**Title: Supported intervention versus intervention alone for management of fecal incontinence in patients with Inflammatory Bowel Disease: a multicentre randomised controlled trial with qualitative evaluation**

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**Conflicts of Interest**

LD: speaker fees from Janssen, AbbVie and Eli-Lilley; consultancy fees from GL Assessments and Crohn’s & Colitis UK

AH: has served as consultant, advisory board member or speaker for AbbVie, Atlantic, Bristol-Myers Squibb, Celltrion, Falk, Ferring, Janssen, MSD, Napp Pharmaceuticals, Pfizer, Pharmacosmos, Shire and Takeda. She also serves on the Global Steering Committee for Genentech.

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**Description of authors’ contributions to the study**

CN: CI, conceived study

CN, LD, JD, AH, CK, HT, AV, SK: study design, funding application

LD: project manager, site set up and oversight, ethics applications, qualitative analysis

DL: PCTU project coordinator

SK: oversight of statistical analysis

VB: health economics evaluation

VM: reviewed the statistical analysis plan and conducted the data analysis

TW: conducted and analysed qualitative interviews with patient participants, clinicians delivering the intervention, and with project staff

MF: chair of steering group, study review and monitoring

All authors contributed to manuscript writing and / or revising of drafts.

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**ABSTRACT**

**Purpose** To test a non-invasive self-management intervention supported by specialist nurses against the intervention alone in patients with Inflammatory Bowel Disease (IBD) with fecal incontinence and to conduct a qualitative evaluation of the trial.

**Design** Multicentre parallel group randomised controlled open label trial, with qualitative evaluation.

**Subjects and Setting:** Patients from a preceding case-finding study who had reported fecal incontinence and met the study requirements participated in the RCT, delivered via IBD outpatient clinics in six UK hospitals. Sixteen participants and 11 staff were interviewed for the qualitative evaluation.

**Methods**

Over a three-month period, participants received either four 30-minute sessions with an IBD Clinical Nurse Specialist and a self-management booklet, or the booklet alone; low retention numbers precluded statistical analysis; Individual face-to-face or telephone interviews, recorded digitally and transcribed professionally, were conducted to evaluate the RCT. Transcripts were analysed thematically using an inductive method.

**Results**

RCT: 67 participants of the target of 186 were recruited (nurse + booklet: n=32; booklet alone: n=35) and 21 completed the study. Forty-six participants were lost to follow-up or withdrawn. Given the low recruitment and high attrition, statistical analysis of quantitative data was considered futile. Interviews: four themes described the experiences of patient participants and of staff, and provided insight into reasons for low recruitment and attrition, and the difficulties of delivering resource-heavy studies in busy health service environments.

**Conclusions** Alternative approaches to trials of nurse-led interventions in hospital settings are needed.

**KEYWORDS:** attrition**,** fecalincontinence, inflammatory bowel disease, nurse-led intervention

**INTRODUCTION**

Inflammatory bowel disease (IBD) is a term for a group of relapsing-remitting auto-immune conditions that share a common feature of mucosal inflammation of the bowel wall. Ulcerative colitis (UC), Crohn’s disease (CD) and IBD Unclassified (IBD-U) are the commonest forms of IBD which predominantly affect Caucasians, although incidence is rising in other populations1,. These conditions cause unpredictable urgency of defecation, which for some patients, leads to fecal incontinence (FI). Studies report prevalence of FI between 12.6% and 76% of patients with IBD compared to the estimated 2-4% of the general population2,3. Amongst patients with IBD, up to 66% continue to experience urgency and 10% continue to experience FI, whilst IBD is in remission3–5. Alongside disease activity, known risk factors for FI in patients with IBD include childbirth, previous colorectal surgery, and being female6. Urgency and FI have a negative impact on quality of life, causing social and employment-related restrictions, and causing some people to avoid leaving the house7,8.The UK National Institute for Health and Care Excellence (NICE) has produced guidelines advising active-case finding, and a step-wise algorithm for the treatment of FI in at risk populations, starting with the least invasive9. In non-IBD populations with FI, conservative interventions improve FI in many patients.

We aimed to test a non-invasive intervention, effective in other populations with FI, in patients with Inflammatory Bowel Disease (IBD) who have bowel control difficulties by: 1) delivering a randomised controlled trial (RCT) to test an intervention with patients wanting help for FI; and 2) collecting qualitative data to understand participants’, clinicians’ and the study teams’ experiences of the RCT.

