The role of self-efficacy in the self-care of patients with chronic conditions

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THE ROLE OF SELF-EFFICACY IN THE SELF-CARE OF PATIENTS WITH CHRONIC CONDITIONS

by

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A thesis submitted in total fulfilment of the requirements for the Doctoral Degree in Nursing Science

University of Rome Tor Vergata

Faculty of Medicine and Surgery

Joint Degree with the

Australian Catholic University

Year of Submission

2022

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ACKNOWLEDGMENTS

Firstly, I would like to express my infinite gratitude to my advisors Prof. Ercole Vellone and Prof. Barbara Riegel for their continuous support during my PHD program. Their guidance helped me anytime during my time of research, and constantly evoked my motivation and studies.

Secondly, I would like to thank all the colleagues who contributed to ending this brilliant PHD program: Rosaria Alvaro, Professor at the University of Rome Tor Vergata, Christopher S. Lee and Karen Lyons, Professors at the Boston College University for your co-authorship during my PHD program.

Finally, I would like to thank my family, who sustained me indirectly during this endeavor. They have meant to me more than they will ever know.

ABSTRACT OF THE DISSERTATION

Background. The management of chronic conditions requires that patients perform specific self-care behaviors and obtain the contribution of their families (e.g., for taking medications as prescribed and eating a healthy diet). Self-care is associated with better outcomes in chronic conditions (e.g., improved quality of life and mortality). However, patients often struggle to perform self-care. Self-efficacy, defined as the confidence to perform a certain behavior despite barriers, can improve patient self-care behaviors and the contribution of their family caregivers. However, so far, we still do not know whether patient self-efficacy can influence the relationship between family support and self-care in populations with multiple chronic conditions (MCC). Self-efficacy represents an easily targetable construct; the use of psychoeducational interventions such as motivational interviewing (MI) can improve intermediate outcomes (e.g., quality of life and self-care). However, little is known whether this intervention can also improve distal outcomes (i.e., mortality and health services use) as a result of self-care behavior change.

Objective. The objective of this research program was to (i) describe the mechanism by which family support influences self-care in people with multiple chronic conditions, with particular focus on patient self-efficacy; (ii) develop an instrument to measure caregiver self-efficacy in contributing to patient self-care (CSE-CSC scale) in MCC, and (iii) investigate the influence of a MI intervention that targets self-efficacy, in improving health service use and mortality in a chronic disease population (i.e., heart failure) as a result of sustained behavior change.

Methods. In the first cross-sectional study we analyzed data from the SODALITY study, which enrolled a sample of 541 older adults affected by MCC (mean age = 76.6 ± 7.3 years, 55.6% females) from seven Italian regions. Data were analyzed by descriptive statistics and a series of structural equation models. In the second cross-sectional study, we enrolled 358 caregivers (mean age = 54.6 ± 15.1 years, 71.5% females) of patients from the SODALITY

study. Data were analyzed with descriptive statistics, exploratory and confirmatory factor analysis, and reliability analysis. In the third study we analyzed longitudinal data from the MOTIVATE-HF trial. Patients and caregivers were randomized to Arm 1 (MI for patients), Arm 2 (MI for patients and caregivers) or Arm 3 (control group). months. We enrolled 510 patients (median age 74 years, 58% male) and caregivers (median age 55 years, 75% female) and we collected data at baseline and at 3, 6, 9 and 12 months. Above and beyond descriptive statistics, we performed a longitudinal generalized linear mixed model and unadjusted Cox proportional-hazards regression model.

Results. In the first study depression and self-efficacy were significant mediators of the relationship between family support and self-care; however, in men, depression was not a significant mediator. In the second study, the dimensionality analysis of the CSE-CSC confirmed 2 factors within the scale. Construct validity testing showed significant correlations between the scores of the CSE-CSC scale and the scores of the Caregiver Contributions to Self-Care of Chronic Illness Inventory scales. Reliability coefficients were also satisfactory. In the third study, we found that 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 differences. 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 ($p=0.04$), but no difference was found at subsequent follow-ups.

Conclusion. This doctoral dissertation offers new knowledge on the self-efficacy construct in patients and caregivers in the context of MCC. The finding that self-efficacy is reaffirmed as essential in the dynamics of family and self-care in MCC allows us to target this construct more effectively in clinical environments. We also provided investigators with a new instrument to measure self-efficacy of the caregivers; this tool has adequate psychometric properties and is ready for use both in clinical practice and research. Finally, we provided evidence on the effectiveness of motivational interviewing on mortality in heart failure

patients. Health care professionals will have stronger evidence to rely on, to incorporate MI into their interactions with patients. These results contribute to advancing the science of family nursing in HF self-care.

Keywords. Caregivers, depression, family support, heart failure, instrument development, multiple chronic conditions, self-care, self-efficacy.

CHAPTER 1 - Introduction

Overview

According to the Centre for Disease Control and Prevention (CDC), chronic conditions are disorders that last more than 12 months, necessitate ongoing medical attention, and significantly limit activities of daily living (Airhihenbuwa, Tseng, Sutton, & Price, 2021). The World Health Organization (WHO) also states that chronic conditions are those that cannot be passed from person to person and possess characteristics of long duration and slow progression (WHO, 2014).

Globally, the impact of chronic conditions is considerable; recent updates estimate about 40 million deaths worldwide, of which, almost a half are accounted for by cardiovascular diseases (WHO, 2021). Not surprisingly, the management of chronic diseases remains a major challenge for the health care systems, which have been mostly designed to deal with acute care rather than provision of care for people affected by long-term conditions (Reynolds et al., 2018).

Being affected by a chronic condition means experiencing a life-changing event that potentially impacts all aspects of life (Benkel, Arnby, & Molander, 2020). Patients are required to manage their disease, be knowledgeable about disease trajectory and learn how to identify and manage symptoms. Self-care is increasingly recognized as a promising strategy for treating chronic conditions. Self-care was defined as a naturalistic decision-making process aiming at maintaining health and managing illness (Barbara Riegel et al., 2004). Thought of as an evolutionary approach compared to that of the traditional patient-provider relationship, during self-care, individuals play a key role in driving their care, either autonomously or in collaboration with the health-care providers (Grady & Gough, 2014). As chronic conditions continue to grow, self-care will increasingly be conceived as indispensable for promoting well-being and managing the chronic disease.

The burden of multiple chronic conditions

What makes the management of chronic conditions so challenging is that they do not often exist or occur in isolation. This describes a situation of multiple chronic conditions (MCC), defined as the presence of two or more chronic medical conditions simultaneously (Wang, Palmer, Cocker, & Sanderson, 2017). MCC, which are highly prevalent in older populations of many high-income countries (approximately between 20% and 70%) (Xu, Mishra, & Jones, 2017), are estimated to increase globally. Driven by the aging of the population, urbanization, and the growing burden of single chronic conditions, MCC make this epidemiological scenario an emerging global priority (Lancet, 2018). Not surprisingly, MCC are known to have a detrimental impact on several health outcomes.

Pooled results from systematic reviews highlight important negative associations between MCC and physical functioning (Ryan, Wallace, O'Hara, & Smith, 2015), health-related quality of life (Makovski, Schmitz, Zeegers, Stranges, & van den Akker, 2019), and overall survival (Wei & Mukamal, 2018). Three major chronic conditions that are frequently found in a context of MCC are chronic obstructive pulmonary disease (COPD), heart failure (HF) and diabetes mellitus type 2 (DM). They have in common a high morbidity, mortality, and prevalence, and the fact that they often coexist or are found in a context of MCC, that is, with other chronic conditions (e.g., COPD and HF, or HF and atrial fibrillation, or DM and stroke and so on), may complicate care, its treatment and patients' lives. For example, patients with asthma may need to be treated with steroids but in case they have diabetes, steroid treatment can increase blood glucose; steroids for the treatment of chronic airways disease can also create complications in comorbid HF patients, due to the potential increase in sodium and consequent fluid retention (Caughey, Roughead, Shakib, Vitry, & Gilbert, 2011).

Self-care in chronic conditions

The management of chronic conditions is tremendously complex, as it requires that patients perform specific self-care behaviors and obtain support from their families (Liddy, Blazkho, & Mill, 2014). As noted above, self-care was defined as a naturalistic decision-making process aimed at maintaining health and managing illness (Barbara Riegel et al., 2004). According to the Middle Range Theory of Chronic Illness, key health behaviors in self-care include self-care maintenance, self-care monitoring, and self-care management (B. Riegel, Jaarsma, & Stromberg, 2012).

Self-care maintenance represents the set of behaviors that are performed to maintain physical and emotional stability and preserve health; some of these practices can be related to maintaining a healthy lifestyle (e.g., smoking cessation, healthy sleeping) or ensuring adherence to treatment (i.e., taking medications as prescribed). Self-care monitoring is a process of surveillance of the body in search of signs and symptoms of the chronic condition. Some examples of activities related to self-care monitoring are blood sugar testing in diabetes or checking arterial blood pressure in patients with hypertension. Self-care management implies a response to signs and symptoms when they occur and whether the behavior adopted has worked to resolve the issue. A typical self-care management behavior is the consultation with a health-care provider in search of recommendations, or an autonomous intervention (e.g., adjust the diet in case of high blood sugar) when a symptom occurs.

A key aspect of self-care in chronic condition is that maintenance, monitoring, and management are distinct but interrelated behaviors, although they may not take place at the same time. For example, some patients may perform scarce maintenance behaviors and get engaged only when signs and symptoms occur. Others (mainly those asymptomatic or with sufficient clinical stability) may be committed to preventative healthy lifestyles, with the belief that this may keep away signs and symptoms of their disease. In the theory, patients'

self-care maintenance is mastered before self-care monitoring and monitoring is mastered before management.

Outcomes of self-care in chronic conditions

There is mounting evidence underlying positive associations between self-care levels and a variety of proximal and distal health outcomes in single chronic conditions. For example, a systematic review (Abshire et al., 2015) investigated whether interventions to improve nutrition in HF patients could lead to better outcomes; the results indicated improvements in adherence of self-reported diet, but also a decrease in readmission rates. Clinical outcomes improved as well, especially B-type natriuretic peptide and aldosterone.

Other studies found a positive effect on even more distal health outcomes; two important systematic reviews focusing on patients with diabetes and heart failure, respectively, underscored that interventions to promote self-care could improve mortality (He et al., 2017) and readmission rates (Ruppar, Cooper, Mehr, Delgado, & Dunbar-Jacob, 2016). Quality of life is another important outcome with high sensitivity to self-care practices, as revealed by the systematic review by Cannon et al. (2016), in which self-care interventions improved quality of life in COPD patients. Finally, as a consequence of the decrease in health care utilization, self-care also potentially reduces the total costs of the health care systems (Panagioti et al., 2014).

Poor self-care in people with chronic conditions

Although there is mounting evidence that self-care can improve health outcomes in chronic conditions, research on this field consistently finds poor performance of these behaviors. We can divide the evidence as coming from quantitative (e.g., cross sectional studies, systematic reviews) and qualitative studies (e.g., semi-structured or unstructured interviews).

Among the quantitative evidence, we distinguish the work conducted by da Rocha, Silva, and Cardoso (2020). This author systematically examined 34 articles in search of evidence about levels of adherence to self-care in patients with diabetes mellitus type 2. The results indicated that general adherence was poor, and physical exercise was the least frequently performed of all the activities. Another study by Hussen, Adem, Roba, Mengistie, and Assefa (2020) randomly selected 398 hypertensive individuals in a cross-sectional design and found that only in about 30% of this sample levels of self-care adherence was satisfactory; again physical activity was the behavior least performed (i.e., 30.2%), whereas approximately half of the sample had adhered to low salt intake and prescribed medications. Finally, Cocchieri et al. (2015) studied a cohort of 1192 heart failure patients and surprisingly found that only approximately only 20% of the sample had satisfactory self-care. Consistent with the abovementioned studies, exercise was among the least frequent, alongside symptom monitoring and symptom recognition.

One of the most recent qualitative studies investigated reasons of insufficient self-care in people with chronic conditions (Sedlar, Lainscak, & Farkas, 2021), and explored barriers by means of semi-structured interviews. This study highlighted, among other things, the difficulty of changing one's lifestyle, financial burden, and problems with meeting support needs (e.g., avoidance of social activities, and not being motivated by social recognition).

A common reason of poor self-care is also found in a broad body of quantitative research, which consistently found that whenever self-care behaviors is found to be poor or insufficient in patients, correspondingly, their self-efficacy is also poor. We will learn in the next paragraphs that self-efficacy, or the belief in one's abilities to perform a specific task (in this case self-care) is a key to success with a specific behavior itself.

The concept of self-efficacy

Self-efficacy represents a central construct in the social, psychological and behavioral sciences, due to its robust predictive capabilities towards various health behaviors (Gecas,

1989). Self-efficacy was first described by the psychologist Albert Bandura in 1978 in his seminal article *"Self-Efficacy: Toward a Unifying Theory of Behavior Change"* (Bandura, 1978). In this paper the author described self-efficacy as the belief (or expectancy) regarding one's own abilities to perform specific tasks which are perceived as necessary for achieving valued goals.

Bandura also emphasized outcome expectancies, which are closely connected to the self-efficacy construct and identified as the expectations of the outcome resulting from successfully performing a specific behavior (Bandura, 1978). Self-efficacy is posited to have a causal influence on outcome expectancy, especially when a close relationship is present between the performance of the behavior (e.g., calling the health care provider due to experience of pain) and the potential outcome of the behavior (e.g., the pain would disappear or at least decrease).

The Theory of self-efficacy presented by Bandura (1978) postulates that the key determinant of success is the individual perception of his or her personal capabilities, namely his or her self-efficacy beliefs. An important assumption of this theory is that all individuals are inherently competent and able of achieving success, providing they have the opportunity and self-efficacy sufficient to achieve a specific goal (Gallagher, 2012).

Self-efficacy is a task-specific related concept. For example, an individual can exhibit high self-efficacy in exercising regularly, but low self-efficacy in adhering to a healthy diet. Self-efficacy can also be conceived as the perceived ability to perform a behavior in isolation (i.e., task self-efficacy), or rather, under specific conditions, such as in the context of potential barriers or stressful life events. This is particularly the case in health behavior studies, where self-efficacy is defined as the perceived capability to perform a certain behavior, conditioned on specific impediments: for example, self-efficacy in physical exercise can be expressed as the degree of confidence the individual can perform the exercises within the context of a

series of barriers, such as when they feel depressed or if there are potentially more interesting tasks to do (Bandura, 1997).

Sources of self-efficacy

According to Bandura (1997), self-efficacy beliefs develop from four main sources: (1) enactive mastery experiences, (2) vicarious learning, (3) verbal persuasion, and (4) psychological state at the time of behavior performance.

Enactive mastery experiences, defined as the actual performances of the individual, are known to be the most powerful source of self-efficacy information, because they reflect the best authentic evidence that the person can gather the necessary resources in order to succeed (Bandura, 1997). In other words, past and present experience of success raise and strengthen self-efficacy beliefs.

Individuals can also learn self-efficacy beliefs throughout the experience of others. The so-called *vicarious experiences* are gained by observation of others while performing the behaviors successfully, and this phenomenon can generate expectations (modeling) and social comparisons. However, vicarious experience is a less powerful source of self-efficacy than mastery experiences because it relies only on observation of other behaviors, thus it is more susceptible to change than one's own personal success (Bandura, 1978, 1997).

Verbal persuasion (or social persuasion) defines the positive effect that the suggestions and encouragement coming from other individuals (e.g., friends or family) have on self-efficacy beliefs (Bandura, 1997). A classic example of this influence is the coach who makes use of persuasion and encouragement to increase the performance of the team and the likelihood of winning in a competition.

The final source of self-efficacy information comes from the *physiological state*, that is the physical and emotional feedback originating during the performance (Bandura, 1997). Self-efficacy is highly sensitive in this context because any individual experience of stressors (e.g., depression and anxiety) generally makes it more difficult to build one's own self-

efficacy. However, it is not the objective intensity of the stressors that negatively impact on self-efficacy, but rather the perception and interpretation of them (Bandura, 1978). Thus, by managing the stressors effectively, individuals can improve self-efficacy.

Self-efficacy and self-care in chronic conditions

Self-efficacy is intimately interconnected with self-care behaviors. In this field, self-care self-efficacy is defined as the confidence that the individual has in the ability to perform self-care practices and persist despite barriers (Eller, Lev, Yuan, & Watkins, 2018). According to Social Cognitive Theory by Bandura, self-efficacy greatly influences the ability to engage in self-care behaviors (Bandura, 1986).

The construct of self-efficacy has also been extensively studied in patients with chronic conditions and the results are consistent with moderate-to-strong influences on self-care. In a quasi-experimental study conducted on 80 HF patients, higher levels of self-efficacy were associated with better self-care engagement at three months' follow-up after an educational program based on self-care strategies (Peyman, Shahedi, Abdollahi, Doosti, & Zadehahmad, 2020). A recent systematic review conducted on middle-aged and older diabetes mellitus patients, concluded that self-efficacy significantly affects self-care, especially in the practices of physical exercise, diet, and medication adherence; however, these results are likely to differ by race (Qin, Blanchette, & Yoon, 2020). Similarly, another systematic review identified self-efficacy as a determinant of engagement in self-care of hypertensive patients, although this evidence was not strong due to heterogeneity of the studies (Tan, Oka, Dambha-Miller, & Tan, 2021).

However, self-efficacy may not be the only variable influencing self-care. Both cognitive and affective factors, combined with environmental ones (e.g., family social support) can create a dynamic constant process that influences self-care, and people with higher self-efficacy are more likely to engage regularly in self-care behaviors, and maintain this line of action despite the presence of obstacles (e.g., lack of time or desire) (Locke &

Latham, 2013). Interestingly, family support (e.g., the presence of a caregiver) is what mostly intervenes in the process of self-care and probably self-efficacy is key to proper functioning of this mechanism. Unfortunately, we still do not know whether patient self-efficacy can influence the relationship between family support and self-care in MCC populations.

Since the self-care practiced by patients relies on the contribution of their caregivers (Buck et al., 2015; Sarris, Augoustinos, Williams, & Ferguson, 2020), it is not surprising that the construct of self-efficacy has also been studied in supportive families of chronically ill individuals. Caregiver self-efficacy is conceptualized as the caregiver's belief towards one's ability to contribute to the self-care of the patient (Vellone, Riegel, & Alvaro, 2019). It is demonstrated in single chronic conditions, that the higher the caregiver self-efficacy is, the better the patient and caregiver outcomes are. For example, Leung, Chan, Chiu, Lo, and Lee (2020) studied 234 patients with palliative care needs and their caregivers in China and found that above and beyond family support, caregiver self-efficacy was a positive and significant determinant of caregiver burden and patient quality of life. In a study of 152 cancer patients and their caregivers, it was found that higher caregiver self-efficacy was associated with better patient quality of life and symptom control (Porter, Keefe, Garst, McBride, & Baucom, 2008). Consequently, it is important to measure self-efficacy in these members because we would have a proxy measure of how their contribution is working. Unfortunately, this process is hampered by the absence of an instrument measuring this construct in chronically ill populations.

Self-efficacy is also an easily targetable construct, due to its motivational characteristics in promoting and maintaining health behaviors. The promotion of self-efficacy basically means increasing confidence that one can change the behavior, setting a specific goal and making the individual believe that this goal is accomplishable. Motivational Interviewing (MI) is a counselling method that best matches the promotion of self-efficacy due to its foundation on the basic principles of expressing empathy, rolling with resistance,

developing discrepancy, and supporting self-efficacy (Miller & Rollnick, 2009). There is broad evidence that MI can improve addictive behaviors such as smoking, and substance abuse, but also physical inactivity and unhealthy eating in a wide variety of settings and contexts (Frost et al., 2018). MI has also been studied in chronic conditions, such as in heart failure, where the authors demonstrated significant benefits on self-care behaviors (Chen et al., 2018; Masterson Creber et al., 2016; Vellone et al., 2020). However, it is not clear whether this psychoeducational intervention is also able to improve distal outcomes (i.e., health services use and mortality) as a results of behavior change.

Aims of the research program

The objective of this research program was to:

(i) Describe the mechanism by which family support influences self-care in people with multiple chronic conditions, with particular focus on patient self-efficacy.

(ii) Develop an instrument to measure caregiver self-efficacy in contributing to patient self-care (CSE-CSC scale) in multiple chronic conditions.

(iii) Investigate the influence of a motivational interviewing intervention that targets self-efficacy, in improving health service use and mortality in a chronic disease population (i.e., heart failure) as a result of sustained behavior change.

Significance of the work

Self-efficacy is a concept that still needs to be explored in the field of self-care of chronic conditions. The rationale behind the study of self-efficacy in chronic conditions is to obtain new insights on an important target to promote self-care behaviors of the patients and obtain improvements in intermediate (e.g., quality of life, and symptoms) and distal outcomes (e.g., mortality and readmissions). The first study of the present dissertation (Chapter 2) offers new insights on the mechanism by which family support influences self-care in people with multiple chronic conditions and reconfirms the relevance of self-efficacy in this process,

pushing clinicians to focus attention on interventions to augment family support and self-efficacy. The second study (Chapter 3) provided an important tool to screen caregiver self-efficacy in multiple chronic conditions, allowing both researchers and clinicians to have access to a proxy measure of the contribution to self-care.

The third study (Chapter 4) presented in this thesis confirmed that a psychoeducational intervention targeting self-efficacy and motivation, is not only able to improve self-care but also the important distal outcomes of mortality and health services use.

Together, this body of work represents a starting point for improving the self-care of chronic conditions and augment both patients' and caregivers' involvement. More tailored health interventions can also be facilitated with this body of evidence, as self-efficacy has proven once again as an important construct in modulating the dyadic self-care process.

