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Does computerized cognitive behavioral therapy help people with inflammatory bowel disease? A randomized controlled trial

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Abstract

Background: Cognitive behavioral therapy (CBT) may be useful for improving the health-related quality of life (HRQOL) of at least some inflammatory bowel disease (IBD) patients, especially those with psychiatric comorbidities. However, CBT can be difficult to access. These difficulties can be overcome by computerized CBT (CCBT). This is a randomized controlled trial of a self-administered CCBT intervention for IBD patients focused on improving HRQOL. It is hypothesized that CCBT completers will have an improved HRQOL relative to people not allocated to the CCBT.

Methods: IBD patients were randomly allocated to CCBT (n = 113) versus treatment as usual (TAU; n = 86). The IBD questionnaire (IBDQ) at twelve weeks after baseline was the primary outcome while generic HRQOL, anxiety, depression, coping strategies, perceived stress, and IBD symptoms were secondary outcomes. Outcomes were also measured at six months after baseline. Predictors of dropout were also determined.

Results: Twenty-nine CCBT participants (25.7%) completed the CCBT. IBDQ was significantly increased at twelve weeks in CCBT completers compared to TAU patients ($F = 6.38$, $p = 0.01$). SF-12 mental ($F = 5.00$, $p = 0.03$) was also significantly better in CCBT compared to TAU patients at twelve weeks. These outcomes were not maintained at six months. The predictors of dropout were baseline depression, biological use, lower IBDQ scores, and not having steroids.

Conclusion: Improvements at twelve weeks after baseline were not maintained at six months. Future research should aim to improve adherence rates. Moreover, CCBT may not work for IBD patients with comorbid depression.

Key Words

Crohn's disease; ulcerative colitis, psychotherapy; psychology; quality of life

Introduction

Inflammatory bowel disease (IBD), which includes Crohn's disease (CD) and ulcerative colitis (UC), is a chronic relapsing-remitting condition with a range of symptoms including diarrhea, rectal bleeding, abdominal pain, and extra-intestinal symptoms (e.g., arthritis, liver symptoms, skin and eye manifestations) [1]. IBD patients suffer from an impaired health-related quality of life (HRQOL) [2, 3] and have an increased susceptibility to anxiety and depression [2, 4].

Psychotherapy, especially cognitive behavioral therapy (CBT) where people are taught to identify and modify unhelpful thinking styles and maladaptive behaviors [5-7], may be a useful intervention for at least some IBD patients, especially those with psychiatric comorbidities [2, 8, 9]. CBT is based on the premise that altering maladaptive thoughts results in changes in both emotions and behavior[10]. Psychotherapy may improve HRQOL [11, 12] for IBD patients but not all studies have reported psychotherapy to improve HRQOL [13, 14]. However, these studies were highly heterogeneous in terms of interventions, study populations, and measures of HRQOL which will have contributed to the inconsistent findings. The one study to have used CBT and have HRQOL as an outcome variable showed the intervention to improve inflammatory bowel disease questionnaire (IBDQ) scores compared to treatment as usual (TAU) [15]. There are barriers to the implementation of psychotherapy, such as time and travel burden for patients to attend face-to-face sessions, shortages of adequately trained therapists, high costs, potential stigma associated with seeking professional help and lack of accessibility in remote areas [16-19]. These limitations may be overcome by the utilization of computerized interventions like computerized CBT (CCBT), which is CBT that is self-directed (i.e. not facilitated by a therapist) and implemented via a computer [20, 21].

When asked to choose between psychological interventions, a majority of IBD patients expressed a preference for a computerized over face-to-face intervention [22]. Ehealth

interventions (broadly defined) have shown promise in terms of improving HRQOL in gastrointestinal conditions [23]. Computerized psychotherapy may be as effective as traditional psychotherapy [24].

There are a number of different mechanisms by which CCBT can have its effect on HRQOL, anxiety, and depression. These include improved coping strategies, and decreased perceived stress and IBD symptoms. Coping strategies, which are specific methods for responding to stressors, can be adaptive (i.e. improve outcomes) or maladaptive (i.e. worsen outcomes) [25]; CCBT should aim to increase adaptive and decrease maladaptive coping strategies. Perceived stress measures the extent to which people appraise situations or events as "unpredictable, uncontrollable, and overloading" [26]; CCBT should ultimately lead to decreased perceived stress through improving the participant's response to stress. Finally, IBD symptoms are the strictly physical manifestations of IBD as measured by brief IBD symptom questionnaires[27, 28]; a cognitive behavioral approach may improve symptoms in IBD patients [15].

This paper describes a randomized controlled trial (RCT) of a self-administered CCBT intervention for IBD patients focused on improving HRQOL via better management of stress and improved coping with IBD. The comparison condition is TAU which is normal medical treatment. It is hypothesized that CCBT completers will have an improved HRQOL, anxiety, depression, coping strategies, perceived stress, and IBD symptoms relative to people not allocated to the CCBT.

Materials and Methods

Trial design

This study was a multicenter (i.e. Christchurch, West Coast, and Nelson) RCT of CCBT in addition to usual therapy in adults with IBD, with parallel groups, without blinding and with imbalanced randomization. No changes to the trial design occurred during the course of the study.

Participants

Inclusion/Exclusion Criteria

Eligible patients were all adults with IBD aged 18-65, computer literate, and had access to a computer and the internet. Participants were excluded if their disease was too severe (e.g., recent major surgery and/or complicated disease). Participants had to (a) have sufficient knowledge of English to answer the questionnaires and participate in the intervention and (b) be willing to participate in the intervention and answer the questionnaires at baseline, post-intervention (twelve weeks after baseline) and six months after baseline. Patients who had an existing psychotic disorder or were currently receiving any form of psychological intervention (i.e. presently receiving CBT or another therapy from a psychologist or counsellor), or were alcohol or substance dependent were excluded. Those with an ileostomy or colostomy were excluded from the study because the primary outcome measure, namely IBDQ, is not designed for those with an ileostomy or colostomy.

Recruitment Methods and Study Settings

Participants were recruited via five different sources from 29 October, 2012 until 2 October, 2013: Christchurch Hospital Gastroenterology Outpatient Clinic; Greymouth Hospital Outpatient Clinic; Nelson Crohn's and Colitis Support Group; Christchurch

Gastroenterologists' private clinics; and an existing database from two previous observational studies [22, 29] which were unrelated to this RCT.

Most study participants were recruited from Christchurch, New Zealand. If they were interested and eligible, they were approached by the principle investigator and given an information sheet and consent form. Those who opted out were not contacted further and those who did not respond within four weeks were contacted up to three times via two different methods (phone, text message, email or letter).

