Digital cognitive behavioural self-management programme for fatigue, pain, and faecal incontinence in inflammatory bowel disease (IBD-BOOST): a multicentre, parallel, randomised controlled trial

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Summary

Background Fatigue, pain, and faecal urgency or incontinence are common, debilitating symptoms in inflammatory bowel disease (IBD). We developed IBD-BOOST, a digital, interactive, facilitator-supported, self-management intervention, and aimed to assess its effects compared with care as usual in relieving these symptoms and improving quality of life.

Methods This multicentre, parallel, randomised controlled trial was conducted online in the UK, with allocation concealment maintained. Participants aged 18 years or older with IBD who rated the impact of fatigue, pain, and faecal urgency or incontinence as 5 or more on a 0–10 scale in a UK national survey were invited. Participants were randomly assigned (1:1) to the online IBD-BOOST programme or care as usual for 6 months via computer-generated randomisation. Primary outcomes were UK Inflammatory Bowel Disease Questionnaire (UK-IBDQ) and Global Rating of Symptom Relief at 6 months post-randomisation. All randomly assigned participants were included in the intention-to-treat and harms analysis. This trial is registered with ISRCTN.com (ISRCTN71618461) and is closed.

Findings Between Jan 20, 2020, and July 27, 2022, 4449 participants were invited to participate, and 780 participants were randomly assigned: 391 to IBD-BOOST and 389 to care as usual. 524 (67%) of 780 participants were female and 253 (32%) were male. At 6 months, there were no statistically significant differences for UK-IBDQ between the care as usual group (unadjusted mean 62·09 [SD 14·42]) and the IBD-BOOST group (unadjusted mean 60·85 [SD 16·08]; treatment effect estimate: adjusted mean difference –1·67 [95% CI –4·13 to 0·80], p=0·19) or for Global Rating of Symptom Relief (unadjusted mean 3·65 [2·75] *vs* 4·13 [2·81]; adjusted mean difference 0·44 [95% CI –0·56 to 1·44], p=0·39). Complier-averaged causal effects analysis demonstrated that participants who complied with IBD-BOOST reported lower UK-IBDQ scores than those who would have complied in the care as usual group (mean difference –2·39 [95%CI –4·34 to –0·45], p=0·016). Adverse events and serious adverse events were similar between the IBD-BOOST group (55 [14%] of 391) and care as usual group (79 [20%] of 389). There was one possible treatment-related serious adverse event in the IBD-BOOST group (recurrent sleep disorder) and no deaths.

Interpretation IBD-BOOST did not statistically significantly improve disease-specific quality of life or Global Rating of Symptom Relief in patients with IBD with fatigue, pain, or faecal urgency or incontinence compared with care as usual. People who complied with the intervention appeared to derive benefit. Future research should focus on enhancing compliance with interventions and targeting them to individuals most likely to benefit.

Funding UK National Institute for Health and Care Research.

Introduction

Inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis, is a life-long illness. Prevalence is approaching 1% of the UK population and is increasing worldwide.[1] The primary aim of medical management of IBD is to control inflammation using a variety of medications. However, patients endure a burden of symptoms including fatigue, pain, and faecal urgency or faecal incontinence, and unpredictable bowel habits, including when disease appears inactive. These symptoms limit quality of life and the ability to work and socialise.[2] Patients report that these symptoms are not taken seriously by health professionals and they provide minimal help.[3,4] An IBD research priority-setting consensus placed fatigue,

Lancet Digit Health 2025

Published Online https://doi.org/10.1016/j.landig.2025.100906

See Comment https://doi.org/10.1016/j.landig.2025.100929

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Research in context

Evidence before this study

Three systematic reviews of interventions for fatigue, pain, and urgency were conducted before this study. Due to the heterogeneity of the interventions, none were suitable for meta-analysis.

Embase, MEDLINE, CIHAHL, Web of Science, PsycINFO, the British Nursing Index, Scopus, Cochrane Library, CINAHL, and PsycINFO were searched with the search terms "fatigue", "inflammatory bowel disease", and "RCT" for publications published from database inception to October, 2019. Five low quality (high risk) trials of non-pharmacological interventions were identified, including one Cognitive Behavioural Therapy (CBT) trial. The review concluded that fatigue management interventions in IBD remain inconclusive in terms of effectiveness and safety. We searched literature covered in a systematic review of interventions and risk factors for faecal incontinence in IBD. No studies were found that tested a psychological intervention for faecal incontinence in IBD.

A systematic review of interventions for pain in IBD conducted a series of searches including MEDLINE, EMBASE, PsycINFO, CINAHL, and the Cochrane Library from database inception to February, 2016. Search terms included "inflammatory bowel disease" and "abdominal pain". Interventional studies of any design were included, seven of which were non-pharmacological intervention trials. Five of these studies on psychological interventions included disparate populations and interventions, and high risk of bias. Four reported pain reduction.

Across the reviews, no studies addressed pain, fatigue, and urgency in IBD in a single non-pharmacological or psychotherapy intervention. The patient and public involvement in our work underpinned the need for an intervention to address these issues simultaneously, as patients were unable to disentangle them as individual symptom effects.

Added value of this study

This is the first randomised trial of a digital theoretically informed, psychologically focused intervention for the combined symptoms of fatigue, pain, and faecal urgency or incontinence in IBD. The intervention was developed using rigorous methods and extensive patient and nurse input.

Implications of all the available evidence

Evidence to date suggests with moderate certainty, that psychological interventions in IBD have a small effect on improving quality of life in the short term, but there is heterogeneity in the type of interventions and the effect sizes. More work is needed to understand which components of interventions or types of interventions lead to larger and sustainable effects. Most interventions have relied on sessions delivered by health-care professionals, which are unlikely to be routinely available to most people with IBD. Digital interventions are much more scalable, and patients who complied with the intervention derived benefit, but the results of the current trial suggest future work needs to focus on improving engagement and adherence to digital interventions.

pain, and faecal urgency or incontinence in the top ten issues that patients with IBD and clinicians want research to address.[5]

Cognitive behavioural-based models of fatigue and pain in conditions such as multiple sclerosis and rheumatoid arthritis suggest that disease factors (eg, inflammation) trigger symptoms, but cognitive, behavioural, emotional, and physiological responses to symptoms might interact to strengthen and perpetuate them.[6,7] Cognitive behavioural interventions have been reported for mental health issues in IBD,[8] but such interventions are scarce for physical symptoms of IBD.

Online delivery of cognitive behavioural interventions for chronic pain and fatigue in other medical conditions appears to be effective, with enhanced effects seen through the addition of support from health-care professionals.[9–11] There are few digital interventions for faecal incontinence, but behavioural approaches are helpful in the general population.[12] Empirical modelling and systematic reviews of risk factors and interventions for IBD-related fatigue,[13] faecal incontinence,[14] and pain[15] suggest similar interventions addressing emotional, behavioural, and/or cognitive responses to symptoms might reduce the impact and severity of these symptoms in IBD.

