

Self-care in patients affected by inflammatory bowel disease and caregiver contribution to self-care (IBD-SELF): a protocol for a longitudinal observational study

Daniele Napolitano ,¹ Ercole Vellone,^{1,2} Paolo Iovino,³ Franco Scaldaferri,⁴ Antonello Cocchieri⁴

To cite: Napolitano D, Vellone E, Iovino P, *et al.* Self-care in patients affected by inflammatory bowel disease and caregiver contribution to self-care (IBD-SELF): a protocol for a longitudinal observational study. *BMJ Open Gastroenterol* 2024;**11**:e001510. doi:10.1136/bmjgast-2024-001510

► Additional supplemental material is published online only. To view, please visit the journal online (<https://doi.org/10.1136/bmjgast-2024-001510>).

Received 28 June 2024
Accepted 2 August 2024



© Author(s) (or their employer(s)) 2024. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

¹University of Rome Tor Vergata, Roma, Italy

²Wroclaw Medical University, Wroclaw, Poland

³Department of Health Sciences, University of Florence, Florence, Italy

⁴Università Cattolica del Sacro Cuore, Milano, Italy

Correspondence to
Dr Daniele Napolitano;
daniele.napolitano@
policlinicogemelli.it

ABSTRACT

Introduction Supporting patient self-care and the contribution of their caregivers is crucial in chronic illness care. Inflammatory bowel disease (IBD) is a chronic condition whose prevalence is expected to double, especially in Western countries. IBD symptoms can negatively impact patients' well-being, causing high anxiety, depression, stress and reduced quality of life. These symptoms also affect the health of family members and friends, who often take on caregiving roles during exacerbations. Knowledge about self-care in IBD (IBD-SELF) is limited, and few studies have explored this context. This paper outlines a research protocol for a multicentre longitudinal study to investigate patient self-care and caregiver contributions to IBD-SELF.

Methods and analysis A sample of 250 consecutive patients diagnosed with IBD and their caregivers will be recruited from 9 dedicated IBD units in northern, central and southern Italy during outpatient visits. Data collection will occur at baseline, 6 and 12 months after enrolment. Multivariable regressions, path analyses and structural equation models will identify predictors (eg, health literacy, caregiver burden and depression) and outcomes (use of healthcare services, disease severity and quality of life) of self-care and caregiver contributions. Dyadic analyses will control for the interdependence of dyad members.

Ethics and dissemination Ethical approval was obtained from the Territorial Ethics Committee (Lazio 3) N. 0023486/23 and registered on ClinicalTrials.gov (Identifier number: NCT06015789). This study will enhance our understanding of the self-care process in the patient-caregiver dyad in IBD, aiding the design of future educational interventions and promoting greater patient and caregiver involvement in the care pathway.

Trial registration number ClinicalTrials.gov:
[NCT06015789](https://clinicaltrials.gov/ct2/show/study/NCT06015789).

INTRODUCTION

Inflammatory bowel disease (IBD) is a chronic condition characterised by recurrent episodes of inflammation determined by an abnormal immune response to the

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Self-care in inflammatory bowel disease (IBD) is limited, and few studies have explored the context of patient self-care and caregiver contributions.

WHAT THIS STUDY ADDS

⇒ This study will investigate patient self-care, caregiver contribution and their impact on selected outcomes in the IBD patient-caregiver dyad.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The study's insights could inform educational interventions and promote greater patient-caregiver involvement in the IBD care pathway.

gut microflora.^{1 2} Crohn's disease (CD) and ulcerative colitis (UC) are the most predominant forms of IBD. Approximately, 0.5% of the Western population is currently affected by IBD,³ but this prevalence is predicted to increase to 1% by 2030, resulting in 10 million people affected in Western countries.³

The disease course of IBD is generally progressive and unpredictable, with sudden exacerbations of gastrointestinal symptoms.⁴ As a result, individuals with IBD frequently experience complex diagnostic and therapeutic pathways, leading to significant financial burdens for patients, caregivers and healthcare systems.⁵

The effective management of IBD necessitates regular interactions among patients, caregivers and healthcare providers. These interactions are related to medical and surgical treatments, although most of them are needed for symptom management because patients often experience pain, incontinence, bowel urgency or tenesmus,

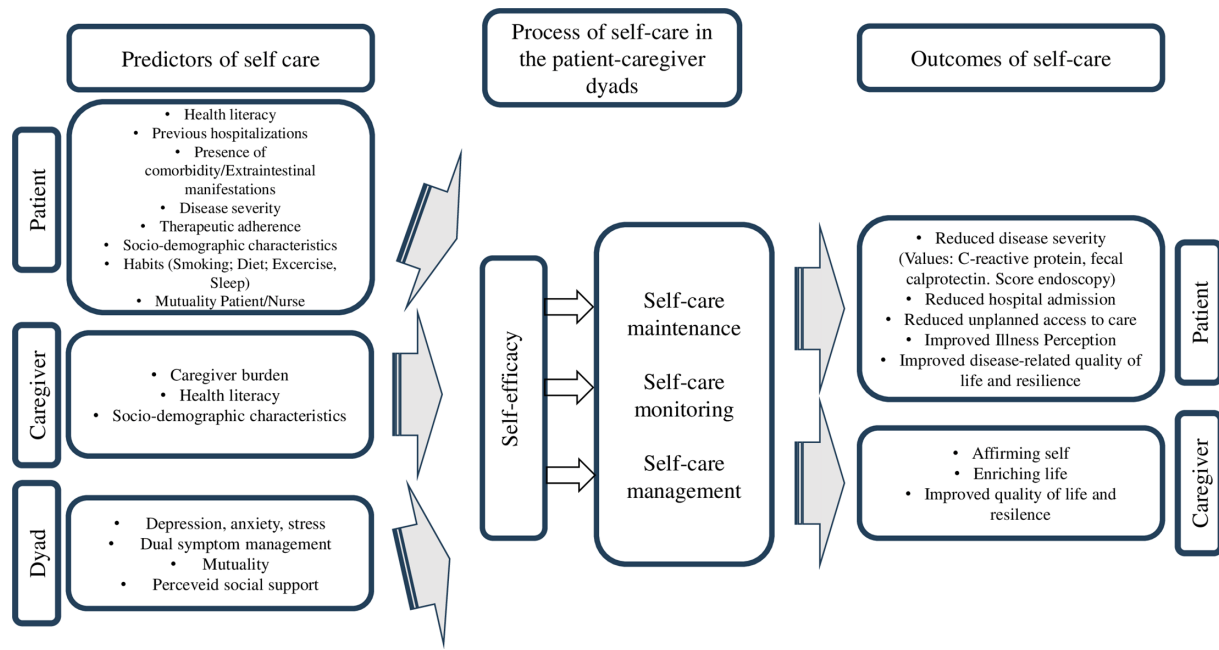


Figure 1 Theoretical framework of self-care in inflammatory bowel diseases.