Interventions

After their consent was obtained, participants were randomized to CCBT or TAU. Those who were allocated to the CCBT group were shown how to login and use the CCBT website; they received a username and password. Once the induction was completed, all participants in both groups were sent a link to the questionnaires via email. All patients in the TAU group were aware of the CCBT patients receiving the CCBT (i.e. no blinding).

Those in the CCBT group received self-administered CCBT in addition to TAU. Those in the TAU group received only usual IBD treatment which is treatment from their physician exactly as they had received previous to the study; they were not referred for mental health intervention. Both groups completed questionnaires at baseline, twelve weeks after baseline, and six months after baseline. The CCBT was implemented using MedMoodle [30]. The CCBT involved eight sessions with sixty-two resources (see Supplementary Table 1 for details of each session). The sessions briefly addressed dealing with stress through relaxation, how thoughts influence feelings and behavior, avoidance, coping, effective communication and attention and distraction for dealing with pain. They were designed based on the existing CBT program for IBD (http://www.tameyourgut.com) which adapted classic CBT activities to address the specific needs of IBD patients (e.g. toilet dependence, open communication about bowel problems, dealing with abdominal pain) but abbreviated the original 10-week

program to 8 weeks to reduce participant burden (the specific program is available via the corresponding author upon request). The activities were designed based on the classic CBT model developed by Beck [5-7]. All participants were expected to complete activities in each session (i.e. there was no matching between participant exact problem and the activities as the therapy was not individualized). The program was focused on improving HRQOL via better management of stress, fixing underlying maladaptive thoughts, and improved coping with IBD.

Outcomes

The timing of all assessments is shown in Supplementary Table 2. Outcomes were assessed by validated questionnaires as described below.

Primary

The primary outcome was IBD-specific HRQOL at twelve weeks as assessed by the IBDQ [31], which contains thirty-two items divided in to four health sub-dimensions: bowel symptoms (e.g., loose stools, abdominal pain; ten items), systemic symptoms (e.g., fatigue, sleeping problems; five items), social functioning (e.g., limited social activity, school or work attendance; five items), and emotional functioning (e.g., irritability, anger, depression; twelve items). Responses are scored on a seven point Likert scale where higher scores indicate a better HRQOL. The IBDQ is reliable and valid [32], has a range of 32 to 224[33], and has a minimum clinically significant change score of twenty points[34].

Secondary

Generic HRQOL was measured with the *Short Form 12* (SF-12) and contains twelve questions [35]. Answers are scored and totaled to produce raw scale scores for a mental and physical subscale which are then transformed to a 0 – 100 scale [36]. These scores have a mean of fifty and standard deviation (SD) of ten [37].

Anxiety and depression were assessed with the *Hospital Anxiety and Depression Scale* (HADS) [38] . It is designed to be used in a hospital context as it omits questions related to symptoms that may be caused by physical illness (e.g. dizziness) concentrating on psychological aspects of anxiety and depression. Sensitivity and specificity are optimum when caseness is defined at eight or above for the anxiety and depression subscales [39]. The HADS has been used extensively in IBD studies [40-42].

Stress was measured with the *Perceived Stress Scale* (PSS). This is the most commonly used measure of the perception of stress [26]. There is a fourteen item, ten item and four item version [26, 43]. The ten item version (PSS-10) was used for this study. The items are answered on a five point Likert scale with higher scores reflecting a greater extent to which situations in a person's life are interpreted as being stressful [26, 43]. Higher PSS scores have been associated with smoking status, colds, and other stress measures [43].

Social functioning was measured with the *Social Functioning Questionnaire* (SFQ) which is an eight item questionnaire [44]. The questions are answered on a scale of zero to three and a score of ten or more indicates poor social functioning [44].

Neuroticism was measured with the *Eysenck Personality Questionnaire–Brief Version* (EPQ-BV) which is used to measure extraversion and neuroticism[45]. This study omitted the extraversion subscale.

The *Brief Coping Operations Preference Enquiry* (Brief COPE) was used to measure coping strategies [46]. It is a validated twenty-eight item questionnaire used to assess coping behaviors known to be adaptive and maladaptive strategies. There are fourteen subscales with two items each. The coping strategies are adaptive problem-focused (use of instrument support, planning, and active coping), adaptive emotion-focused (use of emotional support, religion,

positive reframing, acceptance, and humor), and maladaptive (behavioral disengagement, denial, self-distraction, self-blame, substance use, and venting) coping strategies [47].

The *Harvey Bradshaw Index* (HBI) was used to measure IBD-related symptoms in CD patients [27] and the *Simple Clinical Colitis Activity Index* (SCCAI) was used to measure symptoms in UC and inflammatory bowel disease-unspecified patients [28].

CCBT usage and acceptability

Use of the program for each participant was measured by monitoring the number of logins and resources used by each participant. There were sixty-two resources available for download over eight sessions. People who downloaded half or more of the resources were considered to be "completers".

CCBT acceptability was determined using a ten item questionnaire designed by the authors. Questions were asked about participant enjoyment, the relevance of the program to them, whether it improved their understanding of IBD, whether it improved their psychological or physical health, and whether they would recommend such a program to others with gastrointestinal disorders.

Sample size

Power calculation was conducted on a per-protocol (PP), not intention-to-treat (ITT), basis. It was calculated that two hundred and thirty eight participants would need to be allocated at a ratio of nine-to-eight to the CCBT versus TAU group because more CCBT participants were expected to drop out from the study. This was based on 80% power (p-value 0.05) and the CCBT group (n = 126) having an IBDQ increase of twenty more points (which is the minimum clinical significance[34]) than the TAU group (n = 112).

Randomization

This study was an open label RCT with imbalanced randomization (9 CCBT: 8 TAU). Randomization to CCBT or TAU took place after screening and consent. An excel spreadsheet with 238 numbers randomly allocated to CCBT or TAU at a ratio of nine-to-eight was used and a number between one and 238 was produced by the website random.org [48]. The participants were allocated in groups of six to nineteen (depending on how many were recruited in the fortnight). Allocation concealment was not used but participants were present when they were randomized so they could see how they were allocated to the CCBT or TAU group.

Participant contact via email, text message, and phone call

All participants (CCBT and TAU) were contacted via email to complete the questionnaires. They were text messaged if they did not complete the questionnaire and were then contacted via phone call if they still had not completed the questionnaire.

In addition, participants in the CCBT group were emailed once per week for eight weeks to remind them of the availability of the program and that the next topic was released. CCBT participants were also text messaged at six weeks to encourage them to keep looking at the program and to contact the lead investigator if they had any questions.

