TITLE. CAREGIVER CONTRIBUTIONS TO SELF-CARE IN OLDER PATIENTS AFFECTED BY MULTIPLE CHRONIC CONDITIONS (MCCs)

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INTRODUCTION

Older individuals are on the increase in Europe and globally. Currently, about 20% of the European population is over 65 years old and this percentage is bound to reach over 25% of prevalence in 2030 (Christensen et al, 2009; Lunenfeld et al, 2013). Older people frequently suffer from multiple chronic conditions; it was estimated in Europe, that in 2012, 75.6% of the population between 65 and 74 years had at least one chronic disease, and 48.7% was affected by at least two (Leadley et al., 2012). In addition, it is projected that 55% of the older western population suffer from 5 or more chronic conditions and the prevalence of comorbidity is increasing all over the world (Dennis et al, 2013). The most frequent chronic diseases over 65 years are: heart failure, diabetes mellitus and BPCO.
Among chronic conditions, self-care has gained prominence over the years, as it can reduce associated symptoms and signs and complications. Self-care is aimed at maintaining health, prevent diseases and managing acute and chronic conditions and disabilities (Lommi et al., 2015). Self-care activities can encompass a wide range of individual behaviors (e.g. taking medicines, feeding, bathing etc.), providers and health care systems, but also families and relatives, known also as informal caregivers, that help patients promote and restore physical, mental social and emotional wellbeing. To date, there is lack of research about the caregiver contributions to self-care of patients with multimorbidity. The studies have focues on the caregiver contributions to self-care of patients affected by heart failure (Vellone et al., 2013), and there is also agreement that caregivers and patients reciprocally influence patients' outcomes (Vellone et al., 2011), and stress, engagement and caregiver depression are associated to higher depression and readmissions in patients. Moreover, higher caregiver contributions to self-care of heart failure patients are associated with higher survival of the patient itself (Bidwell et al., 2017).

Research Problem

Informal caregiver contributions to self-care of patients with multiple chronic conditions, and related caregiver and patient outcomes are still not investigated by the literature. In addition, there are no instruments available that measure caregiver contributions.

AIMS

Primary aims of this project are:

- to describe caregiver contribution to self-care of patients with multiple chronic conditions.
- to determine the influence of patient self-care and caregiver contribution to self-care on patient mortality, quality of life, hospital admissions, unplanned access of care and positive aspects of caregiving.
- to identify distinct trajectories of patient self-care and caregiver contribution to self-care in the context of MCCs and characteristics predicting the identified trajectories.

Secondary aims of this project are:

- Design interventions for clinical practice in order to reduce health-care costs associated with chronic conditions in older people and
- Improve survival and quality of life of informal caregivers and of their patient.

Theoretical Framework

This project is based on three theoretical frameworks. The first is the Middle Range Theory of Self-care of Chronic Illness (Riegel et al., 2012), which defines self-care as a naturalistic decision making process, based on experience, where people adopt specific behaviors to maintain physical stability of the disease, through adherence to healthy lifestyles and treatments, symptom monitoring, and the management of symptoms when they occur. Self-care behaviors can be performed both by healthy and ill individuals, and it is important to underline that each person behaves according to his or her subjectivity and personal context (an effective treatment for a patient cannot be as effective for another). The Middle Range Theory of Self-care of Chronic Illness (Riegel et al., 2012) describe three main dimensions of self-care: (i) self-care maintenance, (ii) self-care monitoring, and (iii) self-care management.

Self-care maintenance refers to all those behaviors to improve wellbeing, maintain health and physical and mental functions stable. It also refers to recommendations and suggestions provided by health-care professionals. Maintenance behaviors encompass healthy lifestyles, but also actions derived from clinical recommendations, such as taking medicines at a certain time of a day.

Self-care monitoring encompass those examinations and assessments performed on the body and the surveillance of the illness. Examples are blood tests, glycemia, but also simple dental checks, or body weight. The more expert the patient is on the illness monitoring, the better the communication of complications or improvements to health-care professionals, information that can facilitate caring process (Riegel et al. 2012). Self-care monitoring is to consider the bridge between self-care maintenance and self-care management.