weight loss, lack of energy, rectal bleeding, diarrhoea and fevers.⁶

The impact of IBD symptoms on patients' lives is detrimental, who exhibit correlates of anxiety, depression and stress, and poor quality of life (QoL).⁷ These symptoms can also disrupt the QoL of family members and friends because, during the periods of exacerbations, which occur on average once or twice a year, family members and friends often become caregivers of these patients.^{6,8} Given that IBD is a chronic condition, caregivers must adapt to the disease throughout the entire life of the patient.⁸

Research has demonstrated that chronic diseases place a greater burden on families compared with acute diseases, potentially hindering their caregiving functions.⁹ Consequently, it is crucial for both IBD patients and their caregivers to acquire effective self-care practices and learn how to manage the chronic disease appropriately. To date, only a few studies have explored self-care in IBD (IBD-SELF) while these studies focused on aspects of patients' self-efficacy and self-management interventions, they did not adopt a theoretical framework and did not include the caregivers. Thus, the self-care process remains limited and fragmented in the context of IBD.

Background

The IBD-SELF study will be guided by the theoretical framework presented in [figure 1](#), which draws inspiration from the Middle-Range Theory of Self-Care of Chronic Illness¹⁰ and the Theory of Dyadic Illness Management.¹¹ The Middle-Range Theory of Self-Care of Chronic Illness¹⁰ postulates that self-care is an active process to maintain and promote health in situations of chronic conditions and consists of the behaviours of self-care maintenance, or the actions adopted by patients to maintain the stability of the chronic condition (eg,

taking medications as prescribed), self-care monitoring or the process of monitoring for signs and symptoms of disease (eg, monitoring pain), and self-care management, or the behaviours performed to manage signs and symptoms when they appear (eg, calling the provider in case of exacerbations).¹⁰ The Theory of Dyadic Illness Management postulates that the management of a disease is a dyadic phenomenon, in which patients and their caregivers work as an interdependent team and engage in specific behaviours to manage the health issue together.¹² These two members, who are called 'dyad', influence each other over the course of the disease, and the theory emphasises the importance of joint (ie, dyadic) interventions to improve the health of both members.

The level of self-care engagement in patients with IBD is currently limited. A prior investigation¹³ qualitatively explored the self-care practices among patients with IBD and found that self-care encompassed activities related to symptom recognition (eg, physical sensations such as diarrhoea and bloody stools), symptom management (eg, dietary modifications or medical treatments' utilisation), life planning and exploration of new coping strategies. Similarly, in the context of a recent systematic review,¹⁴ diverse components of self-care were reported in the literature, including symptom management, dietary modifications and exercise. Consistent with our conceptual framework, the process of self-care in the patient-caregiver dyad includes the three dimensions of self-care maintenance, monitoring, and management and the respective contributions to these behaviours by their caregivers. It is not yet known how these three processes influence each other in patients with IBD, but research into other chronic conditions has revealed that at least in patients, self-care maintenance influences self-care

monitoring, which in turn influences self-care management.^{15 16}

Knowledge of the predictors of IBD-SELF patients and the contribution of their caregivers is also scant. However, we know from studies conducted in other chronic diseases that predictors can be referred to the patient, caregiver and the dyad. Consistent with our conceptual framework, patient predictors of self-care and caregiver contribution to self-care include health literacy, inpatient care experience, comorbidity and extraintestinal manifestations, disease severity, therapeutic adherence, sociodemographic characteristics, lifestyle habits (smoking, diet, exercise and sleep) and nurse–patient mutuality.^{12 17–30} Caregiver predictors of self-care and caregiver contribution to self-care include sociodemographic characteristics, health literacy and caregiver burden.^{22 31–34} Finally, the dyadic predictors of self-care and caregiver contribution to self-care include depression, anxiety, stress, dual symptom management, mutuality between patient–caregiver and perceived social support.^{27 35–38} Consistent with previous works,^{12 39–41} we hypothesise that self-efficacy mediates the relationship between the predictors of self-care and the self-care process in the dyad. This variable has been shown to have a positive and significant influence on the daily life of both patients and caregivers in IBD and other conditions.^{33 42}

Patient self-care and caregiver contribution to self-care are associated with positive outcomes for both the dyad members.⁴³ In patients, we hypothesise that self-care reduces disease severity which can be confirmed with lower C reactive protein (CRP) and faecal calprotectin (FCP) levels, reduced clinical and endoscopic disease activity, fewer hospitalisations and use of emergency services, and improvement in illness perception, QoL, and resilience.^{44–48} Our conceptual framework also considers caregiver outcomes such as affirming self, enriching life, and improved QOL and resilience.^{49–52}

Aim

This study aims to investigate and describe patient self-care and caregiver contribution to self-care in the context of IBD. The specific objectives are to (1) describe the levels of patient engagement in self-care maintenance, monitoring and management and the respective contribution of their caregivers to these behaviours; (2) identify patient, caregiver and dyadic predictors of the self-care process and investigate the mediating effects of self-efficacy in these relationships and (3) determine whether patient self-care and caregiver contribution to self-care influence outcomes of both the dyad members; (4) to assess the impact of doctor and nurse involvement on patient–caregiver self-care and overall outcomes in IBD management.

METHODS AND ANALYSIS

Design/methodology

This study will use a multicentre, longitudinal, observational design. The data collection period will extend for 1 year from its start. We will establish an advisory group of five voluntary patients with IBD and caregivers to review and provide feedback on the trial design and questionnaires. A focus group will be used to obtain the patient's and caregiver preferences. Their input will be crucial in refining our approach to better reflect patient and caregiver experiences and priorities.

