The Assessment of Burden of ColoRectal Cancer (ABCRC)-tool; a validity and reliability study

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ABSTRACT

Introduction: Follow-up care after treatment for colorectal cancer (CRC) is increasingly focused on health-related quality of life (HRQoL) and functional outcomes. The Assessment of Burden of ColoRectal Cancer (ABCRC)-tool is developed to measure these outcomes and support patient-oriented care. The tool comprises items assessing burden of disease and lifestyle parameters. It consists of a generic module combined with one of the three CRC specific modules. The objective of this study is to assess the construct validity and reliability of the items of the ABCRC-tool.
Methods: Patients who were receiving follow-up care after surgical CRC treatment were invited to complete the ABCRC-tool together with other validated patient-reported outcome measures (PROMs). Construct validity was assessed by testing expected correlations between items of the ABCRC-tool and domains of other PROMs and by examining predefined hypotheses regarding differences in subgroups of patients. Patients completed the ABCRC-tool twice, with 8 days apart, to evaluate its reliability.
Results: In total, 177 patients participated (64% male) with a mean age of 67 years (range 33–88). The colon, rectum and stoma module were completed by subsequently 89, 53 and 35 patients. Most items correlated as expected with anticipated domains of the EORTC QLQ-C30 or EORTC QLQ-CR29 (all *p*-values <0.05). Furthermore, the ABCRC-tool could discriminate between subgroups of patients. The intraclass correlation coefficient (ICC) was good (>0.70) for most items, indicating good reliability.

Conclusion: The ABCRC-tool is a valid and reliable instrument that is ready for use in a clinical setting to support personalized follow-up care after CRC treatment.

1. Introduction

Oncological outcomes of colorectal cancer (CRC) patients, such as (disease-free) survival, have improved during the last decades as a result of earlier detection of cancer and better treatment options. Because of this, the prevalence of cancer survivors is increasing rapidly. Follow-up care is provided to detect a possible recurrence, but colorectal cancer survivors often also have physical, psychosocial and supportive care needs, for example with regard to intimacy, work, cognitive problems or lifestyle issues [1]. Follow-up care after treatment is therefore increasingly focused on the patient's health related quality of life (HRQoL), functional outcomes and disease burden [2]. Importantly, patients and clinicians advocate a more patient-oriented follow-up after colorectal cancer treatment, with a proper balance between detection of recurrence, HRQoL and functional outcomes [3].

Patient Reported Outcome Measures (PROMs) can be used to support such a patient-oriented follow-up by evaluating HRQoL and functional outcomes of patients and by improving patient-physician communication [4,5]. However, existing PROMs are relatively long and were not designed for use in clinical practice. Moreover, visual feedback of the results to patients and healthcare professionals, which is known to promote their use and increase effectiveness, is lacking [4,5]. To support patient-oriented follow-up in colorectal cancer patients, the Assessment of Burden of ColoRectal Cancer (ABCRC)-tool was recently developed [6]. The tool consists of a PROM that can be divided in three parts; a generic oncological part that measures general complaints such as fatigue and physical functioning, a disease specific part that focuses on specific complaints related to colorectal cancer treatment such as urinary complaints and defecation problems, and a lifestyle part that includes four items about the patient's current lifestyle. Patients can complete the PROM digitally at home after which the outcomes are visualized in a balloon chart (Fig. 1). The purpose of the ABCRC-tool is to cover a wide range of topics for the patient with a minimum number of items, and to visualize the results. Therefore, items of the PROM of the ABCRC-tool are grouped into so called 'domains' in order to create 11 or 12 balloons (depending on the module) in a chart, representing the patient's scores. The color of the balloon (i.e. green, yellow, orange or red) is based on the score of the worst item score within that domain. The balloon chart includes treatment options (that appear by hovering over balloons) and can be used during the consultation with the healthcare professional, to discuss a personalized care plan. The

development process with patients and healthcare professionals, followed by face and content validity testing in a small sample of patients have been reported [6]. The aim of the current study was to quantitatively assess the construct validity and reliability of the PROM (i.e. the items measuring patient outcomes) of the ABCRC-tool in a larger sample.

2. Methods

2.1. Design and patient population

In this cross-sectional study, PROM data were collected digitally via Castor EDC and clinical characteristics via electronic patients records. All patients provided informed consent before participating in this study. The study was approved by the Medical Ethics committee of the academic Hospital Maastricht and Maastricht University (METC 2020-2457).

Patients were recruited from one academic and two non-academic hospitals in the Netherlands between December 2021 and September 2022. In two hospitals, patients were invited to participate via e-mail. In the other hospital, patients were asked to participate during outpatient clinic visits. Patients were eligible if they were 18 years or older, receiving follow-up care after treatment for colorectal cancer, i.e. were up to five years postoperative, and had access to e-mail. Patients could not participate if they were being treated for more than one type of malignancy, were not having active follow-up care in the hospital and if not sufficiently acquainted with the Dutch written and/or spoken language.

