

# The Influence of Caregiver Contribution to Self-care on Symptom Burden in Patients With Heart Failure and the Mediating Role of Patient Self-care

## A Longitudinal Mediation Analysis

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**Background:** Patients with heart failure experience high symptom burden, which can be mitigated with adequate self-care. Caregiver contribution to self-care has been theorized to improve patient symptom burden. The mediating role of patient self-care in this relationship has not been tested yet. **Objectives:** The aim of this study was to test whether (a) caregiver contribution to self-care influences patient self-care, (b) patient self-care influences symptom burden, and (c) patient self-care mediates the relationship between caregiver contribution to self-care and symptom burden. **Methods:** In this study, the authors conducted a secondary analysis of the baseline and 3-month data from the MOTIVATE-HF trial, which enrolled 510 dyads (patient with heart failure and caregiver) in Italy. Multigroup confirmatory factor analysis was used to test measurement invariance. Autoregressive longitudinal path analysis with contemporaneous mediation was used to test our hypotheses. **Results:** On average, caregivers were 54 years old and mainly female, whereas patients were 72.4 years old and mainly male. Better caregiver contribution to self-care maintenance was associated with better patient self-care maintenance ( $\beta = 0.280, P < .001$ ), which, in turn, was associated with lower symptom burden ( $\beta = -0.280, P < .001$ ). Patient self-care maintenance mediated the effect of caregiver contribution to self-care maintenance on symptom burden ( $\beta = -0.079$ ; 95% bias-corrected bootstrapped confidence interval,  $-0.130$  to  $-0.043$ ). Better caregiver contribution to self-care management was associated with better patient self-care management ( $\beta = 0.238, P = .006$ ). The model significantly accounted for 37% of the total variance in symptom burden scores ( $P < .001$ ). **Conclusions:** This study expands the situation-specific theory of caregiver contribution to heart failure self-care and provides new evidence on the role of caregiver contribution to self-care and patient self-care on symptom burden in heart failure.

**KEY WORDS:** caregivers, heart failure, mediation analysis, self-care, symptom assessment

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The MOTIVATE trial (where the data of this study come from) was approved by the university institutional review board. Each participant signed the informed consent form before joining the study.

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Heart failure is a chronic condition affecting 64.3 million people worldwide.<sup>1</sup> Moreover, its prevalence is progressively increasing because of the aging of the population and the improvement in treatment options.<sup>2-4</sup> Heart failure is associated with poor patient outcomes, such as cognitive impairments, sleep disorders, depression, dyspnea, and fatigue,<sup>5-9</sup> which all contribute to lower quality of life,<sup>10-13</sup> and increased hospitalization<sup>14,15</sup> and mortality rates.<sup>10,16</sup> However, heart failure outcomes may improve if patients perform adequate self-care.<sup>17,18</sup> Although self-care behaviors are important, patients experience difficulties in performing them<sup>19-21</sup> because of multiple factors including older age, low self-efficacy, cognitive impairment, comorbidities, and depression.<sup>22-25</sup> In these cases, informal caregivers have a crucial role in contributing to patient self-care.<sup>26</sup>

The situation-specific theory of caregiver contribution to patient self-care defines caregiver contribution to self-care<sup>27</sup> as the process through which caregivers support patients in maintaining heart failure stability (caregiver contribution to self-care maintenance), monitoring symptoms (caregiver contribution to symptom monitoring and perception), and addressing symptoms (caregiver contribution to self-care management).<sup>27</sup> These 3 processes are sequential. Thus, caregiver contribution to self-care maintenance influences caregiver contribution to self-care monitoring and perceptions, which, in turn, influences caregiver contribution to self-care management. This theory identifies (a) caregiver-related (eg, skills), patient-related (eg, duration of the illness) and dyadic-related (eg, dyad relationship) factors that contribute to patient self-care as well as (b) caregiver and patient outcomes associated with caregiver contribution to patient self-care. The theory underlines that such outcomes may be both positive and negative.

The theory of caregiver contribution to heart failure self-care is still in its infancy, and 2 aspects are still unknown. First, despite that caregiver contribution to patient self-care implies supporting and influencing patients in self-care maintenance, symptom perception, and self-care management, patient self-care as a proximal outcome of the theory was investigated in only 1 study, which found an association between caregiver contribution to self-care and patient self-care.<sup>28</sup> Second, because patient self-care is associated with various patient outcomes (eg, reduction of mortality rates, improved quality of life),<sup>17,18</sup> such outcomes could be considered as distal outcomes of the theory. However, these associations have never been tested. Among the distal outcomes of caregiver contribution to self-care, symptom burden is predominant. Indeed, patients with heart failure experience multiple symptoms that contribute to a decreased quality of life,<sup>10-13</sup> and high hospitalization<sup>14,15</sup> and mortality rates.<sup>10,16</sup> However, the association between caregiver contribution to patient self-care and patient symptom burden in heart failure remains unexplored.

The aims of this study were to investigate the influence of caregiver contribution to self-care on patient symptom burden and explore whether patient self-care mediates such a relationship. Knowing this would expand the situation-specific theory of caregiver contribution to patient self-care and the existing knowledge on caregivers' influence on patient outcomes. Considering the theoretical propositions of the situation-specific theories of caregiver contribution to self-care<sup>27</sup> and heart failure patient self-care,<sup>29</sup> we tested whether (a) caregiver contribution to self-care influences patient self-care, (b) patient self-care influences symptom burden, and (c) patient self-care mediates the relationship between caregiver contribution to self-care and symptom burden.