Pilot testing and questionnaire refinement

We will conduct pilot testing with 10 patients with IBD and caregivers to assess questionnaire manageability and time efficiency. Participants will complete all questionnaires and provide feedback on clarity, relevance and completion time. Based on this feedback, we will refine the questionnaires, clarifying ambiguous questions, removing redundancies and optimising the overall structure. This process aims to improve questionnaire quality and reduce completion time from 45 to 30 min.

Population

Participants will be recruited from nine IBD healthcare units evenly distributed across Italy, with four units in the northern region, two in the central region and three in the southern region.

During outpatient visits, patients and caregivers will be invited to participate and will be explained the aims and procedures of the study. Data collection will begin after verbal and written consent is obtained by each participant.

Eligibility criteria

To be considered eligible for the study patients must be at least 18 years old, have a confirmed diagnosis of IBD, receive care at any of the selected outpatient clinics and consent to participate. Patients who have received an IBD diagnosis in the previous 12 months, have undergone IBD-related surgery within the previous 6 months from the start of the study (surgical treatments relieve symptoms in UC),⁵³ suffer from another severe symptomatic chronic disease and are unable to understand written and spoken Italian will be excluded from the study.

To be eligible, caregivers must be at least 18 years old, recognised by the patient within or outside the family network who provides most of the informal care and willing to participate in the study, together with the respective patient. Any psychiatric disorder and unable to understand written and spoken Italian will preclude participation in the study.

Data collection

The data will be collected during outpatient medical visits at baseline (T0), 6 months (T1) and 12 months (T2). The IBD nurses working in the participating clinics will extend invitations to potential participants during outpatient visits. Patients will be enrolled consecutively



only after approving and signing the participation consent form. During the baseline assessment, participants will have the option to self-complete the questionnaires. Alternatively, if they require clarification on items or other assistance, the research assistants will schedule face-to-face interviews. The follow-up data collection will take place either during their outpatient visits or through telephone calls.

Instruments for measuring the predictors of self-care

Patient and caregiver-related predictors

During the outpatient medical examination, the doctor will assess the following disease scores: the Partial Mayo Score (PMS), the Harvey-Bradshaw Index (HBI) and the Montreal Classification.

The PMS⁵⁴ will be used to assess the severity of UC. This scale consists of a 9-point scale to evaluate stool frequency, rectal bleeding and physician evaluation of disease activity. Each item is rated on a 0–3 scale, with a total score of <2 indicating remission, 2–4 indicating mild activity, 5–7 moderate activity and >7 severe activity.

The HBI⁵⁵ is a five-item clinical index to quickly categorise the severity of CD and detect remissions by considering five parameters (patient well-being, abdominal pain, number of liquid stools per day, abdominal mass and presence of complications). Scores for the individual items are summed, with <5 indicating remission, 5–7 indicating mild activity, 8–16 moderate activity and >16 severe activity.

The Montreal classification⁵⁶ is used for the classification of both CD and UC in terms of age of diagnosis, location and behaviour of the disease for CD and extent and location for UC.

A questionnaire developed ad hoc by the research team will be used to collect sociodemographic and clinical characteristics of the participants. Variables for the patients will include age, gender, marital status, education, job, type of pathology, body mass index, previous hospitalisations and use of emergency care, inpatient care experience, length of stay (measured as the time between hospital admission and discharge), presence or absence of perianal disease and ostomy, type of therapy in progress and previous surgeries. Health determinants such as type of work activity, smoking habits, physical activity, sleep, nutrition and use of supplements will also be collected. The caregiver-related variables, along with sociodemographic factors, include the familial relationship dynamics with the patient, living arrangements, duration of caregiving for the chronic condition and utilisation of services for supporting the patient.

We will also investigate patient-centred variables that explore confidence in self-management, impact on QoL and coping strategies. For caregivers, we will evaluate the impact of the role, perceived support and challenges related to treatment adherence.

The Charlson Comorbidity Index (CCI) will measure the effect of comorbidities,⁵⁷ which consider 19 comorbidities with a score from 1 to 6 that can be assigned based

on disease severity. The total score of the CCI goes from 0 to 36 with a higher score meaning more comorbidities.

The Single-Item Literacy Screener will be used to measure health literacy in patients and caregivers. This instrument is composed of a single question assessing the ability to read health information. The item is formulated on a 5-point Likert scale from 1 (never) to 5 (always), with a score of >2 indicating low HL.^{58 59}

The Morisky Medication Adherence Scale^{60 61} is an eight-item scale, which measures medication adherence. Scores of 8, 6–7 and <6 represent high, medium and low adherence, respectively.

The Nurse-Patient Reciprocity in Chronic Illness (NPM-CI)⁶² is a 20-item scale, which measures the level of patient–nurse mutuality. The total score of the NPM-CI ranges from 20 to 100, with higher scores indicating a higher relationship quality.

The Zarit Burden Inventory^{63 64} is a 22-item questionnaire to assess caregiver burden. The items are formulated on a 5-point Likert scale (0='never', 5='almost always'), with cut-off scores of ≤46, 47–55 and ≥56 indicating the absence of burden, light burden and intense burden, respectively.

Dyad-related predictors

The Depression Anxiety Stress Scales 21^{65 66} is a self-reported questionnaire consisting of 21 items to measure depression, anxiety and stress. Respondents score each item from 0 to 3, and item scores are added together and multiplied by two for each domain to generate three subscale scores. Depression subscale scores correspond to normal population with absence of symptoms (0–9), mild (10–13), moderate (14–20) and severe symptoms (21–27). Anxiety subscale scores correspond to normal population with absence of symptoms (0–7), mild (8–9), moderate (10–14) and severe symptoms (15–19). Similarly, stress subscale scores correspond to normal population with absence of symptoms (0–14), mild (15–18), moderate (19–25) or severe symptoms (26–33).

The Dyadic Care-Types Scale is a two-item scale designed to evaluate patient and caregiver symptom management and their satisfaction with symptom management.⁶⁷

The Mutuality Scale (MS) will be used to measure the quality of the relationship between patient and caregiver.^{68 69} The MS is scored from 0 to 4, with higher scores indicating higher relationship quality.

The Multidimensional Scale of Perceived Social Support^{15 70} is a 12-item tool to measure the source of perceived support from family, friends and significant others. Scores range from 1 to 7, with higher total scores indicating a higher level of perceived social support.

