Study Protocol

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Self-Care and Caregiver Contribution to Self-Care in Dyads Receiving Oral Anticancer Treatment (Dyads-in-Cancer): A Protocol for an Observational Longitudinal Study

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Abstract

Introduction. The use of oral anticancer agents (OAAs) has increased in recent years. These medications have many benefits, including improved tolerability, adaptability, and decreased stress compared to intravenous treatments. However, studies have shown that there are potential challenges with these treatments, including poor adherence and limited multidisciplinary support. As a result, it is important to focus on self-care behaviours for managing OAA treatment from a dyadic perspective. However, self-care levels in this population and the contribution of informal caregivers to self-care have yet to be extensively described, along with their predictors and outcomes. Therefore, the aim of this study is to describe a

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research protocol of a multicentre observational longitudinal study designed to investigate the self-care of patients with cancer taking OAAs and the caregivers' contribution to this self-care, and to examine the self-care predictors and outcomes.

Methods. This study will recruit patients with cancer undergoing OAA treatment and their informal caregivers. Data collection will include patient and caregiver sociodemographic factors, patient clinical information, patient self-care and caregiver contribution to self-care, variables at patient-, caregiver- and dyad-level that can predict self-care and caregiver contribution to self-care. We will also investigate whether self-care and caregiver contribution to self-care can predict important patient outcomes (e.g. emergency room access, rehospitalization, survival, quality of life) and/or caregiver outcomes (e.g. the positive aspects of caregiving). Data analyses will include descriptive statistics, regressions, ANOVAs, structural equation modelling, and dyadic analyses.

Discussion. This research will enhance the understanding of self-care in patients with cancer taking OAA and caregivers' contribution to self-care. It will provide insights on the factors that influence self-care and important outcomes. The findings of this study will inform future research and guide tailored interventions to improve patient self-care and caregiver support.

Keywords: Self-Care, Oral Anticancer Agents, Cancer Patients, Caregivers, Dyads

Introduction

In recent years, the use of oral anticancer agents (OAA) for treating cancer has increased, as well as the number of patients affected by cancer (Leong et al., 2021). The use of OAAs for patients with cancer has various benefits, including better tolerability, greater comfort, and adaptability to activities of daily living, and less stress associated with intravenous administration. Moreover, patients and their caregivers usually prefer OAAs because they can manage this treatment at home and avoid hospitalisation (Eek et al., 2016).

Although OAAs have several practical advantages, studies indicate that patients taking OAA are prone to experience poor adherence to treatment. This could be due to a lack of frequent communication with the multidisciplinary team (Given et al., 2011), managing adverse events alone, forgetfulness, depression, emotional distress, and side effects of medication (Barillet et al., 2015; Greer et al., 2016). As a result, patients receiving OAAs should develop adequate self-care skills to manage their therapy effectively.

Self-care (SC) is a process through which patients aim to maintain their physiological and emotional well-being despite their illness (SC maintenance). It involves monitoring for any signs or symptoms related to their illness and its treatment (SC monitoring), and taking action if they recognise any signs of relapse or worsening (SC management) (Riegel, Jaarsma, et al., 2012b). However, patients may sometimes struggle to perform SC on their own. In such cases, informal caregivers often step in to help them, playing an important role in contributing to SC. This is called caregiver contribution to self-care (CCSC), which involves actions to maintain the patient's physiological and emotional stability (caregiver contribution to SC maintenance), monitoring for any signs or symptoms of illness (caregiver contribution to SC monitoring), and recommending actions to the patient in case of worsening health (caregiver

contribution to SC management) (Vellone et al., 2019). Informal caregivers are individuals, typically family members or friends, who offer continuous care, frequently at home, to chronic patients with varying degrees of disability (Castro et al., 2023).

Patient SC and CCSC have been extensively studied in various chronic conditions, including heart failure (Antonio-Oriola et al., 2022; Ercole Vellone, Maddalena De Maria, et al., 2020), diabetes mellitus (Ausili et al., 2017), chronic obstructive pulmonary disease (Clari et al., 2017), as well as in the context of colostomy and urostomy (Villa et al., 2019). Investigators have found that patient SC and CCSC are interdependent and constitute a "dyadic phenomenon" in which patients' behaviours influence caregiver behaviours and vice versa. While the use of OAAs is widespread, there is still a lack of detailed description of patient SC and CCSC in this field (Di Nitto et al., 2022; Sollazzo et al., 2023). Furthermore, predictors and outcomes of these behaviours have yet to be clearly identified. This lack of knowledge may be because instruments to assess patient SC and CCSC have only recently been developed (Lacarbonara et al., 2023).

