

Research paper

Development of a patient-administered self-assessment tool (SATp) for follow-up of colorectal cancer patients in general practice

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ABSTRACT

Background: Treatment for colorectal cancer (CRC) may result in physical, social, and psychological needs that affect patients' quality of life post-treatment. A comprehensive assessment should be conducted to identify these needs in CRC patients post treatment, however, there is a lack of tools and processes available in general practice.

Aims: This study aimed to develop a patient-completed needs screening tool that identifies potentially unmet physical, psychological, and social needs in CRC and facilitates consultation with a general practitioner (GP) to address these needs.

Methods: The development of the self-assessment tool for patients (SATp) included a review of the literature; face and content validity with reference to an expert panel; psychometric testing including readability, internal consistency, and test–

retest reliability; and usability in clinical practice.

Results: The SATp contains 25 questions. The tool had internal consistency (Cronbach's alpha 0.70–0.97), readability (reading ease 82.5%), and test–retest reliability (kappa 0.689–1.000). A total of 66 patients piloted the SATp. Participants were on average 69.2 (SD 9.9) years old and had a median follow-up period of 26.7 months. The SATp identified a total of 547 needs (median 7 needs/patient; IQR [3–12.25]). Needs were categorised into social (175[32%]), psychological (175[32%]), and physical (197[36%]) domains.

Conclusion: SATp is a reliable self-assessment tool useful for identifying CRC patient needs. Further testing of this tool for validity and usability is underway.

Keywords: colorectal cancer, needs assessment, tool development, follow-up care, patient unmet needs

Summary Statement

What do we know?

- Treatment for CRC results in long-term side effects.
- Assessment of CRC-related needs and side effects is important in determining ongoing care for CRC patients.
- Available needs assessment tools are not relevant to specifically capture long-term CRC side effects.

There is no documented CRC needs assessment tool used in general practice for assessing long-term side effects of treatment.

What does this paper add?

- This paper reports the development of a reliable and valid needs assessment tool that is specific for CRC and long-term side effects of its treatment.

Background

Treatment for CRC is associated physical, social, and psychological side effects that affect patients' quality of life many years after completing treatment. Although acute side effects diminish after treatment completion some symptoms persist for years including fatigue, sleep difficulty, fear of recurrence, anxiety, depression, negative body image, activity limitation, sensory neuropathy, gastrointestinal problems, urinary complications, and sexual dysfunction.^{1,2}

There is evidence that these symptoms are not always identified during a routine doctor–patient consultation. The reasons for non-identification include patients' reluctance to initiate a discussion about the needs and health professionals' failure to prompt about these needs during a clinical consultation.³ Consequently, issues may go unchecked or result in delayed diagnosis and/or treatment.

Regular assessment of CRC-related needs and side-effects has recently received attention as being important in the ongoing management of patients.⁴ Assessing and attending to needs is an important step towards patient-centred care as a failure to manage these needs appropriately can lead to poor quality of life.⁵ A standardised screening tool that identifies physical, psychological, and social issues could facilitate consultation between patients and health professionals to address these needs.⁶

To date, relatively few needs assessment tools have been developed with a focus on long-term side effects. Such tools need to be designed for use in a general practice setting where most of the oncology patients receive ongoing treatment for other chronic illnesses.

Many instruments assessing physical and psychosocial side effects of cancer treatment are available, which include Supportive Care Needs Survey (SCNS), EORTC PR29, Supportive Needs Screening Tool (SNST), and Cancer Survivors' Unmet Needs measure (CaSUN).^{3,5,7,8} Some items measured by these questionnaires are relevant, but others are not specific to CRC. Cancer patients' needs vary depending on the type of cancer and the clinical/pathological stage of disease. For example, the needs of stage IV cancer patients differ greatly from those with stages I–III.^{2,5} Moreover, these tools have not been integrated into primary care practice.

This article reports the development of patient-administered needs assessment instrument to guide CRC patients to identify their needs and, where appropriate, consult with their GP.

