

Clinical application of the “Perrotta-Guerrieri Psychological Care for Ostomy Patients” (PCOP) protocol and integrated questionnaire on adult ostomy patients

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Abstract

Background. Much attention is paid in the literature to the psychological profiles associated with ostomies, but until 2022 there was a lack of a psychoclinic instrument that was able to investigate all 9 individual subjective functions possibly impaired by the ostomate condition and the degree of impairment. For this reason, "Perrotta-Guerrieri Psychological Care for Ostomy Patients" (PCOP) was developed for all clinical phases, in 45 items with an L1-5 response scale, for the study of quality of life in the ostomized patient, which was also able to offer from the therapist a holistic understanding of the problem in all its phases (pre-operative, operative, postoperative, follow-up), integrating a patient-specific clinical intervention protocol.

Materials and Methods. Clinical interview and battery of psychometric questionnaires. Results. Of 58 patients (M: 57.3 years), divided into two groups (CG and Cg) of equal distribution, the group in which the protocol was applied (CG) achieved quantifiable benefits to the extent of 50-75% individually and 97% in the total group.

Conclusions. PCOP is a psychoclinical tool that can offer therapists the opportunity to explore the issue of patient quality of life and best focus on the most appropriate and targeted clinical intervention.

Key words: colostomy; quality of life; body image after surgery; ostomy; altered body image; impact of ostomy; Ileostomy; Urostomy; pcop; perrotta-guerrieri psychological care for ostomy patients

Abbreviations

Perrotta-Guerrieri Psychological Care for Ostomy Patients (PCOP). Perrotta-Guerrieri Psychological Care for Ostomy Patients Model (PCOP-M). Perrotta-Guerrieri Psychological Care for Ostomy Patients Questionnaire (PCOP-Q1).

Introduction

The term "ostomy" means "opening" and denotes the result of a surgical procedure that involves attaching a section of the intestines or urinary tract to the skin, thus allowing organic material (feces and urine) to leak outward. The placement involves a substantial change in the person's body plan and fecal and urinary elimination function, involving not only his or her physical integrity but also, more importantly, his or her psychological integrity; therefore, the role of the psychologist should be central in all phases of the health care intervention (preoperative, operative, postoperative, and follow-up). [1-4]

There are several criteria for classifying ostomies, based on packaging, duration, structure, and motivation [5-8]; based on the geographic region of location, for simplicity, they are distinguished into ileostomies [9-11], colostomies [9, 12], and urostomies [9, 13-14]

In the literature, special attention is given to psychological profiles, as ostomy can significantly impair all dimensions of quality of life (physical, psychological, social, economic, and spiritual) in individuals who have not been adequately prepared for the change or who suffer from one or more complications during the grafting and healing phase, or who do not reach a degree of maturity of acceptance of their health condition. Ostomy patients are subject to significant negative psychological impacts, affecting their quality of life in all aspects (physical, psychological, social, economic, and spiritual), especially if they are not properly constructed or if there are complications during the recovery phase. Placing the focus only on managing the physical dimension will hardly allow the person to integrate the ostomy into his or her life. [15-37]

The concept of "quality of life" is therefore central to applied psychology. According to the definition provided by WHO in 1998, it should be understood as "the total of the subjective perceptions that individuals have of their place in life about the cultural context and value system in which they live and about their own goals, standards and interests". Quality of life is thus seen as a multidimensional concept that includes positive and negative perceptions concerning physical, emotional, social, cognitive and spiritual dimensions. Because of this importance, clinical attention in the field of psychology is particularly focused on clinical intervention to restore the patient's quality of life if he or she perceives it to have deteriorated. [38-65] For this reason, there are questionnaires in the literature that address this profile, and among the most cited are the Health-Related Quality of Life Self-Assessment Test (HRQOL), the Short Form Health Survey (SF-36), the WHO Quality of Life (WHOQOL), and the Stoma-Qol. [66] but none of these are able to investigate in a single psychometric instrument all 9 individual subjective functions possibly impaired by the stoma condition as does the "Perrotta-Guerrieri Psychological Care for Ostomy Patients" (PCOP), developed in 2022. [67] Based on this publication, the experiment depicted here was developed.