Statistical methods

SPSS 22-x[49] was used to perform the statistical analyses. There were two populations analyzed for the CCBT group. The first was the ITT population who were participants randomized into the trial; incomplete data was replaced by using last observation carried forward. The second was the PP population who were participants who completed the protocol (i.e. completed $\geq$50% of the resources) and completed the baseline and follow-up assessments.

The primary outcome was the PP comparison of IBDQ change scores for CCBT completers versus TAU participants. Linear mixed effects models were performed for all variables with the change in the outcome as the dependent, CCBT completers versus TAU as the fixed factor and baseline outcome scores as the covariates. ITT analyses were performed last; only the primary outcome (IBDQ) and any measures which were significant in the PP analyses had ITT analyses performed. Attrition rates for the groups and the binary outcome of improvement of IBDQ score (improvers defined as change of $\geq$20 vs. non-improvers) were compared with the Fisher's exact test (two tailed).

Among CCBT participants, binary logistic regressions were performed to determine the predictors for completing the program (i.e. completing $\geq$50% of the resources); unadjusted odds ratios were calculated for each of the predictors before a multivariate model was built.

Incomplete data

All questions had a "Decline to answer" option which meant some questionnaires were not fully completed. When a subscale of a questionnaire had one answer or 10% or less of answers missing, missing or "Decline to answer" answers were replaced with means for the answers on the other questions for that subscale. In cases where more than one answer and more than 10% of answers for a questionnaire were omitted by a participant, the questionnaire was treated as missing for that participant.

Ethical Considerations

The study was conducted with the consent of the New Zealand Health and Disability Ethics Committee (12/NTA/46). Each participant provided informed consent and only de-identified data are presented. The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000922875).

Results

Participant Flow

The participant flow is shown in Figure 1. Of the 231 randomized participants, thirty-two patients were excluded after randomization as they did not complete the baseline questionnaire. One hundred of the CCBT participants (88.5%) logged in at least once and twenty-nine (25.7%) of CCBT participants were “completers”.

Recruitment Issues

Participants were recruited between 22 October, 2012 and 8 October, 2013. The first patient was recruited on 22 October, 2012 and the last patient had their six month follow up performed on 8 April, 2014. Recruitment was ceased short of the power calculation of 238 as it became apparent that the number of dropouts in the CCBT group had been significantly underestimated; it was expected 80% would complete the intervention but 26% did.

Baseline data

Baseline data for the CCBT and TAU groups are shown in Table 1 and Table 2.

Attrition

At baseline, 113 CCBT and eighty-six TAU participants completed the questionnaires. However at twelve weeks only sixty-five CCBT (57.5%) participants completed the primary outcome questionnaire (IBDQ) whereas seventy-eight TAU (90.7%) did so. Among CCBT completers, 24/29 (82.8%) completed the week twelve questionnaires. Drop out in the ITT CCBT for the week twelve questionnaires was significantly higher than in the TAU group (42.5% v. 9.3%, $p = 0.048$), whereas CCBT completers were no more likely to drop out than TAU participants (17.2% v. 9.3%, $p = 0.87$).

Fifty-three CCBT (46.9%) and sixty-six TAU (76.7%) participants completed the IBDQ at six months. Among CCBT participants, 24/29 (82.8%) of completers did the questionnaires at six months. Drop out in the ITT CCBT group was again significantly higher than in the TAU group at the six month assessment point (53.1% v. 23.4%, p = 0.04), and again CCBT completers were no more likely to drop out than TAU participants (17.2% v. 23.4%, p =0.87).

Outcomes and estimation

Per-protocol outcomes

Table 3 shows PP at twelve weeks and six months.

Primary outcome measure

PP CCBT completers had a greater increase in mean IBDQ scores than TAU participants (F = 6.38, p = 0.01) at twelve weeks.

Secondary outcome measures at twelve weeks

SF-12 mental improved in CCBT completers versus TAU participants (F = 5.00, p = 0.03). All other outcomes were not significant (p > 0.05).

Secondary outcome measures at six months

At six months, religion (adaptive emotion-focused coping strategy) decreased more in TAU participants than CCBT completers (F = 4.39, p = 0.04), substance use (maladaptive coping strategy) decreased more in CCBT completers than TAU participants (F = 4.22, p = 0.04), and venting (maladaptive coping strategy) increased more in CCBT completers than TAU participants (F = 6.18, p = 0.02). All other outcomes were not significant at six months (p > 0.05).

Intention-to-treat

Twelve weeks

IBDQ ($F = 0.59$, $p = 0.44$) and SF-12 mental ($F = 0.04$, $p = 0.83$) did not significantly increase at twelve weeks.

Six months

IBDQ did not significantly increase ($F = 0.46$, $p = 0.50$). Substance use ($F = 0.38$, $p = 0.54$) did not significantly decrease and venting ($F = 0.89$, $p = 0.35$) did not significantly increase in CCBT versus TAU. Religion ($F = 4.66$, $p = 0.03$) decreased more in the TAU than CCBT group.

Binary outcomes

When the analysis was performed using IBDQ as a binary outcome, at twelve weeks, 45.8% of CCBT completers improved versus 24.4% of TAU participants and this was not significant ($p = 0.07$). No effects were found at six months for the PP population (41.7% versus 30.3%, $p = 0.32$).

Ancillary analyses

Completion of program

Of the 113 people given access to the CCBT, 100 (88.5%) people downloaded at least one of the sixty-two resources. Twenty-nine (25.7%) completed the intervention. Univariate and multivariate analyses were carried out to determine predictors of study completion (Table 4): biological treatment and baseline depression significantly reduced the odds of completion while currently using prednisone and having an IBDQ score of above 160 increased the odds of completion. A multivariate model with biological treatment, baseline depression, and IBDQ score of above 160 was performed. In this model, none of the predictors were significant.

Patient perceptions of the program

Forty participants (22 completers) completed the questionnaires about their perceptions of the program (35.4%). The majority enjoyed the program (74%), felt it had relevance (87%), felt it improved their understanding of IBD (80%), felt it improved their physical and/or mental health (74%), and would recommend it to others with gastrointestinal disorders (80%).

Discussion

The primary aim of this study was to determine if CCBT significantly increases IBDQ scores in CCBT completers compared with TAU at twelve weeks after baseline. The primary hypothesis was supported in PP analyses although change in IBDQ scores did not differ between the groups in ITT analyses. The clinical significance of this is that those who complete at least 50% of the CCBT have an improvement of HRQOL. At twelve weeks, the mean SF-12 mental score increased more in CCBT completers than TAU participants. At six months, religion decreased in TAU compared to CCBT completers, substance use decreased in CCBT completers compared to TAU participants, and venting increased in CCBT completers compared to TAU participants. Only religion change scores remained significant in ITT analyses.

