities, shared values, reciprocity, and total score) in patients were 3.3 (0.7), 2.8 (0.7), 2.7 (0.8), 2.9 (0.7), and 2.9 (0.6), respectively, whereas in caregivers, they were 3.3 (0.7), 2.7 (0.8), 2.7 (0.9), 2.7 (0.8), and 2.8 (0.7), respectively (Table 1).

Changes in Mutuality Scores Over Time

Supplemental Tables 1 and 2, available at <http://links.lww.com/JCN/A200>, show the change in the HF patients' (1) and caregivers' (2) MSs at each follow-up time. No improvement in patients' MSs was observed over time, and no significant differences were observed between the 3 arms during follow-up.

Among caregivers, from baseline to T3 (9 months), mean MS total score increased more in arm 2 (MI for patients and caregivers) compared with arm 3 (standard of care; difference, 0.2; 95% confidence interval [CI], 0.0–0.3; $P = .0314$), but the difference shrank at T4 (12 months).

Multilevel Dyad Model: Trends Over Time

Table 2 reports the results from the multilevel longitudinal linear model on the trends in MSs over the follow-up time. Significant linear positive slopes were found for patient and caregiver MSs over the 12 months except for the love and affection subscale. Motivational interviewing did not show any impact on changes in the patient and caregiver MSs during the follow-up time. In fact, arms 1 and 2 did not improve significantly more than arm 3, neither in any subscale nor in the total score (patients: $\gamma = 0.00$ [95% CI, –0.05 to 0.04], $P = .8715$,

TABLE 1 Heart Failure 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 |
| Age, median [Q1–Q3], y | 74 [65–82] | 54 [44–64] | 73 [64–81] | 57 [44–68] | 75 [64–83] | 53 [42–64] |
| Sex (male), n (%) | 80 (52) | 36 (24) | 107 (61) | 42 (24) | 109 (61) | 45 (25) |
| Marital status, n (%) | | | | | | |
| Married | 81 (52) | 108 (72) | 123 (70) | 124 (70) | 112 (63) | 129 (73) |
| Widowed | 55 (35) | 6 (4) | 44 (25) | 3 (2) | 51 (29) | 3 (2) |
| Divorced | 10 (7) | 10 (7) | 4 (2) | 14 (8) | 6 (3) | 12 (7) |
| Single | 9 (6) | 25 (17) | 6 (3) | 35 (20) | 9 (5) | 33 (18) |
| Education (high school or higher), n (%) | 41 (26) | 90 (60) | 44 (25) | 86 (49) | 47 (26) | 99 (56) |
| Employment (retired), n (%) | 119 (77) | 33 (22) | 137 (78) | 50 (28) | 131 (74) | 52 (29) |
| Income, n (%) | | | | | | |
| Not the necessary to live | 7 (5) | — | 7 (4) | — | 8 (5) | — |
| The necessary to live | 131 (84) | — | 138 (78) | — | 141 (79) | — |
| More than the necessary to live | 17 (11) | — | 32 (18) | — | 29 (16) | — |
| Time with HF, median [Q1–Q3], mo | 36 [24–72] | — | 36 [15–84] | — | 48 [20–96] | — |
| NYHA class, n (%) | | | | | | |
| II | 98 (63) | — | 108 (62) | — | 107 (61) | — |
| III | 49 (32) | — | 55 (31) | — | 56 (32) | — |
| IV | 8 (5) | — | 12 (7) | — | 13 (7) | — |
| No. medications, median [Q1–Q3] | 6 [4–8] | — | 7 [5–9] | — | 6 [4–8] | — |
| CCI scores, median [Q1–Q3] | 2 [2–4] | — | 2 [2–4] | — | 2 [1–4] | — |
| MoCA scores, median [Q1–Q3] | 25 [21–27] | — | 26 [19–28] | — | 24 [18–27] | — |
| Caregiver living with patient, n (%) | — | 76 (51) | — | 126 (72) | — | 104 (59) |
| Self-care maintenance scores, mean (SD) | 45.7 (15.2) | — | 45.9 (16.3) | — | 44.9 (14.6) | — |
| Self-care management scores, ^a mean (SD) | 41.7 (17.9) | — | 37.6 (18.4) | — | 40.3 (16.4) | — |
| Self-care confidence scores, mean (SD) | 51.5 (20.9) | — | 52.1 (21.2) | — | 50.6 (22.6) | — |
| Mutuality score (MS), mean (SD) | | | | | | |
| Love and affection | 3.3 (0.7) | 3.2 (0.7) | 3.4 (0.7) | 3.4 (0.7) | 3.2 (0.7) | 3.4 (0.6) |
| Shared pleasurable activities | 2.8 (0.7) | 2.6 (0.8) | 2.9 (0.7) | 2.7 (0.8) | 2.7 (0.8) | 2.7 (0.8) |
| Shared values | 2.6 (0.8) | 2.7 (0.9) | 2.8 (0.8) | 2.8 (0.9) | 2.7 (0.9) | 2.7 (0.9) |
| Reciprocity | 2.9 (0.7) | 2.6 (0.8) | 3.0 (0.7) | 2.7 (0.8) | 2.8 (0.7) | 2.6 (0.8) |
| Total score | 2.9 (0.6) | 2.8 (0.7) | 3.0 (0.6) | 2.8 (0.7) | 2.9 (0.6) | 2.8 (0.6) |