Self-care management encompass those behaviors performed when symptoms and signs occur. It requires awareness on the effectiveness of treatments to evaluate whether they can be performed again in the future (Riegel et al. 2012) Awareness towards signs and symptoms promote the assessment of the treatment effectiveness, facilitating a deeper understanding of the negative outcome and its causes, besides the ability to avoid the complication in the future.

The second theoretical framework is the Theory of Caregiver contributions to Self-care in Heart Failure (Vellone et al., 2013). Self-care of patients with heart failure is defined as a decision-making process to maintain physical health and manage symptoms when they occur. This model defines the caregiver contributions to heart failure patients, including provision of time, efforts and support to a patient that needs to perform self-care. This definition is supported by a variety of studies demonstrating in general, that caregivers contribute to improving self-care behaviors in patients with chronic conditions; for example, there is evidence that caregiver contributions to self-care is associated with better medication adherence (Aggarwal, Liao, & Mosca, 2013; Trivedi, Bryson, Udris, & Au, 2012), lower emergency visits (Wakabayashi et al., 2011), and healthier patients' behaviors (Trivedi, et al., 2012). The caring experience can be rather stressful for caregivers; in contributing to self-care, caregivers adapt their behaviors to the abilities of the patients in performing self-care: in some cases, they provide simple recommendations about how to manage the illness (e.g., body weight assessment, specific low-sodium diet, and administration of medicines). However, when patients are not able to perform self-care for whatever reason, caregivers substitute to them across all activities (they weigh the patient, choose and prepare foods with low-sodium content, administer medicines, call the nurse/clinician when symptoms and signs occur). The contributions to self-care maintenance influence 4 main factors of patient self-care: physical activity, symptom monitoring, low-sodium diet control, and treatment adherence to medicines.

The contributions to self-care management encompass two main factors influencing self-care: the one provided directly by the caregiver and the one provided by the patient.

Caregiver confidence in contributing to self-care encompass two levels: the first refers to more specific and complex activities (advanced confidence); the second level refers to basic activities requiring common competences (basic confidence).

The third theoretical framework is the Theory of Dyadic Illness Management (Lyons & Lee, 2018). Despite both members of the dyad are important for the management of a disease, the research focuses almost exclusively on the management of the disease performed either by the patient or the caregiver. The main concept of the Theory of Dyadic Illness Management is that the management of the disease is a dyadic phenomenon; the theory focuses widely on the dyad as an interdependent team that must be assessed and educated as a unit. The dyad is conceived as a unit that influence each other on the behaviors of disease management; each member deal with the disease and influence each other in a recursive way. Optimization of the health of both members is the objective of this theory.

METHODS

Design

This study adopts a longitudinal, multicentric and observational design.

Sample/Participants

The participants enrolled will be patients and their caregivers. Patient inclusion criteria will be:

- age of 65 years and over
- being affected by one of the following diseases: heart failure, diabetes mellitus or COPD, and at least one more chronic disease
- willingness to participate and sign the informed consent form.

Patients will be excluded if:

- Affected by cancer and/or dementia

Caregiver inclusion criteria will be:

- being identified by the patients as the main person who takes the responsibility of their care
- no remuneration
- willingness to participate and sign the informed consent form.
- age of 18 years old and over.

If one of the members is not eligible, both of them will not be enrolled.

Sampling

A consecutive and convenience sample of informal caregiver of patient affected by MCCs (DM, COPD, or HF with another chronic condition) will be enrolled in several healthcare settings outpatient settings specialties (cardiology, chronic diseases, pneumology, diabetology, geriatric and general medicine) of the National Health System.

Sample size

As we estimate an attrition rate of 50%, a sample of 500 patient-caregiver dyads will be enrolled at time 0 to obtain a sample of 250 chronically ill patient–caregiver dyads at time 2 (after 1 year).