Our preliminary research found there is an unmet need among people with IBD who want help for these symptoms: 2335 (29%) of 8062 respondents with IBD to a survey indicated they definitely wanted help for all three symptoms of fatigue, pain, and faecal urgency or incontinence,[16] and wanted to try self-management at home rather than have repeated consultations in hospital.[17] Patients have reported that these symptoms often interact and exacerbate each other.[18] Therefore, we aimed to develop IBD-BOOST, an individually tailored, facilitator-supported online cognitive behavioural self-management programme to address these three key debilitating symptoms together rather than individually.[19] Here we report the results of a randomised controlled trial comparing IBD-BOOST in addition to usual care, with care as usual alone.

Our primary research question was: in individuals with IBD who report one or more symptoms of fatigue, pain, or faecal urgency or faecal incontinence and express a desire to receive intervention, does IBD-BOOST improve IBD-related quality of life and Global Rating of Symptom Relief at 6 months post-randomisation compared with care as usual alone? Secondary questions detailed in the protocol[20] included: (1) what are the effects on primary outcomes at 12 months? (2) Does IBD-BOOST have a greater effect on

severity of fatigue, pain, and faecal urgency or incontinence and generic quality of life at 6 month and 12 months compared with care as usual? (3) Does baseline active IBD, irritable bowel syndrome comorbidity with IBD and/or medical optimisation pretrial moderate treatment results? Health economic findings, effect mediators, and patients' intervention experience will be reported in separate publications.

Methods

Study design and participants

This multicentre, parallel, randomised controlled trial was conducted online in the UK. An internal pilot (first 100 participants) assessed the feasibility (but not outcomes) of the design. These 100 participants were included in the analysis as no changes were made.

Individuals with IBD who completed a national survey[16] were invited (via post or online) to participate. Eligibility criteria were a self-reported diagnosis of IBD; aged 18 years old or older; living in England, Scotland, or Wales; rating the impact of one or more symptoms of fatigue, pain, or faecal urgency or incontinence as 5 or more on a 0–10 scale; and expressing an interest in intervention for these symptoms in the preceding survey. Exclusion criteria were red flags on pre-randomisation screening (ie, issues that warrant urgent medical attention, including new rectal bleeding, acute pain, rapid weight loss, or vomiting); inability to give informed consent; insufficient command of English to understand study documents and procedures; and no access to the online intervention via a computer or mobile device. Data on gender were self-reported; the options provided were male, female, and prefer not to say or to self-define. Ethnicity data were also self-reported. Participants provided written informed consent.

Ethics approval was granted by the London—Surrey Research Ethics Committee (reference 19/LO/0750). The protocol has been published online and is provided in the appendix (pp 2–38).[20] The statistical analysis plan is publicly available online. This trial is registered with ISRCTN.com (ISRCTN71618461) and is complete.

Randomisation and masking

Participants who were eligible, consented, and completed a baseline questionnaire (appendix pp 44–46) were randomly assigned (1:1) to the online IBD-BOOST programme or care as usual via an online clinical trials unit system using stratified block randomisation (block sizes of four and six) and stratified by IBD diagnosis type (ie, Crohn's disease *vs* ulcerative colitis) and whether they had participated in a separate medical symptom optimisation study.[21] The research team informed participants of group assignment and for the intervention group allocated an available facilitator.

The trial steering committee, chief investigators (RM-M and CN), trial statisticians, and health economists were masked to group assignment for the duration of the trial until the statistical analysis plan was signed off. Participants' health-care providers were not informed of participant participation. All outcome measures were completed remotely (online or by post) by participants with no research team involvement, aside from phone and email reminders to complete assessments when needed. Masking of participants and facilitators was not possible due to the nature of the intervention.

Procedures

The development and features of IBD-BOOST digital intervention are published online.[19] IBD-BOOST is a 12-session, interactive, digital, facilitator-supported intervention based on a theoretically informed logic model of gut–brain psychological mechanisms that contribute to symptom maintenance (appendix pp 39–41). Cognitive behavioural-based techniques were used to address relevant mechanisms.

The patient platform uses repeated self-assessment so that participants access material tailored to them. They are advised to complete one session per week, including interactive activities between sessions. The facilitator platform tracks patient progress and enables messaging between facilitators and patients.

The IBD-BOOST group received access to the IBD-BOOST programme for 6 months. Participants who completed session 1 were offered a telephone consultation for up to 30 min with a trained facilitator. Participants also received brief online messages once per week from the facilitator and could send messages to the facilitator via the IBD-BOOST platform for the initial 3 months. Participants also had access to care as usual.

Facilitators (11 IBD nurses, one research nurse, and four non-clinical psychology graduates) received four 1-h training sessions in basic cognitive behavioural methods, the IBD-BOOST intervention, and the facilitating role. All facilitators completed a supervised practice telephone treatment session with a patient volunteer (with feedback), which was repeated if needed. Facilitators attended group supervision once per month to receive support and guidance on responding to patient issues, as well as one-to-one telephone or email support from a member of the research team if requested.

Both groups received care as usual, including usual full access to all NHS primary and secondary services, continuing any prescribed medications, usual monitoring at routine or requested IBD clinic visits and/or via the local IBD helpline, and care from their general practitioner. The care as usual group knew that they would be offered access to the intervention (without a facilitator) after returning 12-month outcome measures.

Trial outcomes were collected via a secure online database with no in-person visits. An unconditional shopping voucher (£5) was sent by post to participants before sending the 6-month and 12-month post-randomisation assessment link, followed by two email and/or text reminders to non-responders, with the option to collect the primary

For the **statistical analysis plan** see https://osf.io/8kdb3/

See **Online** for appendix

outcome measure by telephone if there was no response (no measures were collected this way).

Outcomes

Primary outcomes were the UK Inflammatory Bowel Disease Questionnaire (UK-IBDQ) and Global Rating of Symptom Relief at 6 months post-randomisation. The UK-IBDQ[22] is a composite score of four IBD quality-of-life dimensions of bowel symptoms (eg, loose stools or abdominal pain), systemic symptoms (eg, fatigue or altered sleep patterns), emotional functioning (eg, anger, irritability, or depression), and social functioning (eg, work attendance or need to cancel events). Lower UK-IBDQ scores correspond to better or improved IBD-specific quality of life. The Global Rating of Symptom Relief was modified according to feedback of patient and public involvement representatives from a 0–100 scale to a 0–10 scale (increase in score is a benefit).

Secondary outcomes at 6 months and 12 months post-randomisation comprised both primary outcomes at 12 months; a numerical pain rating scale score (0–10); faecal incontinence score; IBD-fatigue score; Patient Health Questionnaire (PHQ)-9 depression score; IBD-Control score (measures patient's perspective of disease control); EQ-5D-5L (general health-related quality of life); and rating of satisfaction with the IBD-BOOST programme (0–100 visual analogue scale). We also collected data on putative moderators of effect (anxiety, meeting criteria for irritable bowel syndrome [IBS][23] and faecal calprotectin levels) at baseline. References for these measures and justification for their choice are in the protocol.[20] Adverse events and serious adverse events were reported using patient-reported items in the follow-up questionnaire.