Instruments for measuring the process of self-care in the patient–caregiver dyads

The Self-Care of Chronic Illness Index (SC-CII)^{71 72} will be used to assess the self-care behaviours across the domains of self-care maintenance (seven items), self-care monitoring (five items) and self-care management



(six items). Each item is measured using a 5-point Likert scale (0='never', 5='always'). The three scales use a standardised score from 0 to 100, with higher scores indicating better self-care. The cut-off for 'adequate' self-care is 70.

The Self-care Self-Efficacy Scale (SC-SES)⁷³ will be used to measure the self-efficacy of the patients in performing self-care. This instrument consists of 10 items scored on a 5-point Likert scale (1='not confident', 5='extremely confident'), with higher scores indicating better self-efficacy.

The Caregiver Contribution to Self-care of Chronic Illness Inventory (CC-SCCII)⁷⁴ will be used to measure the caregiver contribution to self-care. This instrument consists of the same items and scale as the SC-CII, except that the wording has been changed to evaluate how often the caregiver recommends the patient to perform self-care behaviours. The score ranges from 0 to 100, with higher scores indicating greater contribution to self-care.

The Caregiver Self-Efficacy in Contributing to Patient Self-Care (CSE-CSC) scale⁷⁵ derived from the SC-SES and is used to measure CSE-CSC. The CSE-CSC includes the same items as the SC-SES.⁷³

Instruments for measuring the outcomes of self-care

Disease Severity will be evaluated according to the clinical indicators of CRP and FCP levels, with biochemical remission considered at CRP ≤ 0.5 mg/dL and FCP level ≤ 250 μ g/g, during the outpatient medical examination.

We will also evaluate endoscopic measures over the last 6 months including the Mayo Endoscopic Score for UC⁷⁶ and the Simple Endoscopic Score for CD (SES-CD).⁷⁷

The Mayo Endoscopic score assesses the severity of UC on the basis of endoscopic exploration (Mayo 0=normal mucosa or healing outcomes, Mayo 1=mild activity, Mayo 2=moderate activity, Mayo 3=serious activity). Endoscopic worsening of the disease will be considered at a Mayo Endoscopic Score of ≥ 1 from baseline.

The SES-CD evaluates the size of mucosal ulcers, ulcerated surface area, endoscopic extent and the presence of strictures. Each item is scored from 0 to 3, with a maximum score of 56. A higher score indicates increased severity, and an endoscopic response is considered when a reduction in SES-CD of $\geq 30\%$ from baseline is seen.

The number of hospital admissions at 6 and 12 months from enrolment will be collected from the sociodemographic and clinical questionnaire.

The Brief-Illness Perception Questionnaire scale^{78 79} will be used to assess cognitive and emotional representations of illness. All items (except the causal question) are rated using a 0–10 point response scale. It considers cognitive illness representation (five items), emotional representations (two items), illness comprehensibility (one item) and the choice of the three main factors that the patient believes contributed to the illness.

The Short Form-12 Questionnaire^{80 81} will be used to measure generic QoL in patients and their caregivers. The 12 items are divided into two domains representing

the physical and mental health components, respectively. Scores are standardised 0–100, with higher points indicating better QoL.

The Connor-Davidson Resiliency Scale (CD-RISC 25)^{82 83} will be used to measure patients' and caregivers' resilience. This 25-item scale examines the five factors of personal competence and tenacity, self-confidence and management of negative emotions, positive acceptance of change and secure relationships, ability to self-control and spiritual influences. A higher score on the CD-RISC 25 indicates greater resilience, with a cut-off of ≥ 35 being considered 'high' resilience.

The nine-item Positive Aspects of Caregiving scale⁸⁴ will be used to measure the positive feelings resulting from caregiver contributions to self-care. This scale consists of nine items, scored from 1 to 5, with higher scores indicating more positive perceptions of the caregiving experience.

Sample size

We will enrol 250 patients with IBD and their caregivers. To ensure an unbiased comparison between patients with UC and CD, we employed a 1:1 randomisation strategy. This method was chosen to balance the sample sizes between the two groups, thereby minimising potential confounding variables and ensuring the comparability of the groups. This sample size will provide a ratio of approximately 10:1 between cases and parameters, which is considered appropriate for structural equation models calculated using maximum likelihood estimation.⁸⁵ Assuming approximately 20 parameters for each model, a total sample of 200 individuals would also be sufficient to obtain a power of 80% and a moderate effect size estimate (0.4), based on the above practical rules.

Statistical analysis

The participants' sociodemographic and clinical characteristics as well as the main study variables will be described using means and SD, or medians and IQRs if there are significant departures from normality distribution. To identify patient and caregiver predictors of the self-care process and determine whether self-efficacy plays a mediating role in these relationships, we will implement a structural equation modelling approach. The indicators of the latent constructs will be aggregated into parcels, and the mediating effects of self-efficacy will be estimated using bias-corrected 95% bootstrapped CIs. Model fit will be judged using traditional goodness of fit indices such as the χ^2 test, root mean squared error of approximation, Comparative Fit Index, Tucker-Lewis index and standardised root mean square residual.⁸⁶ To examine the dyadic predictors of the self-care process and investigate the contemporaneous mediating effect of self-efficacy, we will implement actor-partner interdependence mediation models to account for the interdependence between patient and caregiver variables.⁸⁷ Model fit will be judged with the same fit indices mentioned earlier.



The impact of self-care and caregiver contribution to self-care on health outcomes will be estimated with various approaches, depending on the nature of the outcome. For example, to explore the influence on health services use, we will employ longitudinal negative binomial regressions or longitudinal Poisson regressions, depending on the distribution of event frequency. If the outcome is continuous (eg, QoL), longitudinal multiple regression models will be performed. Finally, in line with a person-centered approach, we will perform latent growth mixture models⁸⁸ to estimate longitudinal latent trajectories of the self-care process, both in patients and their caregivers. The optimal number of latent trajectories will be established according to theoretical and empirical judgement, as well as specific statistical indices (ie, entropy, Akaike information criterion (AIC), Bayesian information criterion (BIC), Lo-Mendell-Rubin (LMR), Bootstrapped Likelihood Ratio Test (BLRT)). In case of missing data, an initial analysis will be conducted to describe its percentage at each baseline and follow-up data.