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CHAPTER 2 – The influence of social support on self-care is mediated by self-efficacy and depression in chronic illness: key findings from the "SODALITY" observational study

Source of this chapter is under review in Aging & Mental Health

Abstract

Background. Family is a major source of support for older chronically-ill patients and known to be associated with better self-care. Depression and self-care self-efficacy are associated with healthy behaviors and thus may serve as mechanisms by which family support influences self-care.

Objectives. We explored depression and self-care self-efficacy as mediators of the relationship between perceived family support and self-care.

Methods. Five hundred forty-one older adults with multiple chronic illnesses were recruited from outpatients and community settings. Three structural equation models (SEM) were fit on cross-sectional data. We measured perceived family support (subscale of the Multidimensional Scale of Perceived Social Support, scores range 1-7), depression (Patient Health Questionnaire, scores range 0-27), selfcare self-efficacy (Self-Care Self Efficacy Scale, standardized scores range 0-100), and self-care maintenance, monitoring, and management (Self-care of Chronic Illness Inventory, standardized scores range 0-100).

Results. Participants (mean age = 76.6±7.3 yrs) were predominantly females (55.6%). In the full sample, depression and self-care self-efficacy mediated the relationship between perceived family support and self-care; in the gender-stratified SEM, men's depression was no longer a significant mediator. Depression and self-care self-efficacy were significant mediators of the relation between perceived family support and self-care.

Keywords

Depression, Gender, Multiple Chronic Conditions, Self Care, Self Efficacy, Social Support.

Introduction

Chronic illnesses, defined as conditions that persist at least for one year and require ongoing medical attention, are constantly increasing worldwide (Maresova et al., 2019). Recent estimations indicate that about half of the world's population has one or more chronic illnesses (Chang, Skirbekk, Tyrovolas, Kassebaum, & Dieleman, 2019), and multimorbidity, or the presence of at least two chronic illnesses in the same individual, is predicted to almost double in the next 20 years, especially in older adults (Kingston et al., 2018).

Success in managing chronic illness requires self-care, defined as a process of maintaining health through health-promoting practices and managing illness (Barbara Riegel, Jaarsma, Lee, & Strömberg, 2019; B. Riegel, Jaarsma, & Stromberg, 2012). Self-care involves three interrelated behavioral processes: self-care maintenance, monitoring, and management (Barbara Riegel et al., 2019; B. Riegel et al., 2012). Self-care maintenance includes the daily, routine activities used to keep a chronic illness stable (e.g., medication adherence). Self-care monitoring comprises the process of watching for and interpreting changes in signs and symptoms, whereas self-care management is the response to signs and symptoms when they occur. Considerable research has shown that self-care can improve outcomes (He et al., 2017; C. S. Lee et al., 2018; C. S. Lee, Moser, Lennie, & Riegel, 2011). Specifically, in persons with chronic illness, self-care decreases burdensome symptoms (Auld, Mudd, Gelow, Hiatt, & Lee, 2018; Grégoire et al., 2020) and improves survival (He et al., 2017; Barbara Riegel et al., 2019).

Even after decades of research, clinicians remain unsure how to help people with a chronic illness to embrace self-care behaviors. Mechanistic research has been proposed as an approach to identify how and why behavior changes in response to a particular intervention (Nielsen et al., 2018). Identifying the underlying causal factors is thought to accelerate progress in promoting behavioral change.

Background

Social support is known to be important in improving self-care in persons with chronic illness (Prazeres & Santiago, 2016; Sayers, Riegel, Pawlowski, Coyne, & Samaha, 2008; Song, Nam, Park, Shin, & Ku, 2017; Xiaolian et al., 2002). Social support can be defined as perceived - the subjective perception of support received by or available to an individual when needed - and as received - the support actually accessible to (or received by) an individual (Helgeson, 2003). Perceived social support is most influential in improving health outcomes (Dunkel-Schetter & Bennett, 1990). Family is the main source of social support in chronic illness (Hu, Li, & Arao, 2015; A. A. Lee et al., 2017), particularly in Italy where this study was conducted. Familial cultural norms are characterized by strong ties and mutual support. Adult children feel an intrinsic obligation to care for their older parents, which is facilitated by the intergenerational co-residence (Albertini, 2016; Albertini & Mantovani, 2021). The Catholic Church has contributed to these cultural norms (Luciano et al., 2012).

Family support is known to promote self-care behaviors in patients with chronic conditions (Bahari, Scafide, Krall, Mallinson, & Weinstein, 2019; Hu et al., 2015; Shirvani, Ghaffari, Fotokian, & Monadi, 2020). For instance, Kurniawati, Wahyuni, and Toulasik (2019) described greater medication adherence in persons with hypertension who perceived higher family support compared to those with lower perception. Similarly, Gallagher reported increased levels of dietary and medication adherence in patients with heart failure, especially when the support was provided by partners (Gallagher, Luttik, & Jaarsma, 2011). Considerable research has shown that the self-care improvement may translate in better outcomes (He et al., 2017; C. S. Lee et al., 2018; C. S. Lee et al., 2011). Specifically, in persons with chronic illness, self-care decreases burdensome symptoms (Auld et al., 2018; Grégoire et al., 2020) and improves survival (He et al., 2017; Barbara Riegel et al., 2019).

Despite evidence of a positive association between family support and self-care, the mechanism by which this support influences self-care behaviors is unclear. The Science of Behavioral Change Model of Organizational Behavior (Hekler & King, 2020), based on Social Learning Theory, explains human behavior as a product of the interaction between the socio-cultural environment, individual characteristics, and consequences. Based on this model, we hypothesized that family support represents the socio-cultural environment, which influences patterns of self-care behaviors through the juxtaposition of psychological components (depression) and intentions or beliefs (self-efficacy) (Hekler & King, 2020).

According to the middle range theory of self-care of chronic illness (B. Riegel et al., 2012) the supportive care provided by family and friends, such as communication, decision-making, and instrumental support, can influence self-care self-efficacy, one's confidence in the ability to perform self-care despite difficulties, and thus, the self-care process itself. The social cognitive perspective of social support (Lakey & Drew, 1997) posits that the thought that family members and friends might not provide support when needed can cause substantial psychological distress (Lakey & Cronin, 2008), thus the possibility that the influence of social support on self-care may also occur through psychological mechanisms. Indeed, depression, a key measure of psychological distress, is theoretically and empirically assumed to influence self-care behaviors (Iovino et al., 2020; B. Riegel, Jaarsma, Lee, & Stromberg, 2019). As theorized by Bandura (2012) and Hammen (2006), depression also has a bi-directional relationship with self-efficacy; lack of self-efficacy may lead to feelings of depression, but poor psychological well-being may also hamper self-efficacy beliefs.

In the processes described above, depression and self-care self-efficacy can serve as facilitators or inhibitors of the association between family support and self-care. This is because both these constructs are tightly related to self-care and are in turn influenced by the presence of family members. An important longitudinal study demonstrated that the perception of low family support was associated with higher levels of depressive symptoms at baseline and a slower recovery from depression over time (Kamen, Cosgrove, McKellar, Cronkite, & Moos, 2011). Depression has

also been identified as an independent barrier to self-care (Freedland, Skala, Steinmeyer, Carney, & Rich, 2021). Regarding self-efficacy, an observational study on chronic obstructive pulmonary disease (Kara Kasikci & Alberto, 2007), found that this construct was positively associated with family support, and the same evidence was also corroborated by the more recent study by Bonsaksen, Lerdal, and Fagermoen (2012). Likewise, self-efficacy has a powerful influence on self-care. Notably, Finally, a study by Bahari et al. (2019) demonstrated that self-efficacy could mediate the relationship between family support and self-care in adults with hypertension.

It is also likely that the pathway through which family support influences self-care works differently in men and women. Specifically, women have been shown to have more depressive symptoms than men (Kockler & Heun, 2002), particularly in older age (Girgus, Yang, & Ferri, 2017), and higher vulnerability to a lack of support (Fleming & Agnew-Brune, 2015). Thus, the overall purpose of this study was to investigate mechanisms mediating the relationship between social support from family members and self-care in older adults with multimorbidity.

Objectives

The specific aims of this study were to test our hypotheses that self-care self-efficacy and depression mediate the relationship between family support and self-care in older adults with multimorbidity. An additional aim was to explore gender differences in the hypothesized mediation model. We focused on older adults because they are at greater risk of developing chronic illnesses and experiencing social isolation (Schulz, Eden, National Academies of Sciences, & Medicine, 2016).

Methods

This was a cross-sectional analysis of baseline data from the SODALITY study (*Self-care Of patient and caregiver DyAds in multiple chronic conditions: a LongITudinal studY*), which is described in detail elsewhere (M. De Maria et al., 2019) and summarized briefly below.

Participants

We analyzed data from 561 older adults with a wide range of chronic conditions. Eligible participants were: (i) aged 65 years or older; (ii) diagnosed with diabetes mellitus (DM), heart failure (HF), or chronic obstructive pulmonary disease (COPD) plus one or more other chronic conditions, and (iii) without a diagnosis of dementia and/or cancer. These unmodifiable factors were chosen as exclusion criteria because they could potentially hinder the self-care process.

Data collection

Recruitment occurred across seven regions of Southern and Central Italy between April 2017 and October 2019 in outpatient and community settings. Data collection occurred face-to-face during the routine outpatient visits or directly at the patients' or caregivers' homes.

Trained nurse research assistants identified potential participants, confirmed eligibility, and carefully explained the aims of the study before obtaining informed consent. Participants who were unable to complete the study instruments alone were assisted by a research team member. Participation rate was relatively high (close to 80%) and dropouts were not observed.

Instruments

Perceived family support was assessed with the family support subscale of the Multidimensional Scale of Perceived Social Support (MSPSS) (G. Zimet, Dahlem, Zimet, & Farley, 1988; G. D. Zimet, Powell, Farley, Werkman, & Berkoff, 1990). This specific support is measured by the items #3, #4, #8, and #11, which are rated by the responders on a 7-point Likert scale, ranging from very strongly disagree" (1) to very strongly agree" (7). Higher scores reflect higher perceived family support. The Italian version of the MSPSS was validated on patients with chronic conditions (Maddalena De Maria, Vellone, Durante, Biagioli, & Matarese, 2018), showing good validity and reliability (Cronbach's alpha coefficient for the Family support subscale was 0.92).

Self-care behaviors were assessed with the Self-care of Chronic Illness Inventory (SC-CII) (B. Riegel et al., 2018). This instrument includes three scales – self-care maintenance (8 items), self-care monitoring (5 items), and self-care management (7 items), which are scored separately.

The self-care maintenance scale measures healthy lifestyle (e.g., following healthy diet) and illness-related behaviors (e.g., medication adherence). The self-care monitoring scale addresses monitoring of signs and symptoms related to the chronic illness (e.g., shortness of breath). The self-care management scale measures how patients respond to signs and symptoms when they occur. Responses are measured on a 5-point Likert scale and standardized 0-100, with higher scores reflecting higher levels of self-care. The global reliability indices are adequate for the three scales (self-care maintenance = 0.67, self-care monitoring = 0.81, self-care management = 0.71).

Self-care self-efficacy was assessed with the Self-care Self-Efficacy Scale (SC-SES) (Yu et al., 2021). This 10-item scale captures the extent to which the patient feels confident in his ability to engage in self-care behaviors. Items are composed of a 5-point Likert scale, that ranges from not confident" (1) to very confident" (5). Scores are standardized 0-100, with higher scores reflecting higher self-care self-efficacy. The SC-SES has shown a high level of measurement invariance (i.e., partial scalar) among patients in the United States, China (Hong Kong), Italy, and Brazil and good reliability (Cronbach's alpha coefficient = 0.925 for the Italian sample) (Yu et al., 2021).

Depression was assessed with the 9-item Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001). Each item is scored on a 5-point scale that ranges from "not at all" (1) to "nearly every day (5). Scores range from 0 to 27 with higher values reflecting higher levels of depression. Scores above 5, 10, and 15 indicate mild, moderate, and severe levels of depression, respectively. The instrument, which has also been used in patients with chronic conditions (Spangenberg, Forkmann, Brahler, & Glaesmer, 2011), demonstrated adequate reliability in our sample (Cronbach's alpha coefficient was 0.83).

A sociodemographic questionnaire was administered to collect age, gender, education, employment, perceived adequacy of income, number of chronic conditions, number of people living with the patient, and marital status of the patients.

Statistical methods

Sociodemographic and clinical characteristics were summarized for the total sample, and for males and females separately. Variables are presented as means and standard deviations [SD]), and frequencies and percentages, as appropriate. Preliminary analyses were conducted on the main study variables to check for missing values and outliers and to test whether the data violated multicollinearity and normality assumptions.

A structural equation model (SEM) with observed variables was tested to investigate the simultaneous mediating pathways of depression and self-care self-efficacy (hereafter referred to as self-efficacy) on the relationship between perceived family social support (hereafter referred to as family support) and self-care maintenance, monitoring, and management, respectively. Family support was specified as the explanatory variable (X) in the model, whereas self-efficacy (M1) and depression (M2) as the mediators. Ultimately, the self-care dimensions [i.e., maintenance (Y1), monitoring (Y2) and management (Y3)] were specified as response variables. We also specified a correlational rather than directional, association between M1 and M2, in light of the evidence supporting a bi-directional relationship between self-efficacy and depression. Moderation analysis was conducted by running and comparing the model for males and females separately, as per subgroup approach (Ryu, 2014).

For each mediation model we estimated both the direct (i.e., X on Y1, Y2, and Y3) and indirect effects (i.e., X on Y1, Y2 and Y3 via the mediators). We also reported the sum of the indirect effects (i.e., X on Y1, Y2 and Y3 via both the mediators). Due to their non-normal distributions, confidence intervals (CI) for the indirect effects were obtained with bootstrapping (5,000 replications). The hypothesized model for the full sample and for gender-stratified models were all just-identified; thus, model quality was not evaluated with the classical fit indices, but by inspecting the values and significance of each estimated parameter.

Results are shown as standardized coefficients. Preliminary and descriptive analyses were conducted in SPSS v. 25.0 (George & Mallery, 2018). The SEMs were estimated in MPLUS v. 8.4 (Muthén & Muthén, 2010).

Sample size

The sample size required for each model was calculated to achieve approximately a 10:1 ratio of cases to parameters, which is considered an adequate "rule of thumb" for SEMs computed with Maximum Likelihood Estimation (Jackson, 2003). We expected an estimation of 25 parameters for each model, so a total sample of 250 individuals was considered sufficient for this analysis. The final sample size for the model for the full sample was greater than 250 because the SODALITY study enrolled more participants by the time the present study was conducted.

Ethical considerations

Ethical approval was obtained for the parent study by the ethics committee of a regional healthcare system (Protocol number: ComET ASReM 2017/138). All the participants signed an informed consent form before data collection. This study conforms to the Helsinki Declaration Principles (General Assembly of the World Medical Association, 2014).

Study results

Preliminary analysis

Nine values were identified as univariate outliers (Z score cut off ≥ 3.10) and 11 (1.96%) were multivariate outliers (Mahalanobis distance cut off ≥ 22.46). Since they affected the normality assumption, these values were eliminated from the dataset, leaving a total sample size of 541. No data were missing for the variables used in our models. Multicollinearity was absent and the normality assumption was satisfied.

Characteristics of Participants

Table 1 shows the characteristics of the total sample (n = 541) and by gender (males n= 240, females n = 301). The typical participant was an older adult (mean age 76.6 ± 7.3 years), female (55.6%), married or partnered (64.1%), and retired (96.5%). They had an average of 3.3 ± 1.4 chronic conditions, with DM the most common (72.5%), followed by HF (33.8%) and COPD

(14.1%). The extent of perceived support from family was higher (6.48 ± 0.6) than that from friends and significant others. Self-care and Self-Care Self-Efficacy scale scores indicated low to moderate levels of patient engagement. Depression score was slightly above the cut-point for mild depression (5.80 ± 4.1). Compared to women, there was a significantly higher proportion of men affected by COPD ($p = 0.004$), who were partnered or married ($p < 0.001$), and with a higher educational level ($p < 0.001$). Men also performed significantly higher in self-care maintenance behaviors ($p = 0.003$), had lower depressive symptoms ($p = 0.002$), and had slightly fewer chronic illnesses than women ($p = 0.004$).

Table 1. Sociodemographic and clinical characteristics of participants.

	Full sample (n = 541)		Males (n = 240)	Females (n = 301)		
	n (%) or Mean (SD)		n (%) or Mean (SD)	n (%) or Mean (SD)	X^2 or t-test	p
Chronic illness						
HF	183	(33.8)	77 (32.1)	106 (35.2)	0.585	0.444
DM	392	(72.5)	166 (69.2)	226 (75.1)	3.348	0.187
COPD	76	(14.1)	45 (18.8)	29 (9.6)	10.816	**0.004**
Marital status					64.217	**< 0.001**
Single/never married	11	(2)	2 (0.8)	9 (3.0)		
Married/Partnered	347	(64.1)	196 (81.7)	151 (50.2)		
Divorced/Separated	12	(2.2)	7 (2.9)	5 (1.7)		
Widowed	171	(31.6)	35 (14.6)	136 (45.2)		
Perceived income					2.278	0.517
Less than needed	82	(15.2)	35 (14.6)	48 (15.9)		
Enough for living	435	(80.4)	192 (80.0)	243 (80.7)		
More than needed	24	(4.4)	13 (5.4)	10 (3.3)		
Education					63.560	**< 0.001**
Low level of formal education	22	(4.1)	2 (0.8)	20 (6.6)		
Elementary	306	(56.6)	101 (42.1)	205 (68.1)		
Middle school	116	(21.4)	75 (31.3)	41 (13.6)		
Professional school	22	(4.1)	17 (7.1)	5 (1.7)		
High school	56	(10.4)	34 (14.2)	22 (7.3)		
University	19	(3.5)	11 (4.6)	8 (2.7)		
Occupation						
Unemployed/retired	522.	(96.5)	227 (94.6)	295 (98.0)	4.162	**0.032**
Employed	19	(3.5)	13 (5.4)	6 (2.0)		
Age (years)	76.62	(7.26)	76.49 (7.44)	76.73 (7.12)	-0.39	0.700
MSPSS (1-7)						
Family	6.48	(0.62)	6.47 (61.81)	6.49 (0.63)	-0.797	0.426
Friends	4.26	(1.87)	4.33 (1.87)	4.20 (1.87)	0.823	0.411
Others	3.26	(2.04)	3.31 (2.02)	3.21 (2.05)	0.521	0.603
SC-CII (0-100)						
SC Maintenance	66.56	(14.23)	68.55 (14.61)	64.96 (13.74)	2.940	**0.003**
SC Monitoring	74.10	(19.41)	73.98 (20.39)	74.20 (18.63)	-0.133	0.894
SC Management	63.02	(16.74)	63.02 (17.31)	63.02 (16.35)	0.000	1.000
SC-SES (0-100)	68.76	(18.36)	68.05 (19.09)	69.32 (17.77)	-0.797	0.426
PHQ-9 (0-27)	5.80	(4.14)	5.20 (3.78)	6.28 (4.34)	-3.074	**0.002**
Number of chronic illnesses	3.32	(1.37)	3.13 (1.30)	3.47 (1.40)	-2.904	**0.004**

Note. COPD, Chronic Obstructive Pulmonary Disease; HF, Heart Failure; DM, Diabetes Mellitus; MSPSS, Multidimensional Scale of Perceived Social Support; p, p value; PHQ-9, Patient Health Questionnaire 9; SC, self-care; SD, standard deviation; X^2 chi square test. SC-SES Self-care Self-efficacy Scale. Numbers in parenthesis next to the variable names are the instruments' score ranges.

Main analysis

The results of the model for the full sample are shown in Figure 1. Briefly, self-efficacy was a significant mediator of the relationship between family support and all the self-care behaviors

(i.e., self-care maintenance, monitoring, and management), with the strongest indirect effect being found in the relationship between family support and self-care monitoring (β = 0.111, 95% BC bootstrapped CI: 0.061-0.162) (Table 2). Depression negatively mediated the effect of family support on self-care maintenance and management (Table 2). The strongest indirect effect was found between family support and self-care maintenance (β = 0.033, 95% BC bootstrapped CI: 0.013-0.060) (Table 2). The sum of indirect effects were all significant and positive (Table 2).

A significant direct effect was found between family support on self-care maintenance (β = 0.133, $p < 0.001$). The direct effects of family support on self-care monitoring and management behaviors were not significant (Figure 1).

Figure 2a and 2b depict the results of the models across males and females. In the moderation analysis, inspection of the structural paths in males indicate self-efficacy as a significant mediator of the relationship between family support and each self-care dimension. Conversely, depression did not mediate any of these associations (Table 2). In females, self-efficacy remained a significant mediator of the relationship between family support and each self-care dimension (Figure 2). Moreover, depression appeared to mediate the association between family support and self-care maintenance and management (Table 2). Finally, the sum of indirect effects were all significant and positive in females (Table 2).