Abbreviations: CCI, Charlson Comorbidity Index; HF, heart failure; IQR, interquartile range; MI, motivational interviewing; MoCA, Montreal Cognitive Assessment; MS, Mutuality Scale; NYHA, New York Heart Association.

^aSelf-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.

and $\gamma = -0.02$ [95% CI, -0.06 to 0.03], $P = .4071$; caregivers: $\gamma = 0.03$ [95% CI, -0.02 to 0.07], $P = .2564$, and $\gamma = 0.02$ [95% CI, -0.02 to 0.07], $P = .2731$; Figure 2E, Table 2).

The difference that was closest to being significant was observed in the improvement in the MS for love and affection for caregivers in arm 1 compared with arm 3 over time ($\gamma = 0.05$; 95% CI, 0.00 – 0.09 ; $P = .0626$). The living together condition was significantly associated with patients' MS for love and affection ($\gamma = 0.22$; 95% CI, 0.11 – 0.33), shared values ($\gamma = 0.22$; 95% CI, 0.09 – 0.35), and total score ($\gamma = 0.11$; 95% CI, 0.02 – 0.21), and in caregivers' MS for shared values ($\gamma = 0.22$; 95% CI, 0.09 – 0.35 ; Table 2).

The random effects showed that there was significant variability around the average trajectories for both the patient and caregiver MSs ($P = .0003$ and $P = .0047$ in patient and caregiver MSs for love and affection, respectively; $P < .0001$ in patient and caregiver remaining MSs; Table 2).

The τ correlations ranged from 0.53 to 0.70 ($P < .0001$) across the MSs, indicating moderate-to-strong covariation within the dyads (Table 3).

Discussion

To the authors' knowledge, this is the first trial conducted in the HF patient–caregiver dyadic population to analyze the effect of MI on mutuality. In this RCT, we observed that, although the difference that was closest to being significant was in improvement in the MS for love and affection for caregivers between arm 1 (MI only for the patient) and arm 3 (standard care), MI did not show an impact on changes in the general MS of patients and caregivers during the follow-up time. However, living together condition was significantly associated with patient mutuality dimensions (ie, love and affection, shared values) and total MS, whereas in caregivers, it was associated only with MS for shared values. Although no significant effects were observed, these findings are