The specific objectives of the current study were to develop a patient-completed needs screening tool that:

1. Screens the unmet needs of CRC patients,
2. Identifies potentially unmet physical, psychological and social needs,
3. Is valid and reliable.

Structural framework

The structure of this tool is based on a framework by Pigott et al. and Bonevski et al. which suggests a seven criteria should be used to determine the effectiveness of needs screening tools in cancer follow-up care.^{3,7}

The self-assessment tool for patients (SATp) has several properties: (1) contains integrated physical, psychological, and social aspects to measure multiple domains of CRC care; these domains have also been adopted by Jiwa et al.⁹ in a needs assessment for breast cancer patients; (2) uses a self-reporting approach to facilitate direct and comprehensive assessment of subjective health needs; (3) measures the needs within a defined temporal context—questions relate to needs experienced in the previous 4 weeks. As advocated by the Pigott et al. study, the timeframes used should be useful for clinicians to develop a clear understanding of patients' needs; (4) demonstrates validity and reliability through expert review, test–retest and pilot testing to provide a sound basis for comparison; (5) embraces a user-friendly response framework—yes/no responses to simplify the questions for the patient and prompts the clinician to probe further; (6) contains only 25 items and is 'systemfriendly' by minimising patient and staff time to complete and review, respectively; and (7) provides an opportunity for the clinician to link patients to services—this tool is meant to be a guide to consultation, to assist in a thorough exploration of possible issues or problems.³

Materials and methods.

The construction of the SATp was based on a review of CRC survivorship literature and subjected to a series of validations. The items included focused on long-term issues experienced by patients offered treatment with curative intent (stages I–III). The needs of those with stage IV CRC are entirely different, in most cases they are palliative, and thus were not included.⁵

Item generation

A systematic search was performed using PubMed/Medline, CINAHL, and Cochrane Online Library (reviews and trials) databases from 1980 to 2014. Search terms were used either singularly or in combination in the index lists of the relevant databases. The search terms used were 'lower bowel cancer', 'rectal cancer', 'colon cancer', 'effects of treatment', 'effects of adjuvant therapy', 'effects of surgery', 'follow-up care', 'survivorship care', 'quality of life', and 'patient unmet needs'. Free text words were used to supplement the medical subject heading (MeSH) search terms in the case of Medline.

The reviews focused on long-term effects of CRC treatment and their prevalence. Titles and abstracts of 650 references were reviewed and 69 studies satisfied the following inclusion criteria Figure 1