2. Objectives

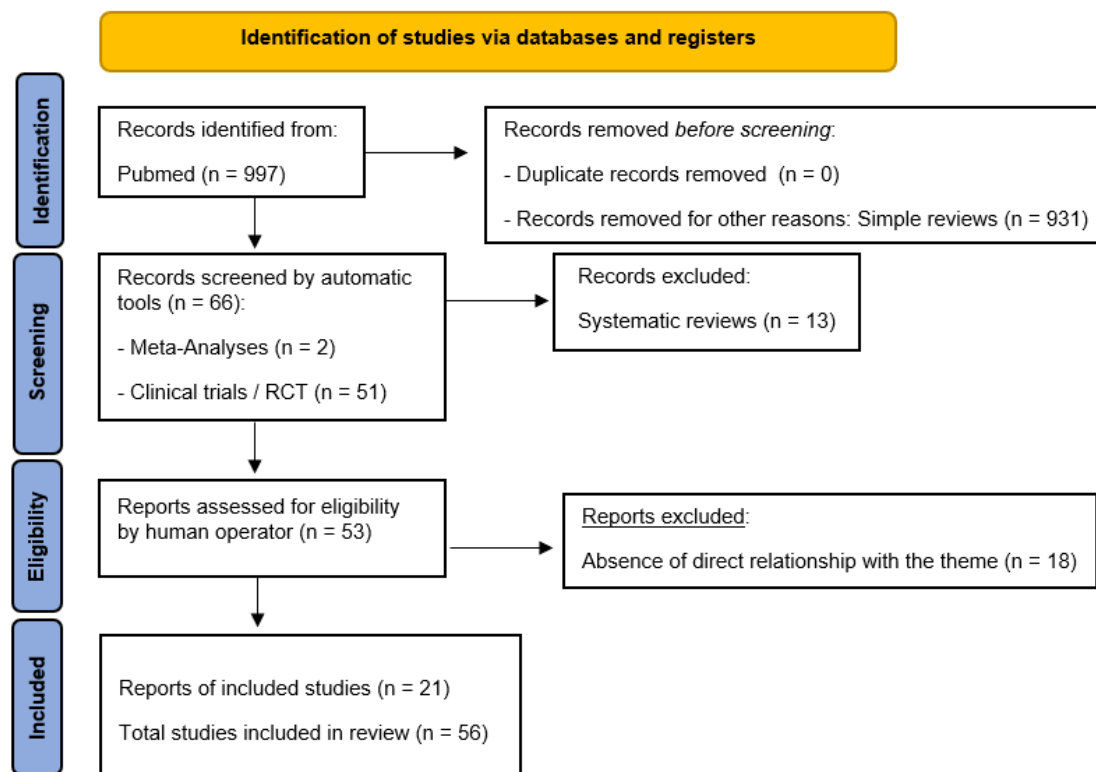
The main objective of the research, based on the results of the literature

and this study, is to demonstrate the clinical utility of PCOP, on the participants of the selected population sample and to try to answer the following profiles: 1) ontological, i.e., whether the reality under investigation exists objectively (and thus whether it is possible to determine the clinical utility of the protocol); 2) epistemological, i.e., whether the reality under investigation is knowable (and whether it is possible to determine the degree to which the patient's quality of life is impaired by applying the questionnaire attached to the protocol) 3) methodological, i.e., whether the reality under consideration is measurable (and whether it is possible to graduate the intervention based on the level of impairment); 4) axiological, i.e., whether the reality under consideration is worthy of study (and thus whether, through the protocol, the structured clinical intervention has greater effectiveness than other approaches).

3. Materials and methods

With a specific search on Pubmed, using the terminological indicators of "ostomy" and "psychology," 56 useful results were selected. No limit was placed on the year of publication, until the completion date of the study (January 2024). [Figure 1]

Figure 1. PRISMA flow diagram template. Matthew J Page et al. BMJ 2021; 372:bmj.n71.