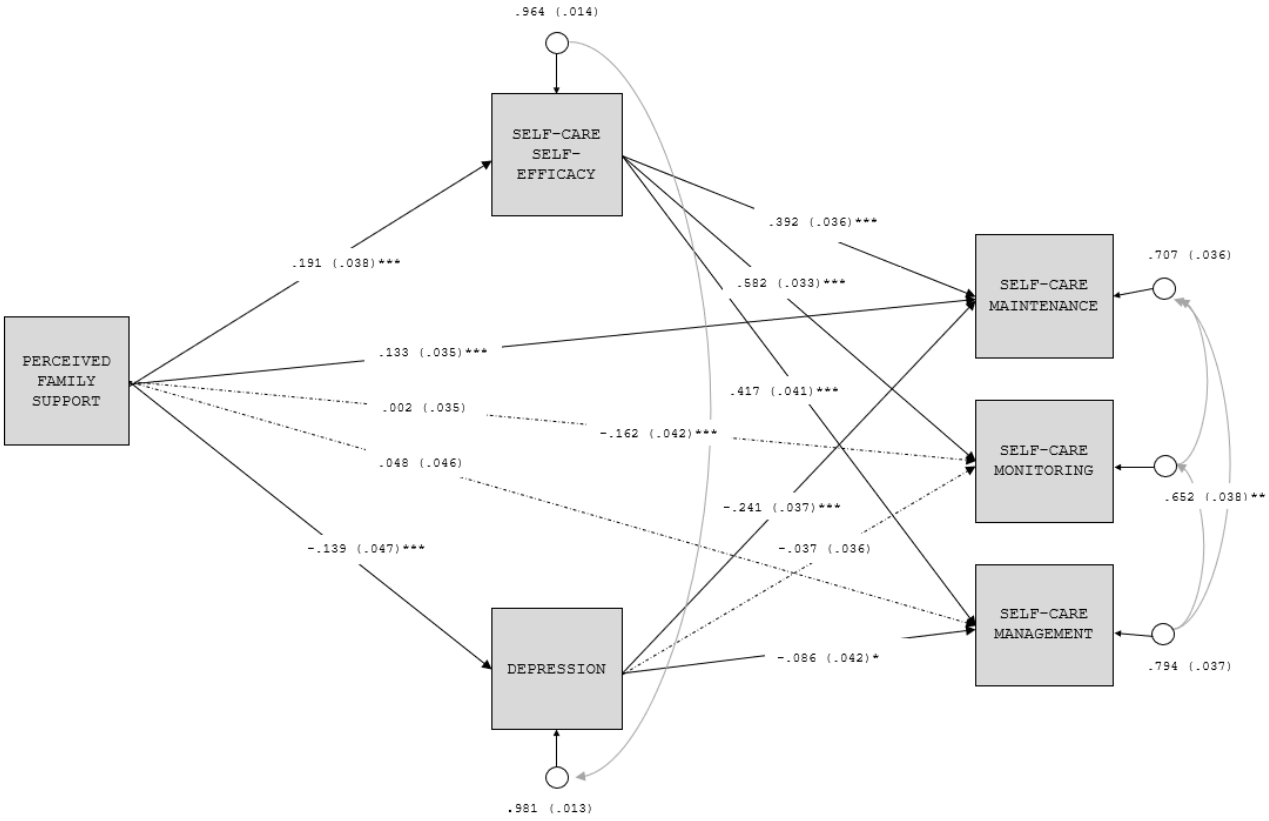
Table 2. Standardized specific and sum of indirect effects of the full and gender-stratified structural equation models.

	Full sample (n=540)	Male sample (n=240)	Female sample (n=301)

	Estimate	95% BC bootstrapped CI		Estimate	95% BC bootstrapped CI		Estimate	95% BC bootstrapped CI	
		Lower	Upper		Lower	Upper		Lower	Upper
Specific indirect effects									
MSPSS-F → SC-SES → SC maintenance	**0.075**	0.040	0.114	**0.090**	0.013	0.158	**0.064**	0.023	0.115
MSPSS-F → SC-SES → SC monitoring	**0.111**	0.061	0.162	**0.121**	0.041	0.211	**0.100**	0.038	0.167
MSPSS-F → SC-SES → SC management	**0.080**	0.043	0.123	**0.098**	0.033	0.178	**0.065**	0.025	0.120
MSPSS-F → PHQ-9 → SC maintenance	**0.033**	0.013	0.060	0.022	-0.005	0.060	**0.040**	0.014	0.079
MSPSS-F → PHQ-9 → SC monitoring	0.005	-0.003	0.018	0.008	-0.001	0.034	0.000	-0.018	0.017
MSPSS-F → PHQ-9 → SC management	**0.012**	0.002	0.030	0.002	-0.009	0.026	**0.022**	0.004	0.054
Sum of indirect effects									
MSPSS-F → SC maintenance	**0.108**	0.065	0.155	0.112	0.040	0.187	**0.104**	0.050	0.168
MSPSS-F → SC monitoring	**0.116**	0.065	0.168	0.130	0.045	0.218	**0.100**	0.034	0.169
MSPSS-F → SC management	**0.092**	0.051	0.138	0.100	0.033	0.181	**0.087**	0.040	0.150

Note. BC, bias corrected; CI, confidence intervals; MSPSS-F, Multidimensional Scale of Social Support - Family; PHQ-9, Patient Health Questionnaire 9; SC, Self-care; SC-SES, Self-care Self-Efficacy Scale. Each specific indirect effect was estimated as the product of the corresponding regression coefficients. Significance of the effects was obtained by the bias-corrected bootstrap confidence intervals (based on 5,000 bootstrap replications). Significant estimates are in bold.

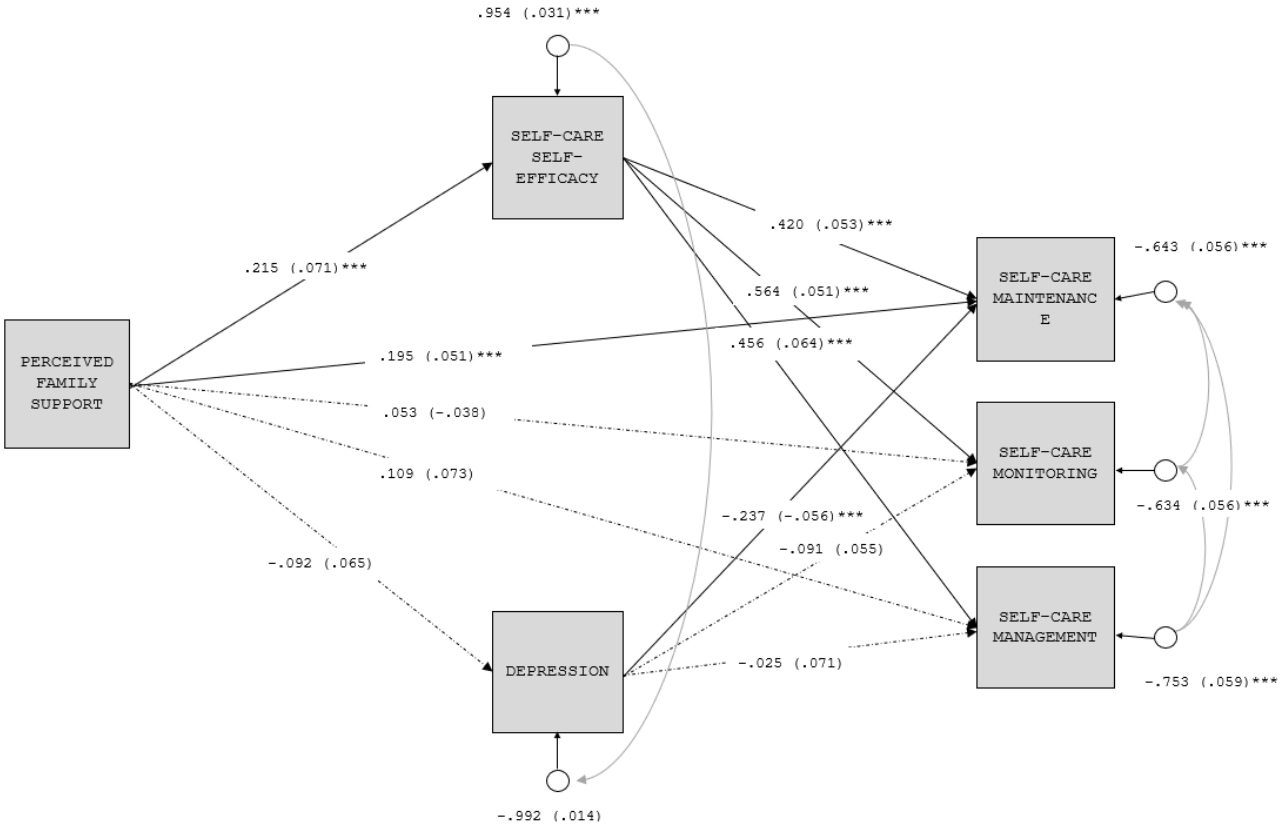
Figure 1. Results of the structural equation model for the full sample (n = 541).



Note. Double-headed arrows entries are correlation coefficients. Single-headed arrows entries are regression coefficients. Small circles entries represent error terms. Dashed lines indicate non-significant paths. Residual covariances of the response variables are omitted for simplicity.

*** p < .001; ** p < .01; * p < .05

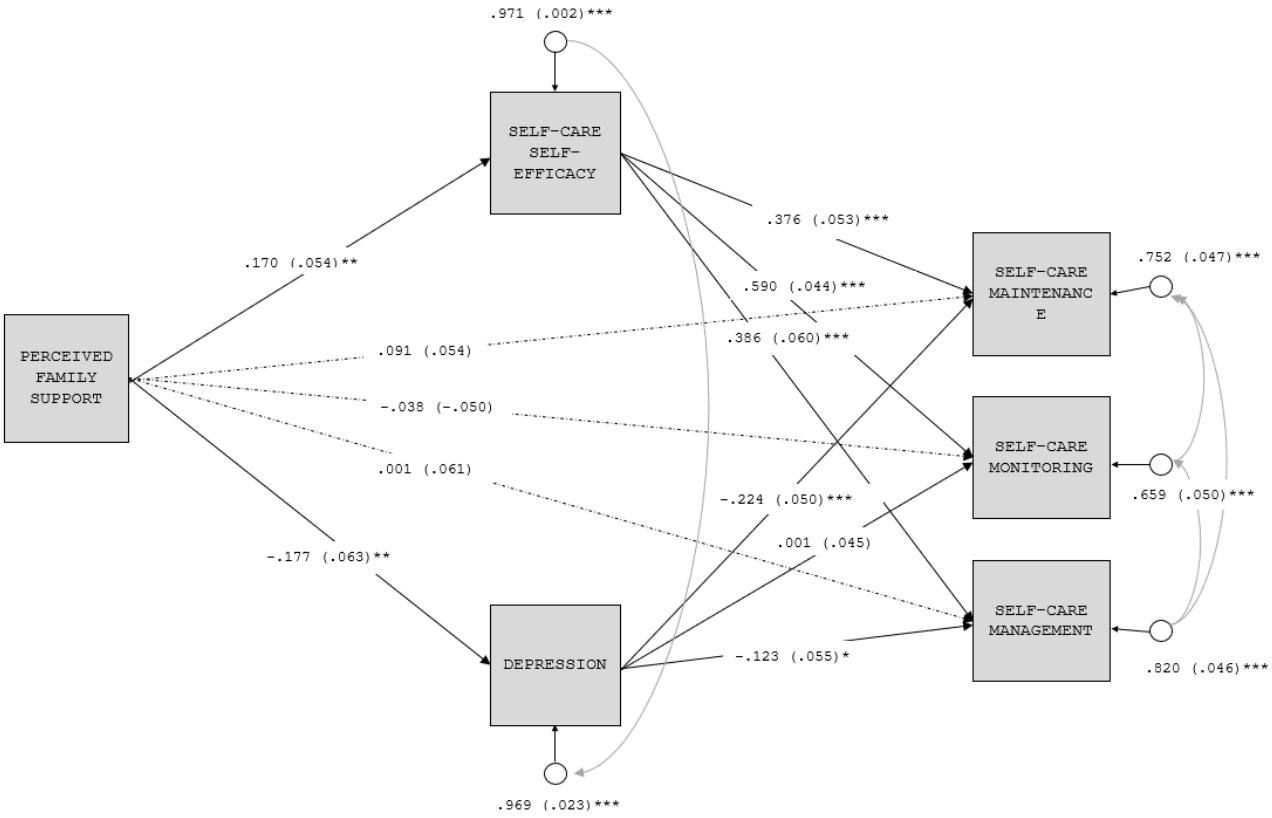
Figure 2a. Results of the structural equation model by males (n = 240).



Note. Double-headed arrows entries are correlation coefficients. Single-headed arrows entries are regression coefficients. Small circles entries represent error terms. Standardized coefficients in parenthesis refer to males. Dashed lines indicate non-significant paths. Residual covariances of the response variables are omitted for simplicity.

*** p < .001; ** p < .01; * p < .05

Figure 2b. Results of the structural equation model by females (n = 301).



Note. Double-headed arrows entries are correlation coefficients. Single-headed arrows entries are regression coefficients. Small circles entries represent error terms. Standardized coefficients in parenthesis refer to males. Dashed lines indicate non-significant paths. Residual covariances of the response variables are omitted for simplicity.

*** p < .001; ** p < .01; * p < .05

Discussion

The objective of this study was to explore depression and self-care self-efficacy as mechanisms by which family support influences self-care in older adults with multimorbidity. We also explored whether these relationships differed by gender. To our knowledge, this is the first study testing these mediators in an older, chronically-ill population. We found that self-efficacy positively mediated the relationship between family support and each of the self-care dimensions, whereas depression negatively mediated two of these self-care dimensions (i.e., maintenance and management). In the exploratory moderation analysis, depression was no longer a mediator of this relationship in males.

In the main analysis with the full sample, self-efficacy mediated the relationship between family support and self-care behaviors. These findings are similar to those of other investigators. In patients with heart failure, Maeda, Shen, Schwarz, Farrell, and Mallon (2013) found that self-efficacy significantly mediated the effect of social support on treatment adherence. Chuang, Kao, Lin, and Chang (2019) identified self-efficacy as a mediator even after controlling for other variables such as depression, health literacy, and knowledge of the disease. Finally, Fivecoat, Sayers, and Riegel (2018) predicted a steeper increase over time in self-efficacy for those perceiving higher instrumental support compared to those with lower perceived support.

Family support was directly related to self-care maintenance in the main analysis. This result is similar to that of Hammash and colleagues (2017) who reported that social support had a specific direct and positive effect on adherence to the medical regimen in patients with heart failure (Hammash et al., 2017). Conversely, we discovered that family support was not directly related to self-care monitoring or management behaviors. The reason may lie in the fact that perceived family support is likely to target tangible patient lifestyle behaviors (such as physical activity or diet), rather than the behaviors requiring predominately cognitive effort (e.g., monitoring of symptoms). These latter types of behaviors are also connected to more complex decision-making processes, which in turn are linked to self-care self-efficacy in patients (B. Riegel et al., 2012). Not

surprisingly, self-efficacy emerged to be a multiple path mediator, thus confirming the inherent cognitive component of these self-care behaviors.

In this study, we confirmed the negative relationship between depression and self-care, which is consistent with prior research demonstrating that depressive symptoms may interfere with adherence to treatments and recommended lifestyle modifications and may also undermine patient confidence (Maeda, Shen, Schwarz, Farrell, & Mallon, 2013). Depression can also interfere with patients' abilities to recognize symptoms and provide adequate responses when chronic disease symptoms occur, thereby delaying professional consultation and prompt treatment-seeking. Iovino et al. (2020) found that self-care maintenance was negatively associated with depression in older patients with multiple chronic conditions. Notably, we found positive effects of perceived family support on depression, as noted by others (Su et al., 2017).

The cross-group exploratory comparison of our model highlighted unique results in men in whom depression did not have a mediating effect. This is an interesting finding that can be explained by the fact that depression is more common in women than men. A meta-analysis conducted by Abate (2013) found that, in a wide variety of patient populations, men were 63% less likely to develop depression than women. There is also data demonstrating greater reactivity to stressful events in women (Verma, Balhara, & Gupta, 2011). Also, in times of stress and illness, women are more likely to strengthen family bonds (Thompson & Heller, 1990). These prior studies are useful in interpreting our finding that higher depression in women was significantly associated with lower perceived family support. Perhaps the higher vulnerability to depression in women is due to perceived inadequacy of family support.

The greater reactivity to stress and the higher levels of depression found in the women in our sample might also explain the stronger association of depression with self-care in women compared to men. The additional detrimental influence on self-care management behaviors is not surprising as such behaviors require greater cognitive efforts than routine lifestyle activities (e.g., physical

activity and diet). Cognitive activity and decision-making processes, the foundation of self-care management behaviors, may be impaired when depression is high (Bishop & Gagne, 2018).

There are a number of limitations to be acknowledged in this study. First, the cross-sectional design does not allow for causal interpretations; longitudinal studies should be conducted to determine the direction of these uncovered relationships, particularly for the mediating variables of depression and self-efficacy. We have a theoretical basis for proposing these bidirectional relationships (Bandura, 2012; Hammen, 2006) and empirical support from prior self-care research (Devarajooh & Chinna, 2017; Tovar et al., 2016), but longitudinal research would help to clarify the relationships more fully. Second, we enrolled a convenience sample in Italy, so the results may not be generalizable to the entire population with chronic illnesses. Third, we used observed variables to test our mediation model; future studies on the field should instead model latent variables because this approach allows controlling for measurement error and consequently provides less biased estimates of the relationships. Finally, the original study enrolled only patients with a caregiver; presuming that caregivers significantly helped patients, caregivers' assistance may have distorted the amount of influence of perceived family support on self-care behaviors.

Major strengths of this study are the novelty of the variables studied; we particularly focused on perceived family support rather that the other sources of support because family is the backbone of support in older chronically-ill individuals. We focused on studying the mechanisms by which family support influences self-care, and how gender moderates these mechanisms, which is innovative in the geriatrics field. Another strength is the large sample size and the absence of missing data in our dataset, which led to increased statistical power.

Implications

Our results have important implications for theory, clinical practice, and research. From a theoretical perspective, our findings contribute to both the social support and self-care theories, particularly in regard to gender differences. Concerning clinical practice, it is important to assess

the extent of family support in older adults with multiple chronic conditions as this situation may simultaneously lead to poor self-efficacy and depression, especially in women. Screening activities should focus on the assessment of self-efficacy and depression, with priority offered to women, in light of their greater vulnerability to the consequences of poor support. We advocate efforts to enhance the support available from family to improve self-care practices. Offering counseling, family therapy, or specific caregiver training to family members may be useful, especially because any improvement in family support may improve self-efficacy and depression, which may promote self-care. However, in some cases, family support cannot be improved. In such situations (e.g., the patient lives alone), targeting self-efficacy and depression directly may improve self-care.

Regarding research implications, this study of mechanisms by which family support influences self-care provides direction for future behavior change research. As noted by Nielsen and colleagues (2018), much of the prior behavioral change research uses a "black box" approach, testing multicomponent interventions without a focus on causal contributors to outcomes. Such an approach is inefficient, slow, and costly. In this study we have confirmed the important roles of family support, self-efficacy, and depression in self-care behavior. These variables can be used in future research aimed at improving the self-care of older adults with multimorbidity.

The findings of this study provide evidence that family support may improve self-care behaviors via self-efficacy and depression. Interventions designed to enhance family support may facilitate a more rapid improvement in self-efficacy beliefs and a decrease in depressive symptoms, particularly among women who exhibit higher vulnerability to depression. In situations where family support is not available, interventions aimed at improving self-efficacy and depression may be useful to improve self-care, but further studies are needed to test these hypotheses.

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CHAPTER 3 - Development and psychometric testing of the caregiver self-efficacy in contributing to patient self-care scale

This chapter is found in the following source:

De Maria M., Iovino P., Lorini S., Ausili D., Matarese M., Vellone E. Development and Psychometric Testing of the Caregiver Self-Efficacy in Contributing to Patient Self-Care Scale. Value in Health. (2021); https://doi.org/10.1016/j.jval.2021.05.003

Abstract

Objectives: Caregiver self-efficacy—a caregiver's belief in his/her ability to contribute to patient self-care—is associated with better patient and caregiver outcomes in single chronic conditions. It is, however, unknown if caregiver self-efficacy improves patient and caregiver outcomes in multiple chronic conditions (MCCs) because there is no instrument to measure this variable. We developed the 10-item Caregiver Self-Efficacy in Contributing to patient Self-Care (CSE-CSC) scale for that purpose, and we tested its psychometric characteristics in caregivers of patients with MCCs. Methods: In this cross-sectional multisite study, we tested the structural validity of the CSE-CSC scale with exploratory and confirmatory factor analysis, and we tested construct validity by correlating CSE-CSC scores with those of the Caregiver Contributions to Self-Care of Chronic Illness Inventory. We also tested reliability, and precision of the CSE-CSC scale. Results: The 358 enrolled caregivers (mean age 54.6 years; 71.5% female) cared for patients with an average of 3.2 chronic conditions. Structural validity was good, and it showed 2 factors within the scale. Construct validity showed significant correlations between scores of the CSE-CSC scale and the Caregiver Contributions to Self-Care of Chronic Illness Inventory. Reliability coefficients were between 0.90 and 0.97. Measurement error yielded satisfactory results. Conclusions: The CSE-CSC scale is valid, reliable, and precise in measuring caregiver self-efficacy in contributing to patient self-care in MCCs. Because caregiver self-efficacy is a modifiable variable, the CSE-CSC scale can be used in clinical practice and research to improve patient and caregiver outcomes.

Keywords: Caregiver, psychometric, questionnaire, reliability, self care, self efficacy, survey, validity

Introduction

Multiple chronic conditions (MCCs), defined as a clinical condition in which two or more chronic illnesses affect a person at the same time, (Assistant Secretary for Health, 2016) are highly prevalent worldwide. In the USA, one in four persons is affected by MCCs, and in Europe the prevalence is estimated at one third, with the highest prevalence in older individuals (Palladino, Pennino, Finbarr, Millett, & Triassi, 2019).

The management of MCCs is complex, and it requires chronically ill individuals and their families to perform several self-care behaviours. Self-care has been defined as a natural decision-making process aimed at preserving health and controlling illnesses (B. Riegel, Jaarsma, & Stromberg, 2012). In the setting of chronic illnesses, self-care involves three interrelated behavioural processes: self-care maintenance, self-care monitoring, and self-care management (Barbara Riegel, Jaarsma, Lee, & Strömberg, 2019; B. Riegel et al., 2012). Self-care maintenance involves the daily, routine activities used to keep a chronic illness stable (e.g., taking medication as prescribed). Self-care monitoring involves the continual process of watching oneself to detect signs and symptoms of the illness (e.g., monitoring blood sugar). Self-care management is the response to signs and symptoms when they occur (e.g., taking an extra medication for symptoms). All these behaviours involve a naturalistic decision-making process that reflects automatic, impulsive, and contextual decisions that people make in typically ambiguous situations, where the options are often vague (B. Riegel et al., 2012).

