



# Implementation of ‘IBD-Specific Cognitive Behavioural Therapy’ for Patients with Inflammatory Bowel Diseases with Poor Mental Quality of Life, Anxiety and Depression

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## Abstract

This paper describes the implementation of inflammatory bowel disease (IBD)-specific cognitive behavioural therapy (CBT) for IBD patients with poor quality of life (QoL), anxiety and depression, in four hospitals in the Netherlands. Treatment outcomes were compared with those of a previously published randomized control trial (RCT) of ‘IBD-specific CBT’, following a benchmark strategy. Primary outcome was IBD-specific QoL (IBDQ) completed before and after CBT, secondary outcomes were anxiety and depressive symptoms (HADS, CES-D). Semi-structured interviews were conducted among a pilot of gastroenterologists, nurse specialists and psychologists to evaluate ‘IBD-specific CBT’. 94 patients started treatment (280 screened). At follow-up, 63 participants (67% compared to 81% in the RCT benchmark) completed the IBDQ. Treatment effect sizes of the implementation study were comparable and slightly larger than those of RCT benchmark. Gastroenterologists, IBD nurses and psychologists found CBT necessary for IBD patients with poor QoL, depression and/or anxiety disorders. ‘IBD-specific CBT’ can be successfully implemented. Regular supervision of psychologists performing ‘IBD-specific CBT’ treatment is needed.

**Keywords** Inflammatory bowel disease · Cognitive behavioural therapy · Implementation

## Introduction

Inflammatory bowel disease (IBD) is a chronic and debilitating inflammatory condition of the intestinal tract comprising of two related conditions: Crohn’s disease (CD) and ulcerative colitis (UC). CD can affect any area between the mouth and the anus, whereas UC is restricted to the colon.

Multiple factors (i.e. genetic predisposition, environmental or microbial factors and dysregulated immune response) are known to contribute to the aetiology of IBD (Zhang & Li, 2014; Singh & Bernstein, 2022). Currently, there is no available cure for IBD. A proportion of IBD patients require lifelong medical treatment along with surgery at some point in their life time (Kilcoyne et al., 2016). Individuals with

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IBD report poorer quality of life (QoL; Bennebroek Evertsz et al., 2012). Moreover, symptoms of common mental disorders are prevalent and persistent in patients with IBD, with up to a third of patients reporting symptoms of anxiety and a quarter reporting symptoms of depression over the past 10–15 years (Barberio et al., 2021). More specifically, about 35% of adult IBD patients suffer from comorbid depression, during exacerbation of the disease, compared to 20% during illness remission. Additionally, 66% of the IBD patients had comorbid anxiety during active disease, compared with 28% during inactive IBD (Mikocka-Walus et al., 2016).

In line with these observations, a previous study on IBD patients who reported a poor mental QoL found the prevalence of psychiatric disorders to be 70% (Bennebroek Evertsz' et al., 2017). Furthermore, another study found that patients with high levels of anxiety and depressive symptoms and poor mental QoL did not receive the required care. Only 18% of them had been treated by a psychologist and 21% had received psychotropic medication (Bennebroek Evertsz et al., 2012). This reinforces the observation that IBD patients with anxiety and depression are often insufficiently treated (Greywoode et al., 2023; Mikocka-Walus et al., 2016). This can be deemed especially relevant seeing that as in the case of other somatic diseases, poor QoL, comorbid depression and anxiety can have adverse effects in the expression and trajectory of the disease (Katon et al., 2007). According to a recent systematic review and meta-analyses, individuals with a history of depression may show an increased risk of IBD, even when the depression is diagnosed several years before the new-onset IBD (Piovani et al., 2023). Association between depression, anxiety and disease activity is well established, but the causal pathway is still unclear (Mikocka-Walus et al., 2016). Several studies found evidence for a bidirectional link between the brain–gut axis (Gracie, et al., 2018). This bidirectional link has been shown to affect the natural history of the disease along with psychological health (Fairbrass et al., 2022).

Cognitive behavioural therapy (CBT) has been shown to be effective in reducing anxiety and depressive symptoms in patients with chronic illnesses (Van Straten et al., 2010). Bennebroek Evertsz' et al. (2017) showed in a randomized controlled trial that 'IBD-specific CBT' led to the reduction of symptoms of anxiety and depression, as well as an improved disease-specific and general QoL in IBD patients.

Recent meta-analyses and reviews point towards the short-term effectiveness of CBT for IBD on mental health (such a QoL, anxiety and depression) (Chen et al., 2021; Li et al., 2019; Reise-Filteau et al., 2021). In the current study, we evaluate whether 'IBD-specific CBT' from the benchmark study can be delivered and implemented with the same effectiveness in hospital settings, outside the research context of a RCT. Moreover, 'IBD specific CBT' is only available in a few specialized hospitals in the Netherlands

and for many IBD patients it is not available. This study will therefore evaluate the treatment results of 'IBD-specific CBT' implemented in several clinical hospital settings in comparison with the aforementioned RCT (Bennebroek Evertsz' et al., 2017), following the so-called "benchmark" strategy (Scheeres et al., 2008; Wiborg et al., 2014).

## Implementation Studies

Implementation is an essential process to enable the dissemination of new therapies and treatment manuals within clinical routine, although this is often a challenge for health-care institutions. It has been estimated that approximately 70% of healthcare organizations' efforts to implement new treatments fail (Beer & Nohria, 2000), and thus it becomes crucial to understand the barriers and facilitators for implementation. These can occur at various levels: At an individual level, i.e. the professionals and patients (*e.g. knowledge, skills or motivation*) but also at broader social, organizational, economic and political levels (*e.g. administration of care processes and policies*). Furthermore, the design of the innovation itself (*e.g. feasibility and attractiveness*) (Grol & Wensing, 2004, 2005) can both facilitate and impede implementation. Many interventions found to be effective in research settings remain unused and do not end up being applied to the patients who need it (Damschroder et al., 2009). A carefully planned and monitored implementation process is required to reach this aim. Screening of high-risk groups of IBD patients allows us to recognize and treat those in need of mental care and treatment. Therefore, we preselected IBD patients with poor mental QoL and unmet care needs, like we did in the benchmark RCT (Bennebroek Evertsz' et al., 2017). Not all IBD patients in the benchmark study with poor mental QoL indicated a need for psychological care for several reasons. The pre-treatment attrition rate (eligible people who decided to not participate in the study) was 67%. Furthermore, 17% of the patients dropped out during treatment (Bennebroek Evertsz' et al., 2017). In the current implementation study, we compared the attrition rates (pre-treatment and during treatment) of the implementation study with those of the benchmark RCT (Bennebroek Evertsz' et al., 2017).

It is important to consider that patient attrition is an expected outcome in trial studies and implementation processes and could be an important source of bias in evaluations if not properly accounted for (Dumville et al., 2006).

## Current Study's Objectives

Based on Bennebroek Evertsz' et al. (2017), the current study examined the dissemination and implementation process of 'IBD-specific CBT' for QoL, anxiety and depression in a multi-centre setting. The study had the following

objectives: (1) Evaluate the effectiveness of the implementation of ‘IBD-specific CBT’ on QoL, anxiety and depressive symptoms among patients with poor mental QoL; (2) Explore facilitators and barriers to the implementation process in different clinical settings by semi-structured interviews; (3) identify reasons of non-participation (pre-treatment) and attrition during treatment of the implementation study.

## Methods

### Study Design

This study employed a mixed methods approach to the implementation of ‘IBD-specific CBT’. It consisted of quantitative analysis, with a pre- and post-treatment assessment, and qualitative data collection and analysis happening simultaneously with data being integrated in a final stage. The methods used included a benchmark statistical analysis of treatment outcomes, semi-structured interviews with a sub-group of participating therapists and gastroenterologists, and an analysis of patient non-participation and attrition.

### Patients and Recruitment

The departments of gastroenterology, hepatology and medical psychology of four participating hospitals (one academic (Amsterdam UMC) and three general hospitals (Noordwest Ziekenhuisgroep (Alkmaar), Isala (Zwolle) & Ziekenhuis Gelderse Vallei (Ede)) participated in the implementation study. IBD patients attending the outpatient clinic of the gastroenterology and hepatology department of any of the four hospitals were screened by gastroenterologists or IBD nurse specialists. Eligible patients had to meet the following inclusion criteria, as in the original benchmark RCT (Bennebroek Evertsz’ et al., 2017): (1) Diagnosis of Crohn’s disease (CD) or ulcerative colitis (UC), with or without inflammation; (2) age above 18 years; (3) score of  $\leq 23$  on the mental health sub-scale of MOS Short Form 36 (SF-36); (4) physically and mentally able to attend eight weekly sessions and (5) sufficient command of Dutch. Exclusion criteria were: (1) current psychotherapy and (2) other severe psychiatric diagnoses (e.g. substance use, bipolar disorder or psychoses). Patients who met the aforementioned criteria received additional information regarding the study design and were asked for informed consent. Patients were then approached by a specialized IBD nurse or a front desk assistant (part of the study team), who collected additional information on patients’ characteristics by administering a case report form (CRF). Thereafter, patients were scheduled with an assigned

psychologist of the department of medical psychology from the participating hospitals.