Statistical analysis

Assuming a minimum clinically important standardised effect size of 0·3, a facilitator intraclass correlation coefficient of 0·04 in the intervention group, a deflation factor of 0·84 (given that baseline values are predictive of post-randomisation values with correlation 0·4), and a projected 20% loss to follow-up, randomly assigning 740 participants was deemed necessary to detect the minimum clinically important standardised effect with 86·4% statistical power at a 2·5% significance level. Specific details about the selection of and rationale for sample size calculation parameters are presented in the statistical analysis plan. The originally planned sample size of 680 was amended to 740 to account for two primary outcomes and fewer facilitators than planned.[24]

Statistical analyses were performed according to the intention-to-treat principle. Demographic factors, clinical characteristics, and outcome variables at baseline were descriptively summarised by study group and were not subjected to between-group hypothesis testing. For primary and secondary outcome analyses, group-level summary statistics (ie, number and percentage of participants included in each analysis and means [SDs]), treatment effect estimates, 95% CIs, and p values are presented.

Primary outcomes—UK-IBDQ and Global Rating of Symptom Relief—were compared between groups at 6 months post-randomisation to assess intervention effectiveness. Primary outcomes were analysed using separate partially nested, three-level, repeated measures, mixed-effects models that accounted for the correlation of post-randomisation outcomes within participants, and the clustering of participants within facilitators (in the intervention group only). Restricted maximum likelihood estimation was used, an unstructured covariance matrix was specified for residual errors of repeated measures, and heteroskedastic error terms (due to the partially nested design) were fitted using a Satterthwaite approximation. The following variables were included in the model as fixed effects: the baseline value of the model outcome; both stratification factors; fatigue, pain, and incontinence at baseline; age; and gender. A Bonferroni correction was applied to the significance level of primary outcomes analysis p values to adjust for multiple comparisons given the use of two multiple primary outcomes. This correction maintains the family-wise type-I error rate at the 5% level. Secondary outcomes were analysed using the same mixed-effects model as the primary outcomes. Primary and all secondary outcomes were analysed as continuous variables.

A prespecified complier-averaged causal effects analysis was performed to estimate the difference, on average, at 6 months post-randomisation between participants who adhered to treatment in the IBD-BOOST group and participants receiving care as usual who would have complied with treatment had they been randomly assigned to the IBD-BOOST group. We pre-specified completing four or more sessions of the intervention as being compliant. Latent mixture modelling was undertaken to identify participants who would adhere in the care as usual group using the following predictors that were selected a priori: age, gender, education level, employment status, relationship status, and symptom scores for pain, fatigue, and incontinence. A mixed-effects model was constructed for the complier-averaged causal effects analysis, which adjusted for primary outcome values at baseline and included a random intercept for clustering of participants within facilitators in the IBD-BOOST group only.

Separate subgroup analyses were performed to investigate whether the effect of IBD-BOOST at 6 months post-randomisation differed in prespecified subgroups defined by the presence or absence of the following baseline characteristics: meeting Rome IV symptom criteria for IBS; IBD remission, defined as faecal calprotectin <200 µg/g stool; depression; and visceral sensitivity index (anxiety). A planned subgroup analysis investigating the effect of participating in a separate medical optimisation study[21] was not conducted as that study did not recruit to target during the COVID-19 pandemic.

Subgroup analyses were performed using the same analysis model as the primary and secondary outcome, but

with an interaction term added between the effect modifying variable and the intervention to determine whether the effect of the intervention was moderated by a third variable. A Likelihood Ratio test compared whether the subgroup analysis model (including the interaction effect) provided a statistically significantly better fit to the data than the primary analysis model (without the interaction term). The Likelihood Ratio test was considered statistically significant at the 5% level.

A sensitivity analysis was performed to assess the robustness of primary outcome analysis results to missing outcome data under the assumption that missing data were missing not at random. A delta-based controlled imputation method was used in which an offset term was added to expected values of missing data that were imputed under missing at random. An additional sensitivity analysis was conducted to investigate the effect of including participants with 6-month and 12-month post-randomisation assessments outside of the assessment follow-up window of 8 weeks and 4 weeks (plus a 2-week grace period), respectively. All individuals who completed the follow-up questionnaires were included in the harms analysis.

The statistical analysis plan was signed off before final database lock and unmasking. Except for progression criteria pre-specified by the programme steering committee for the internal pilot, there were no formal interim analyses or stopping rules.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Jan 20, 2020, and July 27, 2022, 4449 of 8486 respondents to the previous survey[16] were invited to participate in the trial. 780 participants were randomly assigned (391 to IBD-BOOST and 389 to care as usual; figure 1). 676 (87%) of 780 participants returned outcome measures at 6 months post-randomisation. The 12-month post-randomisation assessment was halted early due to delays caused by the COVID-19 pandemic; only 613 (79%) of 780 participants were contacted and 487 (79%) responded. Therefore, data at 12 months do not represent the whole sample. Throughout the findings reported, the numbers given are for participants who answered the respective question. 48 participants with a stoma were excluded from faecal incontinence scores.

Between randomisation and 6-month follow-up, three participants in the care as usual group and 13 in the IBD-BOOST group withdrew from the trial; a further two withdrew from the IBD-BOOST group between the 6-month and 12-month follow-up timepoints. 388 (99%) of 391 participants completed registration, 346 (89%) completed session 1, and 45 (12%) did not complete any sessions.

39 participants in the IBD-BOOST group subsequently requested to withdraw from the intervention: all but six remained in the trial for data collection at 6 months. Most participants cited time constraints or disease flare as a reason for withdrawal, although some did not give a reason. Most participants stayed in the study and returned outcome measures. At 6 months, three in the care as usual group had withdrawn.

524 (67%) of 780 participants were female and 253 (32%) were male. 744 (95%) participants were White (table 1; appendix pp 44–46). 432 (55%) participants had Crohn's disease. Participants' mean age was 49 years (SD 14). 372 (48%) of 780 participants fulfilled Rome IV criteria for IBS,