Although there is limited knowledge about patient SC and CCSC, the Middle-Range Theory of Self-Care of Chronic Illness (Ercole Vellone, Maddalena De Maria, et al., 2020) and the Theory of Caregiver Contribution to Self-Care in Heart Failure (Vellone et al., 2019) can provide essential insights into the predictors and outcomes of these processes from a dyadic perspective (Riegel, Jaarsma, et al., 2012a; Riegel, Lee, et al., 2012) (Figure 1). In this protocol, we propose a conceptual framework based on the above-mentioned theories and available evidence to better understand SC and CCSC among patients with cancer receiving OAAs.

Predictors of self-care

The factors that can influence SC in patients with cancer treated with OAAs can be related to the patients themselves, their caregivers, and the dyad (Figure 1). Predictors of patient-related self-care could include sociodemographic factors (e.g., age) and clinical characteristics (i.e., severity of cancer, cognitive status, and the number of medications taken), comorbidity, self-efficacy (Riegel, Lee, et al., 2012; Riegel et al., 2021), and patient-centeredness. There is currently no evidence in the literature regarding predictors of SC in patients being treated with OAAs. However, in other chronic conditions, it has been well-documented that certain sociodemographic characteristics such as age (Ausili et al., 2016; Ausili et al., 2018; Cocchieri et al., 2015; Vellone et al., 2017), gender (Cocchieri et al., 2015; Vellone et al., 2017), and education (Vellone et al., 2017) can impact SC. Additionally, the severity of the illness (Bidwell et al., 2015), the cognitive status of the patient (Li et al., 2017; Świątoniowska-Lonc et al., 2021), the number of medications taken (Ausili et al., 2016; Vellone et al., 2017), and the presence of other comorbidities have been found to predict patient SC (Buck et al., 2015; Dickson et al., 2011) in other chronic conditions. The researchers who study patients treated with OAAs focused only on the factors that were associated with adherence to treatment. However, adherence is just one aspect of SC. These investigators found that comorbidities were predictors of adherence, but they were unable to understand if more comorbid conditions alter or improve adherence (Ali et al., 2017; Blanchette et al., 2020; Corter et al., 2018; Iacorossi et al., 2016; Oke et al., 2018; Tinari et al., 2015; Yuan et al., 2020; Zahrina et al., 2014).

Self-efficacy has been shown to be associated with SC in patients experiencing chronic conditions (Juarez et al., 2021; Tan et al., 2021) and could play an important role also in SC behaviours for patients with cancer. Moreover, patient-centredness is another patient-related factor that can affect patient SC and the quality of care they receive (Epstein & Street, 2011). When patients feel the care is tailored to their unique needs and preferences (as a whole person), they are more likely to have positive outcomes, such as better quality of care, increased self-efficacy, and trust in their providers (Elkefi & Asan, 2023). We do not have evidence that patient-centredness could also improve patient SC in the context of OAAs, but a higher level of patient-centredness has been found associated with better cancer care (Riegel, Jaarsma, et al., 2012b), which is the distal goal of every SC programme.

Caregiver-related factors that can have an impact on patient SC and CCSC include sociodemographic characteristics, caregiver preparedness, caregiver burden, resilience,

and self-efficacy. Several previous studies in the context of chronic conditions have shown that caregivers who are younger, female, and married to the patient exhibit better CCSC (Bidwell et al., 2015; De Maria et al., 2023; Vellone, D'Agostino, et al., 2015). Additionally, caregiver preparedness has been found to positively influence patient SC and CCSC (Ercole Vellone, Valentina Biagioli, et al., 2020) in chronic diseases, but higher caregiver burden, lower resilience, and lower self-efficacy have been found to not influence SC and CCSC (Durante et al., 2022; Røen et al., 2018; Vellone, Fida, et al., 2015).