## Methods

### Study Design

We conducted a secondary analysis of the MOTIVATE-HF trial, based on the first 2 data collection time points (baseline and 3-month follow-up, sometimes referred to as T0 and T1, respectively).<sup>30</sup> The MOTIVATE-HF study is a randomized controlled trial aimed at improving self-care in patients with heart failure<sup>31</sup> using motivational interviewing.<sup>32</sup> Participants were randomized into 3 arms: arm 1, where only patients received the intervention; arm 2, where both patients and caregivers received the intervention; and arm 3, where participants received standard care. The intervention in arms 1 (only for patients) and 2 (both for patients and caregivers) consisted of a face-to-face motivational interviewing session followed by 3 telephone calls within 2 months to boost the initial intervention. After the intervention, follow-up data were collected at 3, 6, 9, and 12 months from enrollment. Previous analyses demonstrated that the intervention significantly improved patients' self-care,<sup>30</sup> physical symptoms,<sup>33</sup> heart failure-specific quality of life,<sup>34</sup> mortality rates,<sup>35</sup> and caregiver self-efficacy.<sup>36</sup> The study protocol was registered on ClinicalTrials.gov (NCT02894502), and the main results were published elsewhere.<sup>30</sup>

### Participants and Procedures

A total of 510 dyads of patient with heart failure and their caregivers were enrolled from June 2014 to October 2018 across 3 healthcare centers in Italy. Patients were eligible if they had a diagnosis of heart failure<sup>37</sup> (New York Heart Association functional classes II-IV), had poor self-care (score < 2 on at least 2 items of the Self-Care of Heart Failure Index v.6.2<sup>38</sup>), and provided written informed consent. Patients were excluded if they had a myocardial infarction in the previous 3 months, lived in residential facilities, or had severe cognitive impairment (score of 0-4 on the Six-Item Screener<sup>39</sup>). Caregivers were enrolled whenever identified by their respective patients as those providing them with most

of the informal care and if they were willing to participate in the study.

## Measurements

In the MOTIVATE-HF trial, multiple instruments were adopted, but here, only those used in this analysis are reported. Caregiver contribution to self-care (maintenance and management) was measured with the Caregiver Contribution to Self-Care of Heart Failure Index,<sup>40</sup> which is a psychometrically sound questionnaire validated in an Italian population with heart failure.<sup>41</sup> Such questionnaire is composed of 22 items divided into 3 scales: (a) caregiver contribution to self-care maintenance scale, measuring the extent to which caregivers support patients in adhering to pharmacological and behavioral prescriptions and monitoring symptoms; (b) caregiver contribution to self-care management scale, measuring the extent to which caregivers help patients in responding to their symptoms; and (c) caregiver confidence scale, measuring caregiver self-efficacy in contributing to self-care. Each item is scored on a 4-point Likert scale ranging from 1 (never) to 4 (always), and each scale score is standardized (0–100). Higher scores indicate better caregiver contribution to self-care, with a cutoff point  $\geq 70$  for caregiver contribution to self-care adequacy.<sup>41</sup> The reliability of the caregiver contribution to self-care maintenance and management in this study were satisfactory in this study, with factor score determinacy coefficients of 0.82 and 0.87, respectively.

Patients' self-care (maintenance and management) was measured with the Self-Care of Heart Failure Index v.6.2, which is a psychometrically sound questionnaire previously tested in an Italian population with heart failure.<sup>38</sup> This questionnaire is composed of 22 items divided into 3 scales: (a) self-care maintenance scale, measuring healthy behaviors, treatment adherence, and symptom monitoring; (b) self-care management scale, measuring patients' ability to recognize and manage symptoms when they occur; and (c) self-care confidence scale, measuring patient-perceived ability to engage in the self-care process. Each item of the Self-Care of Heart Failure Index can be scored on a 4-point Likert scale ranging from 1 (never) to 4 (always), and each scale score is standardized (0–100). Higher scores indicate better self-care, with a cutoff point  $\geq 70$  for self-care adequacy.<sup>41</sup> The factor score determinacy coefficients of the self-care maintenance and management scale were 0.72 and 0.78, respectively.

The burden of heart failure physical symptoms on patients was measured with the Heart Failure Somatic Perception Scale,<sup>42</sup> a psychometrically sound questionnaire<sup>43</sup> composed of 18 items divided into 4 dimensions: chest discomfort, dyspnea, early and subtle, and edema. Each item can be scored on a 6-point Likert scale ranging from 0 ("I did not have this symptom") to 5 ("extremely bothersome symptom"). The total score

ranges from 0 to 90, with higher scores indicating greater burden of symptoms. In this study, reliability of the Heart Failure Somatic Perception Scale for the whole scale was satisfactory, with a factor score determinacy coefficient of 0.92.

## Statistical Analysis

Statistical analysis was conducted in 3 consequential steps. First, we described the sociodemographic characteristics of the sample. Means and standard deviation were calculated for continuous variables; and percentages and frequencies, for categorical variables. Second, we tested the measurement invariance of the scales. This was essential because we used data from a randomized controlled trial and we needed to understand to what extent the intervention, performed on Arms 1 and 2, had influenced scale scores. The procedures used to measure invariance are detailed in the Appendix. Third, we tested the hypotheses guiding the study. The following variables were entered into the model: (a) caregiver contribution to self-care maintenance and caregiver contribution to self-care management scores at baseline (autoregressive variables) and 3 months (independent variables), (b) patient self-care maintenance and self-care management at 3 months (mediators), (c) Heart Failure Somatic Perception Scale scores at 3 months (dependent variable), and (d) dummy variables of the intervention (covariates). We fitted an autoregressive longitudinal path analysis with contemporaneous mediation (ie, mediation within the same time point).<sup>44</sup> We used path analysis because it can handle multiple dependent variables, mediating variables, and error terms. Contemporaneous mediation was specified because we assumed that the change in mediators (ie, patient self-care maintenance and management at 3 months) began immediately after the first intervention session. To control for stability effects in constructs over time, we specified the autoregressive effects of the scale scores administered at baseline on those at 3 months; with such effects, the stability variance at 3-month follow-up is accounted for, leaving variance that can authentically explain the relationships among the scales of interest (ie, across the mediators and outcomes).<sup>45</sup> We also used the latent factor scores of the scales instead of the observed scores to lower bias due to measurement error. Finally, we adjusted for the effect of the intervention using dummy variables.