Study procedures

The following Gantt chart graphically describes a calendar of project-specific activities that will take place in the 24 months following the start of the project. In particular, the project will be divided into the following 5 activities:

- presentation of the research project to the ethics committees of the hospital companies where the data will be collected.
- data collection carried out through adequately trained research assistants of the research group. Data collection will take place in three different moments: at the time 0 (T0), at 6 months (T1) and at 12 months (T2). Data collection at 6 and 12 months consists in reassessment of variables identified at T0, with the same instruments administered at T0, and a questionnaire developed to collect information on health service use.
- data analysis takes place, in part, together with data collection as some variables will be described, such as the caregiver's contribution to self-care and others related to them (eg burden, positive aspects of care) through an analysis of the data collected at time 0. At the end of the study, the longitudinal data that will allow to define the causal relationship of the variables under study will be analyzed.
- the drafting of the reports concerns several manuscripts and involves all the participants in this project.
- the dissemination of the results obtained takes place both through participation in conferences and through the publication of articles in international scientific journals with an impact factor and indexed.

	Feb 20	Mar 20	Apr 20	May 20	Jun 20	Jul 20	Aug 20	Sep 20	Oct 20	Nov 20	Dec 20	Jan 21	Feb 21	Mar 21	Apr 21	May 21	Jun 21	Jul 21	Aug 21	Sep 21	Oct 21	Nov 21	Dec 21	Jan 21
Literature review	x	x																						
Data collection		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
Data analysis										x	x	x	x	x	x	x	x	x						
Writing manuscripts												x	x	x	x	x	x	x	x	x	x	x	x	
Disclosure of results																			x	x	x	x	x	x

Instruments

Patients’ questionnaires are the following:

- *Modified Charlson Comorbidity Index (mCCI)* (Goldstein et al, 2004). It is an instrument that assesses the presence of 16 weighted comorbidities with a score ranging from 1 (e.g., diabetes without complications) to 6 (e.g., cancer or AIDS). The total score ranges from 0 to 31, with higher values indicating high comorbidity;
- *Montreal Cognitive Assessment (MoCA) (Nasreddine et al, 2005).* It is an instrument that analyzes conditions of cognitive decline. It assesses several cognitive domains: attention and concentration, executive functions, memory, language, visuo-constructive abilities, abstraction and informatic orientation. The highest score is 30; a score of 26 or beyond indicates preserved cognitive functions;
- *Self-Care of Chronic Illness Inventory v.2 Italian (SC-CII v.2).* It is an instrument consisting of three scales that reflect the Middle Range Theory of Chronic Illness (Riegel et al., 2012). It measures self-care of patients affected by chronic conditions. The scores are standardized from 0 to 100 for each scale, with higher scores indicating better self-care. The cut-off for adequate self-care is 70 or above (Riegel et al., 2009).

Caregivers' questionnaires are the following:

- *Caregiver Burden Inventory (CBI)* (Novak et al, 1986). It is an instrument that assesses multidimensional caregiver burden. Caregivers are requested to identify the answer that most closely resembles their condition or personal feeling. CBI is divided in five sections assessing a variety of caring burden: objective, psychological, physical, social and emotive. It is made of 24 items, with higher scores indicating higher burden. Cronbach's alpha for each subscale ranges from 0.76 to 0.96 (Novak et al, 1986);
- *Caregiver Contribution to Self-Care of Chronic Illness Inventory (CC-SC-CII).* It is the parallel version of the SC-CII, developed for caregivers with the same numbers and scales; however, it assesses the extent to which a caregiver recommends self-care or substitutes for the patient in performing self-care. The scores are standardized from 0 to 100 for each scale, with higher scores indicating better self-care;
- *Caregiver Contribution to Self-Care of Heart Failure index v.2 (CC-SCHFI v.2)* (Vellone et al, 2013). It is a parallel version of SCHFI, developed for the caregivers. The items of CC-SCHFI mirror the items of the SCHFI; but instead of asking how often the patients perform self-care, it is asked how often the caregiver recommends the patient the behaviors, or how often the caregiver does something for the patient in case he or she is not able to;
- *Caregiver Contribution to Self-Care of Chronic Obstructive Pulmonary Disease Inventory (CC-SCCOPDI).* It is a parallel version of SCHFI, developed for the caregivers. The items of CC-SCCOPDI mirror the items of the SCCOPDI; but instead of asking how often the patients perform self-care, it is asked how often the caregiver recommends the patient the behaviors, or how often the caregiver does something for the patient in case he or she is not able to;

- *Caregiver Contribution to Self-Care of Diabetes Index (CC-SCODI).* It is a parallel version of SCODI, developed for the caregivers. The items of CC-SCODI mirror the items of the SCODI; but instead of asking how often the patients perform self-care, it is asked how often the caregiver recommends the patient the behaviors, or how often the caregiver does something for the patient in case he or she is not able to.