2.2. Outcome measures and clinical characteristics

Patients completed a set of PROMs including the PROM of the ABCRC-tool, the European Organization for Research and Treatment of Cancer core Quality of Life questionnaire (EORTC QLQ-C30) [7,8], the European Organization for Research and Treatment of Cancer Quality of Life questionnaire for Colorectal Cancer (EORTC QLQ-CR29) [9–11] and the Hospital Anxiety and Depression Scale (HADS) [12,13]. Eight days after completion of this set, patients were sent the ABCRC-PROM again for the purpose of reliability testing. In addition, the age and sex of the patient, tumor stage (Duke's), type of surgery, time post treatment and (if applicable) type of (neo)adjuvant treatment were retrieved from the
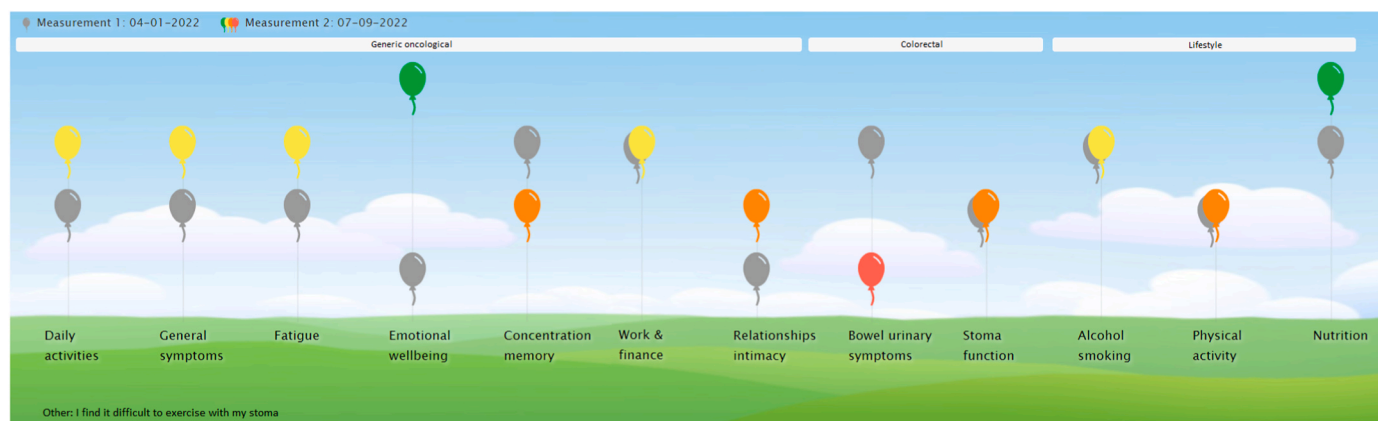

Fig. 1. Visualization of the outcomes within the ABCRC-tool. Green balloons correspond with good scores whereas lower, yellow, orange or red scores indicate possible problems within that domain. Grey balloons show results of the previous measurement.

electronic patient files.

2.2.1. PROM of the ABCRC-tool

The PROM of the ABCRC-tool consists of an oncological generic part, a colorectal cancer specific part and a lifestyle part. The oncological generic part consists of seventeen items, mostly selected from the EORTC item library bank, divided over seven domains, i.e. daily activities, general symptoms, fatigue, emotional wellbeing, concentration and memory, work and finance, and relationships and intimacy [14]. The colorectal cancer specific part consists of three add-on modules; one for colon cancer patients with anastomosis (six items), one for colorectal cancer patients with a stoma (five items) and one module for rectal cancer patients with anastomosis (seven items). The generic items and the disease-specific items of the colon and stoma module generally inform about experienced disease burden and have Likert-type response scales, with four answer options ranging from 1 representing "not at all" to 4 representing "very much". One item about work and study has a "not applicable" option. The disease-specific part of the rectum module is the validated and translated Low Anterior Resection Syndrome (LARS) score [15,16]. In addition, the PROM includes four items about lifestyle (i.e. alcohol consumption, smoking behavior, physical activity and nutrition). The complete structure of the PROM is described in the development paper [6]. The structure and items of the PROM are also shown in Appendix A (Table A1 and A2).

2.3. Data analysis

Psychometric properties of the PROM of the ABCRC-tool were assessed on the item level. Data were analyzed using IBM SPSS statistics version 28. First, some structural properties were tested by assessing the distribution of scores for each item. Second, the construct validity was assessed by testing convergent validity and known-groups validity. Convergent validity refers to how closely a measure is related to other measures of the same construct, while known-groups validity reflects the degree to which a measure can demonstrate different scores for groups known to vary on the items being assessed [17]. Both the convergent validity and known-groups validity of the items of the ABCRC-tool were assessed by examining predefined hypotheses.

2.3.1. Convergent validity

Convergent validity was evaluated by investigating whether scores on the items of the ABCRC-tool correlated well with similar items or domain scores of the EORTC QLQ-C30 and the EORTC QLQ-CR29. A priori hypotheses were made about the expected direction and magnitude of the correlation coefficient (Spearman's Rho) for each item of the ABCRC-PROM and a domain (e.g. functional scale or symptom scale), item or sum of items from the EORTC QLQ-C30 or EORTC QLQ-CR29. A correlation >0.3 is considered medium and a correlation of >0.5 is considered strong [18].

2.3.2. Known-groups validity

We investigated known-groups validity by testing whether scores on items of the PROM of the ABCRC-tool varied between subgroups of patients for whom scores were expected to be different based on literature or clinical expert opinion. The following hypotheses were tested:

- Patients <70 years old score different on the ABCRC-tool compared to patients aged >70 years old. Specifically, it was expected that patients >70 years score worse on the items about daily activities (items 1 and 2), and fatigue (items 6 and 7) [19] and that patients <70 years score worse on the items about emotional wellbeing (items 8, 9 and 10) [20] and work and finance (items 13 and 14).
- Patients <1 year post treatment score worse on the ABCRC-tool, specifically on the domain around daily activities and general symptoms (items 3,4,5), compared to patients >1 year post treatment [21,22].