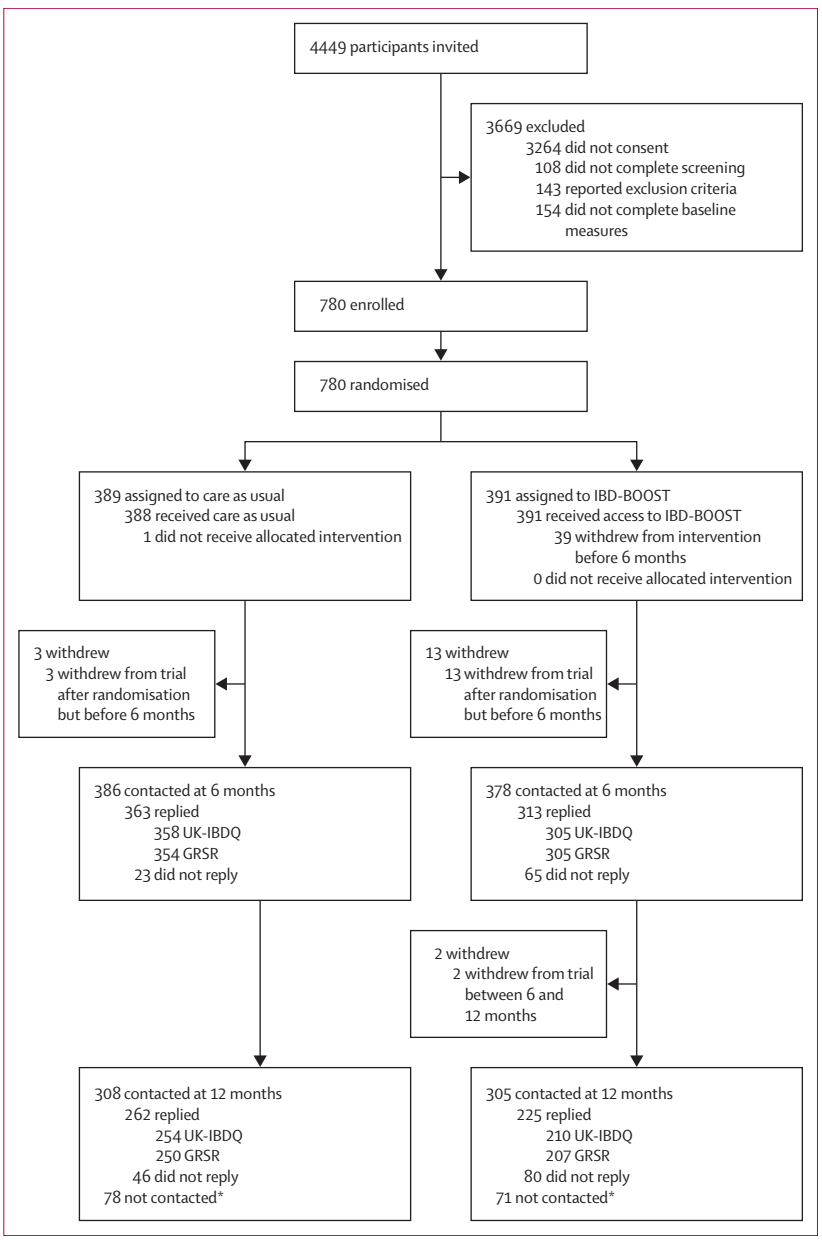

Figure 1: **Trial profile**
GRSR=Global Rating of Symptom Relief. *Some participants were not contacted at 12 months as follow-up was curtailed.

	Care as usual (n=389)	IBD-BOOST (n=391)
IBD diagnosis		
Crohn's disease	215 (55%)	217 (55%)
Ulcerative colitis*	174 (45%)	174 (45%)
Gender		
Female	258 (66%)	266 (68%)
Male	129 (33%)	124 (32%)
Prefer not to say or to self define	2 (1%)	1 (<1%)
Age, years	48 (14)	49 (14)
Ethnicity		
White	373 (96%)	371 (95%)
Not White	16 (4%)	20 (5%)
IBD activity status†		
Remission‡	242/305 (79%)	243/294 (83%)
Active§	63/305 (21%)	51/294 (17%)
Rome IV criteria		
No	207 (53%)	200 (51%)
Yes	182 (47%)	190 (49%)
Depression status (PHQ-9)		
Not depressed	221 (57%)	219 (56%)
Depressed¶	168 (43%)	172 (44%)
UK-IBDQ score (primary outcome)‖	63·76 (14·40)	64·80 (15·48)
Average pain intensity in past 7 days**	2·62 (2·20)	2·57 (2·15)
Lowest pain intensity in past 7 days**	1·31 (1·83)	1·24 (1·71)
Highest pain intensity in past 7 days**	4·30 (2·89)	4·31 (2·81)
Pain intensity in the past 7 days**	2·25 (2·35)	2·24 (2·32)
Faecal incontinence score††	9·30 (4·87)	8·88 (5·19)
IBD fatigue score‡‡	8·71 (3·55)	8·93 (3·49)
IBD Control score	8·88 (4·16)	8·79 (4·48)
IBD control VAS score§§	6·58 (2·10)	6·47 (2·19)
EQ5D utility score¶¶	0·73 (0·22)	0·73 (0·22)

Data are n (%), mean (SD), or n/N (%). IBD=inflammatory bowel disease. UK-IBDQ=UK Inflammatory Bowel Disease Questionnaire. VAS=Visual Analogue Scale. *Includes ulcerative colitis and all other forms of IBD except Crohn's disease. †Faecal calprotectin only; for those who returned the postal faecal sample. ‡Faecal calprotectin <200 µg/g. §Faecal calprotectin ≥200 µg/g. ¶Numbers scoring above the PHQ-9 cutoff for caseness (≥10 on a 0–27 scale). ‖UK-IBDQ scores range from 30–120, with higher scores reflecting worse quality of life. **Numerical pain intensity scores range from 0 to 10, with high being worse pain. ††Range 0–24: excludes 48 with a stoma. ‡‡Range 0–20. §§Range 0–10. ¶¶EQ5D utility score range –0·594 to 1.

Table 1: **Baseline demographics and clinical characteristics and baseline outcome measure scores**

and 340 (44%) were above the PHQ-9 clinical cutoff for depression. Baseline data suggested large variability in severity and impact of symptoms (appendix pp 44–46). Of those who returned a faecal sample, 242 (79%) of 389 in the care as usual group and 243 (83%) of 391 in the IBD-BOOST had no evidence of active inflammation, as defined by faecal calprotectin <200 µg/g stool. 500 (81%) of 619 participants who provided both measures were above the published cutoff on the IBD-Control score or had a faecal calprotectin level over 200 µg/g stool, suggesting that only 119 (19%) of patients would be considered in remission on this combined definition, which clinical members of the research team considered clinically implausible. There was only a small correlation between faecal calprotectin and IBD-Control scores at baseline and a strong correlation between depression scores and IBD-Control score, suggesting the IBD-Control score reflects symptom distress rather than active inflammation. IBD-Control score is dependent on symptoms whereas faecal calprotectin gives an objective assessment of disease activity. The fact that 485 (81%) of those who returned a sample had well controlled disease based on the faecal calprotectin objective assessment indicated that the cohort of patients overall have a high symptom burden even when in remission as assessed by calprotectin. This led us to note that it is implausible that only 20% were in clinical remission defined by IBD-Control. Therefore, we reverted to faecal calprotectin cutoff to define remission and for the subgroup analyses.

221 (57%) of 391 participants in the IBD-BOOST group completed the pre-defined adherence dose of four sessions. There were no statistically significant differences for UK-IBDQ between the care as usual group (unadjusted mean 62·09 [SD 14·42]) and the IBD-BOOST group (unadjusted mean 60·85 [SD 16·08]; treatment effect estimate: adjusted mean difference –1·67 [95% CI –4·13 to 0·80], p=0·19) or for Global Rating of Symptom Relief (unadjusted mean 3·65 [2·75] *vs* 4·13 [2·81]; adjusted mean difference 0·44 [95% CI –0·56 to 1·44], p=0·39) at 6 months (figure 2). The 95% CIs for the UK-IBDQ treatment effect excludes the prespecified minimum clinically important standardised effect of 6 points, whereas the 95% CIs for Global Rating of Symptom Relief overlaps the minimum clinically important standardised effect size of 0·3 calculated from 6-month variability estimates. Outcomes at 12 months are shown in the appendix (p 47).

Participants in the IBD-BOOST group had better quality of life according to the EQ-5D utility score than did the care as usual group at 6 months (table 2), but a significant difference was not observed at 12 months. There was evidence of an effect of the intervention on the faecal incontinence score at 6 months (p=0·021) and 12 months (p=0·0009; appendix p 47). At 6 months, there were no statistically significant differences in the IBD-Fatigue score (p=0·18), average pain intensity in the past 7 days (p=0·81), IBD-Control (p=0·18), and global satisfaction (p=0·64) scores between groups; there were also no differences at 12 months (appendix p 47).