### Treatment Manual

The ‘IBD-specific CBT’ intervention used the same treatment manual as the benchmark study, designed and described in Bennebroek Evertsz’ et al. (2012). Treatment consisted of eight hourly sessions to be completed on a weekly basis, each lasting one hour. In the first session of ‘IBD-specific CBT’, therapists determined if patients met the criteria of anxiety and/or depression of the DSM V axis I disorders (See Table 1 overview treatment). A treatment manual based on the CBT model (Beck, 2005) was used to enhance treatment integrity. Every participant received three modules; writing assignments with regard to traumatic experiences in their illness history; cognitive interventions focussed on specific illness beliefs (for example ‘my illness has major consequences for life’ or ‘my illness causes difficulties for those who are close to me’) and on dysfunctional attitudes (for example ‘I have to be perfect to be happy’) along with a relapse prevention plan (for an extensive description see Bennebroek Evertsz et al., 2012). There were two additional optional modules depending on the specific psychiatric disorder: (1) a behavioural activation and an exposure-based intervention including response prevention (for depressive and anxiety disorders, respectively) and (2) imagery and rescripting (for posttraumatic stress disorders). In case of complaints of incontinence or uncontrollable diarrhoea attacks, we asked patients to compose a survival backpack (i.e. clean clothes, pants, spray, toilet paper, wipes, nappy, bin bag). The aim of this intervention is to diminish the patient’s avoidance behaviour.

Skilled CBT therapists specialized in treating chronically ill patients with comorbid psychiatric disorders were trained in the application of the treatment manual ‘IBD-specific CBT’ for two days with six-hour sessions each. Information about IBD was given and the ‘IBD-specific CBT’ treatment manual was shown alternatingly with video fragments of the treatment of IBD patients and role play, in which therapists practiced with specific interventions tailored for IBD (for example talking about faecal incontinence and introducing the ‘survival backpack’ and exposure to a diarrhoea attack in public using imagery and rescripting). After the training, the participating therapists received supervision on demand.

### Measurements

Patients were asked to fill in questionnaires online before and after the CBT treatment. Follow-up measurements took place within a month after the completion of the last therapy session.

**Table 1** Overview Treatment

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Session 1

Introduction, rationale CBT and intake (i.e. criteria of anxiety, depression, PTSD), focus on IBD complaints (introduction ‘survival backpack’, in case of diarrhoea);

Explanation: recognizing & addressing avoidance behaviour. “What are you not doing since your illness?”, “How was this before you became ill?”, “What can you no longer do, because of your physical limitations?”

Homework:

Compile a ‘survival backpack’, complete two questionnaires (Cognitive-Behavioral Avoidance Scale, Ottenbreit & Dobson, 2004); Weekly rating intrusive memories/images scale. Brewin et al., 2004, Dutch translation, Bennebroek Evertsz, 2009 and write an assignment about your illness history (most painful experiences)

Session 2

Follow-up after recognizing & addressing avoidance behaviour (e.g. exposure and response prevention). Practising alternative behaviours (e.g. assertiveness; saying you have to sit near the toilet, or telling your boss that your illness requires you to take breaks). Behavioural activation for depression

Reading aloud the writing assignment and/or rationale imagery & rescripting in case of PTSD

Homework:

Set your personal therapy goals (short and long term)

Read your writing assignment to a trusted other. Make a hierarchy of the most shocking events in order of severity. In consultation, a situation is chosen for imagery & rescripting

Session 3

In case of PTSD, imagery & rescripting of the chosen situation. Explanation CBT: influence of thoughts on feelings and old restrictive living rules. “How did you get them?” discussion (i.e. parents, traumatic experiences)

Homework:

Fill in Dysfunctional Attitude Scale (de Graaf et al. (2009). Recording old restrictive living rules, pros and cons

Session 4

Explanation: continuum technique to challenge old living rules. Brief mid-term evaluation of the treatment results

Homework:

Application of continuum technique to formulate desirable living rules

Session 5

Rationale: awareness of relapse into old restrictive living rules

Homework:

Formulate desirable living rules; create a flashcard with desirable living rules and benefits. Recording: relapse into old restrictive living rules and use the flashcard with desirable living rules, that is read them aloud at the time of relapse

Session 6

Rationale: ingraining desirable precepts with flashcard

Homework:

Read and embed flashcard with desirable living rules at least 3 × a day

Session 7

Fill in the relapse prevention plan: (1) “How do I recognise relapse?” Signs, symptoms, complaints, (2) “Do I fall back into old restrictive lifestyles?”, “What are my negative thoughts?”, “What behaviours am I avoiding?”, (3) “What can I do?”, “What helps?” Try and evaluate alternative behaviours. Formulate desirable living rules

Homework:

Continue filling in the relapse prevention plan; recognize signs of relapse. Continue to read flashcard with desirable living rules at least 3 × a day and let it sink in

Session 8

Follow-up after filling in the relapse prevention plan

Evaluation & closure: “Are short-term personal goals achieved?”, “What remains to be done in the long term?”

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The primary outcome was the total score on the Inflammatory Bowel Disease Questionnaire (IBDQ), which comprises 32 items assessing the following four domains: bowel symptoms, systemic symptoms, and emotional and social functioning (Russel et al., 1997).

The secondary outcomes were depression and anxiety, which were assessed using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), a measure specifically designed for patients with a somatic illness. A score  $\geq 8$  on either sub-scale indicates a possible anxiety and/or depressive disorder and a score  $\geq 11$  indicates a

probable disorder in the same category. The Centre for Epidemiologic Studies Scale (CES-D) measuring depressive symptomatology in the general population was additionally used (Radloff, 1977).

### Ethics Approval

This implementation study design has been approved by the Medical Ethics Committee of the Amsterdam UMC (location AMC: dossier number: XT4-148).

## Statistical Analysis

### Quantitative Analysis: Evaluation of Effectiveness of Therapy

All statistical analyses were conducted in IBM SPSS Statistics. A statistical benchmark analysis (see Scheeres et al., 2008; Wiborg et al., 2014) was performed comparing the outcomes of the current implementation study with those obtained in the context of a randomized clinical trial as reported by Bennebroek Evertsz' et al. (2017). Employing the original data from the prior trial study, an analysis of covariance (ANCOVA) was performed using the difference in mean scores of the primary and secondary outcomes across two conditions, i.e. the experimental group of the trial study and the treatment group in the implementation study. Analyses were adjusted for age, sex and diagnosis (M Crohn, colitis ulcerosa). Analyses were done from an Intention-to-Treat (ITT) approach to avoid an over-estimation of the treatment effect. In addition, per protocol (PP) analyses were performed using the data of patients who attended at least five CBT sessions. Multiple imputation using chained equations (MICE) was employed to handle missing values, combining results from 5 imputed data sets into pooled estimates (White et al., 2011). To compare the relative magnitude of the effects, mean scores were standardized on the

continuous outcomes to Cohen's *d* using the pooled standard deviation of the baseline scores. Cohen's *d* of 0.3, 0.5 and 0.8 indicating a small, moderate and large effect sizes (ES), respectively, were calculated. Effect size estimates were presented with a 95% confidence interval (CI). The level of significance ( $\alpha$ ) was set at a two-sided 0.05. We compared the percentage of patients who dropped out (pre-treatment and during treatment) between the benchmark RCT and the implementation study using Chi-squared tests.

All analyses were repeated omitting data of the therapist from the Academic Medical Center with the most experience in implementing the psychological intervention previous to the study (i.e. who designed the original 'IBD-specific CBT' treatment manual from the benchmark study, Bennebroek Evertsz' et al. (2017).

### Qualitative Analysis: Semi-Structured Interviews

Qualitative analysis of the implementation process is important to reveal strengths and limitations of the treatment manual and its implementation. Considering contributions of prior implementation studies (van der Vaart et al., 2019), a semi-structured interview for therapists was designed taking into account the following dimensions: the value of the therapy, factors of success, use of the treatment manual, patient heterogeneity, implementation challenges and recommendations for improvement (See Table 2). Furthermore, an interview for gastroenterologists was constructed, considering the screenings procedure, referral of patients, future improvements and the usefulness of 'IBD-specific CBT' for patients with poor OoL anxiety and depressive complaints (See Table 3). Therapists and gastroenterologists involved in the implementation of the 'IBD-specific CBT' treatment manual of the four participating hospitals were invited to be interviewed. Interviews were administered via email, telephone or face-to-face, according to the preference of the respondent. A thematic analysis was performed by the first author (Bennebroek Evertsz') on the collected data in order

**Table 2** QL!C Implementation study – Semi-structured Interview for therapists

- 1 Considering your recent experience with IBD-specific CBT, what do you value about this type of therapy for IBD patients? Do you consider it a successful therapy in your experience and why?
- 2 Which modules of the therapy protocol have you found to be effective and have you applied most?
- 3 What are the strengths and limitations of the planned therapy protocol, in your experience?
- 4 Have you been able to follow the therapy protocol as planned or have you introduced modifications? If so, what type of modifications?
- 5 How has your experience applying the therapy protocol varied from patient to patient? Are there particular circumstances that make some patients more or less challenging to treat than others?
- 6 What other challenges have you faced while implementing the therapy protocol?
- 7 What could be done differently in the future to overcome these challenges?