- Patients with anxiety or depression (based on the HADS) overall score worse on the ABCRC-tool compared to patients without anxiety or depression, specifically on the items about fatigue, emotional wellbeing and concentration and memory (items 11 and 12) [23,24].
- Patients who had rectal surgery with (neo)adjuvant chemo radiation would score worse on the ABCRC-tool, specifically on the items about daily activities, compared to patients who had colon surgery.
- Patients who were treated with (neo)adjuvant chemotherapy score worse on the items about fatigue, concentration and memory, and on the item about tingling and numbness (item 18) [25].

Differences between groups were assessed using the Mann-Whitney *U* test. Median scores and the first and third quartile were reported with corresponding *p*-values for differences. A *p*-value <0.05 was considered significant.

2.3.3. Reliability

All patients were sent the ABCRC-PROM for a second time, eight days after their initial completion (test–retest). The Intraclass Correlation Coefficient (ICC) was used to test the reliability of the items between the two measurements. Reliability reflects the extent to which scores for patients who have not changed are the same for repeated measurements over time [26]. ICC estimates and their 95% confidence intervals were calculated based on absolute agreement and a 2-way mixed-effects model. Following recommendations by Terwee et al., the reliability is positively rated when the ICC is at least 0.70 [17].

3. Results

3.1. Patient characteristics

A total of 177 patients (64% male) with a mean age of 67 years (range 33–88), with a variety of tumors and with varying post treatment times completed the set of PROMs. Characteristics of the patients are displayed in Table 1.

Table 1
Patient characteristics.

Characteristics, *N* (%)	Total *N* = 177	*Colon N=89*	*Rectum N=53*	*Stoma N=35*
Men	113 (64)	51 (57)	38 (72)	24 (69)
Mean age (range) *in years*	67 (33–88)	69 (46–87)	64 (33–80)	67 (33–88)
Tumor stage, *N* (%)				
0	6 (3)	0	4 (7)	2 (6)
1	50 (28)	22 (25)	21 (40)	7 (20)
2	59 (33)	40 (45)	9 (17)	10 (28)
3	54 (31)	22 (25)	19 (36)	13 (37)
4	8 (5)	5 (5)	0	3 (9)
Time post treatment, *N* (%)				
0–1 year	36 (20)	24 (27)	5 (9)	7 (20)
1–2 years	43 (24)	21 (24)	16 (30)	6 (17)
2–3 years	36 (20)	17 (19)	12 (23)	7 (20)
3–4 years	44 (25)	20 (22)	15 (29)	9 (26)
4–5 years	18 (11)	7 (8)	5 (9)	6 (17)
Neoadjuvant, *N* (%)				
Chemotherapy	5 (3)	1 (1)	0	4 (11)
Radiotherapy	8 (4)	0	5 (10)	3 (9)
Chemotherapy + Radiotherapy	40 (23)	0	23 (43)	17 (49)
Adjuvant, *N* (%)				
Chemotherapy	34 (19)	23 (26)	6 (11)	5 (14)
Surgery, *N* (%)				
Laparoscopic	132 (75)	79 (89)	34 (64)	19 (54)
Open incision	16 (9)	6 (7)	2 (4)	8 (23)
Robot assisted surgery	29 (16)	4 (4)	17 (32)	8 (23)
Additional therapy for metastasis or recurrence, *N* (%)				
Yes	6 (3)	2 (2)	3 (6)	1 (3)

3.2. Structural properties

The distribution of responses for each item of the generic part of the ABCRC-tool are shown in Fig. 2. There were no missing data in this study as patients were obliged to answer all questions. In eleven out of nineteen items, all answer options were used by the patients. Item 13, about work and finance, is the only question with a "not applicable" option available and this option was selected by 33% of patients.

The distribution of scores of the lifestyle items and the disease specific items are shown in Appendix B (Table B1, B2 and B3).

3.3. Construct validity

3.3.1. Convergent validity

The a priori hypotheses and the correlation coefficients (Spearman's rho) with corresponding p-values for the assessment of convergent validity are shown in Table 2. All a priori hypotheses were met except for the hypotheses made for items 1, 13 and 19, where significant, but either weaker or stronger correlations than expected were found.

3.3.2. Known-groups validity

Results showed that younger patients (<70 years) had significantly higher scores on item 8 (worry), item 10 (depressed) and item 13 (work and study) than older patients (aged >70 years), as expected. Contrary to our expectations, older patients did not score worse on the items about daily activities or fatigue. There were also no significant differences between scores of patients <1 year and >1 year post treatment.

Patients with (borderline) depression (based on HADS) scored significantly worse on the items 7 (lack of energy), 9 (feel tense), 10 (feel depressed) and 11 (concentration) as hypothesized, but also on items 2 (daily activities, limitations), 3 (pain), 13 (work and study), 14 (finance) and 15 (relationships) compared to patients with no (borderline) depression. Patients with (borderline) anxiety (based on HADS) scored significantly worse on the items 6 (tired), 7 (lack of energy), 8 (worry), 9 (feel tense), 10 (feel depressed), 11 (concentrating) and 12 (remembering) as hypothesized, but also on the items 3 (pain) and 15 (relationships) compared to patients with no (borderline) anxiety.

As expected, patients who had rectal surgery with (neo)adjuvant

chemoradiation scored significantly worse on item 2 (daily activities) compared to patients who had colon surgery. Finally, patients who received (neo)adjuvant chemotherapy had significantly worse scores on item 6 (tired), item 11 (concentrating) and item 18 (tingling and numbness) compared to patients who did not receive (neo)adjuvant chemotherapy. The median scores with corresponding first and third quartile and p-values for all subgroups on all items can be found in Appendix C (Table C1).