We have identified five dyad-related predictors of patient SC and CCSC from studies on chronic diseases. These variables are named dyad related as they are present in both patients and caregivers. They include social support, depressive state, dual symptom management, mutuality, and generic SC and CCSC. Several studies have found lower levels of SC and CCSC when patients and caregivers receive poor social support (Ausili et al., 2018; Freedland et al., 2021), are depressed (Dickson et al., 2011; Egede et al., 2009; Freedland et al., 2021; Riegel et al., 2011), not good at managing symptoms together (Buck et al., 2015; Dickson et al., 2011), and have less mutuality (Hooker et al., 2018; Vellone et al., 2018) (e.g., a worse relationship). We currently lack evidence to confirm whether generic SC and CCSC behaviours, as measured through instruments developed for all chronic conditions (e.g., follow the recommended diet) can predict SC and CCSC in patients with cancer receiving OAAs. However, we believe that individuals who engage in generic SC behaviours to manage their own health or that of their loved ones are more likely to perform the specific SC practices required to manage OAAs.

Overall, we know several predictors of patient SC and CCSC in chronic conditions, but we lack evidence on whether these predictors influence SC and CCSC in the context of patients with cancer treated with OAAs.

The process of SC and CCSC

The process of patient SC and CCSC includes three dimensions: (patients and caregiver contribution to) SC maintenance, SC monitoring, and SC management. These dimensions are all interdependent, either in the relationship between patients and caregivers (for example, patient SC maintenance may influence CCSC maintenance and vice versa). Moreover, each dimension (of patient's SC or

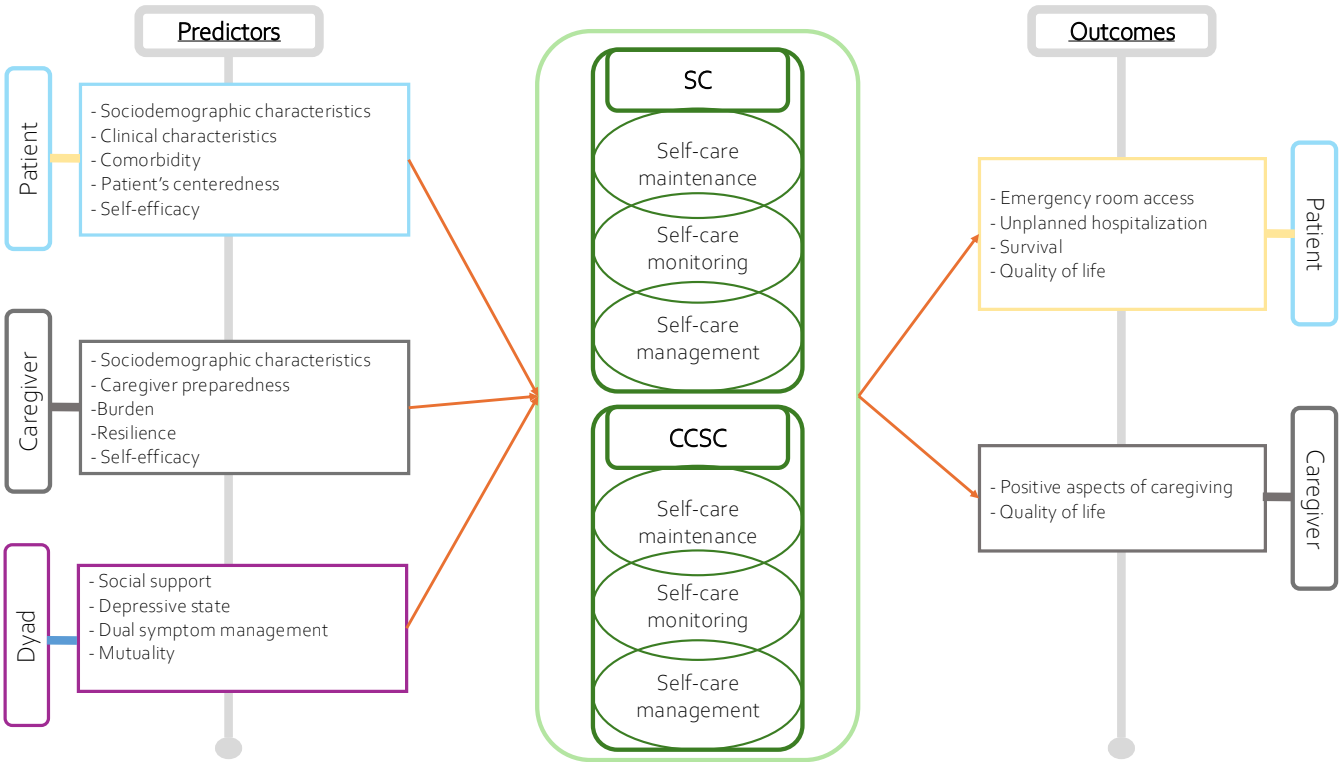


Figure 1. Theoretical framework of the study.