TABLE 2 Multilevel Model Fixed and Random Effects Results Predicting Patient and Caregiver Mutuality Scale Scores Over Time From Treatment Arm, and Its Interaction With Visit Number and Living Together Condition (N = 510 Dyads)

| | Patient | | | Caregiver | | |
|---|----------|---------------|--------|-----------|----------------|--------|
| | Estimate | 95% CI | P | Estimate | 95% CI | P |
| Love and affection | | | | | | |
| Fixed effects | | | | | | |
| Intercept ^a | 3.04 | 2.93–3.16 | <.0001 | 3.33 | 3.22–3.44 | <.0001 |
| Linear slope ^b | 0.02 | –0.01 to 0.06 | .2194 | 0.02 | –0.02 to 0.05 | .3386 |
| MI only for patients (arm 1) vs standard of care (arm 3) at baseline | 0.02 | –0.13 to 0.16 | .8184 | –0.14 | –0.28 to –0.01 | .0413 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at baseline | 0.09 | –0.05 to 0.23 | .1935 | –0.01 | –0.14 to 0.12 | .8788 |
| MI only for patients (arm 1) vs standard of care (arm 3) at follow-up | 0.03 | –0.03 to 0.07 | .3299 | 0.05 | 0.00–0.09 | .0626 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at follow-up | –0.02 | –0.06 to 0.03 | .5282 | 0.02 | –0.03 to 0.07 | .3866 |
| Living together (yes vs no) | 0.22 | 0.11–0.33 | <.0001 | 0.09 | –0.01 to 0.19 | .0797 |
| Random effects | | | | | | |
| Intercept | 0.27 | 0.22–0.33 | <.0001 | 0.24 | 0.19–0.30 | <.0001 |
| Linear slope | 0.01 | 0.01–0.02 | .0003 | 0.01 | 0.00–0.01 | .0047 |
| Shared pleasurable activities | | | | | | |
| Fixed effects | | | | | | |
| Intercept ^a | 2.67 | 2.55–2.78 | <.0001 | 2.74 | 2.61–2.87 | <.0001 |
| Linear slope ^b | 0.09 | 0.05–0.12 | <.0001 | 0.04 | 0.01–0.08 | .0202 |
| MI only for patients (arm 1) vs standard of care (arm 3) at baseline | 0.07 | –0.08 to 0.22 | .3404 | –0.10 | –0.26 to 0.06 | .2091 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at baseline | 0.12 | –0.02 to 0.26 | .0848 | –0.05 | –0.20 to 0.10 | .5113 |
| MI only for patients (arm 1) vs standard of care (arm 3) at follow-up | –0.03 | –0.08 to 0.03 | .3092 | 0.03 | –0.02 to 0.09 | .2274 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at follow-up | –0.01 | –0.06 to 0.04 | .6191 | 0.04 | –0.01 to 0.09 | .1057 |
| Living together (yes vs no) | 0.04 | –0.07 to 0.15 | .4352 | 0.04 | –0.08 to 0.16 | .4997 |
| Random effects | | | | | | |
| Intercept | 0.31 | 0.26–0.38 | <.0001 | 0.39 | 0.33–0.47 | <.0001 |
| Linear slope | 0.02 | 0.01–0.03 | <.0001 | 0.01 | 0.01–0.02 | <.0001 |
| Shared values | | | | | | |
| Fixed effects | | | | | | |
| Intercept ^a | 2.54 | 2.40–2.67 | <.0001 | 2.57 | 2.42–2.71 | <.0001 |
| Linear slope ^b | 0.07 | 0.02–0.11 | .0026 | 0.05 | 0.01–0.10 | .0137 |
| MI only for patients (arm 1) vs standard of care (arm 3) at baseline | –0.10 | –0.27 to 0.07 | .2430 | –0.02 | –0.19 to 0.16 | .8679 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at baseline | 0.08 | –0.09 to 0.24 | .3524 | 0.07 | –0.10 to 0.24 | .4317 |
| MI only for patients (arm 1) vs standard of care (arm 3) at follow-up | 0.02 | –0.05 to 0.08 | .5550 | 0.02 | –0.04 to 0.08 | .5085 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at follow-up | –0.02 | –0.08 to 0.04 | .5042 | 0.00 | –0.06 to 0.05 | .9039 |
| Living together (yes vs no) | 0.22 | 0.09–0.35 | .0008 | 0.22 | 0.09–0.35 | .0013 |
| Random effects | | | | | | |
| Intercept | 0.44 | 0.37–0.53 | <.0001 | 0.49 | 0.41–0.58 | <.0001 |
| Linear slope | 0.03 | 0.02–0.04 | <.0001 | 0.02 | 0.01–0.04 | <.0001 |
| Reciprocity | | | | | | |
| Fixed effects | | | | | | |
| Intercept ^a | 2.74 | 2.62–2.85 | <.0001 | 2.60 | 2.47–2.74 | <.0001 |
| Linear slope ^b | 0.08 | 0.05–0.12 | <.0001 | 0.06 | 0.02–0.10 | .0013 |
| MI only for patients (arm 1) vs standard of care (arm 3) at baseline | 0.00 | –0.15 to 0.14 | .9580 | 0.00 | –0.17 to 0.17 | .9891 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at baseline | 0.14 | 0.01–0.28 | .0384 | 0.04 | –0.13 to 0.20 | .6629 |
| MI only for patients (arm 1) vs standard of care (arm 3) at follow-up | –0.01 | –0.06 to 0.04 | .7430 | 0.02 | –0.04 to 0.07 | .5018 |