In single chronic conditions, such as heart failure (HF) and diabetes mellitus (DM), self-care has been shown to influence health and economic outcomes, including improving the quality of life (Kessing, Denollet, Widdershoven, & Kupper, 2017), preventing disease complications (Povey & Clark-Carter, 2007), and reducing rehospitalisations (McAlister, Stewart, Ferrua, & McMurray, 2004). Despite this evidence, self-care is not performed sufficiently in several chronic conditions (Ausili et al., 2018; Cocchieri et al., 2015; Restrepo et al., 2008). In those situations, an informal

caregiver, such as a family member, is extremely helpful in contributing to the patient's self-care process (Waligora, Bahouth, & Han, 2019).

Caregiver contributions (CC) to patients' self-care was conceptualised as the process of recommending to (or substituting for) the patient in performing behaviours aimed at maintaining the stability of the illness, facilitating the monitoring of symptoms, and responding to signs and symptoms of an exacerbation (Vellone, Riegel, & Alvaro, 2019). There is evidence that CC to self-care are associated with positive patient outcomes, such as better adherence to medication (Aggarwal, Liao, & Mosca, 2013; Trivedi, Bryson, Udris, & Au, 2012), fewer emergency department visits (Wakabayashi et al., 2011), and healthier patient behaviours (Trivedi et al., 2012). Several variables at caregiver, patient, and dyadic levels (Iovino et al., 2020; Sterling et al., 2020; Vellone, Chung, Alvaro, Paturzo, & Dellafiore, 2018) have been conceptualised and found to impact CC to patient self-care, but all those contributors could be influenced by caregiver self-efficacy. Bandura (1986) defined self-efficacy as individuals' beliefs about their ability to achieve positive outcomes by performing a course of action, irrespective of the challenges and difficulties involved (Albert Bandura, 1986; A Bandura, 1997). Self-efficacy drives behavioural actions through increasing cognitive understanding and control over the situation, upturning self-regulatory power, and reducing emotional reaction towards the difficulties encountered (A Bandura, 1997). As such, self-efficacy shapes one's level of commitment and persistence to manage a specific situation (A Bandura, 1997).

Caregiver self-efficacy has been defined as the caregiver's belief in his/her ability to contribute to patient self-care (Vellone et al., 2019). Several studies in single chronic conditions have found that better caregiver self-efficacy is associated not only with better patient self-care, and consequently better patient outcomes, but also with better caregiver outcomes. For example, in patients with lung cancer, better caregiver self-efficacy was associated with better symptom control and quality of life (Porter, Keefe, Garst, McBride, & Baucom, 2008). In caregivers of patients with Alzheimer's disease, better self-efficacy was associated with lower depression and burden (Cheng,

Lam, Kwok, Ng, & Fung, 2012; Grano, Lucidi, & Violani, 2017). There is also evidence, from randomised controlled trials, that caregiver self-efficacy is a key modifiable characteristic, which can be targeted with psychoeducational interventions (Piersol et al., 2017; Terpstra, Chavez, & Ayala, 2012).

Although caregiver self-efficacy has been found associated with positive health outcomes for both patients with chronic conditions and their caregivers, so far an instrument to measure caregiver self-efficacy has been explored only in single chronic conditions, such as HF and dementia (Lyons et al., 2018; Piggott, Zimmerman, Reed, & Sloane, 2017; Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Glaser, et al., 2013). It has not been tested in situations of MCCs. Consequently, an instrument to measure caregiver self-efficacy in contributing to patient self-care of chronic illness would be helpful in this context.

Objective

To develop and test the psychometric characteristics (validity and reliability) of the Caregiver Self-Efficacy in Contributing to Patient Self-Care (CSE-CSC) Scale in MCCs.

Methods

Instrument Development

The CSE-CSC scale was derived from the Self-Care Self-Efficacy Scale (SC-SES) (Yu et al., 2020), an instrument that measures patient self-efficacy in performing self-care behaviours with a single disease and MCCs. Based on the Middle Range Theory of Self-care of Chronic Illness (B. Riegel et al., 2012), the CSE-CSC scale was proposed to measure caregiver self-efficacy in contributing to patient self-care maintenance, -monitoring, and -management of chronic illness. The CSE-CSC scale includes the same items as the SC-SES, except that the wording of the introduction and the items in the scale has been changed to make it clear that the scale investigates the caregiver self-efficacy in contributing to patient self-care in the context of MCCs. For example, in the SC-

SES, patients are asked to report the extent to which they feel confident about keeping their disease stable and without symptoms, or about following the treatment plan that clinicians have given them. In the CSE-CSC scale, caregivers are asked, in reference to the person they care for, to report the extent to which they feel confident about keeping the patient's diseases stable or about helping the patient to follow the prescribed treatment plan. This procedure of changing the patient version of an instrument into a caregiver version has been used extensively in prior studies (Buck et al., 2017; Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Glaser, et al., 2013; Villa et al., 2019). Like the the SC-SES, the CSE-CSC scale uses a five-point Likert format, with responses from "not confident" to "very confident". The CSE-CSC score is standardised on a scale of 0–100, where higher scores mean higher caregiver self-efficacy in contributing to MCC patient self-care.

The CSE-CSC scale was developed in English, then translated into Italian by two independent Italian researchers who were fluent in English and had expertise in chronic diseases. The Italian translation of the CSE-CSC scale was then translated back into English by a bilingual researcher with expertise in medical English. After this back-translation, minimal refinements were done with the SC-SES developer to ensure the equivalence of meaning between the two versions. After translation, cognitive interviews were conducted with 10 caregivers of MCC patients using think-aloud techniques to verify if all items of the CSE-CSC scale were easily and correctly understood. Those interviews demonstrated that all items were correctly understood.

Sample and Settings

To test the psychometric characteristics of the instrument, we used the baseline data of the ongoing SODALITY study, a longitudinal multicentre investigation, that aims to describe patient self-care and CC to patients' self-care in MCCs. The detailed study protocol was published by De Maria et al. (2019). In brief, in the SODALITY study, we enrol patients aged 65 years or older, with HF or DM or chronic obstructive pulmonary disease (COPD) and at least one other chronic illness, in community and outpatient settings—except for patients with cancer or dementia. We excluded

patients with dementia because the presence of cognitive deficits could make responses to self-reported questionnaires unreliable (Tourangeau, Rips, & Rasinski, 2000). We did not include patients affected by cancer in association with other chronic conditions because, due to the specific medical (chemotherapy and radiotherapy) and surgical treatments, the cancer has a dominant effect on health-related quality of life (Huang, Hudson, Robison, & Krull, 2017).

We also enrol each patient's informal caregivers with the following characteristics: > 18 years old, identified by the patient as the primary informal caregiver (person, inside or outside family, who takes the responsibility and provides most of the informal care to the patient), and willing to sign the informed consent form. We enrolled only matching patient and caregiver dyads. Therefore, if one member of the dyad refused to participate in the study, the other member also was excluded. Patient and caregiver dyads were enrolled in seven regions of central and southern Italy. A sample of seven caregivers per item was needed to allow adequate inference in exploratory or confirmative factor analysis (Terwee et al., 2007; Terwee et al., 2018). Considering the number of CSE-CSC scale items (10), a sample of 70 caregivers would have been adequate to address the main study objective; however, we enrolled 358 participants to support a more stable analysis.

Data Collection

Three hundred and fifty-eight caregivers were enrolled by research assistants, who first identified potential participants based on the inclusion criteria. They explained the aims of the study and obtained the participants' informed consent. Data collection took place during routine outpatient visits or directly at the patient's and caregiver's home.

Instruments

The Caregiver Contribution to Self-care of Chronic Illness Inventory (CC-SC-CII) is a 19-item instrument used to measure CC to self-care in chronic conditions (Ercole Vellone, Silvia Lorini, et al., 2020). It consists of three separate scales: seven CC to self-care maintenance items measure how often a caregiver recommended the patient to adopt behaviours aimed at maintaining

physical and mental stability of a chronic condition; five CC to self-care monitoring items measure how often a caregiver recommended the patient to monitor signs and symptoms of his/her chronic illness; and seven CC to self-care management items measure how often a caregiver contributed to the recognition or interpretation of symptoms and responded to exacerbation of chronic illness symptoms.

Psychometric analysis of the CC-SC-CII in our study demonstrated that it has good construct validity (comparative fit index [CFI] ranging between 0.936 and 0.981 among the three scales) and reliability (Cronbach's alpha and factor determinacy coefficients ≥ 0.765 for the three scales) (E. Vellone et al., 2020). For responses, the CC-SC-CII uses a five-point Likert format ranging between "never" and "always". Each CC-SC-CII scale has a standardised 0–100 score, with higher scores meaning better CC to patient self-care. The CC-SC-CII was used in this study for construct validity via hypothesis testing, since higher scores in caregiver self-efficacy are associated with better CC to self-care (Vellone et al., 2019). We also collected sociodemographic characteristics of the caregivers (i.e., age, gender, education, years of caregiving…) with a specific questionnaire.

Data Analysis

Data analysis was conducted in six phases. First, we used descriptive statistics, including means, standard deviations (SDs), frequencies, percentages, skewness, and kurtosis, to analyse the sociodemographic characteristics of participants, the scale scores, and the univariate distribution of scale items. Second, we used Bartlett's test of sphericity and the Kaiser–Meyer–Olkin (KMO) test to examine the adequacy of the sample and the suitability of data for factor analysis, which we used to test the structural (factorial) validity of the CSE-CSC scale. Bartlett's test of sphericity should have a significant $\chi 2$; the KMO should have a value ≥ 0.70 (Tabachnick & Fidell, 2013).
Third, according to classical test theory (Kline, 2005), we tested the structural validity of the CSE-CSC scale with a cross-validation procedure, using both exploratory factor analysis (EFA) and

confirmatory factor analysis (CFA). Specifically, we randomly split the entire sample into two subsamples, named A and B. These two subsamples were equivalent in term of age [t (358) = -0.174 p = 0.7], gender [$\chi 2$ (1,358) = 0.234, p = 0.64], and education [$\chi 2$ (1,358) = 0.655, p = 0.37]. In subsample A, to address the issue of the number of latent dimensions underlying the CSE-CSC scale's items, EFA was performed. To define the number of plausible factors to extract, parallel analysis was performed on the total sample (Crawford et al., 2010; Glorfeld, 1995; Horn, 1965; Timmerman & Lorenzo-Seva, 2011).

In subsample B, we validated the factorial solution obtained from EFA with CFA (Anderson & Gerbing, 1988). This approach has been applied successfully in several other studies (Piredda et al., 2017),(Sili, Biagioli, Caruso, & Zaghini, 2018) and also with instruments that measure self-care and self-efficacy in self-care (Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Antonetti, et al., 2013). Because the expected factors were assumed to correlate, EFA was performed with the maximum likelihood (ML) extraction method and GEOMIN rotation (Muthén & Muthén, 1998-2012). Due to the normal distribution of CSE-CSC scale items, we used an ML estimator (Muthén & Muthén, 1998-2012).

The factorial solution obtained by EFA in subsample A was tested with CFA in subsample B. To evaluate model fit, we adopted a multifaceted approach that considered goodness-of-fit indices (Byrne, 2013; Meade, Johnson, & Braddy, 2008), the CFI (Bentler, 1990), the Tucker–Lewis Index (TLI) (Tucker & Lewis, 1973), the root mean square error of approximation (RMSEA) (Steiger, 1990), the standardised root mean square residual (SRMR) (Jöreskog & Sörbom, 1996), and chi-square significance. CFI and TLI should have values ≥ 0.90 or better ≥ 0.95 (Hu & Bentler, 1999); RMSEA values ≤ 0.08 or ≤ 0.05 indicate a good fit, as well as the rejection of the null hypothesis (for $p < 0.05$) associated with its 90% confidence interval (Bollen & Long, 1993; Browne & Cudeck, 1992) and $p > 0.05$ for the test of close-fit. SRMR should have values ≤ 0.08 in. The chi-square test was also interpreted together with the above indices. The model's misfit was improved by considering the eventual residual covariances justified to theoretical and

methodological reasons. After performing EFA and CFA on the two subsamples, to obtain solid estimates for the final loadings, we re-ran the CFA on the entire sample. Finally, since the two factors extracted from EFA and CFA were significantly correlated, we examined a second-order hierarchical factor loading of those two factors.

Fourth, we tested the CSE-CSC scale's construct validity via hypothesis testing by examining the correlation between the scores of the CSE-CSC scale and the fourth CC-SC-CII scale using the Pearson correlation coefficient r (two-tailed). Correlation coefficients of 0.10, 0.30, and 0.50 were considered to be small, medium, and large, respectively (Cohen, 1988). We hypothesised that caregiver self-efficacy would be positively correlated from moderate to strong with CC to self-care, as reported in the theory (Vellone et al., 2019) and in prior studies (Durante et al., 2019; Ercole Vellone, Valentina Biagioli, et al., 2020).

Fifth, we estimated the reliability of internal consistency of the CSE-CSC scale. Specifically, we computed the composite reliability coefficient (C. Fornell & Larcker, 1981) and the factor score determinacy (Muthén & Muthén, 1998-2012) for each first- and second-order factor extracted from CFA, and we computed the global reliability index for multidimensional scales (Raykov, 2012) and Cronbach's alpha coefficient (Barbaranelli, Lee, Vellone, & Riegel, 2015) for the overall scale. All these reliability estimates should have a value >0.70 (Richard P Bagozzi & Yi, 2012).

Finally, we evaluated the measurement error of the CSE-CSC scale by computing the standard error of measurement (SEM) and the smallest detectable change (SDC). The SEM was computed with the following formula: SD x √(1 - reliability coefficient) (Brown, 1999). Here the SD was the SD of the CSE-CSC scale score, and the reliability coefficient was the Cronbach's alpha coefficient. If the SEM has a value < SD/2, the instrument is considered precise (Beckerman et al., 2001). The SDC was computed with the following formula: 1.96 x √ 2 x SEM (Beckerman et al., 2001). The SDC value indicates how many points in the CSE-CSC scale are considered clinically significant.

Mplus software v 8.2 (Muthén and Muthén, Los Angeles, CA, USA) was used for the factorial analyses, and SPSS® Statistics v. 22 (IBM Corp., Armonk, NY, USA) was used for the descriptive statistics.

Study results

Sample Characteristics

Of the 417 eligible caregivers, 367 (88%) agreed to participate, and 50 (12%) declined due to lack of time or interest. Nine participants were identified as outliers and were excluded from all analysis, as recommended by Tabachnich and Fidel (2007), because they were influential data points in factor analyses. The outliers showed a low level of education (six participants had a middle school) and were mainly older adults (seven participants were over 70 years old). Therefore, we hypothesized that education and age, often associated with cognitive impairment, led these participants to not fully understand the content of some items. Consequently, all analyses were performed with a final sample of 358 caregivers. Most caregivers were female (71.5%), employed (68.2%), and with a medium–high level of education (88.4 %) (Table 1). They were the children (57.8%) or the spouse (31.1%) of patients, and the majority (55%) lived with the patients. The caregivers provided 25.5 hours of care per week, on average, and they had been providing care for an average of 8.9 years. The patients were mostly females (53.9%), with a mean age of 76.6 years and a low educational level (55.9%), and they were afflicted with 3.2 chronic conditions on average (Table 1).

Table 1. Clinical and sociodemographic characteristics of caregivers and patients (N = 358).

	Caregiver		Patient	
	M (range)	± SD	M (range)	± SD
Age	54.6 (19–86)	15.1	76.6 (65–93)	7.3
	n	%	n	%
Sex				
Female	256	71.5	193	53.9
Male	102	28.5	165	46.1
Marital status				
Married	252	70.4	229	64
Never married	75	20.9	11	3
Divorced	25	7	12	3.4
Widowed	6	1.7	106	29.6
Education				
Illiterate	2	0.6	8	2.2
Elementary	39	10.9	200	55.9
Middle/professional school	118	32.9	97	27.1
High school	138	38.5	39	10.9
University	62	17	14	3.9
Employment status				
Employed	192	68.2	15	4.3
Retired/unemployed	166	31.8	343	95.7
Income				
Have less than needed to make ends meet	15	4.2	18	5
Have enough to make ends meet	291	81.3	304	84.9
Have more than needed to make ends meet	52	14.5	36	10.1
Relationship with patient				
Spouse/partner	111	31.1	-	-
Child	207	57.8	-	-
Grandchild	28	7.8	-	-
Sister/brother/friend	12	3.3	-	-
Living with patient				
No	161	45	-	-
Yes	197	55	-	-
Secondary caregiver				
No	146	40.8	-	-
Yes	212	59.2	-	-
	M (range)	±SD	M (range)	±SD
Caregiving hours per week	25.5 (1–168)	36.1	-	-
Years of caregiving	8.9(1–45)	7.2	-	-
Chronic illnesses (number)	-	-	3.2 (2–9)	1.3

Descriptive Analysis of Scale Items

Table 2 shows the descriptive statistics of the CSE-CSC scale items. All the items were normally distributed. The item with the highest score was "Follow the treatment plan he/she has been given." The item with the lowest score was "Can keep him/her stable and free of chronic illness symptoms."

Table 2. Descriptive statistics of individual items, factors, and the total score of the Caregiver Self Efficacy in Contributing to Self-Care scale (N = 358).

Items of the Caregiver Self-Efficacy in Contributing to Self-Care scale	M	DS	Skewness	Kurtosis
In general, in reference to the person you care for, how confident you are that you can:				
1. keep the illness of the person you care for stable and free of symptoms?	3.447	0.965	0.300	-0.671
2. follow the treatment plan that has been given to the person you care for?	4.140	1.000	-0.736	-0.571
3. persist in following the treatment plan even when difficult?	3.913	1.051	-0.537	-0.619
4. routinely monitor the condition of the person you care for?	3.930	1.060	-0.567	-0.625
5. persist in routinely monitoring the condition of the person you care for even when difficult?	3.807	1.063	-0.464	-0.590
6. recognize changes in the health of the person you care for if they occur?	3.927	0.941	-0.279	-0.994
7. evaluate the importance of symptoms?	3.911	0.978	-0.361	-0.796
8. do something to relieve symptoms of the person you care for?	3.894	1.007	-0.561	-0.369
9. persist in finding a remedy for symptoms of the person you care for even when difficult?	3.723	1.115	-0.521	-0.569
10. evaluate how well a remedy works?	3.824	1.045	-0.485	-0.491
Illness management factor	19.237	4.389	-0.491	-0.632
Symptom management factor	19.279	4.425	-0.367	-0.374
Total score of CSE-CSC	71.291	20.728	-0.347	-0.728

Legend. M: Mean; SD: Standard deviation. Note. Item numbering reflects the sequence in the scale.

Structural and Construct Validity of the CSE-CSC Scale

Since the Bartlett test of sphericity was significant ($p < 0.001$) and the KMO index was 0.84, the data were suitable for factor analysis. Parallel analysis suggested that a two-factor solution

was the more adequate for the dataset; consequently, we tested the two-factor solution on subsample A. Table 3 shows EFA results: all the primary factor loadings were adequate (> 0.30). They ranged from 0.487 ("Can keep him/her stable and free of chronic illness symptoms") to 1.024 ("Doing something to relieve his/her symptoms"). They were loaded with five items each. The fit indices of this solution are reported in row 1 of Table 4, and they yielded a partial misfit for the RMSEA.

Table 3. Exploratory Factor Analysis and item factor loadings for the Caregiver Self-Efficacy in Contributing to patient' Self-Care scale (N = 179).

Items of the Caregiver Self-Efficacy in Contributing to Self-Care scale	F 1 loading	F 2 loading
In general, in reference to the person you care for, how confident are you regarding …		
1. can keep him/her stable and free of chronic illness symptoms?	**0.487***	0.181
2. follow the treatment plan him/her have been given?	**0.960***	-0.123
3. persist in following the treatment plan even when difficult?	**0.940***	0.006
4. monitor his/her condition routinely?	**0.690***	0.152
5. persist in routinely monitoring his/her condition even when difficult?	**0.627***	0.323*
6. recognizing changes in his/her health if they occur?	0.349*	**0.507***
7. evaluating the importance of his/her symptoms?	0.071	**0.794***
8. doing something to relieve his/her symptoms?	-0.179	**1.024***
9. persisting in finding a remedy for his/her symptoms even when difficult?	0.003	**0.911***
10. evaluating how well a remedy works?	0.095	**0.714***

Legend. F1: Self-efficacy in self-care maintenance and monitoring; F2: Self-efficacy in self-care management. Note.*p < .05.

The model identified by EFA was replicated on subsample B with CFA, obtaining acceptable fit indices (see row 2 of Table 4). On the basis of the item content, the first factor was labelled "Self-efficacy in self-care maintenance and monitoring", and the second was labelled "Self-efficacy in self-care management". Scrutinising the modification indices revealed that the partial misfit was due to an excessive covariance between item 2 ("Follow the treatment plan he/she

has been given") and item 3 ("Persist in following the treatment plan even when difficult") and between item 6 ("Recognising changes in his/her health if they occur") and item 7 ("Evaluating the importance of his/her symptoms"). There are solid methodological reasons that justify these error covariances (Wang & Wang, 2019). All of these covariances are related to items with an adjacent position in the scale (items 2 and 3, and items 6 and 7). Adjacent pairs of positively worded items may show a pattern of increasing correlation that decreases with increasing inter-item distance, described by Weijters et al. (2009) as a "proximity" effect. Error covariance can be used to account for the extra source of item covariance introduced by item proximity (Marsh, 1996). It is worth noting that all these covariances were also generalised across the total sample. The model specified with these covariances obtained good fit indices (see row 3 of Table 4).