CCSC) can be related with the other one (e.g., SC maintenance with SC management, etc.). Specifically, in individuals with heart failure and chronic diseases (Ausili et al., 2016; Clari et al., 2017), the above three dimensions work in a sequential manner (e.g., SC maintenance influences SC monitoring and SC monitoring influences SC management). However, it is not yet clear whether this sequential relationship is confirmed in patients with cancer receiving OAAs. Moreover, in previous studies self-efficacy has been found to be a mediator between social support and SC (Iovino et al., 2023) but in patients with cancer this relationship has not been confirmed, and only one study examined the role of self-care as a mediator between self-efficacy and quality of life in patients with breast cancer receiving systemic chemotherapy (Chin et al., 2021).

Outcomes of self-care and caregiver contribution to self-care

The processes of SC and CCSC have been found to be associated with several positive outcomes related to the patient and caregiver. Studies conducted on other chronic diseases have shown that SC and CCSC can lead to improved quality of life for patients (QoL) (De Maria et al., 2019; Jovicic et al., 2006), reduced mortality rate (Gao et al., 2013; Kueh et al., 2015; Riegel et al., 2011), fewer hospitalisations (Jonkman et al., 2016), and fewer unplanned access to care (Clarke et al., 2017). Similarly, in the case of patients with cancer, studies have shown that inadequate SC behaviours (e.g. treatment non-adherence) can lead to significant worse outcomes, such worse symptom burden (Berry et al., 2015) and quality of life (Jacobs et al., 2019).

We have identified positive outcomes related to caregivers in our framework. These include positive aspects of caregiving and improved quality of life for caregivers. Studies on chronic diseases show that caregivers reported positive benefits of caregiving, such as self-affirmation and life enrichment (Cohen et al., 2002). In addition, higher confidence in CCSC was associated with better quality of life (Vellone et al., 2014). However, these outcomes have not been explored yet in the case of OAAs.

Aim

The aim of this study will be threefold: 1) to describe patient SC and CCSC in OAAs; 2) to identify predictors of patient SC and CCSC in the context of OAAs among patient- (e.g., sociodemographic and clinical characteristics, comorbidity, centeredness, self-efficacy), caregiver- (e.g., sociodemographic characteristics, preparedness, caregiver burden, resilience, self-efficacy), and dyadic-related variables (e.g., social support, depressive state, dual symptom management, mutuality, generic SC); 3) to examine patient and caregiver outcomes of patient SC and CCSC (e.g., patient emergency room access, unplanned hospitalisation, survival, quality of life; positive aspects of caregiving, quality of life).

Design / Methodology

This study will adopt a multicentre, longitudinal observational design.

Study procedures

Recruitment and setting

Data will be collected from five outpatient clinics in Italy, located in the three macro areas of the Italian territory (e.g., north, centre and south). A consecutive convenience sample of patients with cancer receiving OAAs and their informal caregivers will be enrolled. Participants, therefore, will be enrolled through non-probabilistic sampling. All patients visiting the outpatient clinics of the centres involved during the study period will be invited to participate in the study. All individuals who meet the inclusion criteria will be enrolled in the study (see below). Trained research assistants will explain the purpose of the study to all potential participants, and those who agree to participate will be asked to sign an informed consent form. Afterwards, participants (both patients and caregivers) will be asked to complete the study tool battery at enrolment (T0), after 3 months (T1) and after 6 months (T2) of enrolment. The informal caregiver will be asked about any unscheduled admission to the emergency room, rehospitalisation, or death of the patient at T1 and T2. The recruitment started in November 2022 and is planned to end by December 2025.