(continues)

TABLE 2 Multilevel Model Fixed and Random Effects Results Predicting Patient and Caregiver Mutuality Scale Scores Over Time From Treatment Arm, and Its Interaction With Visit Number and Living Together Condition (N = 510 Dyads), Continued

| | Patient | | | Caregiver | | |
|---|----------|---------------|--------|-----------|---------------|--------|
| | Estimate | 95% CI | P | Estimate | 95% CI | P |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at follow-up | -0.03 | -0.07 to 0.02 | .3008 | 0.03 | -0.03 to 0.08 | .3323 |
| Living together (yes vs no) | 0.07 | -0.03 to 0.18 | .1766 | 0.10 | -0.03 to 0.23 | .1272 |
| Random effects | | | | | | |
| Intercept | 0.28 | 0.23-0.34 | <.0001 | 0.45 | 0.38-0.53 | <.0001 |
| Linear slope | 0.01 | 0.01-0.02 | <.0001 | 0.02 | 0.01-0.03 | <.0001 |
| Total score | | | | | | |
| Fixed effects | | | | | | |
| Intercept ^a | 2.75 | 2.65-2.86 | <.0001 | 2.78 | 2.67-2.89 | <.0001 |
| Linear slope ^b | 0.07 | 0.04-0.10 | <.0001 | 0.05 | 0.01-0.08 | .0045 |
| MI only for patients (arm 1) vs standard of care (arm 3) at baseline | 0.01 | -0.12 to 0.14 | .9086 | -0.06 | -0.20 to 0.08 | .4088 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at baseline | 0.12 | -0.01 to 0.24 | .0649 | 0.01 | -0.13 to 0.14 | .9175 |
| MI only for patients (arm 1) vs standard of care (arm 3) at follow-up | 0.00 | -0.05 to 0.04 | .8715 | 0.03 | -0.02 to 0.07 | .2564 |
| MI for patients and caregivers (arm 2) vs standard of care (arm 3) at follow-up | -0.02 | -0.06 to 0.03 | .4071 | 0.02 | -0.02 to 0.07 | .2731 |
| Living together (yes vs no) | 0.11 | 0.02-0.21 | .0227 | 0.10 | -0.01 to 0.20 | .0632 |
| Random effects | | | | | | |
| Intercept | 0.25 | 0.21-0.30 | <.0001 | 0.29 | 0.24-0.35 | <.0001 |
| Linear slope | 0.01 | 0.01-0.02 | <.0001 | 0.01 | 0.01-0.02 | <.0001 |

Abbreviations: CI, confidence interval; MI, motivational interviewing.