3.4. Reliability

In total, 154 patients (87%) completed the second set of questionnaires; in addition to the generic part, 29 patients completed the stoma module a second time (83% of 35 of the first round), 76 patients completed the colon module a second time (85% of 89 of the first round) and 49 patients completed the rectum module a second time (93% of 53 of the first round). The mean number of days between the test and retest was 9 days (SD 2.9).

The ICC was calculated for each item. Eighteen of 35 items have an ICC >0.70, indicating good reliability. Fourteen items have an ICC between 0.6 and 0.7 and three items have ICCs <0.60. The ICCs with corresponding 95% confidence interval for each item are shown in Appendix D (Table D1).

4. Discussion

This study focused on assessing the validity and reliability of the items (i.e. PROM) of the ABCRC-tool and showed sound psychometric properties. Thirteen out of sixteen hypotheses made to assess (convergent) validity were met. The finding of some weaker correlations than expected may be explained by the fact that single items of the ABCRC-PROM were correlated with more elaborate constructs measured with multiple items on the EORTC QLQ-C30, and a single item, may not sufficiently capture the broad construct. Most of the known-groups hypotheses were also met, indicating that the tool is able to differentiate between specific subgroups of patients. In some cases, a significant difference between subgroups was found on some items that were expected, but not all. Contrary to expectations, there were no significant
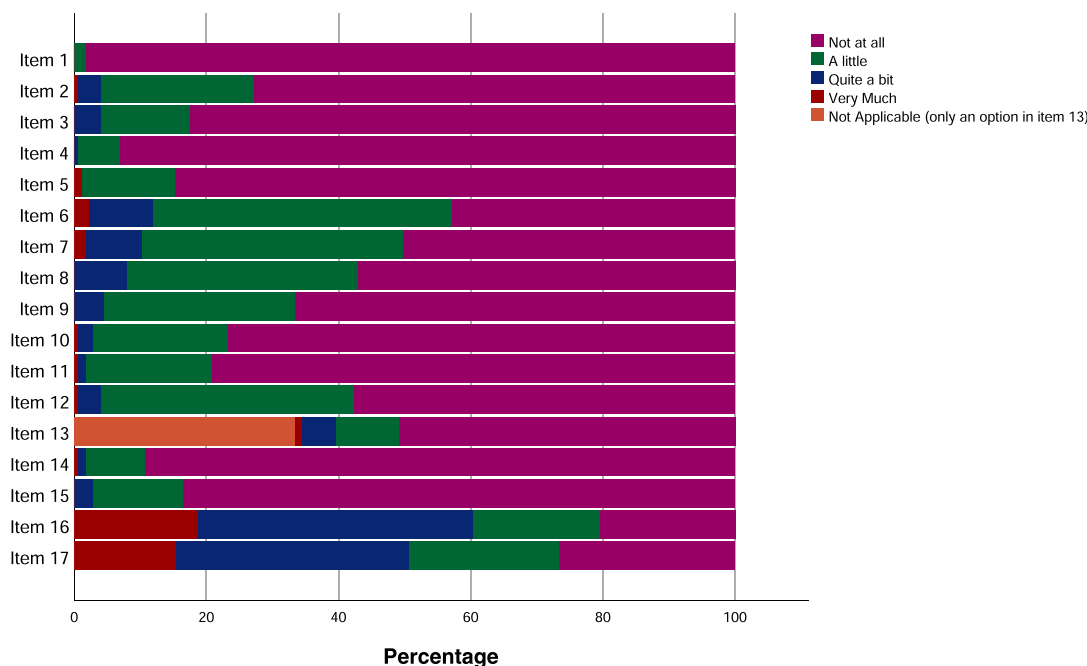

Fig. 2. Stacked bar chart representing the distribution of scores. For each item, the percentage of responses for each answer option is indicated (N = 177 for each item).

Table 2

Correlations between items of the ABCRC-tool and domains or items of existing validated PROMs. ** indicates p < 0.01, *** indicates p < 0.001.

Item	Correlation with	Hypothesis (Spearman's rho)	Outcome (Spearman's rho)	Hypothesis met
1 Do you need help with eating, dressing, washing yourself or using the toilet?	Physical Functioning scale of the EORTC C30	Negative and medium (>-0.3, <-0.5)	−0.199**	×
2 Were you limited in doing either your work or other daily activities?	Role Functioning scale of the EORTC C30	Negative and strong (>-0.5)	−0.702***	✓
3 Have you had pain?	Symptom Scale Pain of the EORTC C30	Positive and strong (>0.5)	0.675***	✓
6 Were you tired?	Symptom Scale Fatigue of the EORTC C30	Positive and strong (>0.5)	0.596***	✓
7 Have you lacked energy?	Symptom Scale Fatigue of the EORTC C30	Positive and strong (>0.5)	0.655***	✓
8 Did you worry?	Emotional Functioning Scale of the EORTC C30	Negative and strong (>-0.5)	−0.627***	✓
9 Did you feel tense?	Emotional Functioning Scale of the EORTC C30	Negative and strong (>-0.5)	−0.712***	✓
10 Did you feel depressed?	Emotional Functioning Scale of the EORTC C30	Negative and strong (>-0.5)	−0.612***	✓
11 Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	Cognitive Functioning Scale of the EORTC C30	Negative and strong (>-0.5)	−0.559***	✓
12 Have you had difficulty remembering things?	Cognitive Functioning Scale of the EORTC C30	Negative and strong (>-0.5)	−0.816***	✓
13 Have you had problems at your work or place of study due to the disease?	Role Functioning scale of the EORTC C30	Negative and weak (>-0.1, <-0.2)	−0.452***	×
15 Has your physical condition or medical treatment interfered with your relationships with your family or friends?	Social Functioning Scale of the EORTC C30	Negative and strong (>-0.5)	−0.664***	✓
19 Did you have problems urinating?	sum score of items 31–34 of the EORTC Cr29	Positive and strong (>0.5)	0.321***	×
20 of the add-on Rectal Module Do you ever have occasions when you cannot control your flatus (wind)?	question 49 of the EORTC Cr29	Positive and strong (>0.5)	0.650***	✓
21 of the add-on Rectal Module Do you ever have any accidental leakage of liquid stool?	question 50 of the EORTC Cr29	Positive and strong (>0.5)	0.794***	✓
23 of the add-on Rectal Module Do you ever have to open your bowels again within one hour of the last bowel opening?	Stool Frequency domain of the EORTC Cr29	Positive and strong (>0.5)	0.581***	✓