The results of prespecified subgroup analyses on the two primary outcomes are shown in figure 3 and the appendix (p 48). IBS diagnosis at baseline did not appear to modify the effect of IBD-BOOST on UK-IBDQ (p=0·092) or Global Rating of Symptom Relief (p=0·29) at 6 months (appendix p 48). Visceral-specific anxiety as measured by the visceral sensitivity index at baseline (used as a continuous variable in analyses) did not statistically significantly modify the effect of IBD-BOOST on UK-IBDQ scores (adjusted treatment effect estimate: mean difference –0·01 [95% CI –0·11 to 0·08], p=0·76; appendix p 48). There was no statistically significant effect of the visceral sensitivity index on Global Rating of Symptom Relief (–0·01 [–0·03 to 0·02],

	Care as usual (n=389)		IBD-BOOST (n=391)		Adjusted treatment effect estimate (95% CI)	p value
Primary outcomes						
UK-IBDQ*	358 (92%)	62·09 (14·42)	305 (78%)	60·85 (16·08)	−1·67 (−4·13 to 0·80)	0·19
Global rating of symptom relief	354 (91%)	3·65 (2·75)	305 (78%)	4·13 (2·81)	0·44 (−0·56 to 1·44)	0·39
Secondary outcomes						
Average pain intensity*	356 (92%)	2·54 (2·23)	305 (78%)	2·37 (2·15)	−0·08 (−0·69 to 0·54)	0·81
Faecal incontinence score	332 (85%)	8·81 (5·05)	287 (73%)	7·74 (5·22)	−0·62 (−1·15 to −0·09)	0·021
IBD fatigue score	355 (91%)	8·57 (3·57)	305 (78%)	8·28 (3·83)	−0·29 (−0·70 to 0·13)	0·18
IBD control score	354 (91%)	8·92 (4·42)	305 (78%)	9·79 (4·68)	0·77 (−0·36 to 1·89)	0·18
IBD control VAS score	354 (91%)	6·59 (2·17)	305 (78%)	6·58 (2·25)	−0·001 (−0·30 to 0·29)	0·99
EQ5D utility score	347 (89%)	0·71 (0·23)	298 (76%)	0·75 (0·21)	0·03 (0·01 to 0·05)	0·010
Global rating of satisfaction	357 (92%)	6·39 (2·97)	306 (78%)	6·66 (2·69)	0·25 (−0·79 to 1·29)	0·64

Data are n (%), unadjusted mean (SD), unless otherwise specified. IBD=inflammatory bowel disease. UK-IBDQ=UK Inflammatory Bowel Disease Questionnaire. VAS=Visual Analogue Scale. *In the past 7 days.

Table 2: **Primary and secondary outcomes at 6 months post-randomisation**

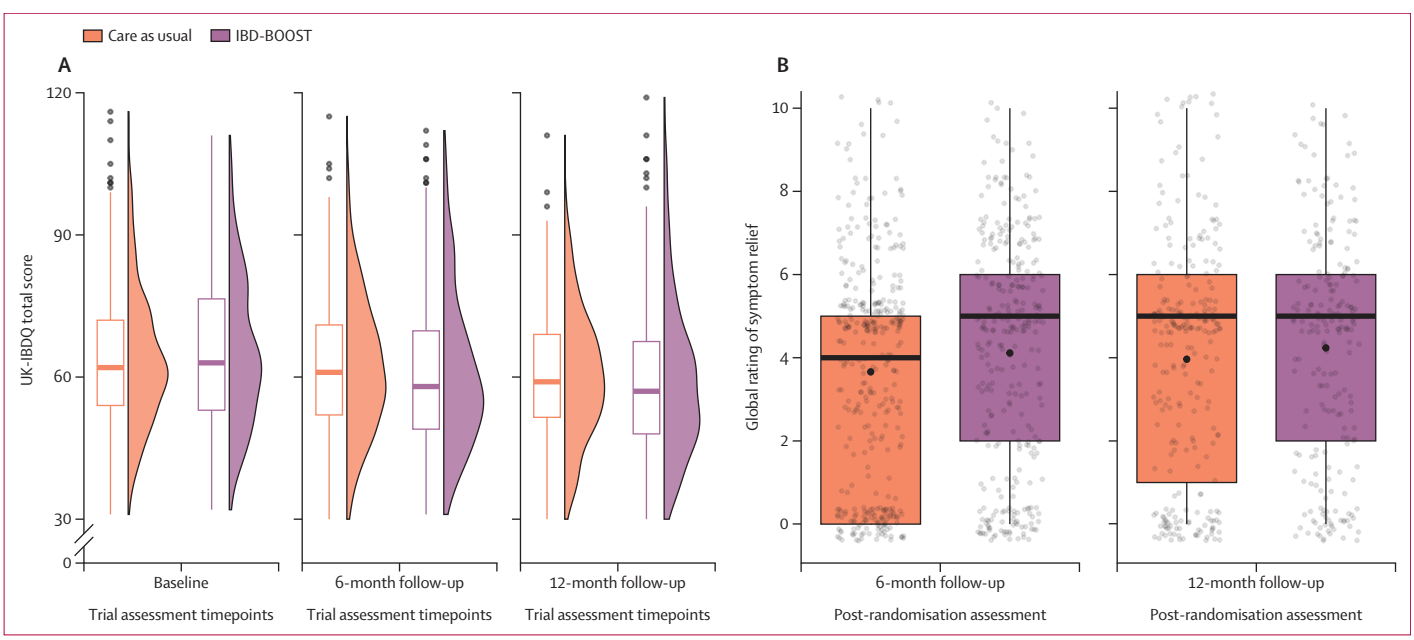

Figure 2: **UK-IBDQ total score and Global Rating of Symptom Relief**
UK-IBDQ total score at baseline, 6 months, and 12 months (A) and Global Rating of Symptom Relief at 6 months and 12 months (B). UK-IBDQ=UK Inflammatory Bowel Disease Questionnaire.

p=0·62; appendix p 48). There was negligible evidence that the effect of IBD-BOOST differed by categories of other prespecified baseline moderators (ie, depression and whether IBD was active or in remission at baseline) in either primary outcome at 6 months (appendix p 48).

221 (57%) of 391 participants met the predefined criterion for adherence (completing at least four sessions). More details on facilitator fidelity and participant adherence will be presented in a separate process evaluation paper. Estimating the treatment effect for participants who adhered (complier averaged causal effects analysis) yielded a statistically significant difference in UK-IBDQ score (mean difference −2·39 [95% CI −4·34 to −0·45], p=0·016). There was no evidence of an effect on Global Rating of Symptom Relief score (table 3).

Sensitivity analyses are reported in the appendix (pp 49–53). All primary analyses were robust to the presence of missing data imputed under missing at random or missing not at random assumptions and to the inclusion of outcomes completed outside the prespecified data collection window.

358 (92%) of 389 participants in the care as usual group and 305 (78%) of 391 in the IBD-BOOST group had UK-IBDQ at 6 months post-randomisation (appendix pp 61–65), which enabled comparison between the baseline characteristics of participants with and without missing outcome data 6 months after randomisation.