**Table 3** QL!C Implementation study – Semi-structured Interview for gastroenterologists

1	Who administered the screening of IBD patients by the mental health sub-scale of the SF-36, the Informed Consent and the Case Report Form, the doctor him or herself or a paramedic? What is your opinion on this method?
2	What are difficulties in the process of referring patients to the therapists of the department of medical psychology?
3	What could be done differently in the future to overcome the challenges in the screening and referral?
4	Do you think this IBD-specific Cognitive Behavioural Therapy is necessary and helpful for Inflammatory Bowel Disease patients with a low quality of life, depression and/or an anxiety disorder?

to explore different dimensions of the implementation. The interviews of therapists and gastroenterologists were analysed separately.

## Results

### Sample Characteristics

Patients were recruited over a period of one and a half years between November 2018 and March 2020. We screened 280 patients for eligibility. Of these, 94 were eligible (meeting inclusion criteria a score of  $\leq 23$  on the mental health sub-scale of the SF-36 and willing to participate) and were allocated to the implementation study. At follow-up, 63 participants (67% compared to 81% for the benchmark RCT study) provided data for analysis for the IBDQ Total score (see Fig. 1).

Of the total group of patients in the implementation study, 26 patients were treated with ‘IBD-specific CBT’ ( $> 5$  sessions) in the University hospital and 37 patients were treated in the three general hospitals.

In the implementation study, a mean of 5.8 sessions ( $SD = 3.2$ ) were completed, whereas 6.1 ( $SD = 3.0$ ) sessions in the benchmark study ( $p = 0.513$ ) were completed, with 66.3% versus 74.6% of all participants (59 of 89 vs 44 of 59) completed at least five sessions ( $p = 0.283$ ).

The first participating hospital screened fifteen eligible patients (i.e. scored  $\leq 23$  on the mental health sub-scale of the SF-36), of whom nine started ‘IBD-specific CBT’ by participating therapists. In total five patients completed ‘IBD-specific CBT’ (followed more than five sessions). Four patients dropped out during treatment and ended therapy after one session; of them two patients had severe psychiatric disorders (i.e. PDD NOS) and two patients did not have enough complaints (no help requests). Six patients dropped out before the treatment started: one patient had no time/logistical problems, one patient was receiving psychotherapy elsewhere, three patients were not contactable and one patient was referred to a sleeping clinic because of problems with fatigue (other reason).

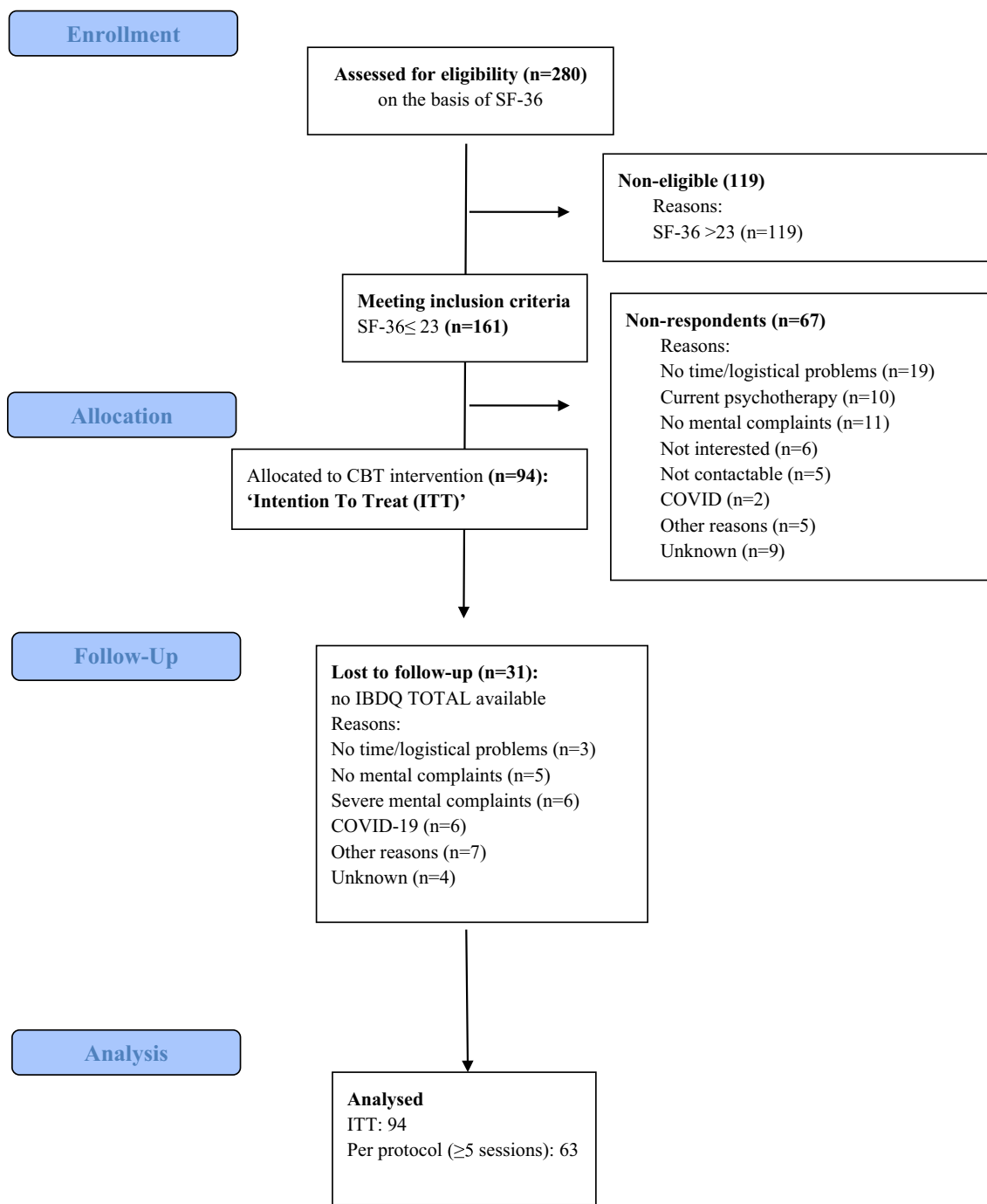
The therapists from this participating general hospital noticed that many of the patients referred by the specialized IBD nurse had other needs than ‘IBD-specific CBT’ (i.e.

they had no need for treatment for anxiety and depression disorders, post-traumatic stress disorders, adjustment disorders and poor QoL). Initially, they proposed to extend the inclusion period by a half-year. Finally, the implementation at this hospital was stalled and has not been continued.

The second participating hospital screened thirty eligible patients (i.e. scored  $\leq 23$  on the mental health sub-scale of the SF-36), of whom twenty-eight patients started ‘IBD-specific CBT’ with participating therapists. In total, twenty-five patients completed ‘IBD-specific CBT’ (followed more than five sessions). Three patients dropped out during treatment (after less than five sessions); one dropped out after one session due to COVID and two others dropped out after one session due to other problems (other reasons). Two patients dropped out before starting treatment; one patient had no time/logistical problems and one patient did not have enough complaints.

The third participating hospital screened twenty eligible patients (i.e. scored  $\leq 23$  on the mental health sub-scale of the SF-36), of whom nine started ‘IBD-specific CBT’ by participating therapists. In total, seven patients completed ‘IBD-specific CBT’ (followed more than five sessions). Two patients dropped out during treatment (after less than five sessions); one had COVID after three sessions and one dropped out after two sessions because of other problems (other reasons). Eleven patients dropped out before starting treatment; two patients were receiving psychotherapy elsewhere, four patients did not have enough complaints, one patient was not contactable, two patients had COVID, one patient had inflammation problems (other reason) and one patient dropped out for unknown reason.

The last participating hospital screened ninety-six eligible patients (i.e. scored  $\leq 23$  on the mental health sub-scale of the SF-36), of whom forty-eight patients started ‘IBD-specific CBT’ by participating therapists. In total, twenty-six patients completed ‘IBD-specific CBT’ (followed more than five sessions). Twenty-two patients dropped out during treatment (after less than five sessions); of them three stopped because of no time/logistical problems, three did not have enough complaints, four had severe mental complaints, four had COVID, four dropped out because of other problems (other reasons) and four dropped out for unknown reasons. Forty-eight patients dropped out before starting treatment; seventeen patients had no time/logistical problems, seven



**Fig. 1** Flow diagram for inflammatory bowel disease patients through the implementation study, including attrition. SF-36=Medical Outcomes Study Short Form 36 Health Survey; CBT=cognitive behav-

ioral therapy; IBDQ TOT=Inflammatory Bowel Disease Questionnaire total score; IBD=inflammatory bowel disease)

patients were receiving psychotherapy elsewhere, six patients did not have enough complaints, six patients were not interested, one patient was not contactable, three patients dropped for other reasons and eight patients dropped out for unknown reasons.