The model fit of the longitudinal path analysis was assessed with the comparative fit index (CFI) and Tucker-Lewis Index (TLI) with acceptable fit ranges of 0.90 and 0.95, or  $>0.95$  indicating a good fit; root mean square error of approximation (RMSEA) with values  $\geq 0.10$  indicating poor fit; and standardized root mean square residual (SRMR) with values  $\leq 0.08$  indicating good fit. We also report traditional  $\chi^2$  statistics but did not use it to interpret model fit.<sup>46</sup> To test the hypotheses that patient self-care maintenance mediates the relationship

between caregiver contribution to self-care maintenance and patient symptom burden (M1) and that patient self-care management mediates the relationship between caregiver contribution to self-care management and patient symptom burden (M2), we assessed indirect effects. Specifically, we tested the indirect effect from caregiver contribution to self-care maintenance to symptom burden through patient self-care maintenance and the indirect effect of caregiver contribution to self-care management to symptom burden through patient self-care management. To test these indirect effects, we used the distribution of coefficients with 10 000 bias-corrected bootstrapped confidence intervals (CIs).<sup>47</sup> We used SPSS v25 to conduct the descriptive data analysis<sup>48</sup> and Mplus 8.4 to do the measurement invariance analysis and the longitudinal path analysis.<sup>49</sup>

## Results

### Characteristics of the Participants

We enrolled 510 caregivers and 510 patients with heart failure. Caregivers had a mean age of 54 years and were mostly female (74.5%), partnered (70.8%), and working (73.5%). On average, their contribution to patient self-care was inadequate (<70) (Table 1). Patients had a mean age of 72.4 years and were mostly male (68%), partnered (62.0%), retired (83.9%), and in New York Heart Association class II (61.4%). On average, their self-care behaviors were inadequate (<70), and their symptom burden was low (Table 1).

### Measurement of Scale Invariance

At baseline, all the scales were fully invariant, except for the caregiver contribution to self-care management scale, which only showed partial strict invariance. Regarding the scales at the 3-month follow-up, the only fully invariant scale was the patient self-care management and caregiver contribution to self-care maintenance scale. The caregiver contribution to self-care management scale reached partial metric invariance, whereas the Heart Failure Somatic Perception Scale and self-care maintenance scales did not even reach the configural step (Appendix).

In the longitudinal invariance models, the Heart Failure Somatic Perception Scale reached partial strict invariance, whereas the patient self-care maintenance and management scales reached partial scalar invariance. The caregiver contribution to self-care maintenance scale was fully invariant, whereas the caregiver contribution to self-care management scale only reached partial metric invariance (Appendix: Table A2). Considering the results of the invariance analysis, the mediation model was fitted with latent factor scores because the scales were not fully invariant across groups and time.

### Hypothesis Testing

The autoregressive longitudinal path analysis yielded adequate fit indices ( $\chi^2[41] = 86.78$ ,  $P < .001$ ; root

**TABLE 1** Descriptive Statistics of the Participants and Instruments' Scores at Baseline and 3-Month Follow-up

	Patients (n = 510)	Caregivers (n = 510)
	Mean (SD) or n (%)	Mean (SD) or n (%)
Baseline measures		
Age, y	72.37 (12.28)	53.97 (15.46)
Gender (female)	214 (42)	380 (74.5)
Education (middle school or higher)	168 (33)	430 (85.9)
Marital status		
Single/never married	24 (4.7)	93 (18.2)
Married/partnered	316 (62)	361 (70.8)
Divorced/separated	20 (3.9)	36 (7.1)
Widowed	150 (29.4)	12 (2.4)
Occupation (retired)	428 (83.9)	135 (26.5)
Relationship with patient		
Spouse	—	189 (37.1)
Child	—	196 (38.4)
Sibling	—	17 (3.3)
Other	—	101 (19.8)
CCI	2.91 (1.98)	—
NYHA class		
II	313 (61.4)	—
III	160 (31.4)	—
IV	33 (6.5)	—
Illness duration, mo	66.7 (76.66)	—
HFSPS	27.78 (16.61)	—
SCHFI maintenance	45.44 (15.39)	—
SCHFI management	39.73 (17.64)	—
CC-SCHFI maintenance	—	51.48 (19.69)
CC-SCHFI management	—	51.24 (20.39)
T1 measures		
HFSPS (n = 146 missing)	23.88 (15.95)	—
SCHFI maintenance (n = 179 missing)	52.13 (20.42)	—
SCHFI management (n = 179 missing)	50.13 (20.42)	—
CC-SCHFI maintenance (n = 191 missing)	—	54.52 (20.63)
CC-SCHFI management (n = 191 missing)	—	58.59 (19.10)

Missing values were handled with the full information maximum likelihood estimation. Percentages may not add up to 100% because of missing values. Abbreviations: CCI, Charlson Comorbidity Index; CC-SCHFI, Caregiver Contribution to Self-Care of Heart Failure Index; HFSPS, Heart Failure Somatic Perception Scale; NYHA, New York Heart Association; SCHFI, Self-Care of Heart Failure Index; SD, standard deviation; T0, baseline; T1, 3-month follow-up.

mean square error of approximation, 0.047; 90% confidence interval, 0.33–0.06;  $P = .63$ ; comparative fit index, 0.93; Tucker-Lewis Index, 0.92; standardized root mean square residual, 0.05). The model significantly accounted for 37% of the total variance in the Heart Failure Somatic Perception Scale scores ( $P < .001$ ). Table 2 summarizes the indirect effects of the hypotheses we tested. The Figure shows the results of testing the hypothesized associations.