Study objectives were to: 1) determine the effectiveness of using IBD specialist nurses to deliver the algorithm of care proposed by NICE for people with FI, compared to provision of the same information in a self-management booklet; and 2) obtain detailed qualitative feedback from patients and staff on the best way of enabling health-seeking, the experience of the intervention and suggestions for future service development.

The overarching research question was: Does implementation of the UK nationally (NICE) recommended approach to management of FI improve bowel control and quality of life in people with IBD?

**Methods**

**Study design**

This study comprised (a) a parallel-arm open label RCT with 1:1 allocation to compare a self-management booklet plus up to four 30 minute sessions with an IBD clinical nurse specialist (CNS) (*Group 1*) with the self-management booklet alone (*Group 2*); and (b) follow-up qualitative interviews to explore effects and acceptability of the intervention, and study delivery issues.

***Intervention booklet***The *Managing Incontinence in Inflammatory Bowel Disease* self-management booklet was developed for the purposes of the study and not subjected to evaluation or formal validation procedures. The study team worked with four people with IBD-FI to operationalise the UK NICE guidance on FI9,10 to produce the booklet, which included practical advice on bowel habit, diet and fluids, anti-diarrhoeal medication, bowel retraining, pelvic floor exercises, practical coping. The booklet draws on available published advice for people with FI11,12, adapted to be IBD-specific.

**Sample and setting**

1. Participants for the RCT were identified from purposively-sampled respondents to a previous case-funding survey (*in press*). Those who had reported experience of FI and were interested in receiving help to better manage the symptom (n=517) were sent the study information for the RCT with an opt-in form to return to the study team, if interested in participating. Sample size calculation for the RCT indicated that 186 participants were needed to show a difference in the primary endpoint (the St Marks score, see below) of 3 points with 90% power using a 5% significance level, as reported in the published protocol13.

*RCT inclusion criteria*

* Confirmed diagnosis of IBD documented in the patient’s medical notes
* Aged 18 - 80 years
* Experience of FI at least once in the preceding 12 months
* In self-reported remission (bowel symptoms as normal for them when not in relapse)

 *RCT exclusion criteria*

* Previous anal fistula surgery OR a current anal fistula
* Has had a course of specialist FI treatment within the previous 12 months (e.g.; biofeedback, tibial nerve stimulation)
* Currently participating in another trial

Inclusion criteria were amended during the recruitment phase in an effort to enhance recruitment. The original requirement for disease activity to be scored as ≤ 5 (to confirm remission) was found to exclude those with persistent frequency and urgency, who would be most likely to benefit from participation. Instead, after discussion with the Steering Committee, participants were asked to provide their own assessment of whether their symptoms were typical of remission for them. Respondents were screened either face to face or via telephone, to check fidelity to the study criteria and confirm eligibility for the trial.

To further enhance recruitment, we sought and secured an ethics amendment to permit participants in Group 1 to attend second and subsequent sessions with the nurse via telephone, expecting that this might encourage participation by reducing the need for patients to make extra journeys to their hospital clinic. One further ethics amendment gave us permission to recruit from callers to the IBD Nurse Telephone Advice Lines in each participating hospital.

2. Participants in the RCT were invited to a follow-up qualitative interview to explore perceptions of the intervention. Clinicians involved in delivery of the study and/or IBD services at participating sites, and research staff employed on the study were sampled purposively to participate in interviews.

*Interview inclusion criteria (patients)*

The single inclusion criterion was prior participation in the RCT.

 *Interview inclusion criteria (staff)*Staff were eligible for interview if they were:

* an IBD CNS who delivered the intervention; OR
* an IBD CNS, or a gastroenterologist providing clinical services; OR
* an NHS service manager with responsibility for IBD services in their hospital; OR
* a member of the study team

There were no exclusion criteria. The case-finding study (*in press*), and the currently-reported RCT, were carried out in the same six hospitals (district and tertiary / specialist hospitals) in England. Interviews were conducted either in private homes (patient participants), or on university or participating hospital premises (clinical and research staff participants).

 **Patient and Public Involvement (PPI)**

The PPI team (six patients with IBD) helped develop the funding application, study design, consent forms and data collection tools, and advised on likely completion burden for participants. They also assisted with analysis of qualitative interview data.
 **Ethical Acknowledgement**Study procedures were reviewed and approved by the NHS Health Research Authority National Research Ethics Service (NRES Committee London-Hampstead), Ref: 15/LO/0051, and registered with Clinical Trials: NCT02355834. Written informed consent was secured from all participants prior to any data collection. The right to withdraw at any time without reason, explanation or consequence, was maintained.