Table 4 provides the sociodemographic and clinical characteristics of the implementation ITT group and the benchmark RCT experimental ITT group. There were significantly more women \*(0.8% vs 66.1%) in the implementation study, patients were more often in

**Table 4** Comparison of study characteristics of the implementation ITT group and benchmark Randomized Controlled Trial experimental ITT group

	Implementation Group (n = 89)	Experimental Group (n = 59)
Gender*		
Female	79 (90.8%)	39 (66.1%)
Age in years (range)	40.1 (18.0–75.0)	39.4 (19.4–76.5)
Marital status*		
In a relationship	60 (69.0%)	30 (50.8%)
Level of education		
Low ( Primary or Secondary)	41 (53.2%)	33 (55.9%)
High (College or University)	36 (46.8%)	26 (44.1%)
Employment		
Employed or studying	55 (63.2%)	31 (52.5%)
Unemployed	32 (36.8%)	28 (47.5%)
Sick leave	13 (14.9%)	12 (20.3%)
Hospital type*		
University	43 (45.7%)	40 (67.8%)
Diagnosis		
Ulcerative colitis	37 (42.5%)	24 (40.7%)
Crohn's disease	50 (57.5%)	35 (59.3%)
Disease duration in years	13.3(2.0–52.0)	11.9 (0.3–46.0)
Number of operations		
None	58 (67.5%)	41 (69.5%)
≥ 1	28 (32.5%)	18 (30.5%)
Stoma	3 (3.5%)	3 (5.1%)
Medication*		
Prednisone	9 (10.6%)	14 (23.7%)
Family member(s) with IBD	25 (29.8%)	14 (23.7%)
Current Axis 1 disorder		40 (67.8%)
Mood disorder		11 (18.6%)
Anxiety disorder		15 (25.4%)
Somatoform disorder		1 (1.7%)
Eating disorder		4 (6.8%)
Adjustment disorder		18 (30.5%)
Alcohol-related disorder		1(1.7%)
Disorder related to substance abuse		0 (0.0%)
Psychotic disorder		0 (0.0%)

Note: ITT = intention to treat; Values are mean (SD) unless stated otherwise; \* is significant ( $p < 0.05$ ). There are some missing data per variable in the implementation group

a relationship (in a relationship 69.0% vs 50.8%) and treated in a university hospital (45.7% vs 67.8%) (see also Table 4).

### Treatment Effect

Both in the intention-to-treat and per protocol analyses, the only statistically significant difference between the benchmark RCT and the implementation study at follow-up was the mean score on the IBDQ sub-scale emotional following treatment (see Tables 5 and 6).

All outcome measures improved significantly over time from baseline to 3.5 months of follow-up (see Tables 7 and 8).

Following CBT, the IBDQ Total score enhanced significantly in the implementation ITT group with a moderate effect size ( $ES = 0.75$ ), compared to the moderate effect size ( $ES = 0.64$ ) of the benchmark RCT study (see Table 7). CBT had a significant improvement on the IBDQ sub-scales Systemic and Emotional, with moderate ( $ES = 0.57$ ) and large effect sizes ( $ES = 0.83$ ), respectively, compared with moderate ( $ES = 0.49$ ) and large effect sizes ( $ES = 0.92$ ) for the benchmark study. The results on the Bowel and Social sub-scales were significantly enhanced with small ( $ES = 0.40$ ) to



**Table 5** Mean scores and mean differences between the experimental and implementation group at (3.5 months) follow-up according to intention-to-treat analysis ITT

Assessment	N	N	Mean (SD) error		Difference in means (95% CI), <i>p</i> -value	
			Experimental group	Implementation group	Estimate without imputation of missing measurements	Estimate with multiple imputation of missing measurements
IBDQ total	48	63	168.42 (24.80)	162.36 (24.43)	6.05 (−3.81 to −15.91) <i>p</i> = .23	3.71 (−3.79 to 11.23) <i>p</i> = 0.33
IBDQ Bowel	48	63	53.88 (8.31)	53.20 (8.19)	0.68 (−2.61 to −3.98) <i>p</i> = .68	0.35 (−2.24 to 2.94) <i>p</i> = .79
IBDQ Systemic	48	63	22.25 (5.23)	21.21 (5.16)	1.04 (−1.04 to −3.11) <i>p</i> = .32	0.59 (−1.10 to 2.28) <i>p</i> = .50
IBDQ Emotional	48	63	65.01 (10.26)	60.55 (10.09)	4.46 (0.36 to −8.56), <b><i>p</i> = .03</b>	2.80 (−0.31 to 5.92) <i>p</i> = .08
IBDQ Social	48	63	27.64 (5.45)	27.21 (5.37)	0.43 (−1.73 to −2.59), <i>p</i> = .70	0.12 (−1.71 to 1.95), <i>p</i> = .90
HADS Anxiety	47	63	6.11 (3.54)	6.966 (3.48)	−0.86 (−2.27 to −0.56), <i>p</i> = .23	−0.77 (−2.21 to 0.66) <i>p</i> = .30
HADS Depression	47	63	4.46 (3.23)	5.04 (3.18)	−0.58 (−1.87 to −0.72), <i>p</i> = .38	−0.58 (−1.78 to 0.62) <i>p</i> = .35
HADS Total	47	63	10.58 (6.14)	12.01 (6.03)	−1.44 (−3.90 to −1.02), <i>p</i> = .25	−1.34 (−3.25 to 0.57) <i>p</i> = .97
CES-D	47	62	12.23 (9.29)	15.65 (9.15)	−3.42 (−7.14 to −0.30), <i>p</i> = .07	−3.03 (−6.44 to 0.19) <i>p</i> = .07

ANCOVA analyses were adjusted for baseline values: age, gender and disease-type  
ITT completer is defined as having a follow-up score on the IBDQ TOT  
 $p < 0.05$  indicating a significant result

moderate effect sizes ( $ES = 0.56$ ), compared to insignificant results of the benchmark RCT study with small effect sizes ( $ES = 0.33$  and  $ES = 0.27$ , respectively).

Following CBT, the HADS Total score and the anxiety and depression sub-scales decreased significantly, all with a moderate effect size ( $ES = 0.76$ ,  $ES = 0.67$ ,  $ES = 0.70$ ) compared to the moderate effect sizes of the benchmark RCT study ( $ES = 0.54$ ,  $ES = 0.54$ ,  $ES = 0.42$ ). Similarly, CBT significantly reduced the CES-D scores, with a moderate effect size ( $ES = 0.76$ ) compared to a fairly large  $ES$  of the benchmark RCT study ( $ES = 0.78$ ) (see also Table 7). Following imputation, the pattern of results was similar (see also Table 7).

When we restricted the analyses to patients who attended at least 5 CBT sessions, the PP sample of the implementation group, results were similar to those in the ITT implementation group (see also Table 8). No adverse events related to CBT were identified in the implementation study.

We repeated all analyses without the therapist from the Academic Medical Center who had the most experience in implementing the ‘IBD-specific CBT’ treatment manual. The pattern of results (both significance and effect sizes) was similar. The effect sizes were slightly lower (data not shown).

The only different result is a significant effect in the mean differences between the experimental and the implementation group in the ITT analyses (not imputed) (resp. 12.02 vs 16.34),  $p = 0.008$  and in the PP analyses (imputed) for the CES-D (resp. 12.84 vs 15.70),  $p = 0.028$ . In both cases, the mean on the CES-D in the implementation group was higher than in the RCT (data not shown).

We compared outcomes of participants who did versus did not receive CBT during the COVID-19 using ANCOVA. We did not find a reduced effect of the CBT for patients who were confronted with the pandemic during their treatment, compared to patients who were treated before the COVID-19 outbreak (data not shown).

### Semi-structured Interview with Gastroenterologists and IBD Nurse Specialist

Three gastroenterologists and one specialized IBD nurse from three participating hospitals were interviewed (one working at the gastroenterology and hepatology department of the University hospital, and three working at the gastroenterology departments of the general hospitals) (see Table 9).