differences between patients aged <70 and patients aged >70 on the items about daily activities and fatigue. This might be explained by the fact that the median age of the study population was 68 years with a first and third quartile of 61–74, leaving little room for differentiation. Furthermore, we were not able to detect differences between patients <1 year in their follow up and >1 year in their follow up. The one year time point was chosen because after one year most patients reach baseline values in HRQoL and functional outcomes again [21,22]. However, only 36 patients were in their first year of follow-up, most of them nearing the end of the first year, creating challenges in finding significant differences between this small group and those patients that passed the 1 year follow-up.

The reliability assessment, using a test-retest, showed high ICCs for most items. Two items scored notably low, i.e. item 5 that evaluates weight loss and item 9 on feeling tense. Possible explanations could be that losing weight can fluctuate over time. Due to the subjectivity of feeling tense this can also be less consistent. Overall, these results show a fair to good reliability of the ABCRC-tool. The ICCs of the items 16 (intimacy) and 17 (sex life) were also relatively low (0.54 and 0.72 respectively). A possible explanation may be that numerous patients commented in a free text space of the PROM that they had no partner and therefore felt unable to answer items 16 (intimacy) and 17 (sex life). Based on these findings, the PROM will be amended to include a "not applicable" option for these items.

One of the strengths of this study is the relatively large sample size and the high number of patients (87%) who completed the PROM a second time for the test-retest analysis. Furthermore, patients from both an academic hospital and non-academic hospitals were represented with a variety of colorectal cancer types and different follow-up times. One limitation is that around 80% of our patients is more than one year post treatment which might have led to some ceiling effects in the response distributions, possibly limiting some of the statistical analyses. It has

been shown that in most rectal cancer patients, HRQoL and the majority of functional outcomes and symptoms are restored around 12 months after surgery [21], and even earlier in most colon patients [22]. However, we do know that some patients will continue to suffer from late sequelae of treatment or disease, also after this first follow-up year [27]. Therefore, we decided to invite patients from both early and late follow-up phases for this validation study. Another limitation is that it was not possible to formulate hypotheses for all individual items of the ABCRC-tool so as to test their validity. The suit of questionnaires sent to patients already comprised more than 100 items from validated questionnaires, hence it was deemed that more questionnaires would come at the expense of feasibility and patient burden. Finally, as only limited stage IV CRC patients were included in this study, one has to be cautious to apply our findings to the more advanced CRC patients.

An important next step is to test the feasibility and usability of the complete tool in daily practice. A pilot study is currently being conducted in the Netherlands. Another area for future research is the impact of the lifestyle items in this tool as a healthy lifestyle can have a positive effect on the disease burden risk of cancer recurrence and should therefore be an integral part of the follow-up care of patients [1,28–30]. The ABCRC-tool has the potential to select patients that can benefit most from lifestyle interventions, but further research is necessary to select evidence-based interventions for the colorectal cancer patient, and set up pathways in the healthcare system to appropriately refer these patients.

5. Conclusion

In conclusion, we have shown that the ABCRC-tool has good validity and reliability and can provide a thorough understanding of the colorectal cancer patient's burden of disease after treatment.

Appendix A. Scale structure and items of the ABCRC-tool

Table A1
Scale structure of the PROM of the ABCRC-tool

Domain	Generic module	Module Stoma	Module Colon	Module Rectum
	Items	Items	Items	Items
Daily activities	1, 2			
General symptoms	3, 4, 5,	18	18	18
Fatigue	6, 7			
Emotional wellbeing	8, 9, 10			
Concentration and memory	11, 12			
Work experience and finance	13, 14			
Relationships and intimacy	15, 16,17			
Bowel and urinary symptoms		19, 20, 21	19, 20, 21, 22, 23	19, 20, 21, 22, 23, 24
Stoma function		22		
Intoxications		23, 24	24, 25	25, 26
Physical activity		25	26	27
Nutrition		26	27	28
Open question		27	28	29

Table A2
Assessment of Burden of ColoRectal Cancer (ABCRC)-PROM (Originally in Dutch)

GENERIC ONCOLOGICAL MODULE					
	Generic oncological module				
	1 Not at all	2 A little	3 Quite a bit	4 Very much	
1 Do you need help with eating, dressing, washing yourself or using the toilet?	☐	☐	☐	☐	
During the past week:	1 Not at all	2 A little	3 Quite a bit	4 Very much	Not applicable
2 Were you limited in doing either your work or other daily activities?	☐	☐	☐	☐	
3 Have you had pain?	☐	☐	☐	☐	
4 Have you lacked appetite?	☐	☐	☐	☐	
5 Have you lost weight?	☐	☐	☐	☐	
6 Were you tired?	☐	☐	☐	☐	
7 Have you lacked energy?	☐	☐	☐	☐	
8 Did you worry?	☐	☐	☐	☐	
9 Did you feel tense?	☐	☐	☐	☐	
10 Did you feel depressed?	☐	☐	☐	☐	
11 Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	☐	☐	☐	☐	
12 Have you had difficulty remembering things?	☐	☐	☐	☐	