- (1) Published in English
- (2) Reported empirical research

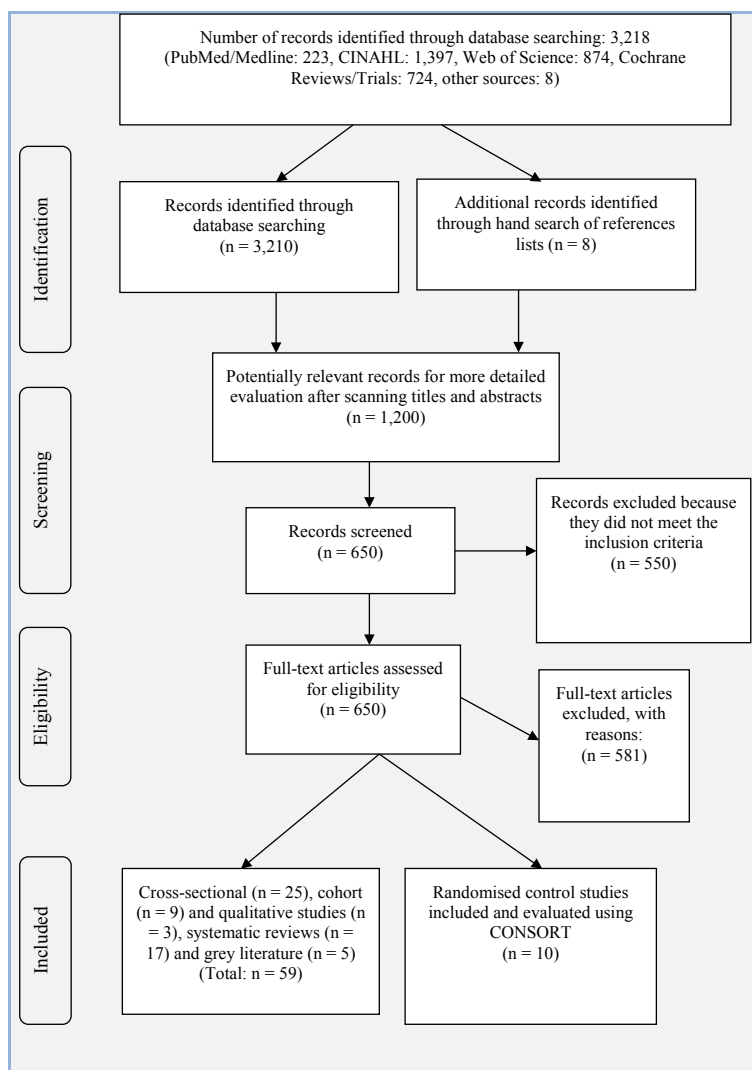


Figure 1: Flowchart of the Methods used to identify evidence relevant to this study.

- (3) Reported on epidemiology of CRC
- (4) Focused on developing a symptoms/needs assessment questionnaire for patients post cancer treatment, in particular, CRC
- (5) Reported side effects of CRC treatment
- (6) Focused on patients' quality of life after CRC treatment

From the 69 reviewed papers, 340 needs were extracted. Duplicates were removed yielding 100 items. These items were then assessed for face validity by a team of three clinicians (medical doctor, public health specialist, and nurse). Unclear items and those with similar meanings were identified and removed leaving problems/issues considered common one year or more after treatment completion. Thirty-two problems were grouped into three domains: psychological (n=6), physical (n=20), and social (n=6) Figure 2 as advocated by Pigott et al. and Jiwa et al.^{3,9}

Item reduction

The 32 identified items were further reduced through modelling for frequencies based on published prevalence of the side effects. Any items that had a frequency of ≤ 5 were removed as this was deemed as uncommon by the expert panel. The modelling was based on a typical cohort of 100 patients

with CRC.

From the reviewed articles, the epidemiology of CRC suggests that approximately 70% of cases are located in the colon and 30% in the rectum.¹⁰ As shown in Figure 3, 50% of patients with colon cancer are likely to be in stage II or III at diagnosis but rectal cancer cases are evenly spread across all stages.^{20,21}

For stages I–III CRC, nearly all patients (98%) undergo surgery, but treatment with chemotherapy and radiotherapy depends on the location (colon or rectum) and the stage. For colon cancer, the majority (75.5%) of stage III patients get chemotherapy, while for stages I and II percentages are lower as there is no general agreement on its use in these patients.^{22–24} Approximately 19.6% of patients are offered chemotherapy in stage I and 20–24% in stage II.^{25,26} Radiotherapy has a limited role in the treatment of colon cancer, but for rectal cancer patients it may be offered at all stages: stage I, 19.6%; stage II, 36%; and stage III, 57%.^{22,25,26}

Furthermore, literature suggests that patients may have treatment side effects in the physical, psychological, and social domains.^{1,27,28} The prevalence of the published side effects under these domains have been summarised in Figure 3. Most side