**TABLE 2** Standardized Specific Indirect Effects of the Longitudinal Mediation Model

Indirect Effects	Estimate (β)	95% BC Bootstrapped CI	
		Lower	Upper
CC to self-care maintenance (T0) → CC to self-care maintenance (T1) → SCHFI maintenance (T1) → symptom burden (T1)	<b>-0.038</b>	-0.063	-0.021
CC to self-care maintenance (T1) → SCHFI maintenance (T1) → symptom burden (T1)	<b>-0.079</b>	-0.130	-0.043
CC to self-care management (T0) → CC to self-care management (T1) → SCHFI management (T1) → symptom burden (T1)	0.009	-0.012	0.044
CC to self-care management (T1) → SCHFI management (T1) → symptom burden (T1)	0.013	-0.016	0.060

"T0" and "T1" are the time points at baseline and 3-month follow-up, respectively. The significance of the effects was obtained by the bias-corrected bootstrap confidence intervals (based on 10 000 bootstrap replications). Significant estimates are indicated in bold. Abbreviations: BC, bias corrected; CC, caregiver contribution; CI, confidence interval; SCHFI, Self-Care of Heart Failure Index; β, standardized coefficient.

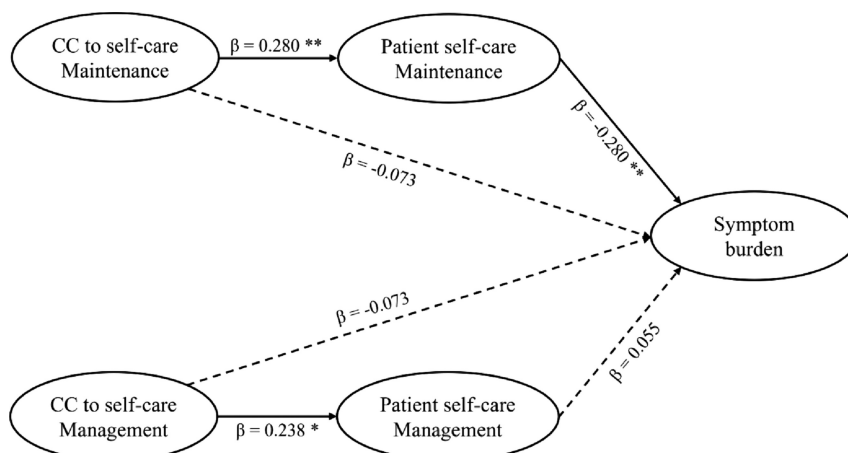
Most of our hypotheses were confirmed (Tables 1 and 2, Figure). Most importantly, we found that caregiver contribution to self-care maintenance positively influenced patient self-care maintenance, which, in turn, negatively influenced symptom burden. Moreover, patient self-care maintenance negatively mediated the association between caregiver contribution to self-care maintenance and symptom burden ( $\beta = -0.079$ ; 95% bias-corrected bootstrapped CI, -0.130 to -0.043). That is, better caregiver contribution to self-care maintenance led to lower symptom burden via patient self-care maintenance.

### Discussion

The overall aims of this study were to investigate the influence of caregiver contribution to self-care on symptom burden in patients with heart failure and to explore whether patient self-care mediates such a relationship. We found that caregiver contribution to self-care

maintenance influenced patient symptom burden through the mediation of patient self-care maintenance. Although caregiver contribution to self-care management influenced patient self-care management, there was not a significant path between patient self-care management and symptom burden. These findings are particularly important because they (a) expand the situation-specific theory of caregiver contribution to heart failure self-care and (b) develop the existing knowledge about the role of caregivers in heart failure self-care and the impact of caregivers on patient outcomes.

The situation-specific theory of caregiver contribution to heart failure self-care specifies how caregiver contribution to self-care can have positive and negative outcomes on both patients and caregivers. Regarding the patient outcomes, better caregiver contribution to self-care maintenance and management have been shown to be associated with higher patient quality of life<sup>50</sup> and lower mortality.<sup>51</sup> One study showed that caregiver contribution to self-care



**FIGURE.** Results of the longitudinal path analysis. The relationship between CC to self-care maintenance and symptom burden is mediated by patient self-care maintenance ( $\beta = -0.079$ ; 95% bias-corrected bootstrapped confidence interval, -0.130 to -0.043). The autoregressive longitudinal path analysis yielded adequate fit indices ( $\chi^2[41] = 86.78$ ,  $P < .001$ ; root mean square error of approximation, 0.047; 90% confidence interval, 0.33–0.06;  $P = .63$ ; comparative fit index, 0.93; Tucker-Lewis Index, 0.92; standardized root mean square residual, 0.05). The model significantly accounted for 37% of the total variance in the Heart Failure Somatic Perception Scale scores ( $P < .001$ ). Abbreviations: CC, caregiver contribution; β, standardized coefficient, \* $P < .01$ ; \*\* $P < .001$ .

maintenance was positively associated with patient self-care management, and another study showed that caregiver contribution to self-care management mediated the relationship between caregiver preparedness and patient readmission at 3 months and length of hospital stay.<sup>51</sup> In this study, we have shown that caregiver contributions to self-care maintenance and management influence patient self-care maintenance and management, respectively, and that caregiver contribution to self-care maintenance influences patient symptom burden through the mediation of patient self-care maintenance. In practice, this means that if caregivers recommend behaviors such as physical activity, medication taking, or follow-up visit attendance, patients are better at performing such self-care behaviors and, eventually, experience lower symptom burden. Interestingly, we did not find a direct effect of caregiver contribution to self-care maintenance on symptom burden ( $\beta = -0.07, P = .159$ ), and this highlights that caregiver contribution to self-care maintenance improves symptom burden *only through* patient self-care. To our knowledge, this is the first study demonstrating an impact of caregiver contribution to self-care on patient symptom burden and the second one<sup>28</sup> demonstrating that patient self-care is a proximal outcome of caregiver contribution to heart failure self-care.