The gastroenterologists believed that CBT is necessary and helpful for patients with Inflammatory Bowel Diseases and a poor quality of life, depression and/or an anxiety

**Table 6** Mean scores and mean differences between the experimental and implementation group at (3.5 months) follow-up according to Per Protocol analysis completers\*

Assessment	N		Mean (SD)		Difference in means (95% CI), <i>p</i> -value	
	Experi- mental Group	Imple- mentation group	Experimental group	Implementation group	Estimate without imputation of missing measurements	Estimate with multiple imputation of missing measurements
IBDQ Total	43	59	168.97 (25.05)	162.63 (24.58)	6.33 (−4.12 to 16.79) <i>p</i> =0.23	6.72 (−3.45 to 16.89) <i>p</i> =0.20
IBDQ Bowel	43	59	53.87 (8.37)	53.08 (8.23)	0.79 (−2.69 to 4.28) <i>p</i> =0.65	0.66 (−2.74 to 4.05) <i>p</i> =0.71
IBDQ Systemic	43	59	22.59 (5.15)	21.41 (5.06)	1.18 (−0.96 to 3.32) <i>p</i> =0.28	1.36 (0.74 to 3.46) <i>p</i> =0.20
IBDQ Emotional	43	59	65.07 (12.30)	60.66 (8.79)	4.41 (0.01 to 8.80) <b><i>p</i>=0.049</b>	4.61(0.13 to 8.88) <b><i>p</i>=0.04</b>
IBDQ Social	43	59	27.62 (5.52)	27.43 (5.42)	0.19 (−2.11 to 2.49) <i>p</i> =0.87	0.34 (−1.91 to 2.59) <i>p</i> =0.77
HADS Anxiety	43	59	6.34 (3.54)	6.87 (3.50)	−0.54 (−2.02 to −0.95) <i>p</i> =0.47	−0.71 (−0.75 to 0.75) <i>p</i> =0.34
HADS depression	43	59	4.54 (3.19)	4.79 (3.13)	−0.25 (−1.57 to 1.08) <i>p</i> =0.71	−0.35(−1.65 to −0.94) <i>p</i> =0.59
HADS Total	43	59	10.88 (7.37)	11.68 (6.14)	−0.81 (−3.35 to 1.74) <i>p</i> =0.53	−1.10 (−3.60 to 1.40) <i>p</i> =0.39
CES-D	43	59	12.51 (9.27)	15.41 (9.12)	−2.89 (−6.75 to 0.97) <i>p</i> =0.14	−3.17 (−6.94 to 0.60) <i>p</i> =0.10

\* ‘Per protocol analysis completers’ is defined as completed equal or more than 5 sessions CBT and having a follow-up score on the IBDQ TOT

\*\* Adjusted for age, sex, diagnosis, respectively

*p* < 0.05 indicating a significant result

disorder. They further remarked that it was beneficial for future quality of life and also improved compliance with medical treatment. Gastroenterologists argued that nurses are the professionals most suitable to screen IBD patients on poor QoL on a regular basis because they have got more time with patients to discuss psychological issues.

Two of the gastroenterologists did not experience any difficulties in the process of referring patients to the therapists of the department of medical psychology. One of them mentioned the lack of reimbursement of the department of medical psychology and lack of attention by the caregivers as an explanation for missed referrals of patients with mental disorders in the past.

Recommendations: paramedical care by a clinical nurse specialist, specializing in IBD care, should be the standard of care for IBD patients. A uniform workflow for a daily routine screening for anxiety and depression of IBD patients by a nurse specialist would be beneficial for the implementation of the CBT. Standard screening with the SF-36 could help overcome noticed time constraints, especially as the treating physician or nurse specialist would be alerted when the patient scores low ( $\leq 23$ ) on the mental health sub-scale of the SF-36.

### Semi-structured Interviews with Four Therapists

A total of twelve therapists were trained in the ‘IBD-specific CBT’ according to the treatment manual. All therapists received an invitation to be interviewed. Due to time constraints of most therapists, four therapists were interviewed from three out of four participating hospitals. The ‘IBD-specific CBT’ is considered successful and valuable for patients by the participating therapists. The therapy is not very strict and contains many different modules to fit the needs of individual patients. All modules were used (i.e. writing assignment, exposure part in imagery and rescripting). The cognitive therapy modules were found to be the most effective and were applied most. The strength of the treatment manual, in the experience of the therapists, is the availability of different modules which enables personalization. Also, the treatment manual is patient group specific (IBD), which can provide direction to therapists with respect to medical questions and complaints. However, according to one of the therapists, a limitation of the treatment manual is that there is a lack of psychoeducation about fatigue in the treatment manual.

**Table 7** ITT analyses completers\* implementation group; changes over time between baseline and at 3.5 months of follow-up

Assessment N	Mean (SD)		Difference in means (SD), (95% CI), <i>p</i> -value, ES	
	Implementation group baseline	Implementation group follow-up	Estimate without imputation of missing measurements	Estimate with multiple imputation of missing measurements
IBDQ total N = 111	143.59 (27.44)	164.98 (27.27)	–21.40 (28.70) (–26.80 to –15.10), <i>p</i> < 0.01 ES = 0.75	23.83 (29.58) (16.12–31.54) <i>p</i> < 0.01 ES = 0.81
IBDQ Bowel N = 111	49.59 (10.23)	53.50 (8.96)	–3.91 (9.764) (–5.75 to –2.07), <i>p</i> < 0.01 ES = 0.40	4.76 (9.85) (2.20–7.33) <i>p</i> < 0.01 ES = 0.48
IBDQ Systemic N = 111	18.40 (5.06)	21.66 (5.65)	–3.26 (5.63) (–4.32 to –2.20), <i>p</i> < 0.01 ES = 0.58	3.27 (5.53) (1.86–4.68) <i>p</i> < 0.01 ES = 0.59
IBDQ Emotional N = 111	51.60 (11.48)	62.48 (10.71)	–10.87 (13.08) (–13.33 to –13.33), <i>p</i> < 0.01 ES = 0.83	11.73 (13.37) (8.32–15.14) <i>p</i> < 0.01 ES = 0.88
IBDQ Social N = 111	23.99 (6.63)	27.40 (6.56)	–3.41 (5.99) (–4.53 to –2.28), <i>p</i> < 0.01 ES = 0.57	4.17 (6.47) (2.53–5.82) <i>p</i> < 0.01 ES = 0.64
HADS Anxiety N = 110	9.282 (3.91)	6.60 (3.72)	2.68 (4.02), (1.85 to 3.22), <i>p</i> < 0.01 ES = 0.67	–2.95 (3.47) (–3.83–2.06) <i>p</i> < 0.01 ES = 0.85
HADS Depression N = 110	7.33 (3.86)	4.79 (3.63)	2.54 (3.62), (1.85 to 3.22), <i>p</i> < 0.01 ES = 0.70	–2.69 (3.24) (–3.52–1.87) <i>p</i> < 0.01 ES = 0.83
HADS Total N = 110	16.61 (6.84)	11.40 (6.69)	5.21 (6.82), (3.92 to 6.50), <i>p</i> < 0.01 ES = 0.76	–5.63 (5.65) (–7.07–4.18) <i>p</i> < 0.01 ES = 0.10
CES-D N = 109	21.87 (9.75)	14.17 (9.56)	8.25 (10.78) (6.13–10.36) <i>p</i> < 0.01 ES = 0.76	–7.24 (10.77) (–9.99–4.49) <i>p</i> < 0.01 ES = 0.67

Adjusted for baseline value and stratification variables: gender, disease type and academic vs peripheral

ITT completer is defined as having a follow-up score on the IBDQ TOT

SD = standard deviation

95% CI = 95% Confidence Interval

*p* < 0.05 indicating a significant result

ES = Cohen's *d* effect size with 0.3, 0.5 and 0.8 indicating a small, moderate and large ES, respectively

The screening workflow (by gastroenterologists or IBD nurse specialists) also makes it more acceptable for patients to receive help from medical psychology, and it increases the contact between patients and the 'MDL' department. Therapists were not always able to follow the frequency of the sessions in the treatment manual as planned, (8 weekly sessions) because of full clinics, patients' holiday plans or surgical operations. Therefore, some therapists introduced modifications like extending the duration of the treatment by changing the frequency of the sessions. Moreover, the number of sessions was not ideal for every patient, some patients needed more or less sessions than eight.

There are particular circumstances that make some IBD patients more or less challenging to treat according to the treatment manual than others such as remission of disease inflammation, comorbidity, severe psychiatric disorders (i.e. psychosis, addiction) or insufficient suffering. In some cases, problems unrelated to IBD were

the reason patients scored high on depression or anxiety questionnaire (HADS).

There were a few other challenges faced by the therapists while implementing 'IBD-specific CBT'. Therapists of different hospitals had limited contact with therapists of other participating hospitals. It was indicated by them that they would prefer more contact with other participating therapists (Table 10).