The predictors of non-completion of CCBT were biological treatment (i.e. infliximab or adalimumab), depression, low IBDQ score, or not using prednisone at baseline. Generally, patients with more severe depression at baseline have a less favorable response to psychotherapy [50, 51] and there is poor adherence with medication among psychologically distressed people with IBD [52-54]. Moreover, an IBS study reported that HRQOL was more impaired in dropouts than treatment completers [55], which is similar to what was found in this study. Severe disease (as indicated by low IBDQ scores) predicted dropout in this study and so it is consistent that those on biological treatment dropped out more because biological treatment is given to those with more severe and refractory disease[56]. On the other hand, the phenomenon of those on prednisone at baseline being less likely to drop out is more difficult to explain. Of note was that a relatively small percentage of the total sample was on biological treatment and prednisone and the mean dose of prednisone was low.

The CCBT did not improve social functioning, perceived stress, or IBD symptoms. Nevertheless, most people who completed the acceptability questionnaire reported that the CCBT was enjoyable, relevant, improved understanding of IBD, improved physical and/or mental health, and would recommend the program to other people with IBD or other gastrointestinal disorders. Also, the open-ended qualitative answers were generally positive about the CCBT.

Implications

Overall, the findings were modest although promising in the short term among those who completed the CCBT. There is an unfortunate paradox with the prediction of completion of the CCBT: those who may benefit most from CCBT, namely those who experience psychological distress, are less likely to complete the intervention. Given that the effect of depression was not significant in the multivariate model (once baseline IBDQ scores and biological use were controlled for) suggests that the effect of depression is confounded by disease severity. Therefore, treating the disease itself is probably one of the most effective ways of treating the psychiatric morbidity associated with IBD.

Some participants reported positive benefits from the CCBT, including an increase in their knowledge of their disease. There were no reported harms from this cheap intervention and so it is possible this program can be made available to many IBD patients via Crohn's and Colitis websites in North America, Australasia, and Europe. At the very least, it provides a good basis for providing constructive information to IBD patients.

Limitations and future directions

There was no sham treatment and so participants were not blinded to whether they were receiving the treatment or not. Blinding was not seen as practical or worthwhile because the

main aim was to see if the CCBT is better than the status quo. Blinding would not have improved the results in favor of the CCBT.

This study did not reach the numbers calculated in the power calculation. Nevertheless, 199 randomized participants is a significant number in a study of this nature and this is one of the largest CCBT studies in physically ill patients to date [21].

The low adherence was of concern. Part of the reason for the modest adherence in the present study may have been that the website used was not as modern and user-friendly as other similar websites, such as one for depression [57]. Nevertheless, it is common for CCBT studies to have high dropout rates, especially when there is no therapist contact [58, 59]. For example, arguably the strongest RCT ever performed in CCBT for chronic physical illnesses was in patients with diabetes and reported only fifty-three out of 125 (42.4%) CCBT participants completed all sessions [60]. Indeed, the participants in the present study anecdotally reported the CCBT was demanding and time consuming and it has been reported in a systematic review that dropout is more common as treatment length increases [61]. Overall, attempts can be made to improve adherence through more human contact, less sessions, or a better website, but it is also possible modest adherence may be inevitable in CCBT studies irrespective of the quality of the website or therapist contact. Furthermore, increased human contact would decrease cost-effectiveness and the intervention in this study is already average in length in the context of CCBT studies [21].

The high dropout, which is commonplace in such studies as this one [23], has an important implication: the PP analyses were highly susceptible to self-selection biases. Nevertheless, ITT analyses were performed in an attempt to detect treatment effects not caused by self-selection. It cannot be expected that participants who do not utilize the materials of the CCBT

can gain any benefits and so the PP analyses were acceptable in this context. Again, future research should focus on increasing treatment adherence.

There was an initial improvement in IBDQ scores among CCBT completers but these positive effects were not maintained at six months. If there are no long terms gains from the CCBT, the CCBT may not be of use beyond the time at which the participants participate in it. Future research needs to attempt to address this through offering "booster" sessions of CCBT after it is completed. For example, booster sessions may improve long term outcomes in conventional CBT for depression [62, 63]; future studies should explore this possibility in the context of CCBT for IBD participants.

The amount of time since diagnosis was not recorded. This is problematic because perhaps newer diagnoses are more likely to complete or benefit from CCBT. Future research should record the time since diagnosis of each patient in the CCBT study.

Finally, it was unknown whether some patients began psychiatric treatments of a medical or psychosocial nature outside the boundaries of the study. Future studies should ask the participants at twelve weeks and six months if they have started taking a new psychiatric medication or attending psychotherapy outside of the prescribed CCBT in the study since the study began.

Conclusions

This study aimed to improve the HRQOL of people who participate in a CCBT program. There were some improvements in IBDQ scores at twelve weeks after baseline but these were not maintained at six months. The high dropout rate from the CCBT group was of concern and future research should aim to improve adherence rates. Nevertheless, the CCBT helped some participants to better understand their IBD. Therefore, this type of intervention should

be further tested in subgroups which may benefit and considered further by patient organizations as a means of educating their constituents.