Table 4. Fit indices for the Caregiver Self-Efficacy in Contributing to patient' Self-Care scale derived from Exploratory Factor Analysis and Confirmatory Factor Analysis

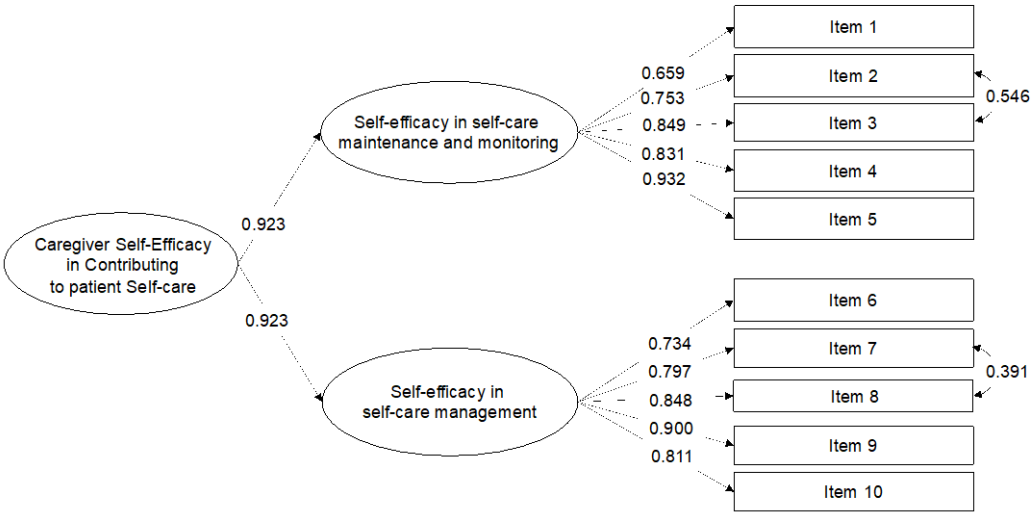
	N	χ^2	DF	p(χ^2)	TLI	CFI	SRMR	RMSEA, (90% C.I.), p (RMSEA<0.05)
EFA in subsample A	179	79.351	26	<0.001	0.906	0.946	0.027	0.107, (0.081 0.134), p <0.001
CFA in subsample B without residual covariances	179	115.069	34	<0.001	0.889	0.916	0.046	0.115, (0.093 0.139), p<0.001
CFA in subsample B with residual covariaces	179	59.860	32	0.002	0.960	0.971	0.037	0.070 (0.042 0.097), p= 0.114
CFA first-order in total sample	358	87.614	32	<0.001	0.958	0.970	0.037	0.070 (0.052 0.087), p= 0.031
CFA second-order in total sample	358	92.080	33	<0.001	0.956	0.968	0.051	0.071 (0.054 0.088), p= 0.023

Legend. N: sample size; χ^2: chi-square; DF: Degree of Freedom; TLI: Tucker and Lewis Index; CFI: Comparative Fit Index; SRMR: Standardized Root Mean Square Residual; RMSEA: Root Mean Square Error of Approximation; CI: 90% Confidence Interval.

The CFA was run on the entire sample of 358 participants and with the same specifications as the CFA conducted on subsample B. It identified a model with good fit indices, reported in row 4 of Table 4. Since the two CFA factors were significantly correlated at 0.852, we examined a

second-order hierarchical model that produced a good fit as well: χ^2 (33, N = 358) = 92.080, p < 0. *p* <0 .001, CFI = 0.968, TLI = 0.956, RMSEA = 0.071 (90 % CI = 0.054 - 0.088), *p* = 0.023, SRMR = 0.051(row 5 of Table 4). All factor loadings were significant, ranging from 0.659 to 0.932 (Figure 1). All residual covariances were also generalised across the total sample.

Figure 1. Graphical representation of the second-order hierarchical model (N = 358).



Note. Factor loadings of the second-order hierarchical model from the Mplus output for completely standardized solutions are reported. All coefficients are statistically significant (p < .05).

The construct validity of the CSE-CSC scale was supportive as well. The Pearson's correlation coefficients between the CSE-CSC scale scores and the CC to patients' self-care maintenance, monitoring, and management were moderate to high: r = 0.452 (*p* = 0.01), r = 0.582 (*p* = 0.01), and r = 0.609 (*p* = 0.01), respectively.

Internal Consistency Reliability and Precision of the CSE-CSC Scale

The internal consistency reliability of the CSE-CSC scale was supportive. The composite reliability coefficients for the self-efficacy in self-care maintenance and monitoring factor, the self-

efficacy in self-care management factor, and the overall CSE-CSC scale were 0.904, 0.911, and 0.951, respectively. The factor score determinacies for the self-efficacy in self-care maintenance and monitoring factor, the self-efficacy in self-care management factor, and the overall scale were 0.967, 0.963, and 0.937, respectively. The global reliability index for the multidimensional scale was 0.923, and the Cronbach's alpha coefficient was 0.942 for the whole scale.

The SEM of the CSE-CSC scale resulted in 1.36 for the self-efficacy in self-care maintenance and monitoring factor, 1.32 for the self-efficacy in self-care management factor, and 6.19 for the total CSE-CSC score. These measures were considered adequate. The SDC resulted in 3.23 for the self-efficacy in self-care maintenance and monitoring factor, 3.19 for the self-efficacy in self-care management factor, and 6.19 for the total CSE-CSC score. The SDC coefficients evidence the points in the CSE-CSC scale, at factor and scale levels, that we can consider for a meaningful change.

Discussion

The aim of this study was to develop an CSE-CSC scale and test its psychometric characteristics. To the best of our knowledge, the CSE-CSC scale is the first instrument that measures the self-efficacy in contributing to patient's self-care in MCCs. We found that the CSE-CSC scale showed good validity and reliability in this sample of caregivers of MCC patients.

Regarding structural validity, we used both EFA and CFA to ensure a more solid validation. In the CSE-CSC scale, we found two distinct factors that referred to the caregiver's self-efficacy. One was managing the patient's illness (e.g., monitoring patient conditions), and the other was managing the patient's symptoms (e.g., doing something to relieve symptoms). In the SC-SES, from which this scale was derived, only one such factor was identified. Instead, the factorial structure of the CSE-CSC scale is similar to the Self-care Confidence scale of the Caregiver Contribution to Self-care of HF Index (Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Glaser, et al., 2013), which measures caregiver self-efficacy in contributing to HF self-care. In fact, in this instrument, a first factor named "basic confidence", including behaviours related to illness

management (e.g., following the treatment plan), and a second factor named “advanced confidence”, including behaviours related to the management of symptoms (e.g., keeping the patient free from HF symptoms), were found.

The fit model of the CFA was improved by the estimations of residual covariances between two item pairs: between item 2 (Follow the treatment plan he/she has been given) and item 3 (Persist in following the treatment plan even when difficult), and between item 6 (Recognising changes in his/her health if they occur) and item 7 (Evaluating the importance of his/her symptoms). These excessive correlations between these two item pairs could be justified by the fact that both item 2 and item 3 pertain to following the treatment plan, and both item 6 and item 7 are related to self-efficacy in symptoms. According to Bagozzi (Richard P. Bagozzi, 1983) and Claes Fornell (1983) the covariances between item residuals can be allowed if this is methodologically or theoretically reasonable, as in our case.

Construct validity of the CSE-CSC scale was demonstrated via hypothesis testing through moderate and strong significantly positive correlations with the CC-SC-CII scale scores. As described in the theoretical (B. Riegel et al., 2012; Vellone et al., 2019) and empirical literature (Chen, Zou, Zhang, Fang, & Fan, 2017; Vellone et al., 2015), self-efficacy is an important predictor of CC to self-care. Consequently, this finding gives strength to the existing theories and the available clinical evidence (Chen et al., 2017; Vellone et al., 2015) on the role between self-efficacy and self-care.

Internal consistency reliability of the CSE-CSC scale, tested through both unidimensional and multidimensional indices, was optimal. This means that if we measure either the two dimensions of the CSE-CSC scale or the entire caregiver self-efficacy, we can have reliable values. In addition, the precision of the instrument was good for the two dimensions and the entire scale, as the SEM was <SD/2. The small detectable change of 6.19 for the entire scale score is informative of the minimum change in the scale score to have a clinically meaningful change.

There are a couple of limitations that are worth considering in this study. First, although the factor structure of this scale was established by a cross-validation procedure, by exploring the factorial structure of the CSE-CSC scale with EFA and then by confirming the obtained factorial structure with CFA, we tested the instrument in a single convenience sample. Second, validation against more than one criterion, discriminant validity, responsiveness, test-retest reliability were not tested because it wasn't the principal aim of the study. Future studies are needed to verify these psychometric characteristics of the CSE-CSC scale.

Third, we excluded patients with severe health issues (i.e., those with important cognitive deficits and cancer). In consideration of these two limitations, generalisability of our findings should be done with caution in other countries and in other caregiver populations. For these reasons, we recommend further testing of the CSE-CSC scale in samples enrolled in other countries and eventually affected by different health issues.

Our study might have important clinical and scientific implications. Clinicians could use the CSE-CSC scale to measure the extent to which caregivers feel confident in helping patients affected by MCCs to perform self-care. Since patient self-care and CC to self-care are associated with positive patient outcomes (e.g., better quality of life, rehospitalisations) (Kessing et al., 2017; McAlister et al., 2004), it is important to identify variables that influence patient self-care and CC to self-care. Consequently, clinicians using the CSE-CSC scale can evaluate if caregiver self-efficacy is adequate, and in case it is not, they can support caregivers with tailored interventions aimed at improving their self-efficacy. From a scientific point of view, the use of the CSE-CSC scale in future studies, especially in randomised controlled trial, could be important to understand which interventions could improve caregiver self-efficacy.

Conclusion

In conclusion, the present study gives evidence of validity, reliability, and precision to a new instrument that can be used in clinical practice and research to evaluate caregiver self-efficacy in contributing to self-care in MCCs. We recommend the use of the CSE-CSC scale in combination

with the CC-SC-CII to better understand the relationship between caregivers' self-efficacy and their contributions to self-care in MCCs. In fact, while several studies on single chronic conditions (e.g., HF) show that caregiver self-efficacy influences CC to self-care (Vellone et al., 2015), knowledge is poor on MCCs. Also, we recommend using the SC-SES used for patients in combination with the CSE-CSC scale. This would allow to perform dyadic analyses, which are important because caregivers and patients influence each other.

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CHAPTER 4 - Effectiveness of motivational interviewing on health-service use and mortality: a secondary analysis of the MOTIVATE-HF

This chapter is found in the following source:

Iovino P., Rebora P., Occhino G., Zeffiro V., Caggianelli G., Ausili D., Alvaro R., Roegel B., Vellone E. (2021). Effectiveness of Motivational Interviewing on Health-service Use and Mortality: a Secondary Analysis of the MOTIVATE-HF trial, ESC Heart Failure, XXX, doi: https//doi.org/10.1002/ehf2.13373.

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.** 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. A face-to-face MI plus three telephone calls were performed in Arms 1 and 2. The sample consisted of 510 patients (median age 74 years, 58% male) and caregivers (median age 55 years, 75% female). 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 in 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 stronger interventions and longer follow-ups are needed to clarify the benefits on health-care service use and mortality.

Keywords:

Health service use, heart failure, hospitalization, mortality, motivational interviewing, randomized controlled trial

Introduction

With over 23 million people affected worldwide, heart failure (HF) is currently considered a global pandemic (Roger, 2013). Only in the US, estimates of prevalence indicate approximately 6 million individuals (Virani et al., 2020), whereas Europe has an additional burden of at least 15 million (Ambrosy et al., 2014). By 2030, the proportion of individuals suffering from HF is expected to increase by 46% (Mozaffarian et al., 2016), accompanied by an uprise in costs from the actual average of $30 to $50 billion (Heidenreich et al., 2013).

Greater health-care service use is common in patients with HF (Long, Koyfman, & Gottlieb, 2019). The physiopathology of the disease, which is characterized by many potential precipitating factors (e.g., acute decompensation, arrhythmia, renal impairment, infection, and hypertension) (Long et al., 2019) leads to an important amount of emergency service use and hospitalizations. Over 650,000 presentations to the emergency department occur annually in the US with about 80% of them ending up with a hospital admission (Blecker, Ladapo, Doran, Goldfeld, & Katz, 2014).

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 a level of 20-30% at 1 year after the diagnosis, with up to 50% over 5 years of follow-up (Benjamin et al., 2017).

To reduce health-care service use and mortality rates, individuals with HF are recommended to practice self-care, which also includes treatment adherence (Ponikowski et al., 2016). 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) (Riegel, Dickson, & Faulkner, 2016). Evidence shows that HF self-care improves patient outcomes, such as health-care service use and mortality (Ruppar, Cooper, Mehr, Delgado, & Dunbar-Jacob, 2016).

Although it has positive effects, patients with HF find it difficult to perform self-care (Seid, Abdela, & Zeleke, 2019) and researchers are looking for interventions aimed at improving such

behaviours; this 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 consistently in patients with chronic conditions (Zomahoun et al., 2016). MI evokes and enhances self-efficacy and intrinsic motivation, consequently reducing resistance and promoting a more sustainable health behaviour change (Miller & Rollnick, 2002).

The Motivational interviewing to improve self-care in heart failure patients (MOTIVATE-HF) study (Vellone et al., 2020) 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 (Vellone et al., 2017), we evaluated if MI was effective on two secondary outcomes: health-care service use (e.g., emergency service use and hospitalizations) and mortality rates at 3, 6, 9 and 12 months from 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 (Vellone et al., 2017). 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 performed only for patients; Arm 2, in which MI was performed with patients and caregivers; or Arm 3, standard of care.

Participants

Eligibility criteria for patients were: (i) a diagnosis of HF; (ii) New York Heart Association (NYHA) functional class ≥ 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) (Riegel, Lee, Dickson, & Carlson, 2009); and (iv) willingness to participate in the

study. Exclusion criteria for patients were: (i) severe cognitive impairment (a score of 0–4 on the Six-item screener (Callahan, Unverzagt, Hui, Perkins, & Hendrie, 2002); (ii) acute coronary syndrome event within the last 3 months; (iii) living in residential settings (e.g., nursing home); and (iv) caregiver not willing to participate in the study. Eligibility criteria for caregivers were: (i) identification by the patient as the primary caregiver (e.g., the main unpaid figure that mostly provided the informal care) and (ii) 18 years old of age or older.

Intervention and control

The intervention included a first 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 (Laws et al., 2018), 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 and 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 minutes, the interventionist continued to use an emphatic approach with the participants, particularly with those that 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 into the enrolment criteria, the research assistant administered the battery of the MOTIVATE-HF tools separately to patients and caregivers. Research assistants were blinded as to the assignment to the study arms both at baseline and follow-ups (3, 6, 9 and 12 months from enrolment) 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 (Vellone et al., 2017), 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 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 for every 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 (Wehby, Jones, Ullrich, Lou, & Wolinsky, 2016) and, generally, when the questions implied more objective aspects (e.g., hospitalizations and use of preventative services) (Li, Harris, & Lu, 2015).

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 (Vellone et al., 2017; Vellone et al., 2020). Briefly, we performed a 1:1:1 randomization by using a computer-generated randomization list with blocks of 15 patient and caregiver dyads. Three randomization lists with 400 random assignments per centre closed in envelopes were prepared by a research assistant not involved in data collection and analysis. In each centre, each time a patient and caregiver dyad had been enrolled, another research assistant opened an envelope to assign the patient and caregiver dyad to one of the three arms. If patient and caregiver dyads were assigned to Arm 1 or 2, the research assistant informed the interventionist to perform MI, and the subsequent telephone contacts, only to patient or to patient and caregiver, respectively. This second research assistant could not influence arm assignment. The interventionist was not blinded to assignment to Arms 1 and 2 but did not collect any data.

Treatment fidelity

Treatment fidelity related to the intervention has been reported extensively in prior publications (Vellone et al., 2017; Vellone et al., 2020). To evaluate whether the interventionists complied with the technical and relational components of MI, we adopted the Motivational Interviewing Treatment Integrity (MITI) scale, a behavioural coding scheme, that returns a score ranging from 1 to 5 (higher scores represent higher MI quality in its technical and relational components). For this purpose, we randomly audiotaped 48 MIs in Arm 1 and 97 MIs 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) (Vellone et al., 2020). 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 done as planned at each follow-up (respecting the 2-month interval).

Statistical analysis

Health-care service use (emergency service use and hospitalizations) and all-cause mortality among patients were summarized as absolute numbers and their frequencies among the three arms of treatment at each follow-up time (3, 6, 9 and 12 months from enrolment). Statistical differences of health-care service use and all-cause mortality at each follow-up among the three arms were assessed by 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 categorical variable (to account for non-linearity), the randomization arm, and the interaction between the 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.

Study 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 only for patients; Arm 2=MI for patients and caregivers) or control group (Arm 3). The baseline characteristics and flow chart of the participants by each study arm and each follow-up are presented in the primary study (Vellone et al., 2020). Briefly, patients (median age=74 years), were mostly male (58%), retired (76.2%), NYHA Class II (61.9%) and had an ischemic HF cause (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 (Vellone et al., 2020). Reasons for loss at each follow-up were due to refusal to continue the study or death event.

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.

Table 1. Health-care service use among patients with HF at each follow-up.

	Arm 1			Arm 2			Arm 3			
Follow-up	N patients with available information	N health-care services	%	N patients with available information	N health-care services	%	N patients with available information	N 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

Note. 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.

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.

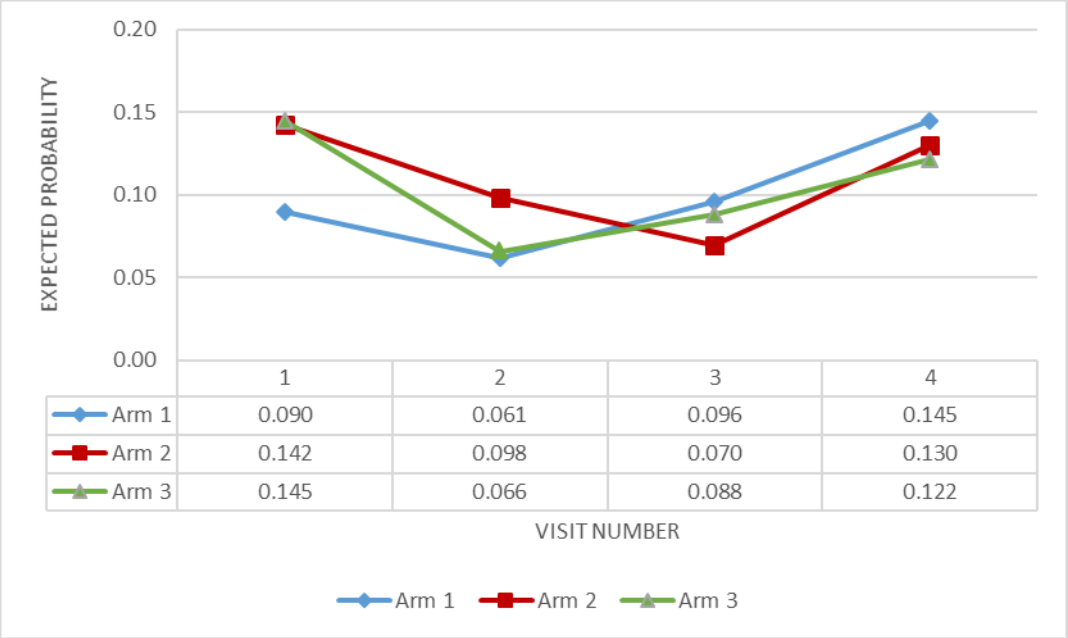
Table S1. Longitudinal generalized linear mixed model results on health-care service use.

Effect	OR	OR (95% CI)
Visit number: 2 vs 1	0.416	(0.147; 1.182)
Visit number: 3 vs 1	0.571	(0.207; 1.579)
Visit number: 4 vs 1	0.817	(0.309; 2.162)
Arm: 1 vs 3 at visit 1	0.581	(0.213; 1.587)
Arm: 2 vs 3 at visit 1	0.979	(0.403; 2.378)
Arm: 1 vs 3 at visit 2	0.927	(0.261; 3.299)
Arm: 2 vs 3 at visit 2	1.543	(0.492; 4.832)
Arm: 1 vs 3 at visit 3	1.099	(0.336; 3.597)
Arm: 2 vs 3 at visit 3	0.774	(0.230; 2.604)
Arm: 1 vs 3 at visit 4	1.224	(0.400; 3.738)
Arm: 2 vs 3 at visit 4	1.078	(0.362; 3.215)

Note. CI, confidence interval; OR, odds ratio. Arm 3 and visit number 1 considered as reference levels. Arm 1=motivational interviewing (MI) only for patients; Arm 2=MI for patients and caregivers; Arm 3=standard of care. Visits number 1, 2, 3 and 4 correspond to 3, 6, 9 and 12 months from enrolment.

Model-based estimates of health-care service use among patients are shown in Figure 1.