Inclusion and exclusion criteria

Patient inclusion criteria are: (1) adult patients (≥ 18 years); (2) ability to give informed consent; (3) diagnosis of a metastasised or locally advanced solid tumour; (4) understanding of the Italian language; (5) active treatment with OAAs (conventional chemotherapy, molecular targeted therapy, hormone therapy) started since at least 3 months. This interval was chosen because individuals with metastatic cancer typically have a short prognosis, as their clinical status might deteriorate quickly. Patients will be excluded if they have a diagnosis of haematological malignancy or serious cognitive impairment which could prevent them from understanding the meaning of the items.

Caregiver inclusion criteria are: (1) adult subjects (≥ 18 years); (2) ability to give informed consent; (3) understanding of the Italian language; (4) indicated by the patient as the main caregiver (in the case of more than one caregiver). Caregivers will be excluded if they receive any form of payment for their caregiving activities.

Instruments for measuring the predictors of self-care

Instruments for patient-related predictors of self-care

Sociodemographic and clinical characteristics of patients with cancer (e.g., age, sex, tumour site) and sociodemographic characteristics of caregivers (e.g., age, gender) will be collected using a specific questionnaire developed by the research team.

Comorbidity will be assessed with the Self-Administered Comorbidity Questionnaire (Sangha et al., 2003). This instrument consists of 12 items representing 12 medical conditions (e.g., hypertension, diabetes) and 3 optional conditions (e.g., not included in the 12 conditions). Participants will be asked to indicate whether– with yes or no - they have each condition, if they are receiving treatment for it, and if it limits their activities of daily living. Thus, an individual can receive a maximum of 3 points for each medical condition: 1 point for the presence of the problem, another point if he/she receives treatment for it, and an additional point if the problem causes a limitation in functioning. Since there are 12 defined medical problems and 3 optional conditions, the potential score ranges from 0 to 45.

The revised Patient Perception of Patient-Centeredness Questionnaire (PPPC-R) (Ryan et al., 2019) - is a valid and reliable instrument that measures patient centredness through the healthcare continuum. It includes 18 items and three factors: the healthcare process (items 1-8) (e.g., to what extent was your main problem(s) discussed today?), roles (items 9 and 10) (e.g., to what extent did you and your provider discuss your respective roles?) and context and relationship (items 11-18) (e.g., to what extent does your provider know about your family life?). Each item has a 4-point Likert scale, with responses ranging from 1 (very much) to 4 (not at all). The total score is the mean score of all items, with higher scores indicating a lower patient-centredness.

Instruments for caregiver-related predictors of self-care

The Caregiving Preparedness Scale (CPS) (Pucciarelli et al., 2016) is a valid and reliable instrument that consists of 8 items. The CPS measure the extent to which caregivers feel prepared in various aspects of caregiving (e.g., provision of physical care or emotional support). Each item has a 5-point Likert scale for responses ranging from 0 (not at all) to 4 (very much). The total score is computed by averaging all item scores. A higher CPS score means that the caregiver is better prepared.

The Caregiver Burden Inventory (CBI) (Novak & Guest, 1989) is a psychometrically sound instrument that will be used to measure caregiver burden. It comprises 24-items divided into five factors (e.g., time-dependent, developmental, physical, social, and emotional burden). The score can be calculated by adding up all the items, with a minimum of 0 and a maximum of 100 points (the physical burden score is multiplied by 1.5). Higher scores indicate a greater burden on the caregiver.

The Connor-Davidson Resilience Scale (Connor & Davidson, 2003; Ehrich et al., 2017) is a valid and reliable instrument that evaluates resilience as an individual's ability to cope with stress. This scale consists of 25-items (e.g., there is someone in my life who can help me

if I need), each scored from 1 (at all true) to 4 (almost always true). The score can range from 0 to 100, with higher scores indicating greater resilience.

Instruments for dyad-related predictors of self-care

Several valid and reliable instruments will be used to measure the same variables in both patients and caregivers in the dyads.

The Multidimensional Scale of Perceived Social Support (MSPSS) measures perceived social support. It is consisting of 12-items (e.g., my family is working hard to help me) with scores from 1 (strongly disagree) to 7 (strongly agree). The total score ranges from 12 to 84, with a higher score indicating a higher level of perceived social support (Zimet et al., 1988).

The Patient Health Questionnaire-9 (PHQ-9) (Arroll et al., 2010) will be used to assess patient and caregiver depression levels. The questionnaire comprises 9 items (e.g., feeling down, sad or desperate/a), with scores ranging from 0 to 27. Each item is rated on a scale from 0 (never) to 3 (almost every day). Scores between 5 and 9 indicate mild depression. Scores > 10 suggests a clinically significant level of depression.