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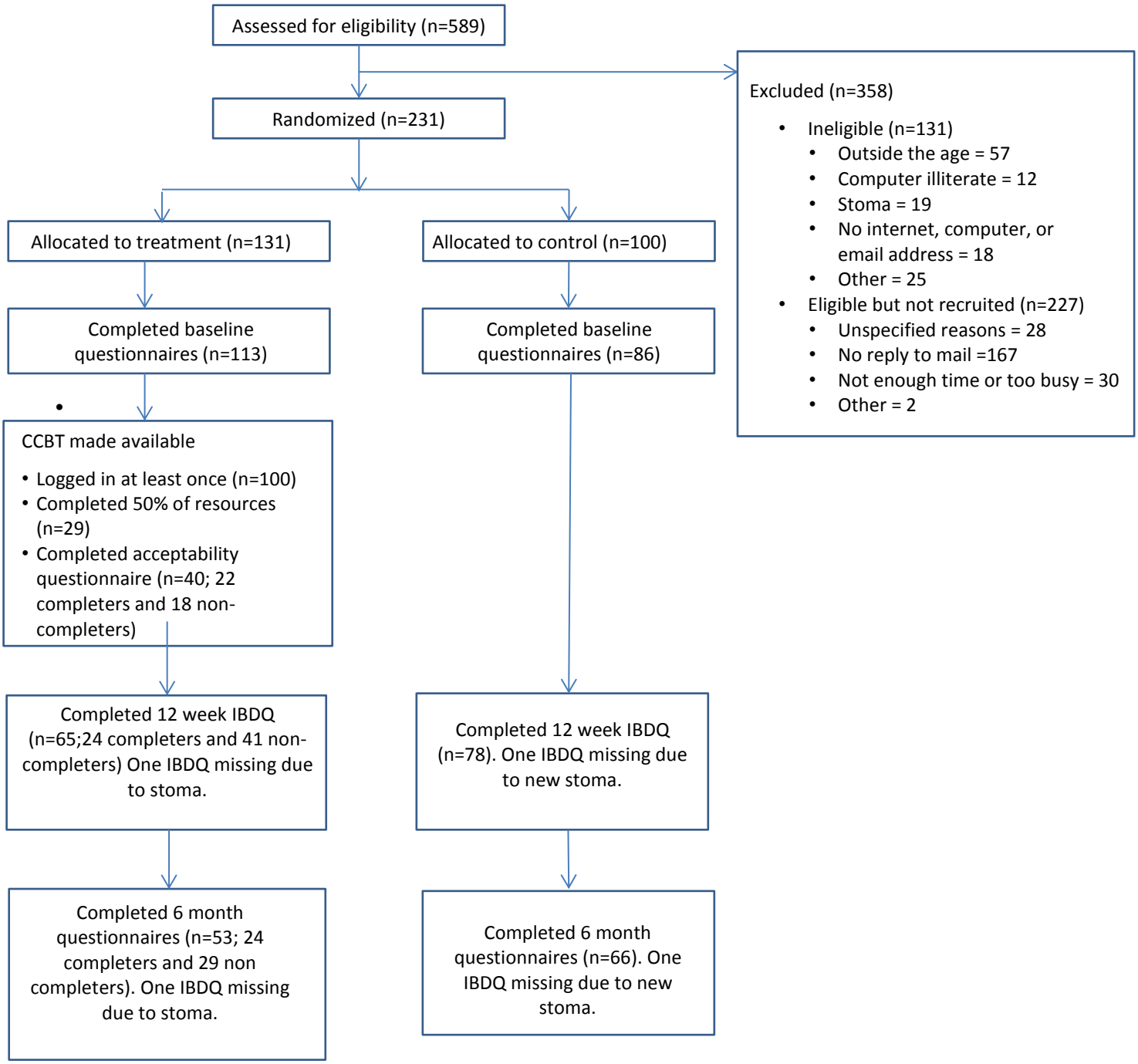

Figure 1: Participant flow diagram

Table 1: TAU and CCBT participants' demographics at baseline[a]

Variable	TAU[b] (n[c]=86) n (%)	CCBT[d] (n=113) n (%)
Age[e]	39. 6 (11.8)	38.3 (12.8)
Male Sex	33 (38.4)	38 (33.6)
Diagnosis CD[f]	62 (72.1)	75 (66.4)
UC[g]	20 (23.3)	34 (30.1)
IBD-U[h]	4 (4.7)	4 (3.5)
New Zealand born	69 (80.2)	93 (82.3)
Ethnic group NZ European (solely)	75 (87.2)	100 (88.5)
Other ethnicity	11 (12.8)	13 (11.5)
Marital status Married, de Facto, engaged or civil union	41 (47.7)	51 (45.1)
Single	32 (37.2)	46 (40.7)
Divorced, bereaved, or separated	12 (14.0)	14 (12.4)
Not specified	1 (1.2)	2 (1.8)
Highest Education Tertiary	31 (36.0)	50 (44.2)
High School	41 (47.7)	50 (44.2)
No high school, other or not specified	14 (16.3)	13 (11.5)
Employment Full time work	44 (51.2)	64 (56.6)
Part time work	22 (25.6)	30 (26.5)
Full time study	3 (3.5)	11 (9.7)
Part time study	5 (5.8)	6 (5.3)
Beneficiary (any)	7 (8.1)	10 (8.8)
Smoking status Current	13 (15.1)	11 (9.7)
Former	30 (34.9)	35 (31.0)
Never or decline to answer	43 (50.0)	67 (59.3)
Previous surgery	26 (30.2)	28 (24.8)
"j-pouch" surgery	0 (0.0)	1 (0.9)
IBD[i] Medication at baseline		
Pentasa	42 (48.8)	45 (39.8)
Azathioprine or mercaptopurine	35 (40.7)	45 (39.8)
Methotrexate	4 (4.7)	11 (9.7)
Biological	15 (17.4)	21 (18.6)
Asacol	8 (9.3)	10 (8.8)
Colifoam	5 (5.8)	4 (3.5)
Prednisone	9 (10.5)	9 (8.0)
None	3 (3.5)	9 (8.0)
Other	6 (7.0)	7 (6.2)
Average prednisone dose/day (SD[j]) in mg	1.6 (5.8)	2.1 (9.1)

[a] Percentages included for discrete data and standard deviations for continuous data. Continuous data includes age and average prednisone dose; [b] TAU= treatment as usual ;[c] n= number in group; [d] CCBT=computerised cognitive behavioural therapy; [e] Age obtained for 111 CCBT and 82 TAU (6 missing) ;[f] CD= Crohn's disease ;[g] UC= ulcerative colitis; [h] inflammatory bowel disease-unspecified ;[i] IBD=inflammatory bowel disease; [j] SD=standard deviation..

Table 2: ITT CCBT and TAU participants' questionnaire scores at baseline

Questionnaire subscale	n[a]	TAU[b] (n=86)	CCBT[c] (n=113)
IBDQ[d]	199	160.5 (35.7)	163.6 (32.3)
SF-12[e] Mental	198	44.4 (12.00)	45.2 (10.1)
SF-12 Physical	198	43.5 (9.9)	47.4 (8.9)
HADS[f]-Anxiety	199	6.9 (4.1)	7.0 (4.1)
HADS-Depression	199	4.9 (4.4)	4.6 (3.5)
EPQ-BV[g] Neuroticism	196	28.3 (9.4)	29.1 (10.5)
SCCAI (UC and IBD-U)[h]	61	2.2 (2.3)	2.3 (2.4)
HBI (CD)[i]	135	4.5 (4. 5)	3.6 (4.00)
SFQ[j]	190	6.7 (3.7)	5.8 (3.6)
PSS-10[k]	196	17.6 (7.1)	16.6 (7.4)
Brief COPE[l]-adaptive problem focused TOTAL	192	13.4 (4.9)	12.7 (4.7)
Active coping	195	4.8 (1.9)	4.8 (1.9)
Use of instrument support	194	3.9 (1.9)	3.6 (1.7)
Planning	193	4.6 (2.0)	4.3 (1.8)
Brief COPE-adaptive emotion focused TOTAL	189	21.3 (5.7)	20.6 (5.8)
Use of emotional support	195	4.1 (1.8)	4.0 (1.9)
Positive reframing	193	4.2 (2.0)	3.8 (1.9)
Humour	193	3.8 (1.7)	4.0 (2.0)
Acceptance	195	6.2 (1.8)	6.2 (1.7)
Religion	193	3. 0 (1.8)	2.7 (1.4)
Brief COPE-~~Maladaptive~~ maladaptive TOTAL	192	19.0 (6.0)	18.2 (5.0)
Self-distraction	194	4.4 (2.0)	4.2 (1.8)
Denial	196	2.6 (1.3)	2.5 (1.1)
Substance use	195	2.7 (1.4)	2.6 (1.3)
Behavioural disengagement	194	2.8 (1.2)	2.7 (1.2)
Venting	194	3.4 (1.3)	3.3 (1.4)
Self-blame	194	3.2 (1.6)	3.0 (1.1)