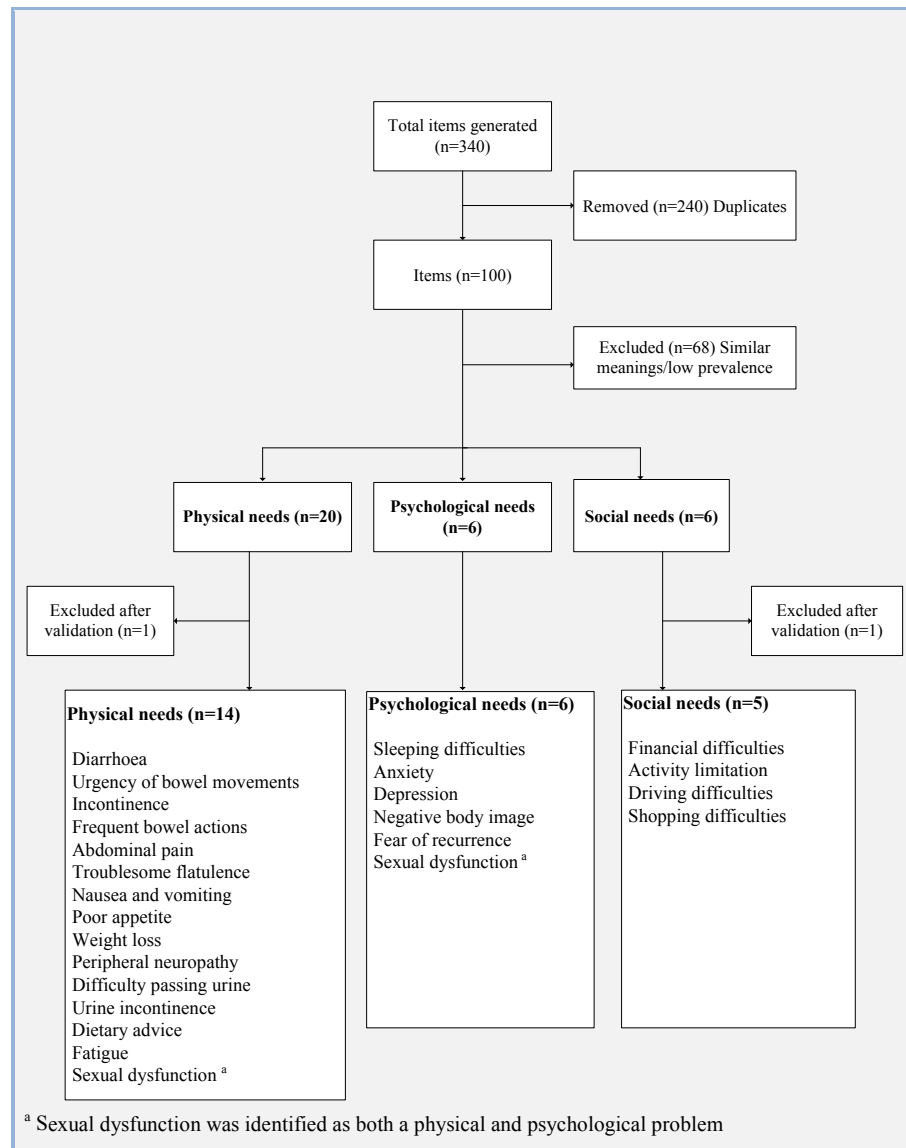


Figure 2: Process of item generation/reduction/validation.