Statistical significance will be determined with a $p < 0.05$. Data analysis will be conducted by using SPSS (V.26, IBM), JAMOVI software (V.2.5, (Computer Software), retrieved from <https://www.jamovi.org>) and MPLUS V.8.11.⁸⁹

Validity and reliability/rigour

This study will use valid and reliable instruments tested on chronic disease populations. The general characteristics as well as the validity and reliability of each questionnaire are reported in online supplemental file 1. In order to ensure consistency and a unified way of data collection, all the research assistants will be trained in data collection procedures.⁹⁰

DISCUSSION

The general aim of the IBD-SELF study will be to describe the levels of self-care of patients affected by IBD and the relative contribution of their caregivers. This investigation is complemented by the study of the predictors of such dyadic engagement, the exploration of the mediating effects of self-efficacy and determining whether patients' and caregivers' health behaviours influence outcomes of both the dyad members.

To the best of our knowledge, there have been no studies evaluating these aspects among this population. This is surprising, given the detrimental impact of IBD on the QoL of both patients and their caregivers, and the role of the self-care construct as a means to improve health outcomes in this population.⁶ The role of caregivers in IBD is quite unexplored, although it has been increasingly investigated in recent years.⁹¹ Uncovering the relationships between predictors of self-care and the process of self-care in patients and their caregivers has the opportunity to direct specific educational interventions, enabling nurses and other health workers to adapt the interventions at the level of the dyads, and ultimately

modifying potential modifiable risk factors that interfere with the dyadic disease management.

A further novel aspect of this study is the focus on changes in PCR, FCP and endoscopic disease severity in response to different intensities of self-care engagement. In particular, this will allow assessment of how particular aspects of introspective and appropriate disease management influence self-care and how the care outcomes of IBD patients can be improved.³³ The prevalence of IBD is estimated to increase significantly in the coming years and evaluating outcomes such as QoL, resilience, hospital admissions and unplanned visits to urgent care over time will improve planning for clinical activities in healthcare facilities, in turn improving the sustainability of care for patients with IBD.³ Dietary adherence⁹² and habits such as smoking³⁴ have been proven to have significant impact on IBD, and we will investigate the recognition of symptoms related to intestinal preocclusion in patients with CD or severe bleeding from UC compared with colon cancer, perianal disease, management of harmful therapies and vaccinations. Furthermore, considering that IBD are chronic diseases in which patients often experience repetitive psychological stress and reduced self-esteem, as well as exacerbation of physical symptoms, they may be particularly prone to maladaptation. A meta-analysis⁹³ confirmed that intervention programmes had significant effects on patient resilience, indicating that a more systematic intervention programme may improve resilience and perception of the underlying chronicity. Investigating the relationships between stress, anxiety, depression, clinical history (hospitalisations and surgical interventions), clinical scores and patient QoL in relation to self-care will provide new insights. Furthermore, studying self-care in relation to gender differences within the population affected by IBD could lead to investment in targeted educational programmes, as has been demonstrated for other pathologies.⁹⁴ Self-care is related to the engagement of patient and caregiver,⁹⁵ which is a key element of nursing specificity within a treatment path capable of changing and adapting to critical phases of the patient lifecycle. Such adaptation allows a multidisciplinary approach and ensures continuity between hospital and home in a proactive manner. In addition, studying the variables that influence the clinical course of IBD could identify potential educational approaches specifically for high-risk or low-risk patients, enabling proper therapeutic management of new biological drugs as they are introduced. Therefore, new medical therapies could be supported by targeted educational programmes for patients with low levels of self-care and predominantly negative predictive factors, where they may not be indicated otherwise. In this context, investigating the mutualistic relationship between IBD nurses and patients in relation to self-care could inform approaches to improve the skills of these nurses. In addition, understanding the contribution of the caregiver could help to improve the clinical-therapeutic path of patients with IBD.

Limitations and strengths

The study will recruit participants from healthcare settings in Italy; therefore, cultural differences related to other countries will not be captured. The evaluation of data from two points (6–12 months) could cause some scheduled follow-ups to be missed. The analysis of clinical scores requires an outpatient medical visit, which will not always coincide with the timing of the study design. This could lead to further loss of compliance with the questionnaires of both patients and caregivers. A notable strength of the study lies in its longitudinal design, which will ensure the trends of the various constructs over time.

CONCLUSION

Self-care in the context of IBD remains significantly under-researched. Studies focusing on other chronic diseases have strongly demonstrated the potential of investigating this aspect of patient self-care in order to inform targeted interventions by health professionals. The predicted increase in the prevalence of IBD in the coming years is likely to put stress on healthcare systems in terms of managerial and organisational difficulties in treatment paths. As the new insights from this study will be available, professionals and healthcare settings will have the opportunity to increase the involvement of the patient-caregiver dyad in the treatment path. Understanding the role of self-care in symptom management, QoL, daily life and self-efficacy could lead to improvements in educational programmes delivered by IBD healthcare centres.

Acknowledgements The MMAS-8 Scale, content, name and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A licence agreement is available from MMAR, www.moriskyscale.com.

Contributors DN is the chief investigator, wrote the first draft of the article and is the guarantor for the study. DN, EV and AC conceptualised and designed the study. PI and FS have made contributions to data acquisition and interpretation of data. All authors have been involved in drafting the manuscript or revising it critically for important intellectual content, given final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval The study will be conducted in accordance with the requirements of Good Clinical Practice and the Revised Declaration of Helsinki. Written informed consent will be obtained from all participants prior to enrolment. Full oral and written information about the study aims and procedures will be given to participants. The study protocol was reviewed and approved by the Territorial Ethics Committee (Lazio 3) N. 0023486/23.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability

of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iD

Daniele Napolitano <http://orcid.org/0000-0003-2481-5354>

REFERENCES

- Maaser C, Sturm A, Vavricka SR, *et al*. ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 1: initial diagnosis, monitoring of known IBD, detection of complications. *J Crohns Colitis* 2019;13:144–64.
- Piovani D, Danese S, Peyrin-Biroulet L, *et al*. Environmental Risk Factors for Inflammatory Bowel Diseases: an Umbrella Review of Meta-analyses. *Gastroenterology* 2019;157:647–59.
- Kaplan GG, Windsor JW. The four epidemiological stages in the global evolution of inflammatory bowel disease. *Nat Rev Gastroenterol Hepatol* 2021;18:56–66.
- Sturm A, Maaser C, Calabrese E, *et al*. ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 2: IBD scores and general principles and technical aspects. *J Crohns Colitis* 2019;13:273–84.
- Mak WY, Zhao M, Ng SC, *et al*. The epidemiology of inflammatory bowel disease: east meets west. *J Gastroenterol Hepatol* 2020;35:380–9.
- Knowles SR, Graff LA, Wilding H, *et al*. Quality of Life in Inflammatory Bowel Disease: a Systematic Review and Meta-analyses-Part I. *Inflamm Bowel Dis* 2018;24:742–51.
- Rogler G, Singh A, Kavanaugh A, *et al*. Extraintestinal Manifestations of Inflammatory Bowel Disease: current Concepts. *Treat Implic Dis Manag Gastroenterol* 2021;161:1118–32.
- Zand A, Kim BJ, van Deen WK, *et al*. The effects of inflammatory bowel disease on caregivers: significant burden and loss of productivity. *BMC Health Serv Res* 2020;20:556.
- Schulz R, Beach SR, Czaja SJ, *et al*. Family Caregiving for Older Adults. *Annu Rev Psychol* 2020;71:635–59.
- Riegel B, Jaarsma T, Strömberg A. A middle-range theory of self-care of chronic illness. *ANS Adv Nurs Sci* 2012;35:194–204.
- De Maria M, Ausili D, Lorini S, *et al*. Patient Self-Care and Caregiver Contribution to Patient Self-Care of Chronic Conditions: what Is Dyadic and What It Is Not. *V Health* 2022;25:1165–73.
- Lyons KS, Vellone E, Lee CS, *et al*. A Dyadic Approach to Managing Heart Failure With Confidence. *J Cardiovasc Nurs* 2015;30:S64–71.
- Lovén Wickman U, Yngman-Uhlin P, Hjortswang H, *et al*. Self-Care Among Patients With Inflammatory Bowel Disease: an Interview Study. *Gastroenterol Nurs* 2016;39:121–8.
- Iizawa M, Hirose L, Nunotani M, *et al*. A Systematic Review of Self-Management Interventions for Patients with Inflammatory Bowel Disease. *Inflamm Intest Dis* 2023;8:1–12.
- De Maria M, Vellone E, Durante A, *et al*. Psychometric evaluation of the Multidimensional Scale of Perceived Social Support (MSPSS) in people with chronic diseases. *Ann Ist Super Sanita* 2018;54:308–15.
- Vellone E, Fida R, Ghezzi V, *et al*. Patterns of Self-care in Adults With Heart Failure and Their Associations With Sociodemographic and Clinical Characteristics, Quality of Life, and Hospitalizations: a Cluster Analysis. *J Cardiovasc Nurs* 2017;32:180–9.
- Ausili D, Rebora P, Di Mauro S, *et al*. Clinical and socio-demographic determinants of self-care behaviours in patients with heart failure and diabetes mellitus: a multicentre cross-sectional study. *Int J Nurs Stud* 2016;63:18–27.
- Brown BJ. Mutuality in health care: review, concept analysis and ways forward. *J Clin Nurs* 2016;25:1464–75.
- Byron C, Cornally N, Burton A, *et al*. Challenges of living with and managing inflammatory bowel disease: a meta-synthesis of patients' experiences. *J Clin Nurs* 2020;29:305–19.
- Cocchieri A, Riegel B, D'Agostino F, *et al*. Describing self-care in Italian adults with heart failure and identifying determinants of poor self-care. *Eur J Cardiovasc Nurs* 2015;14:126–36.
- de Castro ML, Sanromán L, Martín A, *et al*. Assessing medication adherence in inflammatory bowel diseases. A comparison between a self-administered scale and a pharmacy refill index. *Rev Esp Enferm Dig* 2017;109:542–51.