[a] n=sample size; [b] TAU=treatment as usual; [c] CCBT=computerized cognitive behavioural therapy; [d] IBDQ=Inflammatory Bowel Disease Questionnaire; [e] SF-12= Short Form 12; [f] HADS= Hospital Anxiety and Depression; [g] EPQ-BV=Eysenck Personality Questionnaire- Brief Version; [h] Simple Clinical Colitis Activity Index did not include extraintestinal manifestations; [i] Harvey-Bradshaw Index did not include complications or abdominal masses; [j] SFQ=Social Functioning Questionnaire; [k] PSS-10= Perceived Stress Scale; [l] Brief COPE= Brief Coping Operations Preference Enquiry

Table 3: Per-protocol outcomes at 12 weeks and 6 months

Variable	Mean (and standard deviation) of change score of TAU[a] at 12 weeks	Mean (and standard deviation) of change score of CCBT completers at 12 weeks	Mixed effects F value and p-value at 12 weeks	Mean (and standard deviation) of change score of TAU at 6 months	Mean (and standard deviation) of change score of CCBT completers at 6 months	Mixed effects F value and p-value at 6 months
IBDQ[b]	6.63 (25.21)	15.39 (22.97)	**6.4, 0.01**	11.74 (29.52)	12.64 (26.93)	1.0, 0.32
SF-12[c] Mental	2.57 (8.40)	5.61 (9.32)	**5.0, 0.03**	0.91 (9.77)	2.62 (12.72)	1.0, 0.31
SF-12 Physical	2.52 (7.50)	3.22 (9.19)	1.6, 0.20	3.73 (8.87)	3.58 (9.30)	0.4, 0.54
HADS[d]-Anxiety	-1.08 (2.60)	-1.07 (2.51)	0.2, 0.69	-0.66 (2.96)	-1.63 (3.37)	1.8, 0.18
HADS-Depression	-0.86 (2.74)	-1.33 (2.24)	2.2, 0.14	-0.51 (3.12)	-0.48 (2.68)	0.0, 0.89
SCCAI[e] (UC[f] and IBD-U[g])	-0.05 (1.90)	-1.73 (4.82)	1.2, 0.27	-0.44 (1.54)	-1.82 (2. 75)	1.7, 0.21
HBI[h] (CD)	-0.68 (3.50)	-0.69 (3.04)	1.1, 0.29	-1.60 (4.70)	-0.42 (3.96)	0.4, 0.54
SFQ[i]	-0.86 (2.23)	-0.18 (2.60)	0.5, 0.48	-0.76 (2.87)	-0.03 (2.71)	0.3, 0.58
PSS-10[j]	-1.49 (5.61)	-1.81 (6.21)	1.2, 0.27	1.05 (7.12)	1.51 (7.89)	0.0, 0.88
Problem focused coping TOTAL	-1.01 (4.31)	-0.64 (4.83)	0.2, 0.64	-2.07 (4.14)	-2.52 (3.31)	0.10, 0.82
Active coping	-0.19 (1.85)	-0.30 (2.18)	0.0, 0.92	-0.72 (1.88)	-0.88 (1.51)	0.5, 0.49
Use of instrumental support	-0.51 (1.73)	-0.33 (1.76)	0.0, 0.86	-0.55 (1.72)	-0.75 (1.39)	0.4, 0.51
Planning	-0.31 (1.80)	0.00 (1.69)	0.7, 0.41	-0.79 (1.67)	-0.87 (1.60)	0.1, 0.77
Emotion focused coping TOTAL	-1.49 (4.31)	-0.05 (5.58)	0.3, 0.59	-3.60 (4.54)	-1.32 (4.32)	2.5, 0.12
Use of emotional support	-0.37 (1.43)	-0.09 (1.12)	0.2, 0.69	-0.49 (1.32)	-0.26 (0.96)	0.0, 0.92
Positive reframing	-0.29 (1.74)	0.13 (1.79)	0.1, 0.73	-0.61 (1.61)	0.17 (1.19)	1.9, 0.17
Humour	-0.17 (1.57)	-0.33 (1.49)	0.2, 0.68	-0.34 (1.26)	-0.38 (1.24)	0.0, 0.98
Acceptance	-0.47 (1.89)	-0.13 (1.65)	0.6, 0.43	-1.39 (1.91)	-0.82 (1.71)	0.5, 0.47
Religion	-0.09 (0.85)	0.21 (1.25)	1.9, 0.17	-0.55 (1.49)	0.00 (1.25)	**4.4, 0.04**
Maladaptive coping TOTAL	-1.99 (4.14)	-1.17 (2.96)	0.0, 1.00	-2.00 (3.67)	-0.36 (3.86)	1.3, 0.26
Self-distraction	-0.58 (1.74)	-0.25 (1.33)	0.1, 0.79	-0.68 (1.82)	-0.83 (1.09)	0.0, 0.85

Variable	Mean (and standard deviation) of change score of TAU[a] at 12 weeks	Mean (and standard deviation) of change score of CCBT completers at 12 weeks	Mixed effects F value and p-value at 12 weeks	Mean (and standard deviation) of change score of TAU at 6 months	Mean (and standard deviation) of change score of CCBT completers at 6 months	Mixed effects F value and p-value at 6 months
Denial	-0.32 (0.83)	-0.08 (0.72)	0.5, 0.48	-0.18 (0.90)	-0.95 (2.32)	0.0, 0.98
Substance use	-0.06 (1.13)	-0.29 (0.75)	1.0, 0.32	-0.10 (0.99)	-0.43 (2.41)	**4.2, 0.04**
Behavioural disengagement	-0.38 (1.02)	-0.39 (0.84)	1.5, 0.23	-0.39 (1.13)	-0.22 (2.00)	0.0, 0.91
Venting	-0.27 (1.26)	0.21 (1.18)	1.2, 0.28	-0.17 (1.12)	0.74 (2.67)	**6.2, 0.02**
Self-blame	-0.35 (1.28)	-0.21 (1.47)	0.0, 0.85	-0.43 (1.17)	-0.83 (1.09)	1.3, 0.25