### Patient Attrition Before Treatment and During Treatment

During the pre-treatment phase in the benchmark study, 67% dropped out for several reasons. Most of the patients refused help because they experienced barriers to obtaining help due to logistical and/or time problems. Some patients reported having no mental complaints and were not motivated to receive help or they received already psychological help. Some patients were physically not able to attend. In the

**Table 8** Per Protocol analyses completers\* implementation group; changes over time between baseline and at 3.5 months of follow-up

Assessment N	Mean (SD)		Difference in means (95% CI), p-value	
	Implementation group baseline	Implementation group follow-up	Estimate without imputation of missing measurements	Estimate with multiple imputation of missing measurements
IBDQ total N=59	142.85 (27.73)	165.30 (27.55)	22.45 (29.37), (16.62 – 28.22), $p < 0.01$ ES=0.76	23.83 (29.58) (16.28–31.38) $p < 0.01$ ES=0.81
IBDQ Bowel N=59	49.35 (10.40)	53.41 (9.04)	4.06 (9.93), (2.11–6.01), $p < 0.01$ ES=0.41	4.76 (9.85) (2.25–7.28) $p < 0.01$ ES=0.48
IBDQ Systemic N=59	18.36 (5.07)	21.91 (5.60)	3.55 (5.61), (2.45–4.65) $p < 0.01$ ES=0.63	3.27 (5.53) (1.86–4.68) $p < 0.01$ ES=0.59
IBDQ Emotional N=59	51.14 (11.52)	62.52 (10.93)	11.38 (13.46), (8.74–14.03) $p < 0.01$ ES=0.85	11.73 (13.37) (8.32–15.14) $p < 0.01$ ES=0.88
IBDQ Social N=59	23.99 (6.63)	27.51 (6.59)	–3.52 (6.07) (–2.33–4.71), $p < 0.01$ ES=–0.58	4.17 (6.47) (2.52–5.82) $p < 0.01$ ES=0.64
HADS Anxiety N=59	9.48 (3.90)	6.65 (3.72)	–2.83 (4.06), (–3.63–2.04), $p < 0.01$ ES=–0.70	–2.95 (3.47) (–3.84–2.06) $p < 0.01$ ES=–0.85
HADS Depression N=59	7.35 (3.94)	4.69 (3.60)	–2.67 (3.67) (–3.39–1.95), $p < 0.01$ ES=–0.73	–2.70 (3.24) (–3.52–1.87) $p < 0.01$ ES=–0.83
HADS Total N=59	16.83 (6.93)	11.34 (6.64)	–5.49 (6.91) (–6.85–4.13), $p < 0.01$ ES=–0.79	–5.63 (5.65) (–7.07–4.18) $p < 0.01$ ES=–1.00
CES-D N=59	22.43 (9.59)	14.19 (9.45)	–8.25 (10.79) (–10.36–6.13) $p < 0.01$ ES=–0.77	–7.24 (10.75) (–9.99–4.49) $p < 0.01$ ES=–0.67

\* ‘Per protocol analyse completers’ is defined as completed equal or more than 5 sessions CBT and having a follow-up score on the IBDQ TOT

\*\* Adjusted for surgery and unemployment, respectively

$p < 0.05$  indicating a significant result

implementation, study the percentage of non-participation (pre-treatment dropout) was 41.6% (of the 161 patients eligible for CBT, only 94 patients started CBT). Again, the most common reasons for non-participation were having no time/logistical problems ( $n = 19$ ), having no mental complaints ( $n = 11$ ) or receiving already psychological help ( $n = 10$ ), were not interested ( $n = 6$ ), not contactable ( $n = 5$ ), other reasons ( $n = 7$ ) or unknown ( $n = 9$ ) (see also Fig. 1).

In the case of ‘IBD-specific CBT’, the benchmark RCT reported an attrition of 17%. The most common reasons for dropping out were no time/logistical problems and further health complications such as IBD inflammation. In the implementation study, the attrition rate was 33% (of the 94 patients eligible for ‘IBD-specific CBT’, 63 patients finished treatment). Reasons were having no time/logistical problems ( $n = 3$ ), having no mental complaints ( $n = 5$ ), having severe mental complaints ( $n = 6$ ) or COVID-19 ( $n = 6$ ), other reasons ( $n = 7$ ), unknown ( $n = 4$ ) (see also Fig. 1).

In summary, the pre-treatment attrition percentage was significantly lower in the implementation study compared to the benchmark RCT (41.6% vs 67%,  $p < 0.001$ ).

The attrition percentage during treatment was significantly higher in the implementation study compared to the benchmark RCT (33% vs 17%,  $p = 0.046$ ).

## Discussion

The main aim of this study was to evaluate the effectiveness of ‘IBD-specific CBT’ on QoL, anxiety and depressive symptoms among patients with poor mental QoL when implemented in routine clinical care in hospitals.

The treatment effects of the implemented ‘IBD-specific CBT’ were comparable to those found in the benchmark RCT. Following ‘IBD-specific CBT’, specific IBD-related QoL improved significantly with a moderate effect size in the implementation group (ITT and PP). ‘IBD-specific CBT’ also attenuated anxiety and depressive complaints in the implementation group (ITT and PP), all with a moderate effect size. Effect sizes were similar to those of the benchmark RCT study.

In general, the treatment result of the implementation of ‘IBD-specific CBT’ was successful. In addition, there were relatively lower levels of eligible patients not starting CBT in the implementation group but a higher dropout of patients during treatment compared to the benchmark study.

The favourable effects of ‘IBD-specific CBT’ found in this study are in line with the findings of studies showing positive effects of CBT in patients with IBD (Chen et al.,

**Table 9** Overview interview answers gastroenterologists 30-10-2023

Who	Question 1: Who administered the screening of IBD patients by the mental health subscale of the SF-36, the Informed Consent and the Case Report Form, the doctor him- or herself or a paramedic? What is your opinion on this method?	Question 2: What are difficulties in the process of referring patients to the therapists of the department of medical psychology?	Question 3: What could be done differently in the future to overcome the challenges in the screening and referral?	Question 4: Do you think this IBD-specific Cognitive Behavioural Therapy is necessary and helpful for Inflammatory Bowel Disease patients with a low quality of life, depression and/or an anxiety disorder?
Gastro enterologist (general hospital) 16-04-2020	A paramedic. I think a well trained paramedic is the best equipped person for the care of patients with IBD in clinical remission and should screen for fear and depression on a regular basis	Reimbursement is the major one. Lack of attention by caregivers the second one	Psychological care should be reimbursed (not only on paper, but also in real clinical practice). Caregivers should be trained that fear and depression are one of the major determinants of a poor outcome. Paramedical care by a trained nurse specialist should be the standard of care for IBD patients	YES!
Specialised IBD nurse (general hospital) 08-04-2020	The screening of IBD patients was the responsibility of the IBD nurses or the nurses specialists (NP). I think this is the best way, nurses know the patients well and have more time to discuss psychosocial issues than the doctor	We experienced no problems in the referrals, contact with the psychology department runs well. Sometimes patients had to wait a little longer for an appointment with the psychologist	Screening had to be done during the normal duties of the IBD nurses/nurses specialists, so sometimes in the daily routine screening was forgotten	Yes, I think IBD-specif CBT is definitely helpful for IBD patients with problems regarding coping with IBD or other psychosocial issues like anxiety or depression in relation to IBD Most of the sessions are still ongoing but what I have heard of some of the patients for example: past fears and anxieties are less of an issue today and their coping skills are improved. This is definitely beneficial for future quality of life and compliance In depth I can't specifically comment on the CBT itself, therefore I refer to the psychologists
Gastroenterologist (general hospital) 06-04-2020	Doctor himself and nurse specialist, both actually. It would be most convenient to have the patient filled in at home, possibly online, and that the patient then comes to the poli with the completed list or score	None	Making a better/ clearer/ more uniform workflow: so write a plan of approach in advance, about how patients should be included, who does what (e.g. take away informed consent), now we had to come up with that all by ourselves...	Yes, could possibly be a standard part of the consultation, provided that it is done beforehand, even by filling in the patient and linking it to EPPD (HIX)

**Table 9** (continued)

Who	Question 1: Who administered the screening of IBD patients by the mental health subscale of the SF-36, the Informed Consent and the Case Report Form, the doctor him- or herself or a paramedic? What is your opinion on this method?	Question 2: What are difficulties in the process of referring patients to the therapists of the department of medical psychology?	Question 3: What could be done differently in the future to overcome the challenges in the screening and referral?	Question 4: Do you think this IBD-specific Cognitive Behavioural Therapy is necessary and helpful for Inflammatory Bowel Disease patients with a low quality of life, depression and/or an anxiety disorder?
Gastro enterologist (University hospital) 04-04-2020	The treating physician (gastroenterologist) and the receptionists	None	Time constraints could be a challenge, however screening through Epic could overcome this, especially when the treating physician receives a message when the patient scores at or below the cut-off score ( $\leq 23$ )	Yes
Total	Paramedics, IBD nurses, nurses specialists, the gastroenterologist or a receptionist administered the screening of IBD patients by the mental health subscale of the SF-36, the Informed Consent and the Case Report Form. Gastroenterologists argue that nurses are most suitable for screening the patients because they have more time with patients to discuss psychological issues	No difficulties were experienced in the process of referring patients to the therapists of the department of medical psychology	Paramedical care by a trained nurses specialist should be the standard of care for IBD patients. A uniform workflow for a daily routine screening by a nurse specialist would be beneficial for the implementation of the IBD-specific Cognitive Behavioural Therapy. Screening through Epic could help overcome time constraints, especially when the treating physician or nurses specialist receives a message when the patient scores lower or equal to 23 on the mental health subscale of the SF-36	Every gastroenterologist believes it is necessary and helpful for Inflammatory Bowel Disease patients with a poor quality of life, depression and/or an anxiety disorder. The gastroenterologists notice that it is definitely beneficial for future quality of life and compliance of patients