- 22 Duff W, Haskey N, Potter G, *et al.* Non-pharmacological therapies for inflammatory bowel disease: recommendations for self-care and physician guidance. *World J Gastroenterol* 2018;24:3055–70.
- 23 Kemp K, Dibley L, Chauhan U, *et al.* Second N-ECCO Consensus Statements on the European Nursing Roles in Caring for Patients with Crohn's Disease or Ulcerative Colitis. *J Crohns Colitis* 2018;12:760–76.
- 24 Lenti MV, Selinger CP. Medication non-adherence in adult patients affected by inflammatory bowel disease: a critical review and update of the determining factors, consequences and possible interventions. *Expert Rev Gastroenterol Hepatol* 2017;11:215–26.
- 25 Nejat N, Khan Mohamadi Hezave A, Aghae Pour SM, *et al.* Self-care and related factors in patients with type II diabetes in Iran. *J Diabetes Metab Disord* 2021;20:635–9.
- 26 Sheehan JL, Greene-Higgs L, Swanson L, *et al.* Self-Efficacy and the Impact of Inflammatory Bowel Disease on Patients' Daily Lives. *Clin Transl Gastroenterol* 2023;14:e00577.
- 27 Taft TH, Bedell A, Craven MR, *et al.* Initial Assessment of Post-traumatic Stress in a US Cohort of Inflammatory Bowel Disease Patients. *Inflamm Bowel Dis* 2019;25:1577–85.
- 28 Tinoco J de MVP, Figueiredo L da S, Flores PVP, *et al.* Effectiveness of health education in the self-care and adherence of patients with heart failure: a meta-analysis. *Rev Lat Am Enfermagem* 2021;29:e3389.
- 29 van der Gaag M, Heijmans M, Spoiala C, *et al.* The importance of health literacy for self-management: a scoping review of reviews. *Chronic Illn* 2022;18:234–54.
- 30 Xu Y, Liu T, Jiang Y, *et al.* Psychosocial Adaptation Among Inflammatory Bowel Disease Patients and Associated Factors: a Cross-Sectional Study. *Psychol Res Behav Manag* 2022;15:2157–67.
- 31 Demir Barutcu C. Relationship between Caregiver Health Literacy and Caregiver Burden. *P R Health Sci J* 2019;38:163–9.
- 32 McGilton KS, Vellani S, Yeung L, *et al.* Identifying and understanding the health and social care needs of older adults with multiple chronic conditions and their caregivers: a scoping review. *BMC Geriatr* 2018;18:231.
- 33 Parekh NK, Shah S, McMaster K, *et al.* Effects of caregiver burden on quality of life and coping strategies utilized by caregivers of adult patients with inflammatory bowel disease. *Ann Gastroenterol* 2017;30:89–95.
- 34 Rozich JJ, Holmer A, Singh S. Effect of Lifestyle Factors on Outcomes in Patients With Inflammatory Bowel Diseases. *Am J Gastroenterol* 2020;115:832–40.
- 35 Barberio B, Zamani M, Black CJ, *et al.* Prevalence of symptoms of anxiety and depression in patients with inflammatory bowel disease: a systematic review and meta-analysis. *Lancet Gastroenterol Hepatol* 2021;6:359–70.
- 36 Johnson LE, Lee MJ, Turner-Moore R, *et al.* Systematic Review of Factors Affecting Transition Readiness Skills in Patients with Inflammatory Bowel Disease. *J Crohns Colitis* 2021;15:1049–59.
- 37 Marrie RA, Graff LA, Fisk JD, *et al.* The Relationship Between Symptoms of Depression and Anxiety and Disease Activity in IBD Over Time. *Inflamm Bowel Dis* 2021;27:1285–93.
- 38 Trindade IA, Irons C, Ferreira C, *et al.* The influence of self-criticism on depression symptoms among ambulatory patients with inflammatory bowel disease. *Clin Psychol Psychother* 2019;26:743–50.
- 39 Iovino P, Nolan A, De Maria M, *et al.* 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. *Aging Ment Health* 2023;27:820–8.
- 40 Pereira MG, Costa V, Oliveira D, *et al.* Patients' and Spouses' Contribution Toward Adherence to Self-Care Behaviors in Type 2 Diabetes. *Res Theory Nurs Pract* 2015;29:276–96.
- 41 Song Y, Nam S, Park S, *et al.* The Impact of Social Support on Self-care of Patients With Diabetes: what is the Effect of Diabetes Type? Systematic Review and Meta-analysis. *Diabetes Educ* 2017;43:396–412.
- 42 Thapwong P, Norton C, Rowland E, *et al.* A systematic review of the impact of inflammatory bowel disease (IBD) on family members. *J Clin Nurs* 2023;32:2228–38.
- 43 Iovino P, Lyons KS, De Maria M, *et al.* Patient and caregiver contributions to self-care in multiple chronic conditions: a multilevel modelling analysis. *Int J Nurs Stud* 2021;116:103574.
- 44 Agostini A, Ballotta D, Righi S, *et al.* Stress and brain functional changes in patients with Crohn's disease: a functional magnetic resonance imaging study. *Neurogastroenterol Motil* 2017;29:1–10.
- 45 de Jong MJ, van der Meulen-de Jong AE, Romberg-Camps MJ, *et al.* Telemedicine for management of inflammatory bowel disease (myIBDcoach): a pragmatic, multicentre, randomised controlled trial. *Lancet* 2017;390:959–68.
- 46 Gracie DJ, Williams CJM, Sood R, *et al.* Poor Correlation Between Clinical Disease Activity and Mucosal Inflammation, and the Role of Psychological Comorbidity, in Inflammatory Bowel Disease. *Am J Gastroenterol* 2016;111:541–51.
- 47 Sexton KA, Walker JR, Graff LA, *et al.* Evidence of Bidirectional Associations Between Perceived Stress and Symptom Activity: a Prospective Longitudinal Investigation in Inflammatory Bowel Disease. *Inflamm Bowel Dis* 2017;23:473–83.
- 48 Wintjens DSJ, de Jong MJ, van der Meulen-de Jong AE, *et al.* Novel Perceived Stress and Life Events Precede Flares of Inflammatory Bowel Disease: a Prospective 12-Month Follow-Up Study. *J Crohns Colitis* 2019;13:410–6.
- 49 Jin Y, Bhattarai M, Kuo WC, *et al.* Relationship between resilience and self-care in people with chronic conditions: a systematic review and meta-analysis. *J Clin Nurs* 2023;32:2041–55.
- 50 Sehgal P, Ungaro RC, Foltz C, *et al.* High Levels of Psychological Resilience Associated With Less Disease Activity, Better Quality of Life, and Fewer Surgeries in Inflammatory Bowel Disease. *Inflamm Bowel Dis* 2021;27:791–6.
- 51 Tu W, Xu G, Du S. Structure and content components of self-management interventions that improve health-related quality of life in people with inflammatory bowel disease: a systematic review, meta-analysis and meta-regression. *J Clin Nurs* 2015;24:2695–709.
- 52 van Erp SJH, Brakenhoff LKMP, Vollmann M, *et al.* Illness Perceptions and Outcomes in Patients with Inflammatory Bowel Disease: is Coping a Mediator? *Int J Behav Med* 2017;24:205–14.
- 53 Van Assche G, Dignass A, Bokemeyer B, *et al.* Second European evidence-based consensus on the diagnosis and management of ulcerative colitis Part 3: Special situations. *J Crohn's Colitis* 2013;7:1–33.
- 54 Lewis JD, Chuai S, Nessel L, *et al.* Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. *Inflamm Bowel Dis* 2008;14:1660–6.
- 55 Harvey RF, Bradshaw JM. A simple index of Crohn's-disease activity. *Lancet* 1980;1:514.
- 56 Satsangi J, Silverberg MS, Vermeire S, *et al.* The Montreal classification of inflammatory bowel disease: controversies, consensus, and implications. *Gut* 2006;55:749–53.
- 57 Charlson ME, Pompei P, Ales KL, *et al.* A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.
- 58 Morris NS, MacLean CD, Chew LD, *et al.* The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. *BMC Fam Pract* 2006;7:21.
- 59 Bonaccorsi G, Grazzini M, Pieri L, *et al.* Assessment of Health Literacy and validation of single-item literacy screener (SILS) in a sample of Italian people. *Ann Ist Super Sanita* 2017;53:205–12.
- 60 Morisky DE, Ang A, Krousel-Wood M, *et al.* Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich)* 2008;10:348–54.
- 61 Fabbrini G, Abbruzzese G, Barone P, *et al.* Adherence to anti-Parkinson drug therapy in the 'REASON' sample of Italian patients with Parkinson's disease: the linguistic validation of the Italian version of the 'Morisky Medical Adherence Scale-8 items.' *Neurol Sci* 2013;34:2015–22.
- 62 Cilluffo S, Bassola B, Iovino P, *et al.* Development and validation of two versions of the Nurse-Patient Mutuality in Chronic Illness scale. *J Adv Nurs* 2023;79:3170–82.
- 63 Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *Gerontologist* 1980;20:649–55.
- 64 Chattat R, Cortesi V, Izzicupo F, *et al.* The Italian version of the Zarit Burden interview: a validation study. *Int Psychogeriatr* 2011;23:797–805.
- 65 Lovibond PF, Lovibond SH. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behav Res Ther* 1995;33:335–43.
- 66 Bottesi G, Ghisi M, Altoè G, *et al.* The Italian version of the Depression Anxiety Stress Scales-21: factor structure and psychometric properties on community and clinical samples. *Compr Psychiatry* 2015;60:170–81.
- 67 Buck HG, Kitko L, Hupcey JE. Dyadic heart failure care types: qualitative evidence for a novel typology. *J Cardiovasc Nurs* 2013;28:E37–46.
- 68 Archbold PG, Stewart BJ, Greenlick MR, *et al.* Mutuality and preparedness as predictors of caregiver role strain. *Res Nurs Health* 1990;13:375–84.
- 69 Pucciarelli G, Buck HG, Barbaranelli C, *et al.* Psychometric Characteristics of the Mutuality Scale in Stroke Patients and Caregivers. *Gerontologist* 2016;56:e89–98.