Serious adverse events were similar between the IBD-BOOST group (55 [14%] of 391) and care as usual group (79 [20%] of 389; appendix p 55). One possibly treatment-related serious adverse event was reported in

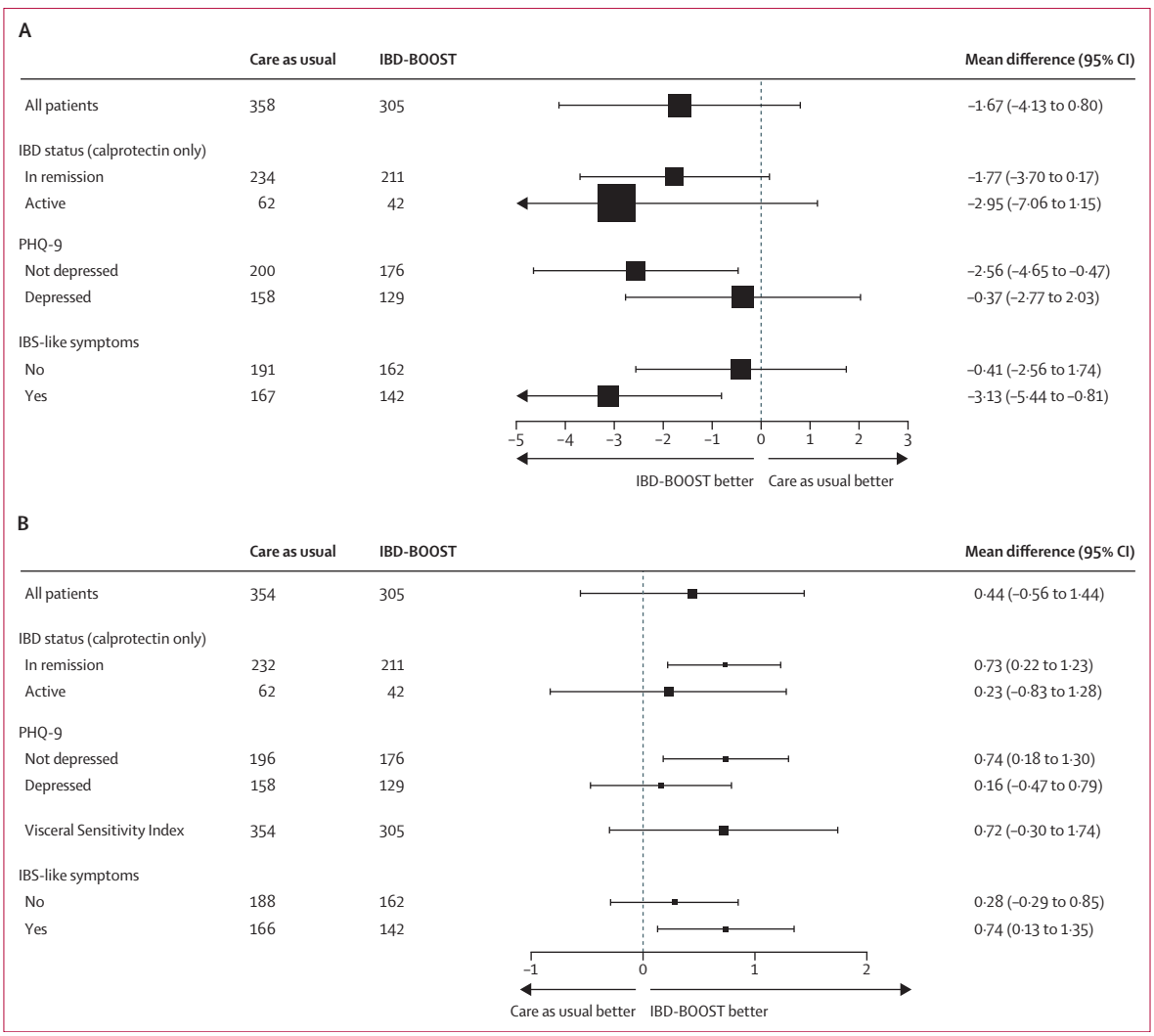

Figure 3: **Forest plot for subgroup analyses of UK-IBDQ and Global Rating of Symptom Relief at 6 months post-randomisation**
UK-IBDQ (A) and Global Rating of Symptom Relief (B). IBD=inflammatory bowel disease. IBS=irritable bowel syndrome. PHQ=Patient Health Questionnaire. UK-IBDQ=UK Inflammatory Bowel Disease Questionnaire. Arrows indicate 95% CIs are beyond that of the x-axis.

	Participants	Effect estimate (95% CI)*	p value
UK-IBDQ			
Intention to treat	663 (85%)	−1·67 (−4·13 to 0·80)	0·19
CACE	663 (85%)	−2·39 (−4·34 to −0·45)	0·016
Global rating of symptom relief			
Intention to treat	659 (84·49)	0·44 (−0·56 to 1·44)	0·39
CACE	659 (84·49)	0·49 (−0·26 to 1·25)	0·20

CACE=complier averaged causal effects. UK-IBDQ=UK Inflammatory Bowel Disease Questionnaire. *The number of participants included in CACE analyses represents the number of participants with observed (ie, non-missing) outcome data for UK-IBDQ and global rating of symptom relief.

Table 3: **CACE analysis of primary outcomes at 6 months post-randomisation**

the IBD-BOOST group and there were no deaths: one participant reported that IBD-BOOST caused a recurrence of a previous sleep disorder. No safety concerns were raised by researchers involved in the programme and no events were reported to the sponsor or ethics committee.

Additional post-hoc analyses (not prespecified in the statistical analysis plan) are provided in the appendix (pp 56–65) but should be viewed with caution as they were exploratory. We explored a possible dose–response effect (appendix pp 56–57). This analysis specified an interaction term between post-randomisation assessment and the number of intervention sessions attended among participants in the IBD-BOOST group. We performed two analyses, with number of intervention sessions attended specified as a continuous variable and categorical variable.

With completed sessions specified as a continuous variable, at 6 months post-randomisation, there was a statistically significant positive association between the number of IBD-BOOST sessions completed and UK-IBDQ (appendix p 56). For each session completed there was a corresponding 0·32-point improvement, on average, in UK-IBDQ (β −0·32 [95% CI −0·63 to −0·003], p=0·048). A stronger dose–response relationship was observed at 12 months post-randomisation in which each intervention

session attended was associated with an improvement in UK-IBDQ, on average, of 0·63 points among participants in the IBD-BOOST group (appendix p 56).

When specifying the number of IBD-BOOST sessions completed as a categorical variable to assess the robustness of the findings, there was no clear dose–response pattern evident at either post-randomisation assessment. The effect estimate 95% CIs (almost) uniformly include zero, indicating no intervention effect at 6 months and 12 months post-randomisation (appendix p 57).

We investigated the effect of IBD-BOOST on faecal incontinence score at 6 months and 12 months post-randomisation depending on the value of the score at baseline (appendix pp 57–60). A three-way interaction was needed, including group, post-randomisation assessment, and faecal incontinence score at baseline. Additionally, we performed this analysis on the entire study population, and for those participants who had clinical faecal incontinence symptoms or problems on enrolment.

Three-way interactions for the entire study population (β 0·02 [SE 0·06], p=0·77) and the subset of participants with faecal incontinence upon enrolment (β 0·05 [0·08], p=0·55) indicated negligible evidence that the effect of the intervention on the faecal incontinence score differed depending on the participant's baseline value. Similarly, there was a high degree of 95% CI overlap between the intervention effect at each baseline value of the faecal incontinence score at 6 months (appendix p 58) and 12 months (appendix p 60).