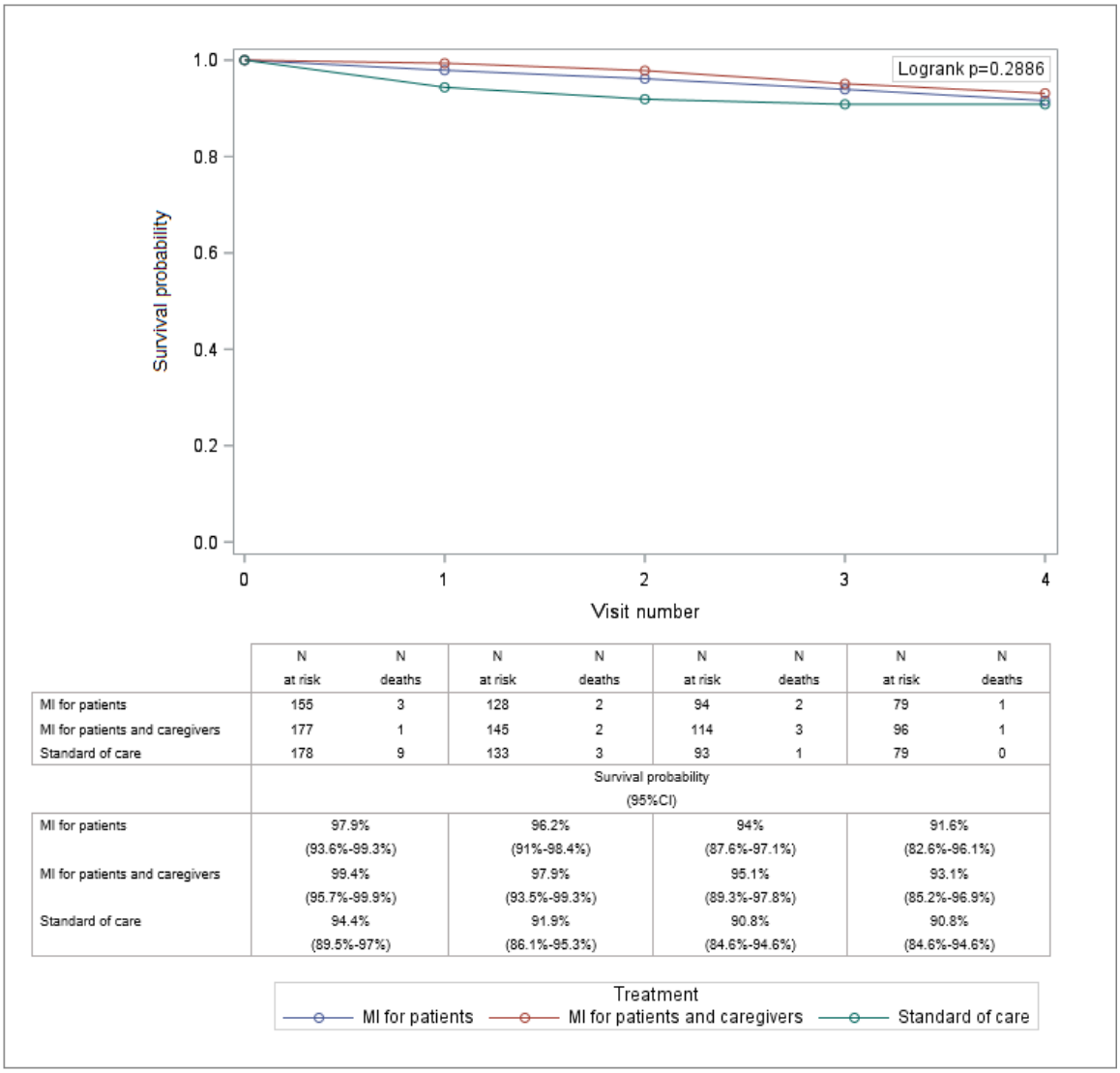
Figure 1. Expected probabilities of health-care service use among patients with HF by treatment arm.



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.

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 reported in Figure 2.

Figure 2. Life-table survival estimate of patients with HF in the three arms.



	N at risk	N deaths	N at risk	N deaths	N at risk	N deaths	N at risk	N deaths
MI for patients	155	3	128	2	94	2	79	1
MI for patients and caregivers	177	1	145	2	114	3	96	1
Standard of care	178	9	133	3	93	1	79	0
	Survival probability (95%CI)							
MI for patients	97.9% (93.6%-99.3%)		96.2% (91%-98.4%)		94% (87.6%-97.1%)		91.6% (82.6%-96.1%)	
MI for patients and caregivers	99.4% (95.7%-99.9%)		97.9% (93.5%-99.3%)		95.1% (89.3%-97.8%)		93.1% (85.2%-96.9%)	
Standard of care	94.4% (89.5%-97%)		91.9% (86.1%-95.3%)		90.8% (84.6%-94.6%)		90.8% (84.6%-94.6%)	

Note. Visits number 1, 2, 3 and 4 correspond to 3, 6, 9 and 12 months from enrolment, respectively. MI: motivational interviewing. N at risk corresponds to the number of patients entering in the time interval minus deaths and refusals.

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 did not show a statistical difference among the three 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). An indication of lower mortality in Arm 1 with respect to Arm 3 in the first 3 months was also present, without reaching statistical significance (HR=0.383, 95% CI:0.104–1.414, p=0.155, Table 2).

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

Note. CI, confidence interval; HR, hazard ratio; p, p-value. Arm 1=motivational interviewing (MI) only for patients; Arm 2=MI for patients and caregivers; Arm 3=standard of care; HR, hazard ratio; p, p-value.

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, but a significant effect on mortality was detected. This finding is noteworthy because it remarks upon the fact that the strategies to improve survival in HF should not be confined to medical treatments only. With this study, we have proved that MI can be an additional investment for motivating patients into more healthy lifestyles and thus the promotion of longer survival.

We found that the intervention improved survival in patients with HF at 3 months. We believe that the substantial reduction of mortality may be attributable to improvements in self-care behaviours. In our primary study (Vellone et al., 2020), 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 (Ruppar et al., 2016). 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 aspect is the trial by Vaillant-Roussel et al. (2016) This study found a lower number of deaths in the intervention group compared to that in the control, but this difference was statistically nonsignificant. The remaining evidence is represented by reviews and meta-analyses (Lundahl et al., 2013; Oyanguren et al., 2016), which substantially agree on the positive effect of MI on mortality; however, the trials adopted a number of self-care interventions that are substantially different from the MI approach.

Taken together, the experimental arms of our study had lower mortality rates, but by performing a Cox model, we found that this reduction was statistically significant in Arm 2 when compared to Arms 1 and 3. This finding is important because it means that, if we use MI in both patients and caregivers, this intervention might be more effective in reducing patient mortality. The presence of the caregivers may act as a protective factor towards the patients, and we hypothesize this simplistically as being determined by 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 with a novel and promising beneficial mechanism; thereby, we recommend the authors of future trials to harness the involvement of the caregivers in the recruitment process, as to make sure of getting the most for the patients out of MI interventions.

Interestingly, in our primary study, Arm 2 had the best self-care level at 3 months, and this might explain why patients had a significantly lower death rate in Arm 2. Self-care also improved constantly across Arms 1 and 2 over time, but we observed an improvement 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 (Pooyan & Frouzande, 2016). At 3 months after the intervention, the effect on these "other variables" may have faded out due to deterioration of the effect of MI, and self-care alone might not have been sufficient enough to reduce mortality. Future secondary analyses are warranted to investigate the possible "trend" of these MI-sensitive variables across follow-ups.

We also found that our MI intervention was not effective in reducing health-care service use in terms of emergency services and hospitalizations. The literature is consistent with the beneficial effects of HF self-care interventions on health-care service use (Jovicic, Holroyd-Leduc, & Straus, 2006), but the studies investigating the efficacy of MI on this outcome are absent, except for two studies (Riegel, Masterson Creber, Hill, Chittams, & Hoke, 2016; Vaillant-Roussel et al., 2016). Riegel, Masterson Creber, et al. (2016) administered one MI dose during patients' home visits followed by up to four follow-up phone calls and found a significant reduction of all-cause readmissions at 3 months. Contrastingly, the study by Vaillant-Roussel et al. (2016) administered a 2-day educational programme, which also included MI but did not detect any significant reduction, although they performed the analyses after 19 months of follow-up.

In our study, the fact that we did not detect any influence might be the linked to the adoption of a composite outcome. This was an unavoidable choice caused by the relative paucity of readmission and emergency services visits during follow-ups. Although composite outcomes are used to enhance the rates of events and increase statistical power, the sensitiveness of each component toward the intervention may be dissimilar from each other. In our study, this may have masked the statistical significance of our composite outcome (McCoy, 2018).

Limitations and strengths

This trial also has a few limits. Despite performing an appropriate power analysis to estimate the effect on the primary outcome, no specific calculations were done for the secondary outcomes. In addition, the general drop-out rate of patients was about 20% at T1, reaching slightly more than 45% at T4. As anticipated, the frequency of readmissions and emergency services visits were lower

than expected, and although we performed a mixed model analysis to compensate for this and the relatively high drop-out rate, the choice of combining these two outcomes may have lowered the likelihood of detecting possible significant effects. Second, although we adopted broad eligibility criteria, we prevalently enrolled participants in NYHA class II and III. Hence, our findings might not apply to populations with greater disease severity.

This trial also has several strengths. First, it is the first of its kind to adopt such a large sample size. In fact, the most recent studies in the field involved no more than 100 participants (Chen et al., 2018; Masterson Creber et al., 2016). 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 individual, who is cared for by a caregiver), and this enhances the external validity of this trial. Third, we assessed treatment fidelity constantly throughout the trial; this gives further credibility to our results and warrants replication of the treatment to future trials.

Conclusion

This secondary analysis 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, further studies that adopt stronger and more reliable intervention, and longer follow-ups are needed to better understand the benefits of MI on health-care service use and mortality.

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CHAPTER 5 - Discussion and conclusion

Summary of results of this doctoral program

The aims of this doctoral program were to describe the mechanism by which perceived family support influences self-care in patients with multiple chronic conditions, to develop an instrument to measure caregiver self-efficacy in contributing to patient self-care in multiple chronic conditions, and to investigate the influence of a motivational interviewing intervention in improving health services' use and mortality in a chronic disease sample as a result of sustained behavior change.

First, we discovered that self-efficacy and depression were significant mediators of the relationship between perceived family support and self-care. Specifically, self-efficacy was identified as a full mediator, in both men and women, whereas depression was a significant mediator only in women. This study adds to the evidence that once again self-efficacy is an important determinant also in patients with multiple chronic conditions since it can modulate the relationship between family support and the self-care process. Moreover, we now have additional evidence that that this process occurs similarly in men and women.

Second, we developed a new instrument, the 10-item Caregiver Self-Efficacy in Contributing to patient Self-Care (CSE-CSC), which measures the level of self-efficacy in the support given by the caregiver to the behaviors of maintenance, monitoring, and management self-care. The psychometric analysis confirms that the instrument has a bifactorial structure reflecting a first dimension of behaviors related to maintenance and monitoring practices, and a second one related to management behaviors. Reliability coefficients are supportive, as well as measurement error indexes, confirming that the instrument is valid, reliable, and precise to measure caregiver self-efficacy.

Third, we discovered that motivational interviewing, which is a self-efficacy-sensitive intervention, can improve mortality in patients with heart failure. The trial was designed so that caregivers could also participate in the intervention; interestingly, the significant reduction in mortality was found only in the arm where both the caregivers and patients received the intervention.

Discussion of results

The first study of this doctoral program confirms self-efficacy as an important mediator of the relationship between perceived family support and self-care also in older chronically ill populations. This is new in the literature because so far, self-efficacy has been studied only in single chronic conditions (e.g., heart failure) (Bahari et al., 2019; Caruso et al., 2019; Tovar et al., 2016; Vellone et al., 2016). The findings of the study are also novel in the fact that self-efficacy does not seem to mediate the relation between family support and self-care in isolation; in fact, depression has been confirmed as another important mediator, thus giving credit that the dynamics involving family processes and self-care behaviors are more complex than previously thought. Furthermore, the results that depression is a mediator only in women, suggests the idea that men are less vulnerable than women to the consequences of lower family support, and therefore are less "at risk" of insufficient self-care. Notably, in the general population, men are less depressed than women. Research on family mechanisms and self-care in chronic conditions are a priority by virtue of the fact that such members are highly involved in the care of these patients, and identification of possible barriers hindering the process definitely will yield more effective self-care support (Rosland et al., 2010).

Perception of family support by the patient can be considered as a proxy of the real support provided (Almeida et al., 2013). As noted previously, family caregivers are the most representative of the family support provided in chronic conditions (Goldberg & Rickler, 2011). Promoting self-efficacy of these supportive members may translate in a higher sense of support by the patient, and ultimately in higher self-care. The second study gives the opportunity to enhance this process, by

providing for the first time a new instrument to measure the self-efficacy of the caregiver. However, self-efficacy is even more important in patients, as we observed in the third study. The rationale was that self-efficacy would be highly responsive to motivational interviewing in patients with chronic conditions, due to the effectiveness on motivation as well (Schunk & Dibenedetto, 2020). The reduction in mortality we observed can be explained by the fact that the intervention enhanced self-efficacy and this in turn enhanced self-care. This hypothesis is supported by the findings of the parent study of the MOTIVATE-HF trial, which confirmed significantly higher levels of self-efficacy in the experimental arms at several follow-up periods compared to the control group (Vellone et al., 2020).

Interestingly, we found that mortality was lower in the arm where the caregivers received motivational interviewing alongside patients. Considering also the related secondary analyses (Caggianelli et al., 2021; Rebora et al., 2021), where a similar improvement was observed in the patient and caregiver arm on quality of life and burden of symptoms, we can confidently conclude that the participation of caregiver members can improve patient outcomes, probably due to the enhancement in their self-efficacy.

Limitations of this doctoral program

The studies included in this doctoral program include limitations that are worth mentioning. First, the enrollment was multicentric but occurred only in Italy; hence the results cannot be generalized to the countries outside this nation. Despite this, the fact that we enrolled the patients over multiple sites of a wide area may have mitigated this limitation. Another limitation that is linked to generalizability issues is relative to the clinical trial, which enrolled predominately individuals in NYHA class II and III. Hence, the findings might not be valid to populations with higher disease severity or to those who are asymptomatic (NYHA class I). Second, in the first study we conducted a cross sectional analysis, and this implies the important limitation of causality inference. In other words, any causality relationships between family support, mediators and self-care cannot be claimed for sure, because data collection occurred at the same timepoint. Third, the

randomized clinical trials suffered from important drop-out rates, and this may have lowered the statistical power to detect significant effects of MI on health care services' use. Similarly, the adoption of a composite outcome of frequency of readmissions and emergency services' visits may have further lowered this power.

Implications for research and clinical practice

The above results are unique in the literature and represent a starting point in the self-care research of multiple chronic conditions. So far, self-care has been mostly studied in single chronic conditions (e.g., diabetes mellitus, heart failure), and the finding that self-efficacy is reaffirmed as essential in the dynamics of family and self-care in multiple chronic conditions, allows us to target this construct more effectively in clinical environments.

The first study has important implications because from a clinical point of view the results underline the urgent need to promote screening activities to assess the extent of family support, along with self-efficacy and depression, with special attention to women, given their greater vulnerability to the negative consequences of poor support. Specific interventions should be delivered to the families, such as counselling, or caregiving training, mostly because any extent of improvement is more likely to reflect on improvement in self-efficacy and depression. The first study also has relevant research implications given the enrichment of behavior change dynamics, which in turn may contribute to further tailoring of family interventions.

The second study offers a new instrument to be used in clinical practice; this tool can for example, be used during screening activities aimed at understanding the levels of self-efficacy of the caregivers. Regarding research implications, the instrument can be implemented in intervention trials in order to understand the most effectiveness educational ingredients in improving self-efficacy.

The third study also has important implications for clinical practice since it adds stronger evidence on the effectiveness of motivational interviewing on mortality in heart failure patients.

Health care providers will have higher evidence from now on, to promote incorporation of MI into their consultations with patients. This study also contributes for the first time to advancing the science of family nursing in HF self-care, because caregivers may act as a protective factor towards the patients when involved in MI-based educational interventions.

In conclusion, the self-efficacy construct has been reconfirmed essential also in the context of MCC patients and their caregivers because it potentially modulates the process of self-care and the contribution of the caregivers. The assessment of self-efficacy in clinical screenings allows to evaluate the patients' and caregivers' empowerment, and the findings can be the baseline for future research aimed at designing more effective health interventions in the care of chronic conditions.

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RESEARCH PORTFOLIO APPENDIX

List of publications

1. Caggianelli, G., Iovino, P., Rebora, P., Occhino, G., Zeffiro, V., Locatelli, G., ... & Vellone, E. (2021). A Motivational Interviewing Intervention Improves Physical Symptoms in Patients with Heart Failure: A Secondary Outcome Analysis of the MOTIVATE-HF Randomized Controlled Trial. Journal of Pain and Symptom Management.
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9. Vellone E., De Maria M., Iovino P., Barbaranelli C., Zeffiro V., Pucciarelli G., Durante A., Alvaro R. (2020) Psychometric Testing of the Self-Care of Heart Failure Index Version 7.2 in an European Population. Research in Nursing and Health 2020; 43:640–650. DOI: 10.1002/nur.22083

10. Monaco D., Zaghini F., Fiorini J., Venturini G., Iovino P., Vellone E., Alvaro R., Sili A. Influence of a Wound Healing Protocol on Patients with Stage III and IV Pressure Ulcers: Preliminary Results of an Observational Study. Journal of Wound Care.

11. Iovino, P., Lyons, K. S., De Maria, M., Vellone, E., Ausili, D., Lee, C. S., Riegel, B., & Matarese, M. (2020). Patient and caregiver contributions to self-care in multiple chronic conditions: A multilevel modelling analysis. International journal of nursing studies, 103574. Advance online publication. https://doi.org/10.1016/j.ijnurstu.2020.103574

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14. Iovino, P., Nolan, A., De Maria, M., Ausili D., Matarese M., Vellone E., Riegel B. (2022). The Influence of Social Support on Self-care is Mediated by Self-efficacy and Depression in Chronic Illness: Key Findings From the "SODALITY" Observational Study. Under Review in the Journal of Aging & Mental Health *(Proof of "refereeing" attached).*

Statement of contributions of others

PAPER	AUTHORS' STATEMENTS	SIGNATURE
The influence of social support on self-care is mediated by self-efficacy and depression in chronic illness: key findings from the "SODALITY" observational study	IOVINO - I acknowledge that the extent of my contribution to this paper is 50%	[redacted]
	NOLAN – I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	DE MARIA – I acknowledge that the extent of my contribution to this paper is 10%	[redacted]
	AUSILI - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	MATARESE - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	VELLONE - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	RIEGEL - I acknowledge that the extent of my contribution to this paper is 20%	[redacted]
Development and psychometric testing of the caregiver self-efficacy in contributing to patient self-care scale	DE MARIA - I acknowledge that the extent of my contribution to this paper is 10%	[redacted]
	IOVINO - I acknowledge that the extent of my contribution to this paper is 50%	[redacted]
	LORINI - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	AUSILI - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]

	MATARESE - I acknowledge that the extent of my contribution to this paper is 10%	[redacted]
	VELLONE - I acknowledge that the extent of my contribution to this paper is 20%	[redacted]
Effectiveness of motivational interviewing on health-service use and mortality: a secondary analysis of the MOTIVATE-HF	IOVINO - I acknowledge that the extent of my contribution to this paper is 50%	[redacted]
	REBORA - I acknowledge that the extent of my contribution to this paper is 10%	[redacted]
	OCCHINO - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	ZEFFIRO - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	CAGGIANELLI - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	AUSILI - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	ALVARO - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	RIEGEL - I acknowledge that the extent of my contribution to this paper is 5%	[redacted]
	VELLONE - I acknowledge that the extent of my contribution to this paper is 10%	[redacted]

PDF papers included in this dissertation

Proof of refereeing for the first paper

From: Aging and Mental Health <onbehalfof@manuscriptcentral.com>

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Date: 20 gennaio 2022 18:03:24 CET

To: maddalena.demaria@outlook.it

Answer to: m.orrell@ucl.ac.uk

20-Jan-2022

Dear Dr De Maria:

Your manuscript entitled "HOW PERCEIVED FAMILY SUPPORT INFLUENCES SELF-CARE OF CHRONIC ILLNESS: AN EXPLORATION OF MECHANISMS" which you submitted to Aging and Mental Health, has been reviewed. The reviewer comments are included at the bottom of this letter.

The reviews are in general favourable and suggest that, subject to minor revisions, your paper could be suitable for publication. Please consider these suggestions, and I look forward to receiving your revision.

When you revise your manuscript please follow these instructions carefully:

1. Indicate the changes you make in the manuscript by using bold or coloured text or highlighting the text ("text highlight color" function in MS Word). As you do so, we ask you to create a document that indicates point-by-point how you have responded to the reviewers' suggestions and any suggestions made by and the editor. You can copy and paste the reviews into a word document and insert your responses as you are making changes in the text. Please be as specific as possible in your response to the reviewer(s), including noting the page number where changes have been made. Be sure you address each point.

2. To submit a revision, go to https://rp.tandfonline.com/submission/flow?submissionId=217873942&step=1. If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you submit the revised manuscript.

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Once again, thank you for submitting your manuscript to Aging and Mental Health and I look forward to receiving your revision.

Sincerely,
Prof. Martin Orrell
Editor, Aging & Mental Health
m.orrell@ucl.ac.uk

Comments from the Editors and Reviewers:

Reviewer: 1

Comments to the Author
This is a well written manuscript whose objective was to explore depression and self efficacy as mediators of the relationship between family support and self-care in older adults with multimorbidity. The hypotheses are that depression and self efficacy mediate this relationship which relationship may have gender differences.
The study has covered the aims and objectives as stated. The discussion, limitations and study implication have been well written. Just minor comments as follows:

1. Background information is well covered except under INSTRUMENTS lines 58-60 Depression was assessed with the 9-item Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001). Each item is scored on a 5-point scale that ranges from "not at all" (1) to "nearly every day (5). Scores range from 0 to 27 with higher values reflecting higher levels of depression. Please note that this scale is scored 0-3 and not 1-5, hence the score range of 0-27 for the 9 questions.

References: Well referenced but,
1. Are these references complete:
Grégoi e, C., Faymonville, M. E., Vanhaudenhuyse, A., Charland-Verville, V., Jerusalem, G., Willems, S., & Bragard, I. (2020). Effects of an intervention combining self-care and self-hypnosis on fatigue and associated symptoms in post-treatment cancer patients: A randomized-controlled trial. Psycho-Oncology.