We were surprised to find that patient self-care management was not associated with symptom burden and, consequently, was not a mediator. The patient self-care management scale evaluates how quickly patients recognize heart failure symptoms (eg, dyspnea), how likely they implement strategies to address symptoms (eg, reduce fluid intake), and how sure they are that the implemented remedy worked. The lack of association between patient self-care management and symptom burden could be explained by the fact that many different scenarios may occur among patients, making it difficult to find a clear and significant association. For example, in some cases, low symptom burden may be associated with low self-care management behaviors (as they would not be necessary in this scenario), whereas in others, high symptom burden may be associated with high self-care management behaviors<sup>52</sup> (as they would be implemented as a compensatory strategy in this scenario). In another scenario, high and effective self-care management behaviors may lead to low symptom burden<sup>53,54</sup> (meaning that they succeeded in reducing the burden caused by the symptoms). Indeed, what is measured is the burden of symptoms (neither the mere incidence of symptoms nor the clinical signs). Therefore, the association between self-care management and symptom burden may vary over time, capturing different points of the self-care process.

In our study, we also found that patient self-care maintenance influenced patient self-care management, as predicted by the theory.<sup>55</sup> However, we did not find any association between caregiver contribution to self-care

maintenance and caregiver contribution to self-care management. So far, only 2 studies<sup>56,57</sup> found that caregiver contribution to self-care maintenance influenced caregiver contribution to self-care management. Therefore, more evidence is needed to support such a relationship.

## Implications for Clinical Practice and Research

Our study has important clinical implications in heart failure care. Although further studies are necessary to confirm what we observed, our findings suggest that interventions targeting caregiver contribution to self-care can improve patient self-care and patient symptom burden. Preventing and alleviating the burden of symptoms in patients with heart failure is essential because physical symptoms, such as dyspnea and edema,<sup>11,14,58,59</sup> contribute to a lower quality of life,<sup>10-13</sup> and increased hospitalization<sup>14,15</sup> and mortality rates.<sup>10,16</sup>

Our results have several implications for research. First, they paved the way for further studies to confirm the association between caregiver contribution to self-care maintenance and physical symptom burden in patients with heart failure. If such a relationship is confirmed, it would be important to assess whether interventions aimed at improving caregiver contribution to self-care can also improve the burden of symptoms. Second, our findings underscore the importance of better investigating the association and the possible causality between caregiver contribution to self-care management, patient self-care management, and symptom burden. Indeed, caregiver contribution to self-care management and patient self-care management may be associated with high symptom burden too (as in our results, although not significant). This could be explained in different ways. It could indicate that the burden caused by the symptoms was high enough to stimulate the caregiver and the patient to engage in more intense self-care management behaviors. However, it could also indicate that, despite intense self-care management behaviors, patients were still burdened by their symptoms, and therefore, these self-care management behaviors might be inadequate. Alternatively, self-care management and symptom burden may be negatively associated.

## Strengths and Limitations

This study is novel in its focus and results that describe how caregiver contribution to self-care can influence the burden of symptoms in patients with heart failure. Similarly, to our knowledge it is the first to show the mediating role of patient self-care between caregiver contribution to self-care and symptom burden. The large sample size and the longitudinal nature of the data, allowed causal inference among the variables. Finally, invariance assessment, subsequent adjustment of the

### What's New and Important

- Higher caregiver contribution to self-care maintenance is associated with lower symptom burden in patients with heart failure.
- Patient self-care maintenance mediates the relationship between caregiver contribution to patient self-care maintenance and symptom burden.

autoregressive model, and use of factorial scores represent additional strengths of the analysis because they limit threats to inference bias, which are typical of randomized controlled trials.

This study also has limitations. First, the patients were mostly in New York Heart Association class II; hence, we do not know whether the burden of symptoms experienced by patients in higher classes could have led to different results. Second, our study purposefully recruited patients with low self-care; thus, the associations that we observed between patient self-care, caregiver contribution to self-care, and symptom burden may be specific to the group of patients with poorer self-care. Third, the measures available at the time of the study had the self-care monitoring elements embedded in the self-care maintenance scales. Consequently, it was not possible to assess whether symptom burden was differently associated to caregiver contribution to self-care maintenance or caregiver contribution to self-care monitoring. The same applies to the mediating role of patient self-care maintenance and self-care monitoring. Finally, we included dummy variables for the intervention group versus the control group for both patients and caregivers to adjust the total scores, however, we do not know whether this led to a complete control given that we used factor scores instead of the single items for each dimension.

### Conclusions

In conclusion, the results of this study expanded the theory of caregiver contribution to heart failure self-care, showing patient self-care as an outcome of the theory. Moreover, this study showed that caregiver contribution to self-care maintenance and patient self-care maintenance can alleviate symptom burden in heart failure.

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## APPENDIX

### Procedures for measurement invariance testing

For this study, we tested for both group and longitudinal invariance. Group invariance was tested across all scales administered at baseline in the 3 arms (eg, caregiver contribution to self-care maintenance in arms 1, 2, and 3) and across all scales administered at the 3-month follow-up. Specifically, regarding the Caregiver Contribution to Self-Care of Heart Failure Index scales, we tested group invariance between arm 2 (in which caregivers had received the intervention) and arm 1 plus arm 3 (in which caregivers had not received the intervention). Regarding the Self-Care of Heart Failure Index 6.2 scales and the Heart Failure Somatic Perception Scale, we tested group invariance between arms 1 and 2 (in which the patients had received the intervention) versus arm 3 (in which the patients had not received the intervention). Longitudinal invariance was tested for all the measures across the 2 time points (baseline and three-month follow-up).