Discussion

This study found that the digital intervention IBD-BOOST was no better than care as usual in improving IBD quality of life and providing relief from symptoms in participants with IBD and symptoms of fatigue, pain, and faecal urgency or incontinence at 6 months or 12 months. For secondary outcomes, there was a statistically significant difference in faecal incontinence score at 6 months and 12 months and a statistically significant difference in generic quality of life at 6 months in favour of IBD-BOOST. There was no evidence of between-group differences on self-reported fatigue and pain at either timepoint.

A 2025 Cochrane review of all individual and cluster-randomised controlled trials of psychological interventions for IBD identified the IBD-BOOST study as the first randomised trial of a psychotherapy intervention to treat fatigue, pain, and faecal urgency or incontinence in IBD. This is the largest randomised controlled trial (n=780) in IBD to date. The Cochrane review included 21 psychotherapy trials (n=1678). Like IBD-BOOST, most psychotherapy interventions included elements of cognitive behavioural therapy, but only one of these studies was a digital intervention. Most provided face-to-face therapy or remote delivered therapy with a health-care professional. In line with IBD-BOOST, 11 of these studies used UK-IBDQ as an outcome. The combined standardised mean difference in the Cochrane review was 0·19 (95% CI 0·06 to 0·33), corresponding to a difference in UK-IBDQ of 4·40 (1·09 to 7·70), which is larger than the difference found in IBD-BOOST (mean difference –1·67 [95% CI –4·13 to 0·80]). This suggests that digitally delivered psychotherapy, and/or psychotherapy that focuses on managing IBD symptoms, is less effective at improving quality of life in IBD than other forms of delivery or interventions specifically targeting quality of life. Alternatively, IBD-BOOST might have been negatively affected by poor engagement in digital sessions. A complier-averaged causal effects analysis among participants who completed four or more sessions of IBD-BOOST showed larger improvements in UK-IBDQ scores than those who completed care as usual.

Overall, the results suggest IBD-BOOST is not an effective treatment for relief of these IBD symptoms, but it might have some benefit for faecal incontinence and generic quality of life rather than IBD-specific quality of life. A possible explanation is that the target population was too broad. Eligibility criterion was rating the impact of at least one symptom of fatigue, pain, or faecal urgency or incontinence as 5 or more (0–10 scale). Analysis of the baseline data suggested large variability in severity and impact of the symptoms (appendix pp 44–46).[25] Severity of all three symptoms was associated with all cognitive and behavioural putative mechanisms of change of the IBD-BOOST intervention. These mechanisms, outlined in the logic model included low mood, visceral sensitivity (anxiety), disease self-efficacy, negative illness perceptions, and all-or-nothing behaviour. Better screening using validated measures of symptoms with clinical cutoffs might be needed to identify individuals most likely to benefit from IBD-BOOST. Alternatively, screening could use the putative mediators, although these do not have clinical cutoffs.

The null findings might have been affected by the timing and choice of the primary outcome. A meta-analysis of psychological therapies for IBD showed statistically significant improvement in IBD-specific quality of life immediately after therapy (16 randomised controlled trials in 1080 participants), but these effects were not sustained at follow-up.[8] This finding underscores the need for strategies to maintain benefits in this lifelong condition. In the IBD-BOOST trial, quality of life was assessed at 6 months, 12 weeks after the facilitator-supported phase ended, potentially missing any short-term treatment effects. Future iterations of IBD-BOOST and similar interventions could incorporate facilitator booster sessions post-treatment to help sustain therapeutic gains.

As with many digital interventions, adherence to IBD-BOOST was low. Only 221 (57%) of 391 participants in the IBD-BOOST group completed the pre-defined adherence dose of four sessions. Complier-averaged causal effects analysis suggested that participants who complied with IBD-BOOST reported significantly higher UK-IBDQ than participants who would have complied in the care as usual group. This finding suggests that the null effects could relate to insufficient uptake of IBD-BOOST, although the same effects were not found for Global Rating of Symptom Relief. Four

sessions were the minimum dose set in this trial, and it is unclear at what level adherence should be set.

IBD-BOOST was carefully designed and adhered to guidance on developing complex interventions, including an underpinning logic model drawing on empirical evidence of mechanisms related to perpetuating symptoms in remission and qualitative interviews with participants and health-care practitioners, and used recommended methods of iterative feedback from numerous patient and public involvement and engagement representatives.[19] The decision to use non-CBT-trained facilitators for IBD-BOOST was pragmatic as few gastroenterology services in the UK have access to trained CBT therapists, but nearly all have IBD nurses. The choice of only one 30-min session with a facilitator alongside on-site messaging once per week was based on interviews, which suggested IBD nurses would not have time for more support.[26] This amount of time might have been insufficient to maximise uptake. A large trial of a web-based CBT intervention for IBS that included three 30-min sessions over 12 weeks intervention, a trained CBT therapist, and two booster sessions, showed higher adherence than the current trial (69% completed four sessions) and statistically significant results on all primary and secondary outcomes at 12 months post randomisation.[27] We did not address acceptability directly in this study but had found the digital intervention acceptable in an earlier feasibility study.[28] Further work should explore how to maximise uptake including either more facilitator support time and/or staff trained on CBT-based methods. A small randomised controlled trial of hybrid acceptance and commitment therapy for IBD, which included 50% therapist-led sessions and 50% self-directed sessions (therapists were CBT or acceptance and commitment therapy-trained psychologists) had greater intervention adherence than the current trial.[29]

It might have been too ambitious to include three symptoms in one treatment (despite patient requests for a single intervention addressing the three symptoms);[17] having separate interventions for each symptom might have greater effects.

This study was a rigorously conducted, large randomised controlled trial, which followed CONSORT and Medical Research Council guidelines for complex intervention trials, was adequately powered, and had reasonable retention of 85% at the primary endpoint. To our knowledge, it is the largest randomised controlled trial of a digital psychological intervention in IBD and the first to attempt to treat the three main remission symptoms in a single intervention. It trialled a rigorously developed intervention specifically for people with IBD that appears safe to deliver. The trial began just a few months before the COVID-19 pandemic started. Processes including screening and recruitment had to be altered. There was a paucity of IBD nurses to support the intervention, and we had to train other facilitators. We had to curtail the 12-month follow-up because of COVID-19 delays. The initial plan had been to optimise medical treatment before the start of the trial. As many health-care staff were moved onto frontline COVID-19 related care, this was not possible. Future trials should explore the optimal facilitators. One option is to provide additional CBT-based training to IBD nurses. Alternately trained CBT therapists might enhance engagement.

As most of the trial recruitment was undertaken during the COVID-19 pandemic, it is possible that advice for people with IBD to shield might have affected engagement with the intervention and outcomes, either positively or negatively. To try and assess this, in a separate study we asked the IBD-BOOST group to complete a survey after completing the primary endpoint questionnaire.[30] 171 (48%) of 354 participants responded. 50% reported no effect, 19% reported a negative effect, and 10% reported a positive effect; the others were unsure or said it varied. Overall, possible negative and positive effects might have evened out, but as fewer than half the participants replied to this survey, this might not be accurate.