^aMean Mutuality Scale score at baseline in arm 3 for dyads not living together.

^bRate of change per 3 months in the Mutuality Scale (assumed to be linear over the 12-month period).

important because it is now known that MI might be effective in improving self-care³¹ in the population with HF but could not improve purely subjective variables such as mutuality, and therefore, researchers and clinicians should consider different approaches to improve mutuality in patients with HF and caregivers.

Regarding changes in MS over time, little improvement was observed. Furthermore, no significant differences were observed between the 3 arms during follow-up. According to studies conducted in HF and other cardiovascular populations,¹⁹ mutuality, considered a positive relationship between 2 subjects (patient and caregiver), is a condition that often remains stable over time. This stability over time could depend on the constructs of the scale used. Indeed, mutuality is composed of 4 dimensions, which are love and affection, shared pleasurable activities, shared values, and reciprocity. Because our sample consisted mainly of couples and children, the mutuality dimensions could be consolidated by the family relationship. In the family, love is established, as is the sharing of pleasurable activities, values, and reciprocity, and for this reason, mutuality could remain stable over time.

This same assumption could provide the reason why we have not observed any significant effects of MI on mutuality. In fact, as described previously, the mutuality in arm 1 (MI with only the patient) and arm 2 (MI

with the patient and caregiver) did not improve significantly more than the mutuality in arm 3 (standard care), for any subscale or total score. Intervention in arms 1 and 2 consisted of only 1 face-to-face MI session (approximately 60 minutes), with 3 telephone follow-up contacts in 2 months. It is probable that, because the intervention in both arm 1 and arm 2 focused on factors more related to HF self-care, such as discrepancies between current behaviors and evidence-based recommended behaviors, support for self-efficacy, and the development of problem-solving abilities, the intervention did not produce any improvements in a variable (mutuality) that in reality is not directly connected with this type of intervention. Indeed, as described by the literature, MI is broadly applicable in the management of diseases that, to some extent, are associated with behavior, whereas mutuality, understood as a positive relationship between 2 subjects, represents not a behavior to be changed but a condition that is established over time. The MI approach was further developed in the 1990s into a collaborative conversation style to strengthen a person's own motivation and commitment to change.³² Motivational interviewing aims to explore and resolve the ambivalence that people might have about health behaviors, in favor of change. It encourages people to say why and how they might change, and pertains to both a style of relating to others and a set of skills to facilitate