The protocol of integrated psychological intervention for ostomate patients (PCOP) provides a specific active procedure consisting of actions aimed at the patient's intake, management, and clinical care; based on the phase in which the intake takes place (preoperative, operative, postoperative or follow-up), the protocol establishes precise clinical actions using the strategic approach in patient care and establishes certain psychometric tools to support the therapist and a precise schedule of therapeutic sessions, with techniques and strategies that also draw from cognitive-behavioral, constructivist, psychodynamic and humanistic approaches. [67]

<<A structured questionnaire (PCOP-Q1) was integrated into the protocol in 3 sections: A, where to enter the patient's biographical and contact data; B, where to enter clinical data related to the ostomy (sex, diagnosis and duration/type/gestion of ostomy); C, which is devoted to the clinical questionnaire structured in 45 items on a L1-5 scale for the study of the quality of life of the stoma patient. Specifically, about section C in particular, the patient must answer all questions, indicating for each one a single definite answer with a numerical value from 1 (never) to 5 (always), referring to the reference question in the current time. The questionnaire cannot be administered again unless at least 60 days have passed since the previous administration. The questions are distributed

according to 9 areas of specific interest: I) Physical functioning (items 1-5): this is the section related to physical limitations, pain and sleep-wake well-being. II) Psychological functioning (items 6-10): this is the section related to psychological well-being and the relationship with oneself. III) Emotional functioning (items 11-15): this is the section related to emotional well-being, energy, vitality strength of spirit, resilience and perceived quality of life. IV) Sexual functioning (items 16-20): is the section related to sexual well-being and relationships with self and others. V) Relational-affective functioning (items 21-25): this is the section related to relational well-being, about friends and friendships. VI) Relational-familial functioning (items 26-30): this is the section relating to relational well-being, about the ties with relatives and relatives-in-law. VII) Sentimental-relational functioning (items 31-35): this is the section relating to relational well-being, about sentimental ties (partners and concubines). VIII) Relational work or school functioning (items 36-40): this is the section on relational well-being, about work or school ties, about work or school ties. IX) Relational-social functioning (items 41-45): this is the section related to relational well-being, about social and community ties (e.g. social activities, volunteering, conferences, congresses, seminars, public events). Each specific area of interest has a maximum score of 25, for a total score of 225>>. [67]

The method consists of applying the PCOP protocol, and using the PCOP-Q1 questionnaire, according to the patient's clinical stage, then comparing it with the group of patients who did not utilise the protocol. The phases of the research were divided as follows: 1) selection of the population sample, according to the parameters indicated in the following paragraph; 2) clinical interview, with each population group and protocol application; 3) administration of the psychometric tests; 4) PCOP-Q1

administration, 2 weeks after ostomy surgery and re-administration after the continuous cycle of psychotherapeutic sessions.; 5) data processing following administration and comparison of data obtained.

4. Setting and participants

Inclusion criteria for the first clinical group (CG) are: 1) age between 21 and 70 years; 2) defined sexual gender (male/female) and of Italian nationality; 3) need for definitive ostomy implantation, for clinical reasons; 4) declaration of submission to the PCOP protocol, following surgical pathway in a health care facility in the Italian System; and 5) absence of psychopathological diagnosis or known neurological and neurodegenerative disorders at the time of study participation. Exclusion criteria for the clinical group (CG) are: 1) age less than 21 years and older than 70 years; 2) undefined sexual gender (transsexual and nonbinary) or nationality other than Italian; 3) need for non-definitive ostomy implantation, for clinical reasons; 4) declaration of non-submission to the PCOP protocol; 5) presence of psychopathological diagnoses or known neurological and neurodegenerative disorders at the time of study participation, of at least one of the two partners.

The selected setting, taking into account the protracted pandemic period, is the online platform via Skype and Video call WhatsApp, both for the clinical interview and for the administration. The present research work was carried out from September 2021 to January 2024.