(continued on next page)

Table A2 (*continued*)

GENERIC ONCOLOGICAL MODULE

	Generic oncological module			
	1 Not at all	2 A little	3 Quite a bit	4 Very much
13 Have you had problems at your work or place of study due to the disease?	☐	☐	☐	☐ ☐
14 Has your physical condition or medical treatment caused you financial difficulties?	☐	☐	☐	☐
15 Has your physical condition or medical treatment interfered with your relationships with your family or friends?	☐	☐	☐	☐
	1 Not at all	2 A little	3 Quite a bit	4 Very much
16 Have you been satisfied with your level of intimacy during the past four weeks?	☐	☐	☐	☐
17 Have you been satisfied with your sex life during the past four weeks?	☐	☐	☐	☐

COLORECTAL SPECIFIC MODULES (18-20/23/24)

During the past week:	Colorectal specific module: colorectal cancer with stoma			
	1 Not at all	2 A little	3 Quite a bit	4 Very much
18 Have you had tingling or numbness in your fingers or toes?	☐	☐	☐	☐
19 Did you have problems urinating?	☐	☐	☐	☐
20 Have you been constipated?	☐	☐	☐	☐
21 Have you had diarrhea?	☐	☐	☐	☐
22 Did you have problems caring for your stoma?	☐	☐	☐	☐

Colorectal specific module: colon cancer with anastomosis

During the past week:	1 Not at all	2 A little	3 Quite a bit	4 Very much
18 Have you had tingling or numbness in your fingers or toes?	☐	☐	☐	☐
19 Did you have problems urinating?	☐	☐	☐	☐
20 Have you been constipated?	☐	☐	☐	☐
21 Have you had diarrhea?	☐	☐	☐	☐
22 Have you had leakage of stools from your back passage?	☐	☐	☐	☐
23 When you felt the urge to move your bowels, did you have to hurry to get to the toilet?	☐	☐	☐	☐

Colorectal specific module: rectal cancer with anastomosis, including LARS score

During the past week:	1 Not at all	2 A little	3 Quite a bit	4 Very much
18 Have you had tingling or numbness in your fingers or toes?	☐	☐	☐	☐
19 Did you have problems urinating?	☐	☐	☐	☐
20 Do you ever have occasions when you cannot control your flatus (wind)?	☐No, never. ☐Yes, less than once per week. ☐Yes, at least once per week.			
21 Do you ever have any accidental leakage of liquid stool?	☐No, never. ☐Yes, less than once per week. ☐Yes, at least once per week.			
22 How often do you open your bowels?	☐More than 7 times per day (24 h). ☐4–7 times per day (24 h). ☐1–3 times per day (24 h). ☐Less than once per day (24 ho0urs).			
23 Do you ever have to open your bowels again within one hour of the last bowel opening?	☐No, never. ☐Yes, less than once per week. ☐Yes, at least once per week.			
24 Do you ever have such a strong urge to open your bowels that you have to rush to the toilet?	☐No, never. ☐Yes, less than once per week. ☐Yes, at least once per week.			

LIFESTYLE MODULE (23-27)/(24-28)/(25-29)

	Lifestyle module
23 During the past week, how many days have you drunk one or more glasses of alcohol?	☐**0 days** ☐**1–2 days** ☐**3–4** days ☐**5 days or more**
24 Do you smoke?	☐**Yes**. ☐No, **quit** smoking less than a year. ☐No, **quit** smoking more than a year. ☐No, **never** done.
25 During the past week, how many days have you been exercising moderately intensive for 30 min or longer? *These are activities during which you start running out of breath and your heartrate increases. For example: walking or cycling at a fast pace.* 3 times 10 min is also possible.	☐0 days ☐1-2 **days** ☐3-4 days ☐**5 days** or more
26 During the past week, how many days have you eaten a varied and healthy diet?*A varied and healthy diet has fruits, vegetables, whole grains, beans, eggs, and nuts, and is low in saturated fats, cholesterol, salt (sodium), and added sugars.*	☐0 days ☐1-2 days ☐3-4 days ☐ 5 days or more
27 Would you like to discuss or get some information about other topics?	

Appendix B. Distribution of scores of the lifestyle items and disease specific items of the ABCRC-tool

Table B1

Distribution of scores of the lifestyle items

Item	Response category - %	Response category - %	Response category -%	Response category - %
Alcohol consumption	0 days - 33	1–2 days - 33	3–4 days - 16	5 days or more - 18
Smoking	Yes - 6	No, quit smoking less than a year - 2	No, quit smoking more than a year - 55	No, never done - 37
Exercise	0 days - 13	1–2 days - 26	3–4 days - 31	5 days or more - 30
Diet	0 days - 2	1–2 days - 3	3–4 days - 27	5 days or more - 68

Table B2

Distribution of scores of the items of the rectal module

Item	Response category - %	Response category - %	Response category - %	Response category - %
18 (tingling and numbness)	Not at all - 71	A little - 21	Quite a bit - 6	Very Much - 2
19 (miction)	Not at all - 73	A little - 23	Quite a bit - 4	Very Much - 0
20 (flatus/wind)	No never - 13	Yes, less than once per week - 25	Yes, at least once per week - 62	
21 (leakage of stool)	No never - 45	Yes, less than once per week - 34	Yes, at least once per week - 21	
22 (frequency of stools)	More than 7 times per day (24 h) - 11	4-7 times per day (24 h) - 38	1-3 times per day (24 h) - 43	Less than once per day (24 h) - 8
23 (stool frequency within one hour)	No, never - 13	Yes, less than once per week - 25	Yes, at least once per week - 62	
24 (hurry to toilet)	No, never - 40	Yes, less than once per week - 26	Yes, at least once per week - 34	