**Table 10** Overview interview answers therapists 30-10-2023

Who	Question 1: Considering your recent experience with IBD-specific Cognitive Behavioural Therapy, what do you value about this type of therapy for IBD patients? Do you consider it a successful therapy in your experience and why?	Question 2: Which modules of the therapy protocol have you found to be effective and have you applied most?	Question 3: What are the strengths and limitations of the planned therapy protocol, in your experience?	Question 4: Have you been able to follow the therapy protocol as planned or have you introduced modifications? If so, what type of modifications?	Question 5: How has your experience applying the therapy protocol varied from patient to patient? Are there particular circumstances that make some patients more or less challenging to treat than others?	Question 6: What other challenges have you faced while implementing the therapy protocol?	Question 7: What could be done differently in the future to overcome these challenges?
Therapist (general hospital) 06-04-2020	<p>It is nice that there is now a protocol for this specific group of patients. This can give me, but also my colleagues, direction in the treatment and some insight in what problems generally occur in this group of patients. Possibly a protocol in combination with a screening also makes it more accessible for patients to accept help from medical psychology, something that many of my patients probably would not have done without this protocol. I find it difficult to answer whether I think it is a successful therapy, because the protocol gives you a lot of freedom, it is broad and I add quite a bit of myself to it. The patients I have seen seem to experience the treatment, under the guidance of the protocol, as valuable. But again, it is difficult for me to distinguish what the difference would be with a treatment without this protocol</p>	<p>I really like to use the writing assignment, in combination with rescripting, to begin therapy. In addition, I like to connect to this with the thought report and (often) some interventions regarding living rules. The topic of avoidance comes up, and I like to have the Avoidance questionnaire filled out, but here I often do it a bit shorter, without the assignments</p>	<p>See also question 1. Strengths: Provides direction, IBD-patient group specific, approachable, increases contact with the MDL department, you explore topics with patients that may not seem immediately applicable at first glance but that people can learn something from. Limitations: I would like to see more psycho-education about fatigue in the protocol, I really miss that. It is a bit too free and general, which makes me wonder if you can measure whether this particular protocol 'works'. The HADS also easily includes people with problems from a different angle</p>	<p>Writing assignment; agree with patient how often and for how long is feasible. Avoidance module: integrate into thought report /CBT module. Don't have everyone fill out Young questionnaire, precepts often emerge well from thought reports already and the Young schemas that emerge are often mild. Add psychoeducation about fatigue</p>	<p>It is more difficult when symptoms are in remission, although there is room for processing then. Yet I also had to refer some patients because of comorbidity that was in the foreground</p>	<p>It would be nice if booklets were available, we had our own scanned copies to give to the patient, but the quality of these is then poor. Little contact with the other hospitals (although an intervention was actually planned)</p>	<p>Possibly some more structure in evaluation (preferably face-to-face), space to spar about how things are going and what could be done differently with the researchers. Possibility of providing original documents</p>

Table 10 (continued)

Who	Question 1: Considering your recent experience with IBD-specific Cognitive Behavioural Therapy, what do you value about this type of therapy for IBD patients? Do you consider it a successful therapy in your experience and why?	Question 2: Which modules of the therapy protocol have you found to be effective and have you applied most?	Question 3: What are the strengths and limitations of the planned therapy protocol, in your experience?	Question 4: Have you been able to follow the therapy protocol as planned or have you introduced modifications? If so, what type of modifications?	Question 5: How has your experience applying the therapy protocol varied from patient to patient? Are there particular circumstances that make some patients more or less challenging to treat than others?	Question 6: What other challenges have you faced while implementing the therapy protocol?	Question 7: What could be done differently in the future to overcome these challenges?
Therapist (University hospital) 24-04-2020	Yes, for people with depression or anxiety due to IBD, this is definitely a successful treatment	Because of my patients' complaints (no trauma), I mainly did the cognitive therapy, which worked well. It is more difficult for me to judge the other modules. The writing assignment some patients found very helpful and other patients (without trauma) less so	Strengths: modular treatment making personalization possible, unambiguous treatment (CBT). The protocol is applicable to both people who meet the criteria for depression, anxiety and PTSD (DSM 5). The protocol is also applicable to people who have less severe symptoms (including adjustment disorders), but do want help	Mostly as planned, with the exception of the term. Due to full outpatient clinics, patients' vacation plans, etc., it was often impossible to see patients every week, and sometimes not every two weeks. Also, one patient became ill in the meantime and underwent surgery, so the protocol was implemented over a longer period of time	See also point 3 - both at the time when people really meet all the criteria (depression, anxiety, PTSD), then I think the protocol is very appropriate. And also at the time when the complaints are milder, specific modules can be applied. The exception is severe psychiatric disorders	Practical point: that one of the questionnaires was only in English in the protocol	-
Therapist (general hospital) 23-04-2020	I value the different modules, so you can switch to the patients needs. The therapy is not a strait jacket I think it is a successful therapy, because all the different obstacles in life were addressed	The cognitive part	Strengths were noted above Limitations: for me that I feel more comfortable with EMDR	With two patients I made the decision not to do therapy, because the problems were not Crohn related	There were some patient with personality problems, these were more challenging, because of the strong-held beliefs	That 8 sessions was in some cases too much, while in other too few	More flexible planning
Therapist (general hospital) 11-05-2020	Yes, I consider it a successful therapy, because the patient profits from it. There is special attention for disease-aspects like avoidance-behavior (for example, not going out, because of fear of diarrhoea) and its concrete. Patients have their own workbook on paper, which they can keep and monitor	Exposure by imagery and rescripting	Strengths: clear intake questions, different modules available to be chosen for best fit patients Limitations: in practise I didn't use the module scheme therapy, it was not relevant for my case-load. Option EMDR in stead of imagery and rescripting should be possible	No modifications, but I was sooner finished than 8 sessions	Sometimes other problems than IBD in stead were the reason why they scored high on depression or anxiety. Indication appeared to be not wright. In this case I excluded them after discussing it with the researcher	-	I would recommend the program to anyone dealing with IBD patients. However, if therapist prefer to work with EMDR that should be possible



Table 10 (continued)

Who	Question 1: Considering your recent experience with IBD-specific Cognitive Behavioural Therapy, what do you value about this type of therapy for IBD patients? Do you consider it a successful therapy in your experience and why?	Question 2: Which modules of the therapy protocol have you found to be effective and have you applied most?	Question 3: What are the strengths and limitations of the planned therapy protocol, in your experience?	Question 4: Have you been able to follow the therapy protocol as planned or have you introduced modifications? If so, what type of modifications?	Question 5: How has your experience applying the therapy protocol varied from patient to patient? Are there particular circumstances that make some patients more or less challenging to treat than others?	Question 6: What other challenges have you faced while implementing the therapy protocol?	Question 7: What could be done differently in the future to overcome these challenges?
Total	<p>The IBD-specific cognitive behavioural therapy is considered successful and valuable for patients by the participating therapists. The therapy is not that strict and contains many different modules to fit the needs of individual patients</p>	<p>All modules were used (i.e. writing assignment, exposure part in imagery and rescripting). The cognitive therapy modules were found to be the most effective and were applied most</p>	<p>The strengths of the protocol, in the experience of the therapists, are the different modules which enables personalization. Also the protocol is patient group specific (IBD), which can give direction to therapists. The screening protocol also makes it more accessible for patients to accept help from medical psychology, and it increases the contact between patients and the 'MDL' department</p> <p>A limitation of this protocol, is that there is a lack of psychoeducation about fatigue in the protocol</p>	<p>Therapists were not always able to follow the therapy protocol as planned, (8 weeks) because of full polyclinics, patients' holiday plans or surgical operations etc. Therefore, therapists introduced modifications like extending the duration of the protocol</p>	<p>There are particular circumstances that make some patients more or less challenging to treat according to the protocol than others, such as: remission, comorbidity, severe psychiatric disorders (i.e. psychosis addition) or personality disorders</p> <p>In some cases, other problems than IBD were the reason patients scored high on depression or anxiety questionnaire (HADS)</p>	<p>There were a few other challenges faced by the therapists while implementing the therapy. Therapists of different hospitals had limited contact with therapists of other participating hospitals. Also, the amount of sessions was not ideal for every patient, some patients needed more or less sessions than 8</p>	<p>These challenges may be overcome in the future through more flexible planning and more opportunities for evaluation and consultation during regular group supervision sessions</p>

2021; Reise-Filteau et al., 2021). However, it is unclear to what extent these favourable effects of CBT directly post treatment are sustained.