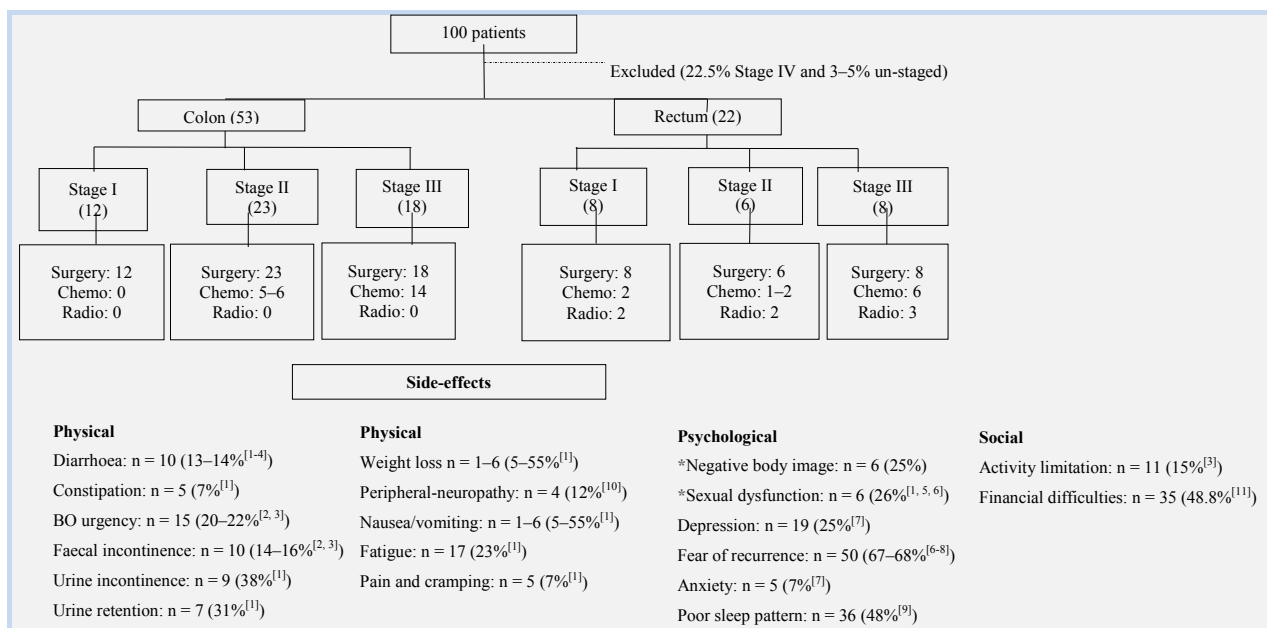


Figure 3: Distribution of side-effects based on a cohort of 100 people with CRC.

effects in the physical domain include bowel (7–20%), urinary (31–38%), and sexual dysfunction (26%).^{1,2,11,12,15,17} Long-term psychological issues commonly reported are fear of recurrence (67–68%) followed by depression (25%).^{1,15–17} For social problems, the greatest burden is financial difficulties (~50%) followed by activity limitation (15%).^{9,21}

Based on these statistics, it is anticipated that in a sample of 100 stage I–III CRC patients (excluding 22.5% stage IV and 3–5% unstaged CRC) with typical epidemiology as above, 53 will have colon cancer and 22 will have rectal cancer. Of these, 75 patients will receive surgery, 36 will be offered chemotherapy, and 11 will be offered radiotherapy Figure 3.

Further modelling of this group to illustrate the frequency of treatment effects in the cohort, shows that five to ten patients will have some form of bowel dysfunction. It is anticipated that about seven to nine patients with rectal cancer (a cohort of 23 patients) who have had surgery and radiotherapy will report urological dysfunction. From this cohort, four patients offered chemotherapy will experience some form of peripheral neuropathy and at least one to six patients will experience nausea, vomiting, and weight loss related to chronic radiation enteritis.¹ Six rectal cancer patients will experience some form of sexual dysfunction.

The extent of psychological and social factors experienced by the whole cohort (colon and rectal) will be high. Nearly 50 patients will suffer some form of psychosocial problem. For example, about 50 patients will have fear of recurrence Figure 3.

Based on the modelling, items with fewer than five patients in the cohort were removed from the list. Two items (fractures and dysuria) were excluded. The results of cohort modelling identified 26 items. These items were used to formulate initial SATp questions, which were further subjected to a series of validation and testing.

Content validity

Content was tested through a Delphi technique ('a method for the systematic solicitation and collation of judgements on a particular topic through a set of carefully designed questionnaires interspersed with summarised information and feedback of opinions derived from earlier responses' - pg. 606).²⁹

Seven health professionals—surgeon, radiation oncologist, medical oncologist, clinical nurse specialist, psychologist, occupational therapist, and dietician—were invited to join a Delphi panel. They were asked to rate the level of importance of each question based on evidence and list other questions they considered important in detecting ongoing or new problems in CRC patients during follow-up period.