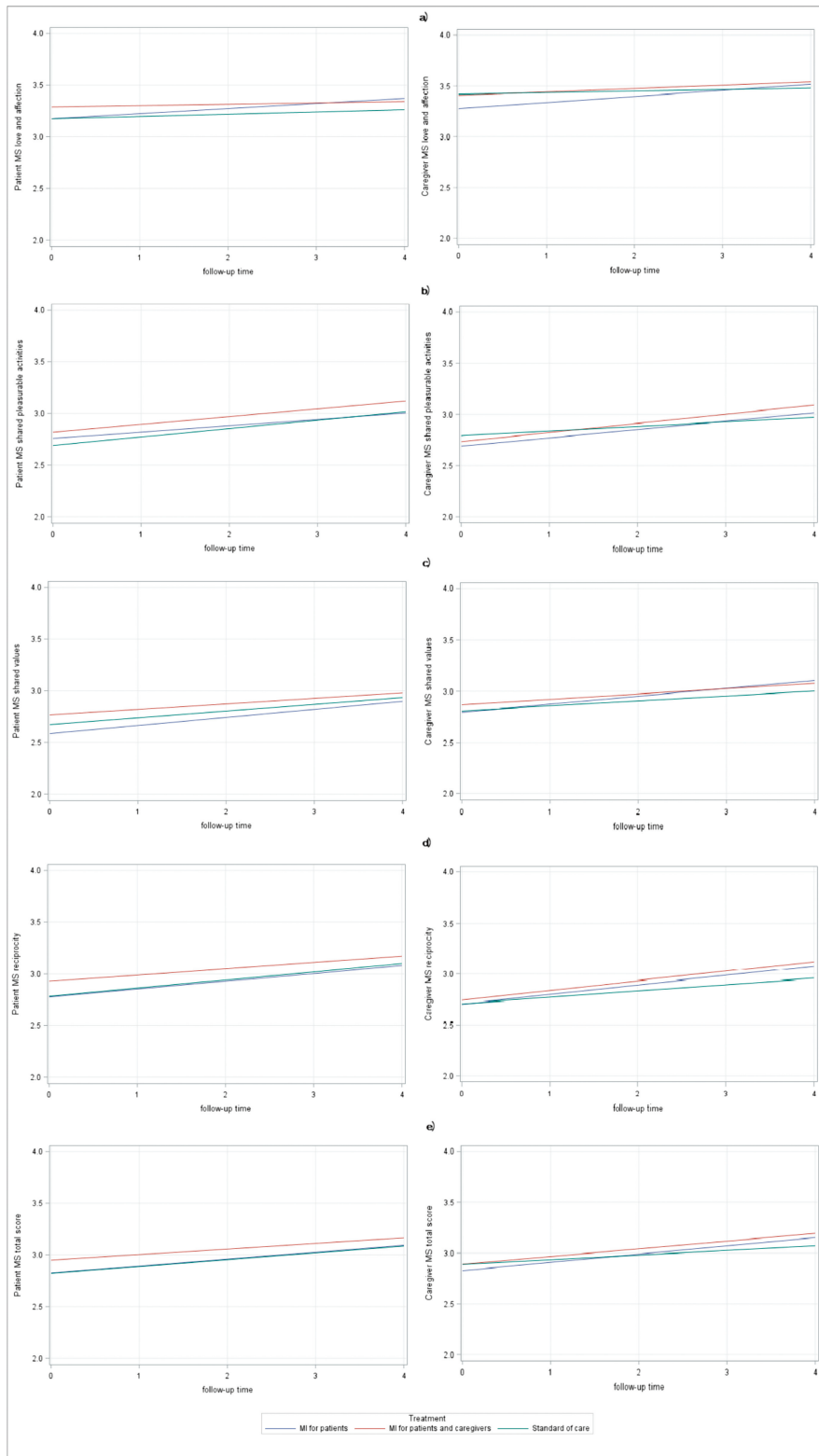


FIGURE 2. Model-based heart failure patient and caregiver Mutuality Scale (MS) scores: love and affection (A), shared pleasurable activities (B), shared values (C), reciprocity (D) and total score (E) by follow-up time. MI, motivational interviewing.

that process. The mutuality dimensions (love and affection, shared pleasurable activities, shared values, and reciprocity) are all dimensions that do not require skills

that can be changed by an MI intervention, but they are aspects that are built between 2 people and become more solid over time.

Some reflections should be done taking into account the conceptual framework that guided our study. In that framework, mutuality is influenced by caregiver and patient factors that can be improved with MI, but this was not the case in our study. Several could be the reasons why our MI intervention did not produce what was reported in the framework: first, Cilluffo et al's conceptual framework is still in its infancy and was developed only with a grounded theory approach, and more evidence is needed to sustain the previously mentioned framework; second, Cilluffo et al's framework was developed to describe the influencing factors, the mutuality process, and the outcomes in formal caregivers (nurse) and patients. These patients were affected by hypertension, lung diseases, and diabetes, 3 diseases that have not many common characteristics with HF; third, as reported previously, the MI intervention, although it developed empathy and communication, was more focused on self-care than on developing greater mutuality between patients and their caregivers. Clearly, more studies are needed to improve the Cilluffo et al framework.