Our sample was predominantly White with limited ethnic diversity. Engaging with the intervention necessitated an ability to read English and access the internet, which is not available to everyone. The heterogeneous group of patients with IBD might have affected the results: some participants had low levels of symptoms; others had high faecal calprotectin levels indicative of active disease. As symptom severity was related to a range of psychological factors, recruiting people with high enough symptom levels to qualify as a clinical case might achieve better results.

We invited 4449 previous survey responders. We were unable to distinguish between participants actively deciding not to consent and instances when an invitation was not read or an email went into a spam folder. Of those who consented, 108 did not complete screening and 143 reported exclusion criteria. As IBD-BOOST was conducted during the pandemic, we relied on self-selection into the programme, which might have affected engagement with a behavioural approach. A referral to IBD-BOOST from a gastroenterologist with a clear rationale as to why a behavioural approach is recommended might increase uptake and engagement.

Finally, there is uncertainty with regards to optimum outcome measures for a trial that includes three symptoms. We opted for Global Rating of Symptom Relief and a disease-specific measure of quality of life.

This large RCT showed that IBD-BOOST, a digital cognitive behavioural-based symptom-management programme, did not significantly improve disease-specific quality of life or Global Rating of Symptom Relief in patients with IBD with fatigue, pain, or faecal urgency or incontinence compared to care as usual alone. Secondary outcomes of faecal incontinence and generic quality of life were improved in the IBD-BOOST group compared with care as usual alone, but there was no difference in fatigue or pain scores. Improved disease-specific quality of life was observed at 6 months in complier-averaged causal effects analysis among participants who completed four or more intervention sessions.

Future work is needed to increase engagement with and adherence to IBD-BOOST, including integration with referral pathways, increasing the amount of facilitator support, and determining who best to provide this support. The focus of this work should be on those with higher levels of symptoms during remission.

Contributors

RM-M: conception and design of the work, funding acquisition, methodology, and the acquisition, analysis, and interpretation of data for the work, supervision of the research team; drafting the work and reviewing it critically for important intellectual content. CN: conception and design of the work, funding acquisition, methodology, and the acquisition, analysis, and interpretation of data for the work, supervision of the research team; drafting the work and reviewing it critically for important intellectual content. AH: conception and design of the work, funding acquisition, methodology, and the acquisition, analysis, and interpretation of data for the work, supervision of the research team; drafting the work and reviewing it critically for important intellectual content. FCB: analysis and interpretation of data for the work; drafting the work (including tables and figures) and reviewing it critically for important intellectual content; directly accessed and verified the underlying data. TH: analysis and interpretation of data for the work; drafting the work (including tables and figures) and reviewing it critically for important intellectual content; directly accessed and verified the underlying data. SM: project administration, the acquisition, curation, and interpretation of data for the work; reviewing it critically for important intellectual content. LM: project administration, the acquisition, curation, analysis, and interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. IS: project administration, the acquisition, analysis, or interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. QA: acquisition of funding, the conception or design of the work and the analysis and or interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. WC-D: acquisition of funding, the conception or design of the work and the analysis and or interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. LD: acquisition of funding, the conception or design of the work and the interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. ME-S: interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. JF: interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. BM: acquisition, analysis, and interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. RP: conception or design of the work, acquisition of funding, and the interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. CR: interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. SS: acquisition of funding, the conception or design of the work and the interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. LS: acquisition, and interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. ST: acquisition of funding, the conception or design of the work and the analysis and interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. VW: Substantial contribution to project administration, the acquisition, analysis, and interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

RM-M reports being a beneficiary of license between King's College London and Mahana Therapeutics; consulting fees from Mahana Therapeutics and 11 London; payment or honoraria for lectures, presentations, or educational events from European Association of Psychosomatic Medicine and British Association for Behavioural and Cognitive Psychotherapies conferences and the Central and North West London NHS Foundation Trust; and a salary from the study NIHR grant. CN reports speakers fees from Medscape, Merck Pharmaceuticals, Tillotts Pharma UK, and Lilly Pharmaceuticals; advisory board membership with Pfizer; research grants from NIHR, including for this work; being a trustee for GUTS UK; and being a chair of Data Monitoring and Ethics Committee for the AMELIE trial (EU funded). AH served as consultant, advisory board member, or speaker for AbbVie, Arena, Atlantic, Bristol-Myers Squibb, Celgene, Celltrion, Falk, Galapogos, Lilly, Janssen, MSD, Napp Pharmaceuticals, Pfizer, Pharmacosmos, Shire, and Takeda; serves on the Global Steering Committee for Genentech; and receives a salary from the study NIHR grant. FCB, TH, SM, LM, IS, LS, and VW receive a salary from the study NIHR grant. QA reports funding from Alpha Sigma; stock or stock options in My health chart, Welbeck, TPC, and QAS-ZEB; funding as a primary investigator from Classado Biosciences; funding from Takeda Pharmaceuticals and Dr Falk Pharma UK for commercial clinical trials; salary from the study NIHR grant. WC-D reports speaker fees from Dr Falk Pharma, Pharma Cosmos, and Crohn's & Colitis Ireland; travel support from Lilly; research funding from Bristol Myers Squibb and Crohn's and Colitis UK; and a salary from the study NIHR grant. LD reports research funding from Takeda and Janssen; royalties from Sage Publications; speaker fees from Abbvie, Dr Falk, Ferring, Janssen, and WebMD; internal funding from University of Greenwich for workshop attendance; and a salary from the study NIHR grant. BM reports support from the National Institute for Health Research Barts Biomedical Research Centre (NIHR203330) and Bowel Research UK studentship (supervisor) and a salary from the study NIHR grant. RP reports paid advisory board membership role for the Galapagos and a salary from the study NIHR grant. CR reports a salary from the study NIHR grant and PhD funding from Bowel Research UK. SS reports funding from the NIHR Research Senior Investigator Award, NIHR School for Public Health Research (grant number NIHR 204000), NIHR Northwest London Applied Research Collaboration, and Imperial NIHR Biomedical Research Centre; and a salary from the study NIHR grant. ST reports a salary from the study NIHR grant; membership of HTA Clinical Evaluation and Trials Committee 2015–19; membership of NIHR Programme Grants for Applied Research Sub-Panel committee 2020–24; receiving NIHR Team Science Award: COMPLEAT; co-applicant of NIHR SPCR IV FR 8 "Assessing The Potential Of Assistive Technology In People With Chronic Obstructive Pulmonary Disease"; programme steering committee membership of PGfAR Programme NIHR206260: CO-ACTION; membership of the data monitoring committee for the RELIEF trial; being a programme steering committee chair of the PGfAR Programme NIHR20441; and an academic capacity development lead (NIHR SPCR 2021–2027). All other authors declare no competing interests.

Data sharing

Data collected for the study and additional related documents, including de-identified participant data and a data dictionary defining each field in the set, will be made available to other researchers on reasonable request to the corresponding author (christine.norton@kcl.ac.uk) with a signed data access agreement.

Acknowledgments

This study was funded by the National Institute for Health and Care Research (NIHR) under its Programme Grants for Applied Research Programme (grant reference number NIHR RP-PG-0216–20001). The views expressed are those of the authors and not necessarily those of the NIHR or the UK Department of Health and Social Care.

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