Average scores for these items were calculated and sent back to the panellists to rate their level of agreement with these counts. Coordination of the expert suggestions (each Delphi) was performed by the researcher until a consensus on the questions was reached. This list of items was also sent to a group of six patients who had completed CRC treatment to rate the importance of raising these issues with their doctor. Average scores were generated and returned to the patients to rate their level of agreement with the count.

The 26 questions were rated on a Likert scale by a panel of

health professionals and patients and 90% had total scores >3 out of a maximum score of 5. Scores ≥ 3 were regarded by the panel as indicating high relevance. One physical item (constipation) and one social need (information need) having a score of 2 were removed from the list. Four other questions were combined into two as they tested the same issue (sexual dysfunction for males and females, and frequent bowel movements during night and day) (Figure 2). An additional two items suggested by the panel (dietary advice and troublesome flatulence) were added to the list. In total, 25 questions were included in the SATp questionnaire Figure 2.

Readability

This list of questions was subjected to Flesch–Kincaid readability test for functions of the number of characters, syllables, words, or sentences in a text sample (this test has been used extensively to measure the readability of health information).³⁰ This ensured that the tool could easily be understood by high school graduates—the minimum level of compulsory school education in Australia.

A grade of 4.4 reading level was attained (acceptable range, grades 4–6) and reading ease was 82.5% (maximum reading ease is 100%; the higher the number, the easier it is for participants to read). On average, SATp takes approximately 5 minutes to be completed.

Data analysis

Statistical analysis of SATp was conducted using SPSS version 19.³¹ The kappa coefficient was used to examine test–retest reliability at the item level and Cronbach's alpha was computed to assess internal consistency. Delphi results of the panellist score were computed and average scores calculated. Items with an average score of <3 out of 5 for healthcare workers and patients were excluded from the list. Descriptive statistics were used to summarise patients' demographics, clinical characteristics, and needs identified by SATp.

Sample and study setting

Participants aged ≥ 18 years, who had been offered treatment with curative intent (stages I–III), had completed CRC treatment, and had been followed up for at least one year in the outpatient cancer clinic were eligible for inclusion in this study.

Eligible participants were asked to sign the consent form and nominate their GP. Once the completed consent form was received, they were sent a copy of the SATp, which they were expected to complete.

A protocol of reminder telephone calls and letters was followed to enhance study compliance. The study was approved by the relevant human research ethics committees from the participating hospital and university (QI3041 and HR 42/2012, respectively).

Pre-test

Test–retest reliability was assessed by administering the tool to a subset of participants who agreed to fill out the questionnaire on two occasions, approximately 2 weeks apart. The questionnaire was sent to 30 participants and then re-sent 14 days later.

The kappa statistic (κ) was calculated to assess the test–retest reliability of the instrument. Kappa can range between 1 (perfect agreement) and a little less than 0 (no agreement); A κ value of >0.80 is considered to reflect almost perfect agreement, 0.61–0.80 substantial agreement, 0.41–0.60 moderate agreement, and 0.21–0.40 fair agreement.³² The question by question comparison showed substantial agreement with kappa in the range of 0.689–1.000 for all questions.

The 25-item SATp achieved moderate to high internal consistency as demonstrated by Cronbach's alpha coefficients for the three domains (psychological, social, and physical) ranging from 0.706 to 0.903. Item-to-total score correlation coefficients for all items exceeded 0.595. This showed that questions within each of the three domains were assessing different aspects of the same construct.