Measurement invariance of all the scales was performed with multigroup confirmatory factor analysis<sup>60</sup> using a stepwise framework,<sup>61</sup> in which the invariance assessment occurs at different hierarchical levels and in multiple groups or time points simultaneously. We used the robust maximum likelihood estimator on all invariance models, because many items in the scales were skewed (skewness and kurtosis > 1), and the multivariate normality testing (Mardia test) was significant ( $P < .001$ ). For each invariance step (ie, configural, metric, scalar, and strict), we compared the fit of the models with the differences in comparative fit index ( $\Delta$ CFI) and root mean square error of approximation ( $\Delta$ RMSEA); invariance is established if  $\Delta$ CFI is  $\leq 0.01$  and  $\Delta$ RMSEA is  $< 0.015$ .<sup>62</sup>  $\chi^2$  Difference test was not used to judge invariance, because this method has high sensitivity to sample size.<sup>46</sup>

### Results of group measurement invariance

The baseline starting models for the invariance testing were selected from the available literature.<sup>38,41,43</sup> The Heart Failure Somatic Perception Scale was specified with 4 factors according to Pucciarelli et al.<sup>43</sup> The fit was marginal due to the presence of a covariance among the residuals of items 14 and 11 and items 6 and 7:  $\chi^2(128, N = 510) = 405.79, P < .001$ ; root mean square error of approximation, 0.065;  $P < .001$ ; 90% CI, 0.06–0.07; comparative fit index, 0.905; Tucker-Lewis Index, 0.89; and standardized root mean square residual, 0.05. These covariances are reasonable because the first couple of items reflect fluid retention and the second reflect 2 symptoms that can coexist in heart failure. Consequently, we respecified the model with these covariances, after which the fit of the model improved:  $\chi^2(127, N = 510) = 342.59, P < .001$ ; root mean square error of approximation, 0.058;  $P < .001$ ; 90% CI, 0.05–0.07; comparative fit index, 0.93; Tucker-Lewis

Index, 0.91; and standardized root mean square residual, 0.05. The latter specification was used to test for group measurement invariance, by which we obtained full invariance at T0 (Table A1). At T1, the starting model did not even obtain configural invariance:  $\chi^2(258, N = 364) = 631.74, P < .001$ ; root mean square error of approximation = 0.089,  $P < .001$ ; 90% CI, 0.08–0.10; comparative fit index, 0.86; Tucker-Lewis Index, 0.84; and standardized root mean square residual, 0.08.

The self-care maintenance scale was specified on the full sample with the factor solution according to Vellone et al.<sup>38</sup> However, the fit of the model was unsatisfactory:  $\chi^2(33, N = 510) = 256.69, P < .001$ ; root mean square error of approximation = 0.115,  $P < .001$ ; 90% CI, 0.10–0.13; comparative fit index, 0.69; Tucker-Lewis Index, 0.58; and standardized root mean square residual, 0.09. An exploratory factor analysis suggested the presence of 2 factors, which were composed of items 1, 4, 6, 7, and 9, and the other with items 2, 3, 5, 8, and 10. The first factor was named *health-promoting behaviors* because all the items were related to preventive behaviors, whereas the second factor was named *illness-related behaviors* because all the items were related to actions to manage the disease. When we specified a new confirmatory factor analysis with this solution, we obtained unsatisfactory fit indices due to the excessive covariances between the residuals of items 2 and 10 and items 7 and 4. These covariances were reasonable because the first couple of items were related to monitoring practices that often co-occur in heart failure, and the second was related to physical activity. When we specified the confirmatory factor analysis with these covariances, we obtained marginal, although acceptable, fit indices:  $\chi^2(32, N = 510) = 104.45, P < .001$ ; root mean square error of approximation, 0.067;  $P < .001$ ; 90% CI, 0.05–0.08; comparative fit index, 0.90; Tucker-Lewis Index, 0.86; and standardized root mean square residual, 0.05. With this model, we obtained full group measurement invariance at T0. At T1, this starting model did not even obtain configural invariance:  $\chi^2(71, N = 364) = 276.53, P < .001$ ; root mean square error of approximation, 0.126;  $P < .001$ ; 90% CI, 0.11–0.14; comparative fit index, 0.82; Tucker-Lewis Index, 0.77; and standardized root mean square residual, 0.12 (Table A1).

The self-care management scale was specified with the factor structure according to Vellone et al,<sup>38</sup> but the fit was unsatisfactory:  $\chi^2(28, N = 298) = 55.98, P = .001$ ; root mean square error of approximation, 0.082;  $P < .001$ ; 90% CI, 0.05–0.11; comparative fit index, 0.80; Tucker-Lewis Index, 0.79; and standardized root mean square residual, 0.08. An inspection of the modification indices revealed an excessive covariance between items 13 and 15. These items were related to the consultation of a doctor or nurse for guidance and the reduction of fluid intake. After specification of this covariance, the fit of the model improved significantly:  $\chi^2(7, N = 367) = 14.20, P = .048$ ; root mean square error of approximation, 0.053;  $P < .001$ ; 90% CI, 0.01–0.09; comparative fit index, 0.96; Tucker-Lewis Index, 0.92; and standardized root mean square residual, 0.03. The

**TABLE A1** Group Measurement Invariance Across the Control and Experimental Groups at Baseline (T0) and 3-Month Follow-up (T1)