Table B3

Distribution of scores of the colon and stoma module

Item	Not at all - %	A little - %	Quite a bit - %	Very Much - %
Stoma item 18 (tingling and numbness)	57	17	12	14
Stoma item 19 (miction)	63	34	3	0
Stoma item 20 (obstipation)	89	11	0	0
Stoma item 21 (diarrhea)	57	26	14	3
Stoma item 22 (taking care of stoma)	86	8	6	0
Colon item 18 (tingling and numbness)	67	19	9	5
Colon item 19 (miction)	80	17	3	0
Colon item 20 (obstipation	71	22	6	1
Colon item 21 (diarrhea)	70	21	9	0
Colon item 22 (leakage of stool)	88	12	0	0
Colon item 23 (hurry to toilet)	55	25	18	2

Appendix C. Known-groups validity

Table C1

Results of the Mann-Whitney U tests performed to examine known-groups validity. The median scores per item and the corresponding first and third quartile are shown for each subgroup. P-values indicate differences between subgroups. Significant p-values (<0.05) are shown in bold.

Item	Age		P	Follow-up		p	Depression		p	Anxiety		p	Treatment		p	Chemotherapy		p
	<70 years N = 102	>70 years N = 75		<1 year N = 36	>1 year N = 141		Yes N = 12	No N = 165		Yes N = 22	No N = 155		Rectal surgery with chemoradiation N = 24	Colon Surgery N = 88		Yes N = 79	No N = 98	
1 (help with daily activities)	1 (1–1)	1 (1–1)	0.750	1 (1–1)	1 (1–1)	0.574	1 (1–1)	1 (1–1)	0.639	1 (1–1)	1 (1–1)	0.512	1 (1–1)	1 (1–1)	1.00	1 (1–1)	1 (1–1)	0.692
2 (daily activities, limitations)	1 (1–2)	1 (1–1)	0.301	1 (1–2)	1 (1–2)	0.495	2 (1–3)	1 (1–1)	**<0.001**	1 (1–2)	1 (1–2)	0.078	1 (1–2)	1 (1–1)	**0.019**	1 (1–2)	1 (1–1)	0.219
3 (pain)	1 (1–1)	1 (1–1)	0.616	1 (1–1)	1 (1–1)	0.448	1 (1–2.75)	1 (1–1)	**0.012**	1 (1–2.25)	1 (1–1)	**<0.001**	1 (1–1)	1 (1–1)	0.665	1 (1–1)	1 (1–1)	0.848
4 (appetite)	1 (1–1)	1 (1–1)	0.946	1 (1–1)	1 (1–1)	0.235	1 (1–1)	1 (1–1)	0.830	1 (1–1)	1 (1–1)	0.653	1 (1–1)	1 (1–1)	0.954	1 (1–1)	1 (1–1)	0.684
5 (weight loss)	1 (1–1)	1 (1–1)	0.282	1 (1–1)	1 (1–1)	0.759	1 (1–1.75)	1 (1–1)	0.347	1 (1–1.25)	1 (1–1)	0.316	1 (1–1)	1 (1–1)	0.820	1 (1–1)	1 (1–1)	0.715
6 (tiredness)	2 (1–2)	1 (1–2)	0.050	2 (1–2)	2 (1–2)	0.381	2 (1.25–3)	2 (1–2)	0.054	2 (1.75–3)	2 (1–2)	**0.004**	2 (1–2)	1 (1–2)	0.202	2 (1–2)	2 (1–2)	**0.038**

(continued on next page)

Table C1 (*continued*)