[a] TAU=treatment as usual; [b] IBDQ= Inflammatory Bowel Disease Questionnaire; [c] SF-12= Short Form 12; [d] HADS= Hospital Anxiety and Depression Scale; [e] Simple Clinical Colitis Activity Index; [f] UC=ulcerative colitis; [g] IBD-U=inflammatory bowel disease-unspecified; [h] HBI= Harvey-Bradshaw Index; [i] SFQ=Social Functioning Questionnaire; [j]PSS-10= Perceived Stress Scale;

Table 4: Predictors of completion of program[a]

		Unadjusted		Adjusted[b]	
Predictor	**N[c]**	**OR[d]**	**95% CI[e]**	**OR**	**95% CI**
Aged 40 or older[f]	52	1.61	0.69-3.76		
Male	38	1.29	0.54-3.11		
In a relationship[g]	51	1.03	0.44-2.42		
Tertiary educated	50	1.24	0.53-2.90		
CD (not UC or IBD-U)	75	0.64	0.27-1.52		
New Zealand born[h]	93	0.97	0.32-2.99		
New Zealand European	100	1.17	0.30-4.59		
Full time employment	64	0.77	0.33-1.79		
Full time study	11	0.62	0.13-3.04		
Beneficiary (any kind)	10	0.30	0.04-2.46		
Current smoker	11	1.76	0.48-6.51		
Pentasa[i]	45	2.29	0.97-5.42		
Azathiopurine or mercaptopurine[i]	45	0.59	0.24-1.44		
Methotrexate[i]	11	0.61	0.12-3.00		
Biological[i]	**21**	**0.11**	**0.01-0.88**	0.15	0.02-1.17
Asacol[i]	10	2.05	0.54-7.87		
Colifoam[i]	4	0.95	0.10-9.54		
Prednisone[i]	**9**	**4.12**	**1.02-16.55**		
Baseline IBDQ[j] above 160	**62**	**2.75**	**1.10-6.91**	2.02	0.77-5.30
Baseline SF-12 mental above 50[k]	39	0.64	0.25-1.62		
Baseline SF-12 physical above 50[k]	53	0.60	0.25-1.42		
Baseline anxiety caseness[l]	43	0.81	0.34-1.97		
Baseline depression caseness[l]	**25**	**0.20**	**0.04-0.89**	0.29	0.06-1.38
Baseline neuroticism above 30	44	1.08	0.46-2.56		
Baseline PSS-10 above 17[m]	52	0.88	0.37-2.05		
Poor social functioning at baseline[n]	18	0.30	0.06-1.39		
Maladaptive coping at baseline above 17[o]	51	0.53	0.22-1.29		
Emotion-focused coping at baseline above 17[p]	75	0.74	0.29-1.89		
Problem-focused coping at baseline above 17[o]	21	1.18	0.41-3.42		

[a] Completion defined as downloading 50% of available resources and irrespective of whether 12 week questionnaires were completed or not; [b] All significant variables from univariate analyses included in multivariate analysis except for prednisone which had a small sample size. Sample size 112 for multivariate analysis; [c] number of people out of 113 in this category ; [d] OR= odds ratio; [e] CI= confidence interval; [f] 112 ages available; [g] 111 relationship statuses available; [h] 112 places of birth available;[i] 112 answers available for medications (one declined to answer medication questions); [j] IBDQ=Inflammatory Bowel Disease Questionnaire; [k] 112 cases available for SF-12; [l] Caseness defined as 8 or more on HADS subscale. 112 available cases for anxiety and 111 for depression; [m] 110 PSS-10 scores available; [n] Caseness defined as 10 or more on SFQ; [o] 108 precontemplation, preparation, action, maladaptive coping, and problem-focused coping scores available; [p] 105 emotion-focused coping scores available

Supplementary Table 1: CCBT topics and resources

Week	Resource	Resource type	Length/Burden	Description of resource
ONE	Introduction and appropriate goal setting			
	Week 1 Resource 1: Introduction to the program	pdf	4 pages	Introduces program in general terms; introduces study co-ordinator; defines cognitive behavioural therapy; and states the aims of the study.
	Week 1 Resource 2: Appropriate goal setting	Pdf/PowerPoint	5 pages/10 slides	Says why goal-setting is important; says what the important characteristics of goal setting are; and challenges participants to set goals.
	Goal setting	Q&A	2 questions	Asks questions about short terms and long term goals.
	Week 1 Resource 3: Recognising stress and symptom checklist	pdf	2 pages	Teaches person how to recognise stress.
	Recognising your stress	Q&A	3 questions	Asks 3 questions about stress, the significance of it, and what their strategies are for managing stress.
	Information video about IBD	Video	18 minutes	Clinical psychologist interviewing gastroenterologist. Available at https://www.youtube.com/watch?t=297&v=nAlJVHXYCpw
TWO	Relaxation techniques			
	Revision of week 1	pdf	1 page	Reiterates what was said in session 1.
	Week 2 Resource 1: Stress management	Pdf/PowerPoint	2 pages/8 slides	Talks about the important of stress and the fight or flight response.
	Stress Awareness Diary	pdf	1 page	A diary with the time, the stressful event, and the physical symptom described.
	Week 2 Resource 2: Relaxation	pdf	1 page	Alludes to body awareness, progressive muscle relaxation, deep diaphragmatic breathing, and the clenched fist

Week	Resource	Resource type	Length/Burden	Description of resource
	techniques			technique which are below.
	Body Awareness	Sound file	9 minutes	
	Progressive muscle relaxation	Sound file	18 minutes	
	Clenched Fist Brief Relaxation	Sound file	8 minutes	All sound files available at the bottom of the following webpage: http://www.tameyourgut.com/#!week-2/cepq
	Deep Diaphragmatic Breathing	Sound file	9 minutes	
	Discuss which stress management techniques you find useful	Q&A	1 question	Asked to discuss which stress management techniques they find most useful.
	Week 2 Resource 3: Worry and sleep	pdf	4 pages	Teaches about sleep hygiene.
	Information video about IBD: part 2	Video	20 minutes	Available at https://www.youtube.com/watch?v=XrnAHwaEPv8
THREE	Thoughts and feelings about IBD (part 1)			
	Revision of Week 2	pdf	1 page	Reiterates what was said in session 2.
	Week 3 Resource 1:Thoughts and feelings about IBD	pdf	8 pages	Talks about thoughts feelings and behaviours and cognitive distortions that can lead to bad feelings and behaviours.
	Week 3 Resource 2: The Downward Arrow Technique	pdf	2 pages	Teaches how to use the Downward Arrow Technique.
	Recognising cognitive distortions	Q&A	3 questions	Asks to give examples of overgeneralisation, negative filtering, and black-and-white thinking.
	Extra information	Video	14 minutes	Available at (in one video)