He, X., Li, J., Wang, B., Yao, Q., Li, L., Song, R., Shi, X., & Zhang, J.-a. (2017). Diabetes self management education reduces risk of all-cause mortality in type 2 diabetes patients: a systematic review and meta-analysis. Springer.

Reviewer: 2

Comments to the Author
This study offers an important evidence to literature as to underlying pathways by which family social support and self-care behaviors are connected. Authors examined two pathways that theorists presumed and found evidence to reject or accept those arguments, which are quite frequently deployed while talking to patients with chronic illnesses. Family support appears quite relevant to self-efficacy and depression. This is a great discovery for patients, family, and clinicians, who have to spend enormous time, energy, and mental capacity to follow through daily dose of self-management activities.
This manuscript is well-written and offers information and ideas necessary in order to present the interesting findings. I offer a few areas of improvement below, so that readers have access to full information of this investigation. But, one critical absence needs author's critical thinking. Why depression and self-efficacy

came up with quite diverging results? Here are a couple of questions that I do not find satisfactory answers from Discussion. Authors will come up with better discussion with findings discovered here.
- Why not depression but self-efficacy significant as a mediator between family support and self-care behaviors? Depression has been a powerful predictor for self-care behavior and a dependent variable reliably predicted by family support in different studies. But, when it comes to indirect effect assessment, why only depression lose its power to link those two attributes?

- As for the null findings of depression's mediation among males, authors speculated that women tend to make an association between family support and depression and that this tendency might be the reason for the diverging gender-specific findings. The rationale offered by authors may focus too much on the relationship between IV and the mediator. What about the path between the mediator and outcomes? I see different strength of associations between depression and self-care outcomes by gender. I think those paths will stimulate authors to come up with ideas to explain why we see some different strength of mediating association by gender. What gender difference we see in terms of depression's impact to different self-care behaviors? You proposed three self-care behavior regimens. I hope to see detailed discussion involving different psychological and cognitive resources necessary for successfully implementing each self-care regimens.

1. Table 2 and page 10 -> Table 2 offers richer information than the text that authors provided in page 10. Authors would provide most key findings of Table 2 as to indirect effects with p-value lower than 0.05. I see so many significant indirect paths, yet only MSPSS-f -> PHQ-9 -> SC
Monitoring path is elaborated. I see more indirect paths that came up significant ($p<.05$). Also, I see diverging results of significance tests between male and female. Those findings have to be highlighted in the text in a more serious manner. Authors sound brush off some significant findings of Table 2.

2. I am having hard time to comprehend Figure 2. I know that authors indicated in Note that "Standardized coefficients in parenthesis refer to males.", which will help readers to find important information from this table. But, many readers often overlook information in a fine print. Authors may want to edit the Figure 2 in a way that readers may not find difficulty. Maybe, numbers in the Figure 2 get enlarged? Maybe, male vs. female distinction is made inside the graphic? Figure 1 needs some help as well. Please edit two figures looking better and readily comprehended.

3. Figure 1 and Figure 2 need a standard error added for the sake of entirety of information.

4. Methods- Sampling -> Would you strengthen the recruitment and sampling strategy section? I understand a concern that this information would compromise the Journal's Blind Review strategy. But what I have here is too little and find the missing information egregious. Since this journal services international population, I hope you gives a brief information about how people in Italy get professional/public supports while managing a chronic illness. Do you have a health care system that make a great use of a primary care doctor while managing a chronic illness? Your sample shows predominantly low educational attainment. Is this normal for older adults in Italy? Are they underserved due to lower SES? This question is very important for US-based scholars who see a great deal of health disparities as to managing chronic illnesses while appreciate sociocultural context from which data were produced. Authors are suggested to offer an assessment of social determinants of health of participants in this sample.

Reviewer: 3

Comments to the Author
Thank you for the opportunity to read this work!
The paper clearly presents all concepts and only minor changes are required:

1)Please include your main variables and the study design in the title

2) In the abstract: use the variables as you report them in the main text (e.g. family support or perceived family support/ self-efficacy or selfcare self-efficacy). Try to be consistent with the terminology throughout the text

3)In the introduction please include the definition of your terms and in background continue with theoretical models and variable association

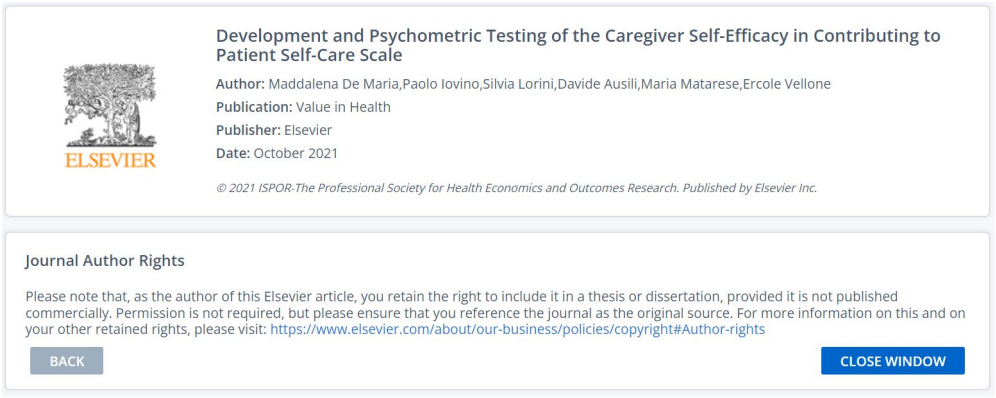
4) Introduction.The purpose of the study should be transferred in the end of the background .

5) In the background, please use 2 more sentences to associate the self-efficacy with social support

6) Please include few more lines in data collection about the process.
when and where the trained researchers selected the data?
Was there a number of drop-outs and what was the participation rate?

7)Instruments section is complete and clear, but you might need to decrease this part in order to be balanced with the rest of the method.

Permission to include the second paper



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Comparative-Effectiveness Research

Development and Psychometric Testing of the Caregiver Self-Efficacy in Contributing to Patient Self-Care Scale

Maddalena De Maria, PhD, RN, Paolo Iovino, MSN, RN, Silvia Lorini, MSN, RN, Davide Ausili, PhD, RN, Maria Matarese, MSN, RN, Ercole Vellone, PhD, RN

ABSTRACT

Objectives: Caregiver self-efficacy—a caregiver's belief in his/her ability to contribute to patient self-care—is associated with better patient and caregiver outcomes in single chronic conditions. It is, however, unknown if caregiver self-efficacy improves patient and caregiver outcomes in multiple chronic conditions (MCCs) because there is no instrument to measure this variable. We developed the 10-item Caregiver Self-Efficacy in Contributing to patient Self-Care (CSE-CSC) scale for that purpose, and we tested its psychometric characteristics in caregivers of patients with MCCs.

Methods: In this cross-sectional multisite study, we tested the structural validity of the CSE-CSC scale with exploratory and confirmatory factor analysis, and we tested construct validity by correlating CSE-CSC scores with those of the Caregiver Contributions to Self-Care of Chronic Illness Inventory. We also tested reliability, and precision of the CSE-CSC scale.

Results: The 358 enrolled caregivers (mean age 54.6 years; 71.5% female) cared for patients with an average of 3.2 chronic conditions. Structural validity was good, and it showed 2 factors within the scale. Construct validity showed significant correlations between scores of the CSE-CSC scale and the Caregiver Contributions to Self-Care of Chronic Illness Inventory. Reliability coefficients were between 0.90 and 0.97. Measurement error yielded satisfactory results.

Conclusions: The CSE-CSC scale is valid, reliable, and precise in measuring caregiver self-efficacy in contributing to patient self-care in MCCs. Because caregiver self-efficacy is a modifiable variable, the CSE-CSC scale can be used in clinical practice and research to improve patient and caregiver outcomes.

Keywords: Caregiver, psychometric, questionnaire, reliability, self care, self efficacy, survey, validity

VALUE HEALTH. 2021; ■(■):■–■

Introduction

Multiple chronic conditions (MCCs), defined as a clinical condition in which 2 or more chronic illnesses affect a person at the same time,[1] are highly prevalent worldwide. In the United States, 1 in 4 persons is affected by MCCs, and in Europe the prevalence is estimated at one-third, with the highest prevalence in older individuals.[2]

The management of MCCs is complex, and it requires chronically ill individuals and their families to perform several self-care behaviors. Self-care has been defined as a natural decision-making process aimed at preserving health and controlling illnesses.[3] In the setting of chronic illnesses, self-care involves 3 interrelated behavioral processes: self-care maintenance, self-care monitoring, and self-care management.[3,4] Self-care maintenance involves the daily, routine activities used to keep a chronic illness stable (eg, taking medication as prescribed). Self-care monitoring involves the continual process of watching oneself to detect signs and symptoms of the illness (eg, monitoring blood sugar). Self-care management is the response to signs and symptoms when they occur (eg, taking an extra medication for symptoms). All these behaviors involve a naturalistic decision-making process that reflects automatic, impulsive, and contextual decisions that people make in typically ambiguous situations, where the options are often vague.[3]

In single chronic conditions, such as heart failure (HF) and diabetes, self-care has been shown to influence health and economic outcomes, including improving the quality of life,[5] preventing disease complications,[6] and reducing rehospitalizations.[7] Despite this evidence, self-care is not performed sufficiently in several chronic conditions.[8–10] In those situations, an informal caregiver, such as a family member, is extremely helpful in contributing to the patient's self-care process.[11]

Caregiver contributions (CCs) to patients' self-care was conceptualized as the process of recommending to (or substituting for) the patient in performing behaviors aimed at maintaining the stability of the illness, facilitating the monitoring of symptoms, and responding to signs and symptoms of an exacerbation.[12] There is evidence that CCs to self-care are associated with positive patient outcomes, such as better adherence to medication,[13,14] fewer

emergency department visits,[15] and healthier patient behaviors.[13] Several variables at caregiver, patient, and dyadic levels[16–18] have been conceptualized and are found to impact CC to patient self-care, but all those contributors could be influenced by caregiver self-efficacy. Bandura[19] defined self-efficacy as individuals' beliefs about their ability to achieve positive outcomes by performing a course of action, irrespective of the challenges and difficulties involved.[20] Self-efficacy drives behavioral actions through increasing cognitive understanding and control over the situation, upturning self-regulatory power, and reducing emotional reaction toward the difficulties encountered.[20] As such, self-efficacy shapes one's level of commitment and persistence to manage a specific situation.[20]

Caregiver self-efficacy has been defined as the caregiver's belief in his or her ability to contribute to patient self-care.[12] Several studies in single chronic conditions have found that better caregiver self-efficacy is associated not only with better patient self-care and consequently better patient outcomes, but also with better caregiver outcomes. For example, in patients with lung cancer, better caregiver self-efficacy was associated with better symptom control and quality of life.[21] In caregivers of patients with Alzheimer disease, better self-efficacy was associated with lower depression and burden.[22,23] There is also evidence, from randomized controlled trials, that caregiver self-efficacy is a key modifiable characteristic that can be targeted with psychoeducational interventions.[24,25]

Although caregiver self-efficacy has been found to be associated with positive health outcomes for both patients with chronic conditions and their caregivers, so far an instrument to measure caregiver self-efficacy has been explored only in single chronic conditions, such as HF and dementia.[26–28] It has not been tested in situations of MCCs. Consequently, an instrument to measure caregiver self-efficacy in contributing to patient self-care of chronic illness would be helpful in this context.

Objective

To develop and test the psychometric characteristics (validity and reliability) of the Caregiver Self-Efficacy in Contributing to Patient Self-Care (CSE-CSC) Scale in MCCs.

Methods

Instrument Development

The CSE-CSC scale was derived from the Self-Care Self-Efficacy Scale (SC-SES),[29] an instrument that measures patient self-efficacy in performing self-care behaviors with a single disease and MCCs. Based on the Middle-Range Theory of Self-Care of Chronic Illness,[3] the CSE-CSC scale was proposed to measure caregiver self-efficacy in contributing to patient self-care maintenance, monitoring, and management of chronic illness. The CSE-CSC scale includes the same items as the SC-SES, except that the wording of the introduction and the items in the scale has been changed to make it clear that the scale investigates the caregiver self-efficacy in contributing to patient self-care in the context of MCCs. For example, in the SC-SES, patients are asked to report the extent to which they feel confident about keeping their disease stable and without symptoms or about following the treatment plan that clinicians have given them. In the CSE-CSC scale, caregivers are asked, in reference to the person they care for, to report the extent to which they feel confident about keeping the patient's diseases stable or about helping the patient to follow the prescribed treatment plan. This procedure of changing the patient version of an instrument into a caregiver version has been used extensively in previous studies.[26,30,31] Like the SC-SES, the CSE-CSC scale uses a 5-point Likert format, with responses from "not confident" to "very confident." The CSE-CSC score is standardized on a scale of 0 to 100, where higher scores mean higher caregiver self-efficacy in contributing to self-care of a patient with MCC.

The CSE-CSC scale was developed in English and then translated to Italian by 2 independent Italian researchers who were fluent in English and had expertise in chronic diseases. The Italian translation of the CSE-CSC scale was then translated back to English by a bilingual researcher with expertise in medical English. After this back-translation, minimal refinements were made to the SC-SES developed to ensure that the intended meaning was retained between the 2 versions. After translation, cognitive interviews were conducted with 10 caregivers of patients with MCC using think-aloud techniques to verify if all items of the CSE-CSC scale were easily and correctly understood. Those interviews demonstrated that all items were correctly understood.

Sample and Settings

To test the psychometric characteristics of the instrument, we used the baseline data of the ongoing Self-care Of patient and caregiver DyAds in multiple chronic conditions: a LongITudinal study, a longitudinal multicenter investigation, that aims to describe patient self-care and CC to patients' self-care in MCCs. The detailed study protocol was published by De Maria et al.[32] In brief, in the Self-care Of patient and caregiver DyAds in multiple chronic conditions: a LongITudinal study, we enroll patients aged 65 years or older, with HF or diabetes or chronic obstructive pulmonary disease and at least one other chronic illness, in community and outpatient settings—except for patients with cancer or dementia. We excluded patients with dementia because the presence of cognitive deficits could make responses to self-reported questionnaires unreliable.[33] We did not include patients affected by cancer in association with other chronic conditions because the specific medical (chemotherapy and radiotherapy) and surgical treatments for cancer have a dominant effect on health-related quality of life.[34]

We also enroll each patient's informal caregivers with the following characteristics: ≥18 years old, identified by the patient as the primary informal caregiver (person, family or otherwise, who takes the responsibility and provides majority informal care to the patient), and willing to sign the informed consent form. We enrolled only matching patient and caregiver dyads. Therefore, if one member of the dyad refused to participate in the study, the other member also was excluded. Patient and caregiver dyads were enrolled in 7 regions of central and southern Italy. A sample of 7 caregivers per item was needed to allow adequate inference in exploratory or confirmative factor analysis.[35,36] Considering the number of CSE-CSC scale items,[10] a sample of 70 caregivers would have been adequate to address the main study objective; however, we enrolled 358 participants to support a more stable analysis.

Data Collection

A total of 358 caregivers were enrolled by research assistants, who first identified potential participants on the basis of the inclusion criteria. They explained the aims of the study and obtained the participants' informed consent. Data collection took place during routine outpatient visits or directly at the patient's and caregiver's home.

Instruments

The Caregiver Contribution to Self-Care of Chronic Illness Inventory (CC-SC-CII) is a 19-item instrument used to measure CC to

self-care in chronic conditions.[37] It consists of 3 separate scales: 7 CCs to self-care maintenance items measure how often a caregiver recommended the patient to adopt behaviors aimed at maintaining physical and mental stability of a chronic condition, 5 CCs to self-care monitoring items measure how often a caregiver recommended the patient to monitor signs and symptoms of his or her chronic illness, and 7 CC to self-care management items measure how often a caregiver contributed to the recognition or interpretation of symptoms and responded to exacerbation of chronic illness symptoms.

Psychometric analysis of the CC-SC-CII in our study demonstrated that it has good construct validity (comparative fit index [CFI] ranging between 0.936 and 0.981 among the 3 scales) and reliability (Cronbach's alpha and factor determinacy coefficients ≥ 0.765 for the 3 scales).[37] For responses, the CC-SC-CII uses a 5-point Likert format ranging between "never" and "always." Each CC-SC-CII scale has a standardized 0 to 100 score, with higher scores meaning better CC to patient self-care. The CC-SC-CII was used in this study for construct validity via hypothesis testing, because higher scores in caregiver self-efficacy are associated with better CC to self-care.[12] We also collected sociodemographic characteristics of the caregivers (ie, age, gender, education, years of caregiving) with a specific questionnaire.

Data Analysis

Data analysis was conducted in 6 phases. First, we used descriptive statistics, including means, standard deviations (SDs), frequencies, percentages, skewness, and kurtosis, to analyze the sociodemographic characteristics of participants, the scale scores, and the univariate distribution of scale items.

Second, we used Bartlett test of sphericity and the Kaiser–Meyer–Olkin (KMO) test to examine the adequacy of the sample and the suitability of data for factor analysis, which we used to test the structural (factorial) validity of the CSE-CSC scale. Bartlett test of sphericity should have a significant chi-square; KMO should have a value ≥0.70.[38]

Third, according to classical test theory,[39] we tested the structural validity of the CSE-CSC scale with a cross-validation procedure, using both exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). In particular, we randomly split the entire sample into 2 subsamples, named A and B. These 2 subsamples were equivalent in term of age (t (358) = −0.174 P=.7), gender (χ^2 [1358] = 0.234, P=.64), and education (χ^2 [1358] = 0.655, P=.37). In subsample A, to address the issue of the number of latent dimensions underlying the CSE-CSC scale's items, EFA was performed. To define the number of plausible factors to extract, parallel analysis was performed on the total sample.[40–43]

In subsample B, we validated the factorial solution obtained from EFA with CFA.[44] This approach has been applied successfully in several other studies[45,46] and also with instruments that measure self-care and self-efficacy in self-care.[47] Because the expected factors were assumed to correlate, EFA was performed with the maximum likelihood extraction method and Geomin rotation.[48] Owing to the normal distribution of CSE-CSC scale items, we used a maximum likelihood estimator.[48]

The factorial solution obtained by EFA in subsample A was tested with CFA in subsample B. To evaluate model fit, we adopted a multifaceted approach that considered goodness-of-fit indices,[49,50] CFI,[51] the Tucker–Lewis Index (TLI),[52] the root mean square error of approximation (RMSEA),[53] the standardized root mean square residual (SRMR),[54] and chi-square significance. CFI and TLI should have values ≥0.90 or better ≥0.95[55]; RMSEA values ≤0.08 or ≤0.05 indicate a good fit, and the rejection of the null hypothesis (for P<.05) associated with its 90% confidence interval[56,57] and P>.05 for the test of close-fit. SRMR should have values ≤0.08. The chi-square test was also interpreted together with the above indices. The model's misfit was improved by considering the eventual residual covariances justified to theoretical and methodological reasons. After performing EFA and CFA on the 2 subsamples, to obtain solid estimates for the final loadings, we re-ran CFA on the entire sample. Finally, because the 2 factors extracted from EFA and CFA were significantly correlated, we examined a second-order hierarchical factor loading of those 2 factors.

Fourth, we tested the CSE-CSC scale's construct validity via hypothesis testing by examining the correlation between the scores of the CSE-CSC scale and the fourth CC-SC-CII scale using the Pearson correlation coefficient r (2 tailed). Correlation coefficients of 0.10, 0.30, and 0.50 were considered to be small, medium, and large, respectively.[58] We hypothesized that caregiver self-efficacy would be positively correlated from moderate to strong with CC to self-care, as reported in the theory[12] and in previous studies.[59,60]

Fifth, we estimated the reliability of internal consistency of the CSE-CSC scale. Specifically, we computed the composite reliability coefficient[61] and the factor score determinacy[48] for each first- and second-order factor extracted from CFA, and we computed the global reliability index for multidimensional scales[62] and Cronbach's alpha coefficient[63] for the overall scale. All these reliability estimates should have a value >0.70.[64]

Finally, we evaluated the measurement error of the CSE-CSC scale by computing the standard error of measurement (SEM) and the smallest detectable change (SDC). SEM was computed with the following formula: SD × $\sqrt{}$(1 − reliability coefficient).[65] Here, SD was the SD of the CSE-CSC scale score, and the reliability coefficient was the Cronbach's alpha coefficient. If SEM has a value <SD/2, the instrument is considered precise.[66] SDC was computed with the following formula: 1.96 × $\sqrt{}$ 2 × SEM.[66] SDC value indicates how many points in the CSE-CSC scale are considered clinically significant.

Mplus software version 8.2 (Muthén and Muthén, Los Angeles, CA) was used for the factorial analyses, and SPSS Statistics version 22 (IBM Corp, Armonk, NY) was used for the descriptive statistics.

Results

Sample Characteristics

Of the 417 eligible caregivers, 367 (88%) agreed to participate, and 50 (12%) declined because of a lack of time or interest. Nine participants were identified as outliers and were excluded from all analysis, as recommended by Tabachnich and Fidel (2007),[67] because they were influential data points in factor analyses. The outliers showed a low level of education (6 participants had completed middle school) and were mainly older adults (7 participants were aged older than 70 years). Therefore, we hypothesized that education and age, often associated with cognitive impairment, led these participants to not fully understand the content of some items. Consequently, all analyses were performed with a final sample of 358 caregivers. Most caregivers were female (71.5%), were employed (68.2%), and had a medium to high level of education (88.4%) (Table 1). They were children (57.8%) or spouse (31.1%) of the patients, and majority (55%) lived with the patients. The caregivers provided 25.5 hours of care per week, on average, and they had been providing care for an average of 8.9 years. The patients were mostly females (53.9%),

Table 1. Clinical and sociodemographic characteristics of caregivers and patients (N = 358).