Item	Age		P	Follow-up		p	Depression		p	Anxiety		p	Treatment		p	Chemotherapy		p
	<70 years N = 102	>70 years N = 75		<1 year N = 36	>1 year N = 141		Yes N = 12	No N = 165		Yes N = 22	No N = 155		Rectal surgery with chemoradiation N = 24	Colon Surgery N = 88		Yes N = 79	No N = 98	
7 (lack of energy)	2 (1–2)	1 (1–2)	0.205	2 (1–2)	1 (1–2)	0.549	2 (1.25–3)	1 (1–2)	**0.018**	2 (1–3)	1 (1–2)	**0.002**	2 (1–2)	1 (1–2)	0.256	2 (1–2)	1 (1–2)	0.096
8 (worry)	1 (1–2)	1 (1–2)	**0.027**	1 (1–2)	1 (1–2)	0.482	2 (1–3)	1 (1–2)	0.077	2 (2–3)	1 (1–2)	**<0.001**	2 (1–2)	1 (1–2)	0.385	1 (1–2)	1 (1–2)	0.695
9 (feel tense)	1 (1–2)	1 (1–2)	0.243	1 (1–2)	1 (1–2)	0.745	2 (1.25–2.75)	1 (1–2)	**<0.001**	2 (2–2)	1 (1–2)	**<0.001**	1.5 (1–2)	1 (1–2)	0.218	1 (1–2)	1 (1–2)	0.790
10 (feel depressed)	1 (1–2)	1 (1–1)	**0.017**	1 (1–1)	1 (1–1)	0.499	2 (1.25–3)	1 (1–2)	**<0.001**	2 (1–2)	1 (1–1)	**<0.001**	1 (1–2)	1 (1–1)	0.070	1 (1–1)	1 (1–1)	0.965
11 (concentrating)	1 (1–2)	1 (1–1)	0.083	1 (1–1)	1 (1–1)	0.804	2(1.25–2)	1 (1–1)	**<0.001**	1.50 (1–2)	1 (1–1)	**<0.001**	1 (1–1.75)	1 (1–1)	0.414	1 (1–2)	1 (1–1)	**<0.001**
12 (remembering)	1 (1–2)	1 (1–2)	0.271	1 (1–2)	1 (1–2)	0.718	2 (1–2)	1 (1–2)	0.141	2 (1–2)	1 (1–2)	**0.023**	1 (1–2)	1 (1–2)	0.745	1 (1–2)	1 (1–2)	0.066
13 (work and study)	1 (1–2)	1 (1–1)	**0.002**	1 (1–1)	1 (1–2)	0.416	2 (1.25–3)	1 (1–1)	**<0.001**	1 (1–2)	1 (1–1)	0.070	1 (1–2)	1 (1–1)	0.158	1 (1–2)	1 (1–1)	0.075
14 (finance)	1 (1–1)	1 (1–1)	0.125	1 (1–1)	1 (1–1)	0.280	2 (1–2)	1 (1–1)	**<0.001**	1 (1–1.25)	1 (1–1)	0.061	1 (1–1)	1 (1–1)	0.317	1 (1–1)	1 (1–1)	0.445
15 (relationships)	1 (1–1)	1 (1–1)	0.850	1 (1–1)	1 (1–1)	0.398	1.5 (1–2)	1 (1–1)	**0.002**	1 (1–2)	1 (1–1)	**0.011**	1 (1–2)	1 (1–1)	**<0.001**	1 (1–1)	1 (1–1)	0.233
18 (tingling and numbness)[2]	1 (1–2)	1 (1–2)	0.124	1 (1–1.75)	1 (1–2)	0.314	1 (1–1.75)	1 (1–2)	0.652	1 (1–3)	1 (1–2)	0.242	1 (1–2)	1 (1–2)	0.935	2 (1–3)	1 (1–1)	**<0.001**

[2]This item is disease specific, but present in all modules. Therefore, we were able to use it for assessing the known-groups validity in our total patient sample ($N = 177$).

Appendix D. Reliability, test-retest

Table D1

The Intraclass Correlation Coefficients calculated for the test-retest as a measure of reliability.

Item	Intraclass correlation coefficient and 95% confidence interval
1 Do you need help with eating, dressing, washing yourself or using the toilet?	0.80 [0.73–0.85]
2 Were you limited in doing either your work or other daily activities?	0.68 [0.58–0.75]
3 Have you had pain?	0.71 [0.62–0.78]
4 Have you lacked appetite?	0.69 [0.60–0.77]
5 Have you lost weight?	0.36 [0.21–0.49]
6 Were you tired?	0.64 [0.54–0.72]
7 Have you lacked energy?	0.71 [0.62–0.78]
8 Did you worry?	0.66 [0.56–0.74]
9 Did you feel tense?	0.48 [0.35–0.60]
10 Did you feel depressed?	0.69 [0.59–0.76]
11 Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	0.64 [0.53–0.72]
12 Have you had difficulty remembering things?	0.65 [0.54–0.73]
13 Have you had problems at your work or place of study due to the disease?	0.60 [0.49–0.70]
14 Has your physical condition or medical treatment caused you financial difficulties?	0.71 [0.63–0.78]
15 Has your physical condition or medical treatment interfered with your relationships with your family or friends?	0.73 [0.64–0.80]
16 Have you been satisfied with your level of intimacy during the past four weeks?	0.54 [0.41–0.64]
17 Have you been satisfied with your sex life during the past four weeks?	0.72 [0.63–0.79]
18 Have you had tingling or numbness in your fingers or toes?	0.80 [0.73–0.85]
19 Did you have problems urinating?	0.69 [0.59–0.76]
stoma item 20 Have you been constipated?	0.64 [0.35–0.81]
stoma item 21 Have you had diarrhea?	0.76 [0.55–0.88]
stoma item 22 Did you have problems caring for your stoma?	0.64 [0.35–0.81]
colon item 20 Have you been constipated?	0.70 [0.56–0.80]
colon item 21 Have you had diarrhea?	0.71 [0.58–0.80]
colon item 22 Have you had leakage of stools from your back passage?	0.65 [0.50–0.76]
colon item 23 When you felt the urge to move your bowels, did you have to hurry to get to the toilet?	0.71 [0.58–0.81]
rectum item 20 Do you ever have occasions when you cannot control your flatus (wind)?	0.82 [0.70–0.90]
rectum item 21 Do you ever have any accidental leakage of liquid stool?	0.75 [0.58–0.85]
rectum item 22 How often do you open your bowels?	0.89 [0.81–0.93]
rectum item 23 Do you ever have to open your bowels again within one hour of the last bowel opening?	0.78 [0.64–0.87]
rectum item 24 Do you ever have such a strong urge to open your bowels that you have to rush to the toilet?	0.77 [0.63–0.86]
Lifestyle-Alcohol: during the past week, how many days have you drunk one or more glasses of alcohol?	0.92 [0.89–0.94]
Lifestyle-Smoking: Do you smoke?	0.98 [0.97–0.99]
Lifestyle-Exercise: During the past week, how many days have you been exercising moderately intensive for 30 min or longer?	0.64 [0.54–0.73]
Lifestyle-Diet: During the past week, how many days have you eaten a varied and healthy diet?	0.60 [0.49–0.69]

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