Week	Resource	Resource type	Length/Burden	Description of resource
	video-week 3 part 1			https://www.youtube.com/watch?v=z_kWDMib3As
	Extra information video-week 3 part 2	Video	13 minutes	
FOUR	Thoughts and feelings about IBD (part 2)			
	Revision of week 3	pdf	1 page	Reiterates what was said in session 3.
	Week 4 Resource 1: Appraisal and mood	Pdf/PowerPoint	4 pages/6 slides	Teaches how to link thoughts, feelings, and behaviours.
	Week 4 Resource 2: Cognitive restructuring	pdf	6 pages	Teaches how to replace cognitive distortions with more helpful ways of thinking.
	Week 4 Resource 3: Challenging negative automatic thoughts	pdf	9 pages	Teaches how to challenge negative automatic thoughts using the A, B, C, D, E approach.
	A note on positive thinking	pdf	1 page	Talks about not having unconditional positive thinking but rather "realistic, balanced, and flexible" thinking.
FIVE	Avoiding avoidance			
	Cognitive distortions: Revision of weeks 3 and 4.	PowerPoint	10 slides	Uses some cartoon pictures to demonstrate cognitive distortions that were talked about in sessions three and four.
	Week 5 Resource 1: Confronting avoidance	pdf	2 pages	Talks about avoidance in IBD patients and how to confront it.
	Week 5 Resource 2: Desensitization	pdf	5 pages	Teaches systematic desensitisation using an anxiety hierarchy.
	Exposure	Q&A	4 question	Asks four questions about what fear a person would like to

Week	Resource	Resource type	Length/Burden	Description of resource
	Hierarchy			overcome, and what low, medium, and high exposures to this fear are.
	Hierarchy Cards(for imagery exposure in "confronting avoidance above	pdf	1 page	A simple resource people can print out to make an exposure hierarchy using cards.
	Imaginal Exposure Instructions	pdf	2 pages	How to make an imaginal exposure hierarchy and practice imagery desensitisation.
	Troubleshooting exposure	pdf	1 page	Talks about some problems that can be encountered during systematic desensitization
SIX	Coping strategies and diet			
	Revision of week 5	pdf	1 page	Reiterates what was said in session 5.
	Week 6 Resource 1: Coping strategies	Pdf/PowerPoint	5 pages/8 slides	Defines coping and separates coping into problem- versus emotion- focused coping.
	Coping resources	Q&A	5 questions	Asks questions about the coping strategies for uncontrollable and controllable stressors.
	Week 6 Resource 2: Diet and IBD (emphasis on FODMAPS)	PowerPoint	30 slides	Talks about how low FODMAP diets can have a role in IBD management.
	Dietary factors in IBD	Discussion forum	4 discussion topics	Asks participants to discuss dietary triggers, dietary symptom relievers, whether they have head of the low FODMAP diet, and if they would consider doing the low FODMAP diet.
	OPTIONAL extra video: Dietician Dr Sheppard video 1	Video	31 minutes	Available at (in one video) https://www.youtube.com/watch?v=OPTCKWkwi2Y
	OPTIONAL extra	Video	29 minutes	

Week	Resource	Resource type	Length/Burden	Description of resource
	video: Dietician Dr Sheppard video 2			
SEVEN	Relationships and effective communication			
	Revision of week 6	pdf	1 page	Reiterates what was said in session 6.
	This supplements and summarises, but does not replace, week 7 resources 1, 2, 3, 4, and 5	PowerPoint	17 slides	
	Week 7 Resource 1: Types of social support	pdf	2 pages	
	Week 7 Resource 2: Effective communication	pdf	3 pages	Collectively, resources 1, 2, 3, 4, and 5 talk about types of social support, how to communicate effectively about IBD, how to manage arguments, what assertiveness, and how to be more assertive.
	Week 7 Resource 3: When things get heated	pdf	2 pages	
	Week 7 Resource 4: Assertiveness	pdf	1 page	
	How Assertive Are You?	pdf	1 page	
	Week 7 Resource 5: Being more assertive and learning how to say “no”	pdf	2 pages	
EIGHT	Attention			

Week	Resource	Resource type	Length/Burden	Description of resource
	distraction techniques and looking to the future.			
	Revision of week 7	pdf	1 page	Reiterates what was said in session 7.
	Week 8 Resource 1: Attention and distraction in pain management sound file	Sound file	5 minutes	This sound byte talks about attention and distraction in pain management
	Week 8 Resource 2: Relaxation, focussing, grounding exercise sound file	Sound file	30 minutes	This sound byte is a grounding exercise sound file
	Week 8 Resource 3: Attention and distraction techniques	pdf	2 pages	This is about taking attention away from the negative aspects of IBD, such as through imagining a “pain free room, ” paying attention to parts of the body that are not in pain, and relocating thoughts.
	Week 8 Resource 4: Other ways for managing pain.	pdf	1 page	Talks about other ways of managing pain, such as through watching a comedy show or movie, listening to music, or exercise.
	Pain management	Discussion forum	1 broad topic	People asked to discuss the methods people use to cope with the pain.
	Wrapping up the program	PowerPoint	6 slides	Talks about what has been learnt over the 8 sessions and how these can be maintained over the long term.
	Healthy me worksheet	pdf	1 page	This worksheet is to assist people in coming up with methods for becoming healthier (e.g., exercise, relaxation, pleasant activities, and having social support).

Supplementary Table 2: Assessment timing

	Screening	Baseline	12 weeks	6 months
Screening criteria and consent	x			
Demographics	x	x		
IBDQ[a] (32 questions)		x	x	x
SF-12[b] (12 questions)		x	x	x
HADS[c] (14 questions)		x	x	x
Brief COPE (28 questions)		x	x	x
SFQ[d] (8 questions)		x	x	x
HBI[e] (3 questions)		x	x	x
SCCAI[f] (5 questions)		x	x	x
PSS-10[g]		x	x	x
EPQ-BV-Neuroticism[h] (12 questions)		x		
Patient perceptions of the program (10 questions)			x	

[a] IBDQ=Inflammatory Bowel Disease Questionnaire; [b] SF-12=Short Form-12; [c] HADS= Hospital Anxiety and Depression Scale; [d] SFQ=Social Functioning Questionnaire; [e] HBI= Harvey-Bradshaw Index; [f] SCCAI= Simple Clinical Colitis Activity Index; [g] PSS-10= perceived stress questionnaire; [h] EPQ-BV-Neuroticism= Eysenck Personality Questionnaire-Brief Version neuroticism subscale