Dyadic-type congruence in SC will be measured using the dual symptom management scale (Buck et al., 2019; H. G. Buck et al., 2013; Harleah G Buck et al., 2013), which assess how patients and their caregivers take care (e.g., decide what to do and how to do) of the patient's illness. Four categories of dyadic care can be obtained by administering the instrument to both members of the dyad: 1) patient orientated, when both members agree that the patient has the main role in managing the illness; 2) caregiver orientated, when both agree that the caregiver has the main role in managing the illness; 3) collaborative or complementary, when the patient and the caregiver agree to do the same things together or they divide them; 4) incongruent, when the patient and the caregiver do not give the same response (e.g. the patient reports that he/she has the main role in managing the illness and his/her caregiver reports a different response). A subsequent question assesses satisfaction with the management of the health-related problem. This question can be rated with a Likert scale ranging from 1 (extremely dissatisfied) to 5 (extremely satisfied). According to research, incongruent dyads tend to have worse outcomes (e.g., lower patient and caregiver quality of life) (Buck et al., 2018; Bugajski et al., 2021; Vellone et al., 2018).

The Mutuality Scale (MS) will be used to measure the quality of the relationship between the patient and the caregiver (e.g., how much does the person you assist help you?) (Archbold et al., 1990). The MS comprises 15 items rated on a 5-point Likert scale ranging from 0 (not at all) to 4 (much). The total scale score is obtained by averaging the scores of all the items. A higher score on the scale indicates a better relationship quality between the patient and the caregivers.

Patients' self-efficacy will be measured using the Self-Care Self-Efficacy scale (SE-SC), which is a valid and reliable instrument consisting of 10 items. It aims to assess the extent to which patients feel confident in performing SC activities (e.g., confidence in following the prescribed treatment plan) (Di Nitto, Durante, et al., 2025). Each item uses a 5-point Likert scale for responses ranging from 1 to 5. The score is standardised from 0 to 100, and a higher score indicates greater self-efficacy.

Caregivers' self-efficacy will be measured using the Caregiver Self-Efficacy in Contributing to Patient Self-Care (CSE-CSC) Scale (De Maria et al., 2021), which is the caregiver version of the SE-SC with the same item and scoring format, but the language has been adjusted to fit caregivers' needs (e.g., confidence in doing something to alleviate patient symptoms). The CSE-CSC scale score ranges from 0 to 100, with higher scores indicating greater caregiver self-efficacy in contributing to patient SC.

Instruments for measuring the specific self-care processes

Specific SC behaviours will be measured using the Self-Care of Oral Anticancer Agents Index (SCOAAI), which is a valid and reliable instrument (Di Nitto, Ucciero, et al., 2025; Lacarbonara et al., 2023) assessing SC in patients with cancer treated with OAAs. This instrument comprises of 32 items which are grouped into three scales: SC maintenance (15 items) that assess behaviours that help maintain the patient's health (e.g. attend all medical visits as schedule); SC monitoring (11 items) that assess behaviours aimed at monitoring symptoms

associated with OAAs side effects (e.g. cancer medication side effects); SC management (6 items) that assesses behaviours implemented in the event of worsening symptoms associated with OAAs (e.g. contact the doctor or nurse to ask what to do in case of unmanageable symptoms). Each item in SCOAAI has a 5-point Likert response scale ranging from 1 (never) to 5 (always). Each scale has a standardised score ranging from 0 to 100, with a higher score indicating better SC.

The caregiver's role in patient SC will be measured using the Caregiver Contribution to Self-Care of Oral Anticancer Agents Index (CC-SCOAAI) (Di Nitto, Lacarbonara, et al., 2025). This index is specifically designed for caregivers and is based on the SCOAAI, consisting of 32 items. The only difference is that the CC-SCOAAI assesses the extent to which the caregiver recommends that patients perform SC behaviours (e.g., attending all medical visits as scheduled or monitoring cancer medication side effects). The CC-SCOAAI uses a 5-point Likert scale for responses (ranging from 1 never to 5 always) and provides a standardised score of 0–100. A higher score corresponds to better CCSC.