The selected first population clinical sample (CG), which meets the requirements, is 29 participants, divided into 6 subgroups [Table 1]:

Age	Male	Female	Total
21-30	1	1	2
31-40	3	3	6
41-50	4	5	9
51-60	4	3	7
61-70	2	3	5
Total	14 (48%)	15 (52%)	29 (100%)

Table 1: Population sample (numerousness) - CG.

The selected first population clinical sample (CG), which meets the requirements, is 29 participants, divided into 6 subgroups [Table 2]:

Age	Male	Female	Total
21-30	1	2	3
31-40	3	2	5
41-50	3	5	8
51-60	5	5	10
61-70	2	1	3
Total	14 (48%)	15 (52%)	29 (100%)

The total population sample is 58 participants (M: 57.3 years).

Table 2: Population sample (numerousness) - Cg.

5. Results

After the selection of the chosen population sample (first phase), we proceeded with the clinical interviews (second phase), from which the first significant data emerged:

1. The total population sample (58 participants) is divided into 2 groups, further divided into 5 equally distributed subgroups to facilitate statistical analysis.
2. Subjects underwent the PICI-3 [69] to check for the absence of psychopathological conditions, but the test confirmed that 38% (22/58) of the total sample (36% in the CG group and 64% in the Cg group) had at least 5 dysfunctional personality traits. Specifically:

- a) 8/22 (36%) patients were identified in the CG group, of whom 6/8 (75%) were from the neurotic cluster and 2/8 (25%) were from the dramatic cluster;
 - b) 14/22 (64%) patients were identified in the CG group, of which 11/14 (79%) were from the neurotic cluster and 3/14 (21%) were from the dramatic cluster.
3. Using, during the interview, strategic language and PHEM-2 [68], the entirety of the selected population sample, in both the first and second clinical groups, show a complete distress orientation, facilitating feelings such as anger, frustration, fear, and disappointment, in the presence of stressogenic events typical of their clinical condition.

4. administration of the Perrotta Individual Sexual Matrix Questionnaire (PSM-Q) [70] found 94.8% positive in the overall sample (55/58) for behavioral dysfunction related to intra-relational (couple's) sexual management following ostomy surgery.

The next phases of the research focused on the administration of PCOP-Q1 and the application of PCOP protocol steps. In particular [Tables 3-4]:

- a) data obtained from the administration of the PCOP-Q1 questionnaire before the course of psychotherapeutic sessions under the protocol and 2 weeks after ostomy surgery showed that the level of quality of life is significantly impaired (with minimum-maximum scores of 156-210);

- b) data obtained from the administration of the protocol confirm an excellent rate of adherence to prescriptions (66/68 patients, 97%) and a good response rate to psychotherapy (54/68 patients, 79%);
- c) data obtained from the re-administration of the PCOP-Q1 questionnaire, after the cycle of psychotherapeutic sessions under the protocol, showed that the previously most impaired level of quality of life had now become more tolerable (with minimum-maximum scores of 46-130), with a range of improvement over the previous administration from 50% to 75%, and an extremely positive response in follow-up with an almost total adherence rate to prescriptions (67/68 patients, 98%) and an excellent response rate to psychotherapy (66/68 patients, 97%).

<u>Test</u>	<u>CG</u>	<u>Cg</u>	<u>Δ CG/Cg</u>	<u>M+DS</u>	<u>P</u>
<i>PCOP-Q1 (before)</i>	100%	100%	0%	CG = 177.6±21.1 Cg = 178.3±20.8	< 0.001
<i>PCOP-Q1 (after)</i>	100%	100%	0%	CG = 83.1±16.3 Cg = 95.6±16.7	< 0.001

Table 3: S.P.S.S., T-test for tests and CG/Cg differential (descriptive)

<u>Test</u>	<u>Groups</u>	<u>CG (n/%)</u>	<u>Cg (n/%)</u>	<u>P</u>
<i>PCOP-Q1</i>	1 (21-30 y)	2 (6.9%)	3 (10.3%)	< 0.001
	2 (31-40 y)	6 (20.7%)	5 (17.2%)	< 0.001
	3 (41-50 y)	9 (31.1%)	8 (27.7%)	< 0.001
	4 (51-60 y)	7 (24.1%)	10 (34.5%)	< 0.001
	5 (61-70 y)	5 (17.2%)	3 (10.3%)	< 0.001

Table 4: S.P.S.S., T-test for tests and groups.