Caregivers and patients' questionnaires are the following:

- *Multidimentional Scale of Perceived Social Support (MSPSS)* (Zimet, 1990). It is an instrument that measures the support from members of family, friends and significant persons. It is composed of 12 items with scores ranging from 0 to 7, with higher scores indicating higher perceived social support. MSPSS has been used in several studies on caregiving (Yu et al., 2013) showing adequate reliability and validity. It has been also used in an Italian sample (Cicero et al., 2009);
- *Patient Health Questionnaire-9 (PHQ-9)* (Kroenke et al, 2001). It is a diagnostic instrument for the assessment of caregiver and patient depression. It has a score ranging from 0 to 27, where a higher score means more severe depression;
- *Short Form Health Survey-12 (SF-12)* (Ware et al, 1996)). It is an instrument with 12 items, that assesses the physical and mental quality of life. Standardizes scores range from 0 to 100, with higher scores indicating better quality of life;
- *Perceived Stress Scale (PSS-10)* (Cohen et al., 1983): It is an instrument with 10 items, measuring the degree of stress perceived by an individual. It has a score ranging from 0 to 40, with higher scores meaning higher perceived stress;
- *Mutuality Scale (MS)* (Archbold et al., 1990). It is an instrument with 15 items, that measure the positive quality of the relationship between patient and caregiver. MS has a score ranging from 0 to 4, with higher scores reflecting higher relationship quality;
- *Dyadic Symptom Management Type Scale* (Buck et al, 2018). It is an instrument with 2 items developed to measure symptoms' management in dyads and the level of satisfaction regarding the illness management;
- *Questionnaire ad hoc* to collect data on health service use (e.g., emergency service use, readmissions over a period of 6 or 12 months from initial enrollment.

DATA ANALYSIS

Descriptive statistics will be used to describe the sociodemographic data and the instrument scores. The validity and reliability of the instruments developed for this study will be tested with exploratory or confirmatory factor analysis and Cronbach's alpha, respectively. Latent growth mixture modelling will be used to identify trajectories of caregiver contribution to self-care. In addition, we will use comparative statistics (e.g., Chi square, ANOVA and multinomial regression) to identify the characteristics of trajectories and the predictors of trajectory belonging. Multiple linear regression will be used to identify the predictor of caregiver contribution to self-care, and the influence of caregiver contribution to self-care on patient outcomes (mortality, quality of life, hospital admissions and the unplanned access of care).

ETHICAL CONSIDERATIONS

The present project will be conducted in agreement with the principles of Helsinki Declaration. Approval will be obtained from the ethical committee of the regional health care system. The dyad patient-caregiver who satisfy enrollment criteria will be contacted by a researcher who will give all the information about the study. The informed consent form will be obtained by both members of the dyad before collecting data. The participants' information will be stored securely with access limited to researchers only. The participants will be identified by a numeric code in all phases of the study.

IMPLICATIONS FOR CLINICAL PRACTICE

This study will be one of the first to explore the caregivers contribution to self-care of older adults affected by multiple chronic conditions. This study aims to fill this gap in our knowledge. Because this study will use a longitudinal approach—1 year—causality among the variables can be explored. First, this study will provide a description of caregiver contribution to self-care within the context of MCCs. No studies have used a MCCs perspective for studying caregiver contribution to self-care; hence, this study will allow for a holistic understanding of caregiver contribution to self-care that considers both disease-specific and general self-care. Second, this study will identify distinct trajectories of caregiver self-care. Few studies have addressed self-care trajectories and they were conducted with HF patients (Lee, Mudd, et al., 2015; Lee, Vellone, et al., 2015). The identification of self-care trajectories is important because trajectories give an overview of the changes in a variable (self-care in our case) over time. This will be important for identifying whether specific patient, caregiver, or dyad characteristics may predict trajectory belonging. For example, the analysis could reveal the existence of a trajectory with constant and lower self-care and this trajectory may be characterized by higher stress within the dyads. By knowing the trajectory characteristics, healthcare providers can personalize the interventions aimed at improving self-care—in this case, adopting strategies to reduce stress in the dyads.

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