Generic SC behaviours will be measured using the Self-Care of Chronic Illness Index v.2 (SC-CII V.2) (Di Nitto, Durante, et al., 2025), which is an instrument developed and validated to measure SC in individuals with various chronic diseases. The tool consists of three separate scales that assess SC maintenance, SC monitoring, and SC management. Each item is rated on a 5-point Likert scale ranging from 1 (never) to 5 (always). On each scale, the score can range from 0 and 100, with a higher score indicating better SC. Scores > 70 indicate adequate SC. The Caregiver Contribution of Self-Care in Self-Care of Chronic Illness Inventory (CC-SC-CII) V. 2 was used to measure CCs to SC behaviours in chronic conditions (E. Vellone et al., 2020). This is a 19-item instrument consisting of three separate scales assessing SC maintenance (how often during the last month a caregiver recommended that the care recipient adopt those behaviours aimed at maintaining physical and mental stability of a chronic illness), SC monitoring (how often a caregiver recommended that the care recipient monitor signs and symptoms of their chronic illness), and SC management (how often a caregiver contributed to symptom recognition/interpretation and responded to symptoms of chronic illness exacerbation). Each scale is composed by 7 items, 5 items and 7 items, respectively. Each item of the CC-SC-CII is rated on a 5-point Likert scale ranging from 1 (never) to 5 (always).

Instruments to measure self-care outcomes

Patient-related outcomes

Several patient-related outcomes will be analysed to test the hypothesis that adequate SC behaviours can improve patient outcomes. Specifically, we will examine emergency room visits, unplanned hospitalisation, and survival rates, along with measuring QoL using the Core 30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) (Marzorati et al., 2019). This is a valid and reliable scale comprising 30 self-reported items that assess different aspects of patient functioning (e.g. physical, role, emotional, cognitive, and social), global health status, and cancer-related symptoms (e.g. fatigue, pain, nausea, and vomiting). The response format for each item is on a 4-point Likert scale ranging from1 (no) –to 4 (very much), except for items 29 and 30, which have a response format of 1-7. For each scale, a score ranging from 0 to 100 can be obtained, with higher scores indicating a better quality of life.

Caregiver-related outcomes

The 9-item Positive Aspects of Caregiving scale (PAC) (Lou et al., 2015; Tarlow et al., 2004) will be used to measure the psychosocial benefits of caregiving. It has good psychometric properties and consists of 9 items in total (e.g. makes me feel more useful). Each item is rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score on the PAC reflects a more positive perception of the caregiving experience.

The caregivers' health-related QoL will be measured using the Short Form-12 Health Status Questionnaire (SF-12) (Gandek et al., 1998), which is a reliable and valid tool. SF-12 consists of 12-items (e.g. he/she had to restrict certain types of work or other activities) that assess two different aspects of health: physical

health and mental health. Both aspects have a score ranging from 0 to 100, with higher scores indicating a higher physical or mental QoL.

Sample size

To ensure that this study can effectively investigate SC, a minimum of 500 patients and their caregivers (500 dyads) will be required. This number was determined according to previous research conducted in patients with chronic diseases, to achieve the necessary power to address all the goals of the study (Ausili et al., 2017; De Maria et al., 2019; Ercole Vellone, Maddalena De Maria, et al., 2020). In addition, a power analysis was performed to determine the minimum sample size required to address the second aim of this study (examine predictors of patient SC). A multiple linear regression will be conducted for this aim. Thus, to achieve a power of 0.80 and a significant level of $\alpha = 0.05$, considering a medium effect size based on Cohen f2 of 0.05 (Cohen, 1998) and 5 predictors (including comorbidity, self-efficacy, patient-centredness, and at least age and gender as sociodemographic predictors), the minimum sample size required would be 263 patients.

Data Analysis

Descriptive statistics (mean, median, frequencies) will be used to describe the sociodemographic and clinical characteristics of participants, as well as the SCOAAI and CC-SCOAAI scores. Subgroup descriptive analysis will be conducted to distinguish different levels of SC based on specific characteristics (e.g., gender, age, OAA used, etc).

To identify the predictors and outcomes of patient SC and CCSC, multiple linear regressions or logistic regressions will be performed. In addition, t-tests, analysis of variance (ANOVAs), simple regressions, multiple regressions, structural equation models, and generalised estimating equations will be performed to estimate the relationship between all patient, caregiver, and dyad factors associated with patient SC and CCSC. Finally, dyadic analyses will be performed to consider the patient-caregiver dyad, so to analyse the level of interrelation between variables of the patient and caregiver from a dyadic perspective. Data analysis will be carried out using Jasp® V. 0.98.0 (JASP Team, 2025), or R® software (R Core Team, 2025).