6. Discussions and limits

The present study showed that with the use of the PCOP protocol and the PCOP-Q1 questionnaire, it is possible to improve the focus on the emotional and interpersonal problems of ostomate patients, centering therapeutic goals and fostering a more humanistic approach.

In the first clinical group (CG), those who scored greater than 50% of the total on the PCOP-Q1 in the first administration were 68/68 (100%); this figure is quite alarming, as it suggests that the psychological preparedness of these patients is severely inadequate and that an instructional plan needs to be put in place for patients before they can face the consequence of surgery. After the course of psychotherapeutic sessions, according to the protocol, data from the re-administration of the questionnaire showed a marked improvement in the psychological approach to ostomy persistence, but the data still show that early intervention could have brought greater benefits. The same argument should be made for the second clinical group (Cg), which has the same peculiarities, with markedly greater subjective data and therefore more alarming.

The use of the PCOP protocol and the PCOP-Q1 questionnaire is strongly recommended in the clinical setting, as their technical input concretely helps the therapist [71-72] in fostering the effectiveness of psychotherapeutic intervention and patients in improving their degree of acceptance by improving their quality of life.

The present study, however, has both structural and functional limitations that, in the opinion of the writer, do not affect the quality of the results obtained, but should be taken into consideration for future research to avoid analytical bias. Structurally, the design of the study involves the use of an unvalidated questionnaire, as there is no questionnaire in the literature capable of investigating all the areas (9 in total) studied by the PCOP-Q1; it was felt, therefore, that it could not be validated in the absence of a questionnaire capable of guaranteeing the correct comparisons, however, in the psychotherapeutic sessions provided by the protocol, as demonstrated in this study, it has demonstrated all its efficiency and effectiveness as a tool. Functionally, the study recruited 58 adult subjects who were permanently ostomized, and recruitment followed the inclusion and exclusion criteria, but there may be a selection bias related to the fact that the physical and mechanical characteristics of the ostomies were not taken into account; however, this bias was ruled out by the investigator who felt for this study not to consider these variables because the number of participants was too small to investigate this aspect in depth.

In the future, therefore, we will try to investigate the technical features even further, introducing in detail the issue of the validation process of the questionnaire used.

7. Conclusions

In conclusion, Perrotta-Guerrieri Psychological Care for Ostomy Patients" (PCOP) protocol and the integrated questionnaire (PCOP-Q1)

can be considered tools that facilitate the process of acceptance of the adult ostomy patient on a definitive basis, helping the therapist to center the psychotherapeutic intervention strategically. However, these tools cannot be considered exclusive but rather must be complementary to the early educational and training intervention to be offered to the patient to help him or her in the difficult process of psychophysical healing.

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Ethics statement: All participants were assured of compliance with the ethical requirements of the Charter of Human Rights, the Declaration of Helsinki in its most up-to-date version, the Oviedo Convention, the guidelines of the National Bioethics Committee, the standards of "Good Clinical Practice" (GCP) in the most recent version, the national and international codes of ethics of reference, as well as the fundamental principles of state law and international laws according to the updated guidelines on observation studies and clinical trial studies.

Informed Consent Statement: Subjects who gave regular informed consent agreements were recruited; moreover, these subjects requested and obtained from GP, as the sole examiner and project manager, not to meet the other study collaborators, thus remaining completely anonymous.

Data Availability Statement: The subjects who participated in the study requested and obtained that GP be the sole examiner during the therapeutic sessions and that all other authors be aware of the participant's data in an exclusively anonymous form.

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Conflicts of Interest: The authors declare no conflicts of interest.

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