Scale	Model	$\chi^2$	<i>P</i>	<i>df</i>	RMSEA	RMSEA (CI)	CFI	$\Delta$ CFI	$\Delta$ RMSEA	Note
Heart Failure Somatic Perception Scale (T0)	Configural	485.002	<.001	254	0.060	(0.052–0.068)	0.923	—	—	Specified
	Metric	500.894	<.001	269	0.058	(0.050–0.066)	0.923	0.000	–0.002	covariances:
	Scalar	518.195	<.001	287	0.056	(0.048–0.064)	0.923	0.000	–0.002	items 14
	Strict	531.421	<.001	305	0.054	(0.046–0.062)	0.925	–0.002	–0.002	and 11,
	Strict with cov.	529.780	<.001	307	0.053	(0.046–0.061)	0.926	–0.001	–0.001	items 6
Self-care maintenance scale (T0)	Factorial	535.350	<.001	313	0.053	(0.045–0.060)	0.926	0.000	0.000	and 7
	Configural	140.945	<.001	66	0.067	(0.051–0.082)	0.900	—	—	Specified
	Metric	147.697	<.001	76	0.061	(0.046–0.075)	0.903	0.003	–0.006	covariances:
	Scalar	157.384	<.001	86	0.057	(0.043–0.071)	0.904	0.001	–0.004	items 4
	Strict	165.883	<.001	95	0.054	(0.040–0.068)	0.905	0.001	0.003	and 7, items
Caregiver contribution to self-care maintenance scale (T0)	Strict cov.	166.184	<.001	97	0.053	(0.039–0.066)	0.907	0.002	0.001	2 and 10
	Factorial	170.342	<.001	98	0.054	(0.040–0.067)	0.903	–0.004	0.001	
	Configural	102.929	<.001	54	0.060	(0.042–0.077)	0.958	—	—	Specified
	Metric	106.517	<.001	65	0.050	(0.032–0.067)	0.964	0.006	–0.010	covariances:
	Scalar	118.991	<.001	75	0.048	(0.031–0.064)	0.962	–0.002	–0.002	items 5
Caregiver contribution to self-care maintenance scale (T1)	Strict	128.736	<.001	85	0.045	(0.028–0.060)	0.962	0.000	–0.003	and 8
	Strict cov.	127.300	.003	86	0.044	(0.026–0.059)	0.964	0.002	–0.001	
	Factorial	143.805	.001	92	0.047	(0.032–0.062)	0.955	–0.011	0.003	
	Configural	96.115	<.001	54	0.070	(0.046–0.092)	0.955	—	—	Specified
	Metric	108.941	.001	65	0.065	(0.043–0.086)	0.954	–0.001	–0.005	covariances:
Caregiver contribution to self-care management scale (T0)	Scalar	128.742	<.001	75	0.067	(0.047–0.086)	0.943	–0.011	–0.002	items 5
	Strict	142.088	<.001	85	0.065	(0.046–0.083)	0.940	–0.002	–0.002	and 8
	Strict cov.	140.232	<.001	86	0.063	(0.043–0.081)	0.943	0.003	–0.002	
	Factorial	158.847	<.001	92	0.067	(0.049–0.085)	0.929	–0.014	0.004	
	Configural	37.745	<.001	14	0.090	(0.060–0.134)	0.927	—	—	Specified
Caregiver contribution to self-care management scale (T1)	Metric	46.984	<.001	20	0.086	(0.054–0.118)	0.917	–0.010	–0.004	covariances:
	Scalar	53.850	.001	26	0.077	(0.047–0.106)	0.914	–0.003	–0.009	items 5
	Strict	67.590	<.001	32	0.078	(0.052–0.104)	0.891	–0.023	0.001	and 8
	Partial strict <sup>a</sup>	56.909	.002	30	0.070	(0.041–0.098)	0.917	0.003	–0.007	
	Configural	28.873	.011	14	0.100	(0.048–0.157)	0.916	—	—	Specified
Self-care management scale (T0)	Metric	41.455	.002	19	0.109	(0.064–0.155)	0.874	–0.042	–0.009	covariances:
	Configural	631.656	<.001	258	0.089	(0.080–0.098)	0.860	—	—	items 13
	Configural	29.643	.029	17	0.064	(0.020–0.101)	0.938	—	—	and 14,
	Metric	37.822	.013	21	0.066	(0.030–0.099)	0.918	–0.020	0.002	items 13
	Scalar	41.125	.030	26	0.056	(0.018–0.088)	0.926	0.008	–0.010	and 12
Heart Failure Somatic Perception Scale (T1)	Strict	45.326	.059	32	0.048	(0.000–0.078)	0.935	0.009	–0.008	items 15
	Strict cov.	46.303	.062	33	0.047	(0.000–0.076)	0.935	0.000	–0.001	and 13
	Factorial	46.271	.078	34	0.044	(0.000–0.074)	0.940	0.005	–0.003	
	Configural	285.637	<.001	69	0.131	(0.116–0.147)	0.812	—	—	Specified
	Configural	24.876	.098	17	0.062	(0.000–0.112)	0.969	—	—	covariances:
Self-care maintenance scale (T1)	Metric	28.136	.136	21	0.053	(0.000–0.100)	0.972	0.003	–0.011	items 4
	Scalar	36.692	.101	27	0.055	(0.000–0.096)	0.962	–0.010	0.002	and 7, items
	Strict	45.999	.066	33	0.058	(0.000–0.094)	0.949	–0.013	0.003	2 and 10
	Strict cov.	46.016	.082	34	0.054	(0.000–0.091)	0.953	0.003	–0.004	
	Factorial	49.874	.049	35	0.060	(0.003–0.095)	0.942	–0.011	0.006	

Abbreviations: CFI, comparative fit index; CI, 90% confidence interval around RMSEA; Cov., covariance; *df*, degrees of freedom; *P*, *P* value of  $\chi^2$ ; RMSEA, root mean square error of approximation;  $\Delta$ CFI, change in the CFI relative to the preceding model;  $\Delta$ RMSEA, change in the RMSEA relative to the preceding model.  
<sup>a</sup>Release of variance of item 12.