To account for the possibility of some patients/caregivers dropping out of the study and limit attrition bias, we will only include participants who took part at least in the initial data collection (T0) and the first follow-up at 3 months (T1). Should some participants drop out of the study at the subsequent follow-up at 6 months (T2) or only partially complete the questionnaires in one of the 3 phases, an analysis of the characteristics of the missing data will be carried out to determine the suitability of an imputation of these missing data using multiple imputation in order to reduce attrition bias (Asendorpf et al., 2014).

Ethical considerations

This study received approval from the Ethics Committee of the "Policlinico Tor Vergata" with reference number #188.22. . The study protocol was developed in accordance with the Good Clinical Practice Standards of the European Union and the Declaration of Helsinki. All participants will be asked to provide their informed consent in written form before they can join the study. They will be informed about the purpose of the study and assured that it does not involve any risks to them. The participants' information will be stored securely with access limited to researchers only. Participants will be identified by numerical codes in all phases of the study. The patient or caregiver can withdraw from the study at any time for any reason. If a participant cannot complete the study or wishes to discontinue participation, the reason for discontinuation will be recorded on the data collection form.

Discussion

This study will identify the different factors related to the patient, caregiver, and dyad that can influence the SC and CCSC in the context of patients with cancer receiving OAAs. Additionally, our study will determine whether the patient SC and CCSC can predict significant outcomes for both the patient, such as mortality, and the caregiver, such as their QoL. To our knowledge, this is the first study

of its kind to investigate SC and CCSC, with a focus on the dimensions of maintenance, monitoring, and management. The study also considers these dimensions in relation to their predictors and outcomes. The investigation will produce essential results that can guide clinical practice for patients treated with OAAs and their caregivers. Moreover, the study could produce evidence to guide future interventions aimed at improving SC and CCSC.

To date, various authors have studied SC and CCSC in different chronic diseases, such as heart failure (Cocchieri et al., 2015) and multiple chronic diseases (De Maria et al., 2022). Their studies have shown that SC and CCSC are crucial predictors of patient and caregiver quality of life (Iovino et al., 2021; Ercole Vellone, Valentina Biagioli, et al., 2020; Vellone, D'Agostino, et al., 2015). It is our belief that these predictors are also applicable to patients treated with OAAs. By measuring the three components of maintenance, monitoring, and management through SCOAAI and CC-SCOAAI, it could be possible to gain a better understanding of which components influence patient and caregiver outcomes.

Our study on SC differs from previous research by using a dyadic approach. As other studies have shown, patient SC and CCSC are interrelated, and patient variables can predict both patient SC and CCSC. In the same way, caregiver variables can predict CCSC and patient SC. Since patients and caregivers are interdependent, our dyadic analysis will allow us to control for this interdependence, leading to a more accurate understanding of the factors that influence each other.

Limitations

As this study will be conducted in a single European country, our results may be generalised with caution to other cultures. Another potential limitation may be related to longitudinal study design which may result in patients and caregivers dropping out. Finally, the convenience sampling approach used in this study is another potential limitation.

Conclusions

Recent advances in the field of oncology, among others, have led to an increased use of OAAs. Differently from cytotoxic anticancer agents, mainly delivered intravenously, OAAs are medicines taken at home under patient and/or caregiver surveillance. Therefore, although OAAs are better tolerated than cytotoxic anticancer agents, the patient and the caregiver must be well-educated to properly manage OAA assumption and their side effects. On the other hand, this "home scenario" highlights not only the importance of the caregiver's well-known role in managing patient disease and its complications but also a further new key role in the management of medicine(s) aimed at controlling cancer evolution. Therefore, knowing which SC behaviours should be implemented and how the caregiver reinforces patient SC behaviours is essential. The "Dyads-in-cancer" study could have significant implications for understanding how patients, caregivers, and dyads manage the SC process in the context of receiving OAAs. This study will also shed light on the factors that determine adequate levels of SC and identify the outcomes that can be improved through adequate SC behaviours. At a broader level, the "Dyads-in-cancer" study will contribute to expanding the knowledge about SC in cancer.

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