Characteristics	Caregiver		Patient	
	M (range)	± SD	M (range)	± SD
Age	54.6 (19-86)	15.1	76.6 (65-93)	7.3
	n	%	n	%
Sex				
Female	256	71.5	193	53.9
Male	102	28.5	165	46.1
Marital status				
Married	252	70.4	229	64
Never married	75	20.9	11	3
Divorced	25	7	12	3.4
Widowed	6	1.7	106	29.6
Education				
Illiterate	2	0.6	8	2.2
Elementary	39	10.9	200	55.9
Middle/professional school	118	32.9	97	27.1
High school	138	38.5	39	10.9
University	62	17	14	3.9
Employment status				
Employed	192	68.2	15	4.3
Retired/unemployed	166	31.8	343	95.7
Income				
Have less than needed to make ends meet	15	4.2	18	5
Have enough to make ends meet	291	81.3	304	84.9
Have more than needed to make ends meet	52	14.5	36	10.1
Relationship with patient				
Spouse/partner	111	31.1	-	-
Child	207	57.8	-	-
Grandchild	28	7.8	-	-
Sister/brother/friend	12	3.3	-	-
Living with patient				
No	161	45	-	-
Yes	197	55	-	-
Secondary caregiver				
No	146	40.8	-	-
Yes	212	59.2	-	-
	M (range)	± SD	M (range)	± SD
Caregiving hours per wk	25.5 (1-168)	36.1	-	-
Years of caregiving	8.9(1-45)	7.2	-	-
Chronic illnesses (number)	-	-	3.2 (2-9)	1.3

M indicates mean; SD, standard deviation.

with a mean age of 76.6 years and a low educational level (55.9%), and they were afflicted with 3.2 chronic conditions on average (Table 1).

Descriptive Analysis of Scale Items

Table 2 shows the descriptive statistics of the CSE-CSC scale items. All the items were normally distributed. The item with the highest score was "Follow the treatment plan he/she has been given." The item with the lowest score was "Can keep him/her stable and free of chronic illness symptoms."

Structural and Construct Validity of the CSE-CSC Scale

Because the Bartlett test of sphericity was significant ($P<.001$) and KMO index was 0.84, the data were suitable for factor analysis. Parallel analysis suggested that a 2-factor solution was the more adequate for the data set; consequently, we tested the 2-factor solution on subsample A. Table 3 shows EFA results: all the primary factor loadings were adequate (>0.30). They ranged from 0.487 ("Can keep him/her stable and free of chronic illness symptoms") to 1.024 ("Doing something to relieve his/her symptoms"). They were loaded with 5 items each. The fit indices of this solution are reported in row 1 of Table 4, and they yielded a partial misfit for the RMSEA.

The model identified by EFA was replicated on subsample B with CFA, obtaining acceptable fit indices (see row 2 of Table 4). On the basis of the item content, the first factor was labeled "Self-efficacy in self-care maintenance and monitoring," and the second was labeled "Self-efficacy in self-care management." Scrutinizing the modification indices revealed that the partial misfit was due to an excessive covariance between item 2 ("Follow the treatment plan he/she has been given") and item 3 ("Persist in following the

Table 2. Descriptive statistics of individual items, factors, and the total score of the CSE-CSC Scale (N = 358).

Items of the CSE-CSC scale	M	SD	Skewness	Kurtosis
In general, in reference to the person you care for, how confident you are that you can:				
1. Keep the illness of the person you care for stable and free of symptoms?	3.447	0.965	0.300	−0.671
2. Follow the treatment plan that has been given to the person you care for?	4.140	1.000	−0.736	−0.571
3. Persist in following the treatment plan even when difficult?	3.913	1.051	−0.537	−0.619
4. Routinely monitor the condition of the person you care for?	3.930	1.060	−0.567	-0.625
5. Persist in routinely monitoring the condition of the person you care for even when difficult?	3.807	1.063	−0.464	−0.590
6. Recognize changes in the health of the person you care for if they occur?	3.927	0.941	−0.279	−0.994
7. Evaluate the importance of symptoms?	3.911	0.978	−0.361	−0.796
8. Do something to relieve symptoms of the person you care for?	3.894	1.007	−0.561	−0.369
9. Persist in finding a remedy for symptoms of the person you care for even when difficult?	3.723	1.115	−0.521	−0.569
10. Evaluate how well a remedy works?	3.824	1.045	−0.485	−0.491
Illness management factor	19.237	4.389	−0.491	−0.632
Symptom management factor	19.279	4.425	−0.367	−0.374
Total score of CSE-CSC	71.291	20.728	−0.347	−0.728

Note. Item numbering reflects the sequence in the scale.
CSE-CSC indicates Caregiver Self-Efficacy in Contributing to Patient Self-Care Scale; M, mean; SD, standard deviation.

treatment plan even when difficult") and between item 6 ("Recognizing changes in his/her health if they occur") and item 7 ("Evaluating the importance of his/her symptoms"). There are solid methodological reasons that justify these error covariances.[68] All of these covariances are related to items with an adjacent position in the scale (items 2 and 3 and items 6 and 7). Adjacent pairs of positively worded items may show a pattern of increasing correlation that decreases with increasing inter-item distance, described by Weijters et al[69] as a "proximity" effect. Error covariance can be used to account for the extra source of item covariance introduced by item proximity.[70] It is worth noting that all these covariances were also generalized across the total sample. The model specified with these covariances obtained good fit indices (see row 3 of Table 4).

CFA was run on the entire sample of 358 participants and with the same specifications as CFA conducted on subsample B. It identified a model with good fit indices, reported in row 4 of Table 4. Because the 2 CFA factors were significantly correlated at 0.852, we examined a second-order hierarchical model that produced a good fit as well: χ^2 (33, N = 358) = 92.080, $P<.001$, CFI = 0.968, TLI = 0.956, RMSEA = 0.071 (90% confidence interval = 0.054-0.088), $P=.023$, SRMR = 0.051 (row 5 of Table 4). All factor loadings were significant, ranging from 0.659 to 0.932 (Fig. 1). All residual covariances were also generalized across the total sample.

The construct validity of the CSE-CSC scale was supportive as well. The Pearson correlation coefficients between the CSE-CSC scale scores and the CC to patients' self-care maintenance, monitoring, and management were moderate to high: $r = 0.452$ ($P=.01$), $r = 0.582$ ($P=.01$), and $r = 0.609$ ($P=.01$), respectively.

Internal Consistency Reliability and Precision of the CSE-CSC Scale

The internal consistency reliability of the CSE-CSC scale was supportive. The composite reliability coefficients for the self-efficacy in self-care maintenance and monitoring factor, the self-efficacy in self-care management factor, and the overall CSE-CSC scale were 0.904, 0.911, and 0.951, respectively. The factor score determinacies for the self-efficacy in self-care maintenance and monitoring factor, the self-efficacy in self-care management factor, and the overall scale were 0.967, 0.963, and 0.937, respectively. The global reliability index for the multidimensional scale was 0.923, and the Cronbach's alpha coefficient was 0.942 for the whole scale.

SEM of the CSE-CSC scale resulted in 1.36 for the self-efficacy in self-care maintenance and monitoring factor, 1.32 for the self-efficacy in self-care management factor, and 6.19 for the total CSE-CSC score. These measures were considered adequate. SDC resulted in 3.23 for the self-efficacy in self-care maintenance and monitoring factor, 3.19 for the self-efficacy in self-care management factor, and 6.19 for the total CSE-CSC score. SDC coefficients evidence the points in the CSE-CSC scale, at factor and scale levels, that we can consider for a meaningful change.

Discussion

This study aimed to develop an CSE-CSC scale and test its psychometric characteristics. To the best of our knowledge, the CSE-CSC scale is the first instrument that measures the self-efficacy in contributing to patient's self-care in MCCs. We found that the CSE-CSC scale showed good validity and reliability in this sample of caregivers of patients with MCC.

Regarding structural validity, we used both EFA and CFA to ensure a more solid validation. In the CSE-CSC scale, we found 2 distinct factors that referred to the caregiver's self-efficacy. One was managing the patient's illness (eg, monitoring patient conditions), and the other was managing the patient's symptoms (eg, doing something to relieve symptoms). In the SC-SES, from which this scale was derived, only one such factor was identified. Instead, the factorial structure of the CSE-CSC scale is similar to the Self-Care Confidence scale of the Caregiver Contribution to Self-Care

Table 3. Exploratory factor analysis and item factor loadings for the Caregiver Self-Efficacy in Contributing to Patient Self-Care Scale (N = 179).

Items of the Caregiver Self-Efficacy in Contributing to Patient Self-Care Scale	F1 loading	F2 loading
In general, in reference to the person you care for, how confident are you regarding:		
1. Can keep him/her stable and free of chronic illness symptoms?	0.487*	0.181
2. Follow the treatment plan him/her have been given?	0.960*	−0.123
3. Persist in following the treatment plan even when difficult?	0.940*	0.006
4. Monitor his/her condition routinely?	0.690*	0.152
5. Persist in routinely monitoring his/her condition even when difficult?	0.627*	0.323*
6. Recognizing changes in his/her health if they occur?	0.349*	0.507*
7. Evaluating the importance of his/her symptoms?	0.071	0.794*
8. Doing something to relieve his/her symptoms?	−0.179	1.024*
9. Persisting in finding a remedy for his/her symptoms even when difficult?	0.003	0.911*
10. Evaluating how well a remedy works?	0.095	0.714*

F1 indicates self-efficacy in self-care maintenance and monitoring; F2, self-efficacy in self-care management.
*P<.05.

of HF Index,[26] which measures caregiver self-efficacy in contributing to HF self-care. In fact, in this instrument, a first factor named "basic confidence," including behaviors related to illness management (eg, following the treatment plan), and a second factor named "advanced confidence," including behaviors related to the management of symptoms (eg, keeping the patient free from HF symptoms), were found.

The fit model of CFA was improved by the estimations of residual covariances between 2 item pairs: between item 2 ("Follow the treatment plan he/she has been given") and item 3 ("Persist in following the treatment plan even when difficult") and between item 6 ("Recognizing changes in his/her health if they occur") and item 7 ("Evaluating the importance of his/her symptoms"). These excessive correlations between these 2 item pairs could be justified by the fact that both item 2 and item 3 pertain to following the treatment plan, and both item 6 and item 7 are related to self-efficacy in symptoms. According to Bagozzi[71] and Fornell[72] the covariances between item residuals can be allowed if this is methodologically or theoretically reasonable, as in our case.

Construct validity of the CSE-CSC scale was demonstrated via hypothesis testing through moderate and strong significantly positive correlations with the CC-SC-CII scale scores. As described in the theoretical[3,12] and empirical literature,[73,74] self-efficacy is an important predictor of CC to self-care. Consequently, this finding gives strength to the existing theories and the available clinical evidence[73,74] on the role between self-efficacy and self-care.

Internal consistency reliability of the CSE-CSC scale, tested through both unidimensional and multidimensional indices, was optimal. This means that if we measure either the 2 dimensions of the CSE-CSC scale or the entire caregiver self-efficacy, we can have reliable values. In addition, the precision of the instrument was good for the 2 dimensions and the entire scale, as SEM was <SD/2. The small detectable change of 6.19 for the entire scale score is informative of the minimum change in the scale score to have a clinically meaningful change.

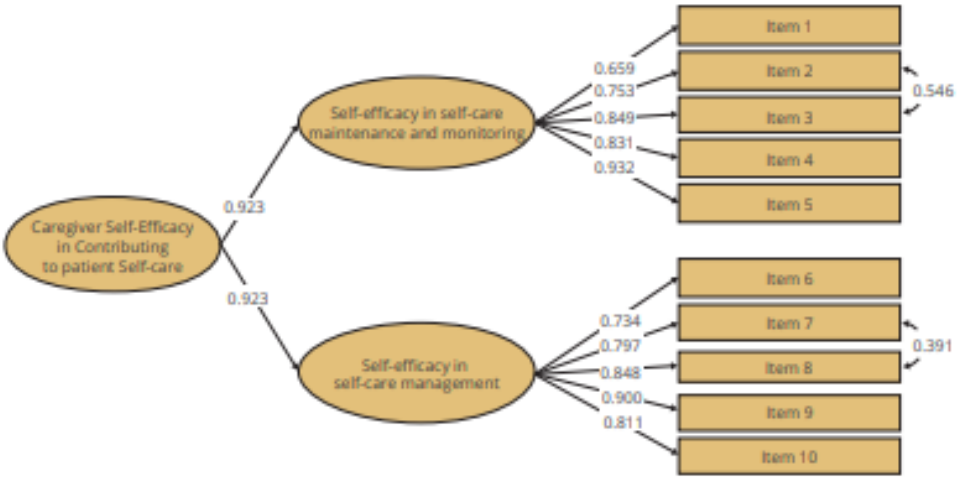
There are a couple of limitations that are worth considering in this study. First, although the factor structure of this scale was established by a cross-validation procedure, by exploring the factorial structure of the CSE-CSC scale with EFA and then by confirming the obtained factorial structure with CFA, we tested the instrument in a single convenience sample. Second, validation against more than one criterion, discriminant validity,

Table 4. Fit indices for the Caregiver Self-Efficacy in Contributing to Patient Self-Care Scale derived from EFA and CFA.

Statistical Models	N	χ^2	DF	P (χ^2)	TLI	CFI	SRMR	RMSEA (90% CI), P (RMSEA < 0.05)
EFA in subsample A	179	79.351	26	<.001	0.906	0.946	0.027	0.107 (0.081-0.134), P <.001
CFA in subsample B without residual covariances	179	115.069	34	<.001	0.889	0.916	0.046	0.115 (0.093-0.139), P <.001
CFA in subsample B with residual covariances	179	59.860	32	.002	0.960	0.971	0.037	0.070 (0.042-0.097), P =.114
CFA first order in total sample	358	87.614	32	<.001	0.958	0.970	0.037	0.070 (0.052-0.087), P =.031
CFA second order in total sample	358	92.080	33	<.001	0.956	0.968	0.051	0.071 (0.054-0.088), P =.023

CFA indicates confirmatory factor analysis; CFI, comparative fit index; CI, confidence interval; DF, degree of freedom; EFA, exploratory factor analysis; RMSEA, root mean square error of approximation; SRMR, standardized root mean square residual.

Figure 1. Graphical representation of the second-order hierarchical model (N = 358).



responsiveness, and test-retest reliability were not tested because it was not the principal aim of the study. Future studies are needed to verify these psychometric characteristics of the CSE-CSC scale.

Third, we excluded patients with severe health issues (ie, those with important cognitive deficits and cancer). In consideration of these 2 limitations, generalizability of our findings should be done with caution in other countries and in other caregiver populations. For these reasons, we recommend further testing of the CSE-CSC scale in samples enrolled in other countries and eventually affected by different health issues.

Our study might have important clinical and scientific implications. Clinicians could use the CSE-CSC scale to measure the extent to which caregivers feel confident in helping patients affected by MCCs to perform self-care. Because patient self-care and CC to self-care are associated with positive patient outcomes (eg, better quality of life, rehospitalizations),[5,7] it is important to identify variables that influence patient self-care and CC to self-care. Consequently, clinicians using the CSE-CSC scale can evaluate if caregiver self-efficacy is adequate, and in case it is not, they can support caregivers with tailored interventions aimed at improving their self-efficacy. From a scientific point of view, the use of the CSE-CSC scale in future studies, especially in randomized controlled trial, could be important to understand which interventions could improve caregiver self-efficacy.

Conclusions

This study gives evidence of validity, reliability, and precision to a new instrument that can be used in clinical practice and research to evaluate caregiver self-efficacy in contributing to self-care in MCCs. We recommend the use of the CSE-CSC scale in combination with the CC-SC-CII to better understand the relationship between caregivers' self-efficacy and their contributions to self-care in MCCs. In fact, although several studies on single chronic conditions (eg, HF) show that caregiver self-efficacy influences CC to self-care,[73] knowledge is poor on MCCs. Additionally, we recommend using the SC-SES used for patients in combination with the CSE-CSC scale. This would allow to perform dyadic analyses, which are important because caregivers and patients influence each other.

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Accepted for Publication: May 19, 2021

Published Online: xxxx

doi: https://doi.org/10.1016/j.jval.2021.05.003

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Critical revision of the paper for important intellectual content: Ausili, Matarese, Vellone
Statistical analysis: De Maria
Provision of study materials or patients: Lorini
Obtaining funding: De Maria, Ausili, Matarese, Vellone
Administrative, technical, or logistic support: Iovino

Conflict of Interest Disclosures: The authors reported no conflicts of interest.

Funding/Support: This work was supported by grant 10.15.20 from the "Insieme per Vita agli anni" Foundation and by grant 2.15.11 from the "Centre of Excellence for Nursing Scholarship."

Role of the Funder/Sponsor: The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the article; and decision to submit the article for publication.

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ESC HEART FAILURE
ESC Heart Failure (2021)
Published online in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/ehf2.13373

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

Received: 17 November 2020; Revised: 25 January 2021; Accepted: 1 April 2021
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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).

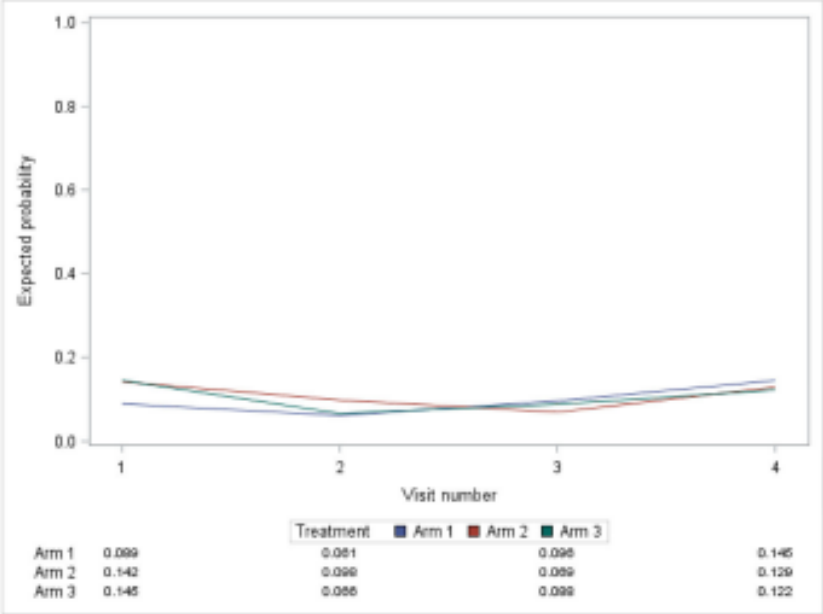
Indeed, the association between better self-care and improved mortality is not new in the literature.[11] However, there is a general lack of evidence on the impact of MI on HF mortality. To the best of our knowledge, the only study investigating this relationship is the trial by Vaillant-Roussel *et 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.

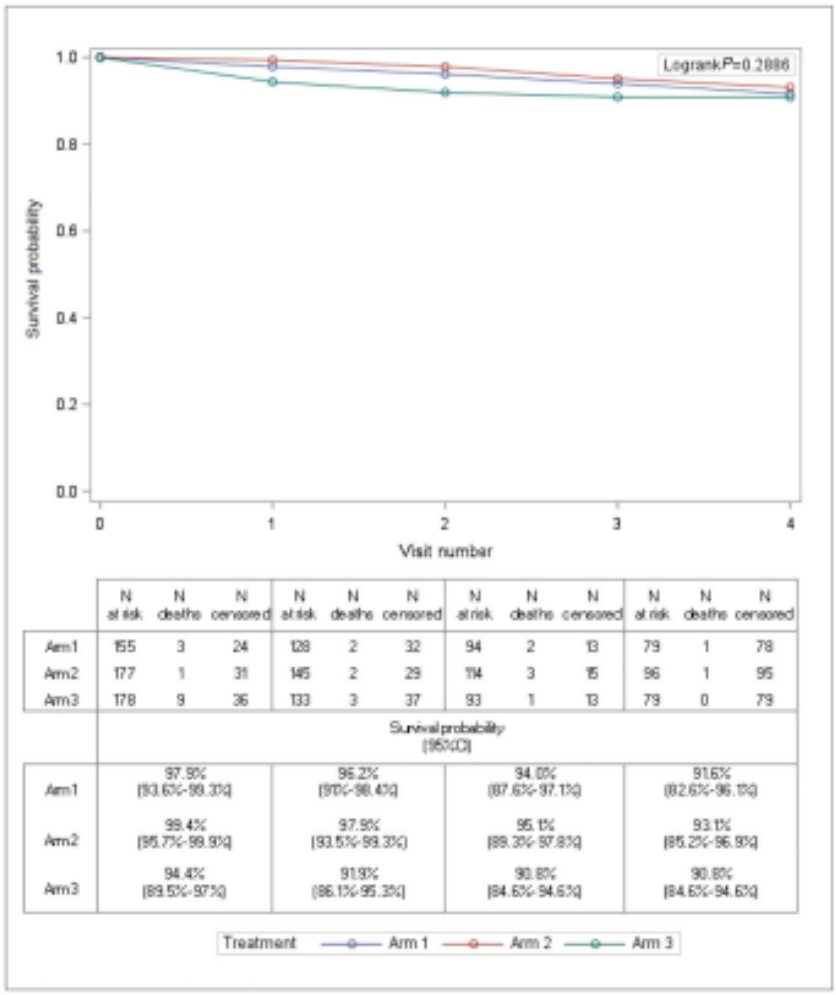
Taken together, the experimental arms of our study had lower mortality rates, but this reduction was statistically significant only in the group in which both patients and caregivers received the intervention. This finding is important because it means that this intervention might be more effective if 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	97.5% (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.

Funding

This study was funded by a grant from the Center of Excellence for Nursing Scholarship (CECRI), Rome, Italy.

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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