Previous research mentions the need for individualized interventions (McCombie et al., 2016). This is in line with the current study focussing on personal therapy goals of patients, challenging and changing basic living rules, and elective interventions (e.g. behavioural activation, exposure and response prevention for anxiety and depression (Gregory, 2021)).

Additionally, previous research proposes that the brain–gut axis consists of bidirectional links and thus not only would IBD have an effect on psychological state but also the other way around. This calls for equal focus on mental health alongside the physical well-being of patients of IBD in the form of collaborative care (Fairbrass et al., 2022; Lores et al., 2021; Peppas et al., 2021).

### Obstacles and Limitations

Unfortunately, the limited treatment capacity of the therapists was a barrier in one of the hospitals. When implementing the CBT treatment manual, it is therefore important to set aside time in the schedule of the professionals in advance.

Moreover, some therapists had several questions during supervision about the selection and motivation of patients and the screening workflow. They indicated that there were many interventions per session in the treatment manual so they had a hard time conducting all interventions in time, whereas other therapists managed to conduct all interventions within the preplanned number of sessions.

The aforementioned problems could have been solved during pro-active consultations. More regular group supervision with all participating therapists would have allowed for better screening and selection of motivated patients, taking into account the exclusion criteria (e.g. severe psychiatric problems). In the University hospital, there was weekly supervision as part of the multidisciplinary meeting, if necessary. In the other general hospitals this could also have been better organized: a more pro-active consultation by the supervisor and not waiting for the therapist's wish and initiative could be beneficial.

The recommendation for regular supervision to increase adherence to the implemented treatment manual is also mentioned in the previous literature (Kramer & Burns, 2008). Kramer and Burns (2008) investigated factors influencing the success of the implementation of CBT for depressed adults in two healthcare centres, via post-study qualitative interviews with clinicians. Potentially crucial factors to increase adherence to the treatment manual are regular supervision and team meetings, which can aid in achieving a shared vision. This and organizational factors combined

could facilitate a more effective implementation (Bruijniks et al., 2018).

During the implementation period, the World Health Organization (WHO) declared a global pandemic of COVID-19 on 11 March 2020 (Cucinotta & Vanelli, 2020). This global pandemic required containment measures to prevent contamination, like social distancing, quarantine and self-isolation. The effect of psychosocial consequences of this global pandemic can be particularly serious for people who are already affected by mental health problems, e.g. anxiety and depression (Fiorillo & Gorwood, 2020; Kumar & Nayar, 2020). As a result, the influx of patients slowed down. Fortunately, we moved on by giving online treatment instead of face-to-face. It was favourable that the digital 'IBD-specific CBT' treatment during the pandemic was as effective as the face-to-face 'IBD-specific CBT' treatment before the COVID outbreak.

A few more limitations of the screening workflow and the 'IBD-specific CBT' treatment manual came to light during this study.

To start with, the frequency of weekly therapy sessions was not feasible in reality, because of full clinics, patients' holiday plans or surgical operations, inflammations, etc. Therefore, the duration of the trajectory differed between patients (a range from 8 weeks till 24 weeks). Flexible scheduling of the therapy sessions would be more convenient than a fixed duration of the trajectory.

Secondly, screening through the electronic patient files of the participating hospitals or standard online examination prior to consultation instead of screening during face-to-face consults by nurses or nurse specialists could help overcome noticed time constraints. Especially when the treating physician or nurse specialist receives a message in the software system when a patient scores low on the mental health subscale of the SF-36 ( $\leq 23$ ).

Thirdly, in the benchmark RCT study, the Generic health status was assessed with the SF-36 (Ware, 1992); the 36 items can be aggregated into a Physical Component Summary (PCS) score and a Mental Component Summary (MCS) score. However, this questionnaire was not used as an outcome measurement in our implementation sample. As a consequence, we have no results regarding this outcome (SF-36, Ware, 1992) in the implementation study.

Lastly, a limitation of the qualitative part of the research is that it is explorative and descriptive on the basis of interviews of only a sub-group of therapists and gastroenterologists and one specialized IBD nurse.

### Strengths and Facilitators

A strength of this study is the distribution of the implementation over one University hospital and three general

hospitals, facilitating generalization of the results and comparison across healthcare settings.

This study contains quantitative research by the means of measuring the effectiveness of the implementation by the number of successful treatments, as well as qualitative research by post-study qualitative semi-structured interviews with gastroenterologists, an IBD nurse specialist and therapists. Both the research combined gives a good inclusive overview of the success of the implementation.

Post-study qualitative semi-structured interviews with gastroenterologists and therapists showed that they believe this ‘IBD-specific CBT’ is necessary and/or helpful for IBD patients with poor mental quality of life, depression and/or an anxiety disorder.

### Patient Attrition

One of the aims of the current study was to investigate the reasons behind patient non-participation (pre-treatment dropout) or attrition during treatment in the implementation group. Compared to the benchmark study, the pre-treatment dropout percentage of IBD patients in the implementation study was significantly lower (respectively, 67% vs 42%). A possible explanation for this is that in the pre-selection of patients in the benchmark RCT, a trained psychologist carried out a telephone version of the validated SCID-I (First et al., 1999) to determine severe psychiatric disorders. In the implementation study, this SCID interview is omitted, because of time constraints. As a consequence, less patients in the implementation study compared to the benchmark study dropped out before treatment. Possibly, dropout was delayed during treatment in the implementation study. This is consistent with the finding that the attrition during treatment in the implementation study was significantly higher compared to the benchmark study (respectively, 33% vs 17%).

Another reason for the last difference was that six patients were affected with COVID in the implementation group and had to discontinue treatment. When leaving out these six patients, the percentage of attrition during treatment in the implementation group would become more or less equal (26.5%) to the average percentage of dropout during treatment mentioned in the previous literature.

A meta-analysis regarding the implementation of CBT conducted by Fernandez et al. (2015) on the dropout data of 115 primary empirical studies showed an average pre-treatment dropout rate of 15.9% and of 26.2% during treatment. Dropout was seen to be significantly associated to the following: the type of diagnosis, having depression the highest attrition rate; the format of delivery treatment; the treatment setting, seeing fewer dropouts in inpatient than in outpatient settings; and the number of sessions, being there a reduction

in attrition rates of treatment starters as the number of sessions increased.

### Practice Implications and Future Recommendations

Arranging more frequent and structured supervision of the participating therapists (and gastroenterologists and specialized IBD nurses) during the implementation of the ‘IBD-specific CBT’ would be beneficial for overcoming the earlier mentioned challenges. Moreover, regular group supervision with more opportunities for evaluation and consultation would be beneficial and presumably make the implementation more successful. Important issues include that the participants have insufficient suffering. On the other hand, the treatment manual has a limit on the severity of psychiatric problems (i.e. psychosis).

Although the current ‘IBD-specific CBT’ treatment manual is suitable for all IBD patients with poor mental QoL and in need of help, not every IBD patient (during a period of disease activity) will be physically able to attend face-to-face sessions. Especially for those IBD patients, an internet-based self-help manual might be of interest. Symptoms like bloody diarrhoea, abdominal pain, fatigue, flares and fistulas discourage some patients from visiting therapists. Therefore, a substantial proportion of IBD patients might prefer online self-help treatment during disease flare activity.

Finally, future research should focus on the long-term effects of CBT for IBD patients with anxiety and depression (Chen et al., 2021). This also applies to the effects of our ‘IBD-specific CBT’.

### Conclusion

‘IBD-specific CBT’ can be successfully implemented in both general and University medical settings. Regular group supervision of psychologists performing the ‘IBD-specific CBT’ treatment is recommended.

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**Author contributions** FBE was the chief investigator grant holder of the implementation QL!C study. She drafted the final manuscript (which was added and modified by all other authors), wrote the original treatment manual ‘IBD-specific CBT’ and was responsible for the training and supervision of the psychotherapists. The statistical analysis plan was set up by FBE, HK and PN are responsible for the statistical analysis and reporting. FBE, HK, CLHB, and ML were responsible for the funding. BO, SP, BN, MD and ZY supported in literature searches, reference preparation and reviewed early drafts of the article. All authors read and approved the final manuscript.

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**Availability of data and material** The corresponding author FBE had full access to the study data and material.

**Code availability** Non-applicable.

## Declarations

**Conflict of interest** Bennebroek Evertsz’, Bockting, Braamse, van Dissel, Duijvestein, Kager, Kool, Löwenberg, Mares, Nieuwkerk, Sipkema, Young, and Knoop declare that they have no competing interests.

**Ethics approval** This implementation study design has been approved by the Medical Ethics Committee of the Amsterdam UMC (location AMC: dossier number: XT4-148).

**Consent to participate** The manuscript has been read and approved by all authors.

**Consent for publication** The corresponding author FBE has final responsibility for the decision to submit for publication.

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