Needs identified

Of the 250 CRC patients attending the target outpatient services, 88 were eligible. Patients with stage IV cancer ($n=39$),

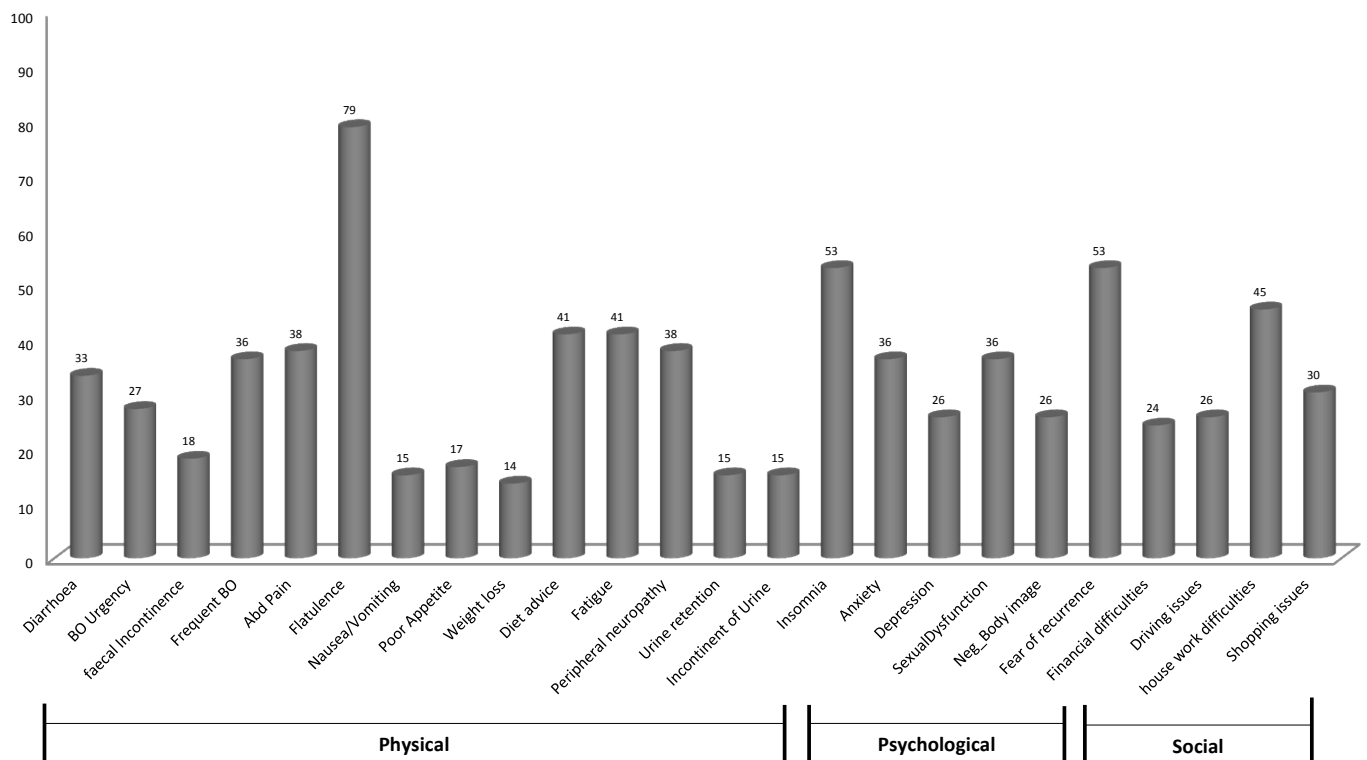
non-English speaking ($n=2$), were living in aged care facilities ($n=6$), and had completed treatment less than 12 months ago ($n=107$) were not included. Of the 88 eligible participants, 66 consented and returned the completed questionnaires. Participants were on average 69.2 (SD 9.9) years old and had been diagnosed with cancer 26.7 months earlier (range 6–92, median 28). As shown in Table 1, 65.2% had colon cancer, 34.8% had rectal cancer, and 81.8% had one or more coexisting chronic illness.

For the 66 participants, a total of 547 needs were identified by SATp, with an average of 8.1 needs per patient (median 7; IQR [3–12.25]). Identified needs were in the physical (175[32%]), psychological (175[36%]), and social (197[32%]) domains. The most commonly reported physical needs were troublesome flatulence (79%) and fatigue (41%). Psychological needs included fear of recurrence (53%), insomnia (53%), sexual dysfunction (36%), anxiety (36%), and negative body image (23%). Social needs included dietary advice (41%) and housework difficulties (45%) Figure 4.