- 70 Zimet GD, Dahlem NW, Zimet SG, *et al.* The Multidimensional Scale of Perceived Social Support. *J Pers Assess* 1988;52:30–41.
- 71 Riegel B, Barbaranelli C, Sethares KA, *et al.* Development and initial testing of the self-care of chronic illness inventory. *J Adv Nurs* 2018;74:2465–76.
- 72 De Maria M, Matarese M, Strömberg A, *et al.* Cross-cultural assessment of the Self-Care of Chronic Illness Inventory: a psychometric evaluation. *Int J Nurs Stud* 2021;116:103422.
- 73 Yu DS-F, De Maria M, Barbaranelli C, *et al.* Cross-cultural applicability of the Self-Care Self-Efficacy Scale in a multi-national study. *J Adv Nurs* 2021;77:681–92.
- 74 Vellone E, Lorini S, Ausili D, *et al.* Psychometric characteristics of the caregiver contribution to self-care of chronic illness inventory. *J Adv Nurs* 2020;76:2434–45.
- 75 De Maria M, Iovino P, Lorini S, *et al.* Development and Psychometric Testing of the Caregiver Self-Efficacy in Contributing to Patient Self-Care Scale. *V Health* 2021;24:1407–15.
- 76 Rutgeerts P, Sandborn WJ, Feagan BG, *et al.* Infliximab for induction and maintenance therapy for ulcerative colitis. *N Engl J Med* 2005;353:2462–76.
- 77 Daperno M, D'Haens G, Van Assche G, *et al.* Development and validation of a new, simplified endoscopic activity score for Crohn's disease: the SES-CD. *Gastrointest Endosc* 2004;60:505–12.
- 78 Broadbent E, Petrie KJ, Main J, *et al.* The brief illness perception questionnaire. *J Psychosom Res* 2006;60:631–7.
- 79 Pain D, Miglioretti M, Angelino E. Sviluppo della versione italiana del brief-ipq (illness perception questionnaire, short version), strumento psicometrico per lo studio delle rappresentazioni di malattia. In: *Psicologia della salute*. 2007.
- 80 Ware J, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220–33.
- 81 Kodraliu G, Mosconi P, Groth N, *et al.* Subjective health status assessment: evaluation of the Italian version of the SF-12 Health Survey. Results from the MiOS Project. *J Epidemiol Biostat* 2001;6:305–16.
- 82 Connor KM, Davidson JRT. Development of a new resilience scale: the Connor-Davidson Resilience Scale (CD-RISC). *Depress Anxiety* 2003;18:76–82.
- 83 DI FABIO A, Palazzeschi L. Connor-davidson resilience scale: proprietà psicometriche della versione italiana. 2012.101–10.
- 84 Siow JYM, Chan A, Østbye T, *et al.* Validity and Reliability of the Positive Aspects of Caregiving (PAC) Scale and Development of Its Shorter Version (S-PAC) Among Family Caregivers of Older Adults. *Gerontol* 2017;57:e75–84.
- 85 Kline RB. *Principles and practice of structural equation modeling*. 2nd edn. New York, NY, US: Guilford Press, 2005.
- 86 Xiong B, Skitmore M, Xia B. A critical review of structural equation modeling applications in construction research. *Autom Constr* 2015;49:59–70.
- 87 Ledermann T, Macho S, Kenny DA. Assessing Mediation in Dyadic Data Using the Actor-Partner Interdependence Model. *Struct Equ Modeling* 2011;18:595–612.
- 88 Jung T, Wickrama KAS. An Introduction to Latent Class Growth Analysis and Growth Mixture Modeling. *Soc & Pers Psych* 2008;2:302–17.
- 89 Muthén B, Muthén L. Mplus: a general latent variable modeling program. In: *Muthén & Muthén. ISO 690*. 2019.
- 90 World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310:2191.
- 91 Mohsenizadeh SM, Manzari ZS, Vosoghina H, *et al.* Family caregivers' burden in inflammatory bowel diseases: An integrative review. *J Educ Health Promot* 2020;9:289.
- 92 Forbes A, Escher J, Hébuterne X, *et al.* ESPEN guideline: clinical nutrition in inflammatory bowel disease. *Clin Nutr* 2017;36:321–47.
- 93 Kim GM, Lim JY, Kim EJ, *et al.* Resilience of patients with chronic diseases: a systematic review. *Health Soc Care Community* 2019;27:797–807.
- 94 Abe R, Sakata Y, Nochioka K, *et al.* Gender differences in prognostic relevance of self-care behaviors on mortality and hospitalization in patients with heart failure - A report from the CHART-2 Study. *J Cardiol* 2019;73:370–8.
- 95 Vellone E, Riegel B, Alvaro R. A Situation-Specific Theory of Caregiver Contributions to Heart Failure Self-care. *J Cardiovasc Nurs* 2019;34:166–73.