The living together condition was significantly associated with changes in the patient MS for love and affection, shared values, and total score, and in the caregiver MS for shared values. Motivational interviewing has the greatest impact on patients and caregivers who live together. This is probably because, as demonstrated in studies conducted in other populations, living together leads to the adoption of the same habits. Living together with the disease, in the same home, could make the patient's and caregiver's love for each other and increase the possibility of sharing the same values. It is probable that, through MI, both patients and caregivers understand how important it is to share their values to face the disease together. We said previously that MI acts on behavior change. This change can only be possible if patients with HF and caregivers share the same values and habits. For this reason, living together could make the sharing of values more solid and, therefore, lead to the adoption of behaviors that are appropriate for the disease. Although in patients with HF and caregivers, living together had higher love and affection and shared values dimensions in caregivers, we

What's New and Important

- The living together condition was significantly associated with patients' MS for love and affection, shared values, and total scores.
- The living together condition was significantly associated with caregivers' MS for shared values.
- The motivational interviews did not show any impact on changes in the patient and caregiver MSs during the follow-up time.

observed only an association with shared values. Although there is no evidence in the literature, we think that these relationships are due to the difficulties encountered during the disease. From the outset, with the diagnosis, patients with HF and caregivers share all the difficulties encountered, such as, for example, the patient's deterioration on the one hand and the caregiving problems on the other. Surely during this period, the patient with HF appreciates how much his/her caregiver is doing for him/her, thus increasing his/her level of love and affection. In addition, through illness, we strengthen each other, and this could increase this sense of sharing values.

This study has several implications. First of all, because it is the first trial that has analyzed the effect of MI on HF patient-caregiver mutuality, new evidence has been added to the literature. Although we observed no significant differences in the 3 arms, this still represents an important result. From a clinical point of view, clinicians and nurses should consider whether MI is the best approach to improve the positive relationship (mutuality) between patients and caregivers to cope with the disease. Motivational interviewing could be effective, but it should be focused specifically on mutuality and not on other aspects of the disease management as we did for self-care. Furthermore, knowing that the greatest effects have been observed in patients with HF who live with their caregivers, clinicians should reflect on adopting specific interventions for patients who may be most at risk, such as those who live alone.

However, this study also has several limitations. First of all, MI is a personalized, tailored approach that is difficult to standardize. For this reason, the data may not be generalizable to other populations and countries. In addition, MI is not easy to perform unless the interventionist has adequate technical and relational skills. For the future, we strongly recommend further studies in which the interventionists performing MI are trained for longer periods and their MI skills are evaluated before they are allowed to perform the intervention and are specifically trained to improve mutuality if this is the target variable of the intervention. Another limitation is that we used the MS scale that analyzed only the "positive relationship" between patients with HF and caregivers. As we know, not all family relationships

TABLE 3 Multilevel Model Random-Effect Results: Tau Correlations Between Patient and Caregiver Mean Mutuality Scale Scores at Baseline (N = 510 Dyads)

| Mutuality Subscale | τ Correlation | 95% CI | P |
|-------------------------------|--------------------|-----------|--------|
| Love and affection | 0.62 | 0.51–0.73 | <.0001 |
| Shared pleasurable activities | 0.60 | 0.51–0.68 | <.0001 |
| Shared values | 0.70 | 0.62–0.77 | <.0001 |
| Reciprocity | 0.53 | 0.44–0.63 | <.0001 |
| Total score | 0.58 | 0.49–0.68 | <.0001 |

Abbreviation: CI, confidence interval.

could be positive, making caregiving stressful. For these reasons, we suggest using an instrument that could analyze both positive and negative relationships between patients with HF and caregivers in further studies.

Conclusions

In conclusion, MI performed by a general population of trained nurses was not effective in improving mutuality for patients with HF and caregivers. Effects were observed in patients with HF and caregivers who live together. Because this was not a trial developed with the intention of improving mutuality between patients with HF and caregivers, future studies should ultimately consider an MI intervention not focused on the disease but on the relationship within the dyad (patient and caregiver).

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