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latter model was used as the baseline for testing the group measurement invariance. Table A1 indicates that, with this scale, we reached full invariance between the groups at both T0 and T1.

The caregiver contribution to self-care maintenance scale was specified according to Vellone et al.<sup>40</sup> The fit was marginal due to the presence of 2 correlated errors between items 8 and 5. This covariance is reasonable because these are items specifically related to adhering to the healthcare provider recommendations. After specification of this covariance, the fit of the model was satisfactory:  $\chi^2(27, N = 510) = 70.82, P < .001$ ; root mean square error of approximation, 0.057;  $P < .228$ ; 90% CI, 0.04–0.07; comparative fit index, 0.96; Tucker-Lewis Index, 0.94; and standardized root mean square residual, 0.03. This model was used to test for group measurement invariance. Table A1 shows the results of the group invariance; the scale achieved full invariance at both T0 and T1.

The caregiver contribution to self-care management scale was specified according to Vellone et al.<sup>40</sup> The fit of the initial model was marginal due to the presence of 4 correlated errors, that is, between items 14 and 13 and items 13 and 12. These covariances are reasonable because the 2 pairs of items

indicate the remedies used in case of fluid retention. After specification of these 2 covariances, the fit was good:  $\chi^2(7, N = 365) = 18.96, P = .008$ ; root mean square error of approximation, 0.068;  $P = .176$ ; 90% CI, 0.03–0.11; comparative fit index, 0.96; Tucker-Lewis Index, 0.92; and standardized root mean square residual, 0.04. This model was used as a baseline to test group invariance. At baseline, the scale reached full scalar invariance, whereas at T1, it only achieved the configural step (Table A1).

### Results of longitudinal measurement invariance

All the models specified in this step were identical to those used to test group measurement invariance. The Heart Failure Somatic Perception Scale reached partial strict invariance (Table A2). The self-care maintenance and management scales were partially scalar invariant, whereas the caregiver contribution to self-care management scale only reached partial metric invariance. The only fully invariant scale was the caregiver contribution to self-care maintenance scale (Table A2).

**TABLE A2** Longitudinal Measurement Invariance Across Baseline (T0) and 3-Month Follow-up (T1)

Scale	Model	$\chi^2$	P	df	RMSEA	RMSEA (CI)	CFI	$\Delta$ CFI	$\Delta$ RMSEA	Note
Heart Failure Somatic Perception Scale	Configural	1151.554	<.001	544	0.047	(0.043–0.051)	0.910			Covariances: items 14 and 11, items 6 and 7
	Metric	1186.162	<.001	562	0.047	(0.043–0.050)	0.908	–0.002	0.000	
	Scalar	1280.180	<.001	580	0.049	(0.045–0.052)	0.897	–0.011	0.002	
	Strict	1451.870	<.001	598	0.053	(0.049–0.056)	0.874	–0.023	0.004	
	Partial strict <sup>a</sup>	1379.702	<.001	596	0.051	(0.047–0.054)	0.885	–0.012	–0.002	
Self-care maintenance scale	Configural	429.919	<.001	146	0.062	(0.055–0.069)	0.892			Covariances: items 7 and 4, items 2 and 10
	Metric	467.923	<.001	156	0.063	(0.056–0.069)	0.881	–0.011	0.001	
	Scalar	625.799	<.001	166	0.074	(0.068–0.080)	0.825	–0.056	0.011	
	Partial scalar <sup>b</sup>	508.972	<.001	160	0.065	(0.059–0.072)	0.867	–0.014	0.002	
Self-care management scale	Configural	77.831	.001	41	0.046	(0.030–0.062)	0.939			Covariances: items 15 and 13
	Metric	96.564	<.001	47	0.050	(0.036–0.065)	0.918	0.021	0.004	
	Scalar	135.519	<.001	53	0.061	(0.048–0.074)	0.863	–0.050	0.009	
	Partial scalar <sup>c</sup>	104.007	<.001	50	0.051	(0.037–0.065)	0.910	–0.008	–0.010	
Caregiver contribution to Self-care maintenance scale	Configural	230.915	<.001	128	0.040	(0.032–0.048)	0.964			Covariances: items 5 and 8
	Metric	259.329	<.001	139	0.041	(0.034–0.049)	0.958	–0.006	0.001	
	Scalar	281.660	<.001	149	0.042	(0.034–0.049)	0.954	–0.004	0.001	
	Strict	316.400	<.001	159	0.044	(0.037–0.051)	0.946	–0.010	0.002	
	Strict cov.	314.336	<.001	160	0.044	(0.037–0.051)	0.947	0.000	0.001	
Caregiver contribution to self-care management scale	Factorial	319.672	<.001	166	0.043	(0.036–0.050)	0.947	0.000	–0.001	Covariances: items 13 and 14, items 13 and 12
	Configural	87.362	<.001	39	0.057	(0.041–0.072)	0.934			
	Metric	106.977	<.001	45	0.060	(0.045–0.074)	0.916	–0.018	0.003	
	Partial metric <sup>d</sup>	102.606	<.001	43	0.060	(0.045–0.075)	0.919	–0.015	0.000	

Abbreviations: CFI, comparative fit index; Cov., covariance; df, degrees of freedom; P, P value of  $\chi^2$ ; RMSEA, root mean square error of approximation; 90% CI, 90% confidence interval around RMSEA;  $\Delta$ CFI, change in the CFI relative to the preceding model;  $\Delta$ RMSEA, change in the RMSEA relative to the preceding model.

<sup>a</sup>Release of variances of items 9 and 13.

<sup>b</sup>Release of intercepts of items 2, 5, 8, 9, and 10.

<sup>c</sup>Release of intercepts of items 13, 14, and 15.

<sup>d</sup>Release of loadings of items 15 and 16.