Table 1: Participant demographic and clinical characteristics*.

Participant characteristics (n=66)		Number of participants (%)
Gender	Male	26 (39.1)
	Female	40 (60.9)
Age	Mean (SD)	69.2 (9.9)
Age (years)	≤60	12 (12)
	61–70	23 (34.8)
	71–80	21 (31.8)
	≥81	10 (15.2)
Marital status	Never married	10 (15.2)
	Widowed	13 (19.7)
	Married	31 (48.5)
	Divorced/separated	10 (15.1)
	De-facto partner	1 (1.6)
Education level	Completed primary school	7 (10.9)
	Year 10 or equivalent	29 (43.8)
	Year 12 or equivalent	4 (6.1)
	Trade certificate/TAFE	12 (18.2)
	University/CAE (College of Advanced Education)	14 (21.2)
Employment	Self-employed	4 (6.3)
	Employed for wages, salary, or payment in kind	10 (10.6)
	Engaged in home duties	1 (1.5)
	Unable to work	2 (3.0)
	Unemployed	1 (1.5)
	Retired	47 (71.2)
	Other reasons	4 (6.1)
Cancer location	Colon	43 (65.2)
	Rectum	23 (34.8)
Cancer stage	Stage I	17 (25.8)
	Stage II	30 (45.5)
	Stage III	19 (28.8)
Comorbidity	Yes	54 (81.8)
	No	12 (18.2)

* Clinical characteristics were formulated based on patient-assessment questions identified in the Australian guidelines for cancer follow-up (Cancer Council Australia 2004).



Key: BO – bowel action; Abd – abdominal; Neg – negative

Figure 4: Percentage distribution of needs per patient identified by SATp.

Discussion

This study reports the development of a reliable and valid instrument to assist doctors and patients in identifying symptoms/problems that may stem from CRC treatment. SATp satisfies the prerequisites for assessing the long-term needs of CRC survivors as it measures multiple dimensions of CRC-related needs.

The items included in SATp have been developed through a rigorous literature review and by modelling the items into a simulated cohort of CRC patients to derive the most common symptoms experienced by this group. Furthermore, the instrument has integrated the experience of patients in follow-up care and expert input from health professionals involved in the care of CRC patients.

Preliminary results indicate that SATp fulfils the current methodological standards for acceptability, internal consistency, validity, and usability. Through an internal consistency process, it was possible to demonstrate evidence for a strong, structurally reliable SATp with Cronbach's alpha coefficients exceeding 0.7 in all three domains. The test-retest reliability also showed a level of agreement that was not due to chance, as was evidenced by a kappa of 0.689–1.000.

Despite being at 1 year post-treatment, each patient was experiencing a median of 7 unmet needs, all in the three domains (physical, psychological, and social). These domains have been reported with past research suggesting that these issues are important aspects for long-term survivors of CRC.¹

The initial results confirm that the tool can be self-

administered. By examining the needs rated as 'yes', the survey could potentially be used to alert practitioners to refer these patients to secondary care or other appropriate allied health support services. For this instrument to be useful, regular use in general practice is required. Also, it is yet to be shown whether SATp facilitates proactive management of related problems in general practice and how GPs might address some problems identified such as fear of recurrence. This evidence will be outlined in the second part of this study. The research team is currently in the process of trailing SATp longitudinally to further test its value for regular use in a general practice setting.

Despite these limitations, the research outlines some of the practical and operational benefits of a specific instrument for CRC patients attending general practice. Furthermore, the practicality of self-administration of this measure obviates the need for follow-up phone interviews from health professionals. Thus, this instrument increases the practical feasibility and acceptability of assessing patient needs on an ongoing basis as a routine part of care. The application of the instrument in general practice may potentially yield a valuable pool of data on patient needs.

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