**Instruments**

*Primary Outcome measure*

* The St Mark’s Incontinence Score14, widely used in studies of FI. A three-point difference in score has been demonstrated as clinically relevant14.

 *Secondary outcome measures*

* The Crohn’s Disease Activity Index (CDAI)15 and the Simple Clinical Colitis Activity Index (SCCAI)16 were used to assess bowel activity in participants with Crohn’s Disease, Ulcerative Colitis and IBD-Unclassified, respectively.
* The IBD-Q17 and the ICIQ-IBD18 were used to collect disease-specific quality of life data; the Brief Illness Perceptions Questionnaire (BIPQ)19 and the EQ5D20 were used to collect generic illness-related quality of life data.
* MY-MOP21 was used to report and assess self-identified most troublesome symptoms
* Study-specific health economics tool: patient and NHS resource use (consumables used, clinical appointments, time off work, travel). Consumables included incontinence protection products, toilet paper, and gut motility mediations

Free text data on components of the intervention used and found useful by participants were also collected. Full details of baseline and outcome data collection tools and rationale for their inclusion are available in the published protocol13.

**STUDY PROCEDURES**

Data were collected between September 2015 and August 2017 and stopped at the pre-scheduled time to permit data cleaning and analysis within the funded study period.

***RCT***Eligibility Screening
Due to organisational and operational practices, there was often a delay between a patient indicating willingness to participate in the RCT and the date of randomisation. To ensure participants remained eligible, they were screened again to confirm they still met the inclusion criteria, before proceeding to randomisation. To prevent any unnecessary hospital visits, these eligibility screening checks were conducted over the telephone, with the participant attending the clinic within one week for consent, baseline data collection and randomisation.

Consent and baseline evaluation
Following collection of written informed consent by the IBD CNS at the participating site, baseline data (St Mark’s Incontinence Score14, CDAI15, SCCAI16, IBDQ17, ICIQ-IBD18, BIPQ19, EQ-5D20, MYMOP 221) were collected. The baseline data booklet (20 sides of A4) contained clear instructions, was self-completed by the participant and checked for completion by the nurse who had collected consent, and who then carried out randomisation.

Randomisation

Consenting participants were randomised by computer-generated online block randomisation to either Group 1 (Intervention: IBD CNS CONSULT + BOOKLET) or Group 2 (Control: BOOKLET alone), stratified by participating centre and presence/absence of an ileo-anal pouch (which is associated with a high rate of FI), using randomised blocks of 2, 4 or 6. Randomisation was designed and managed online by a Pragmatic Clinical Trials Unit (PCTU). Participating centres were blinded to sequence allocation until they logged into the system and confirmed participant eligibility. Neither participant nor intervention nurse could be blinded after allocation due to the nature of the intervention.

Training the IBD intervention nurses

One or two IBD CNS’ at each participating center (maximum of 12 in total) delivered the IBD nurse intervention. An intensive one-day scripted training program on managing FI was delivered by two members of the study team (CN, JD). A checklist for content of intervention sessions was followed to facilitate fidelity to the intervention and was completed by the intervention nurse at each session.

Group 1 (intervention) visits

Participants in Group 1 *(IBD CNS CONSULT + BOOKLET)*received up to4 x 30-minute face-to-face outpatient sessions over three months with an IBD CNS, focusing specifically on bowel control. Participants completing at least 3 sessions were considered to have completed the intervention. They also received the self-management booklet and had access to all usual IBD care, including the local nurse-led IBD advice line.

Group 2 (control)
Participants in Group 2 *(BOOKLET alone)* received the same booklet to work through on their own, and at their own pace. Participants in this group retained access to usual IBD care, as did Group 1.

Outcome evaluation

Outcome data (as listed above) were collected by paper questionnaire posted to the participant six months after randomisation. The outcome data booklet (28 sides of A4) contained instructions for each measure, and reminders to check for completeness. Participants received two postal and one follow-up telephone reminder to return their outcome data.

***Qualitative interviews***

Participants in the RCT, clinicians and research staff were interviewed in July and August 2017. The purpose was to understand:

1. patients’ experiences and perceptions of their participation in the RCT
2. clinicians’ experiences of delivering the intervention and / or the study to inform future adaptation and delivery of the intervention in clinical practice, and
3. the challenges of delivering research within the UK National Health Service (NHS).

Written informed consent was collected from all participants immediately before interview. Semi-structured interviews were conducted by a single qualitative researcher (TW) either face-to-face or via telephone, recorded on a digital audio recorder and transcribed verbatim by an independent professional.

**DATA ANALYSIS**

**Analysis of RCT data**

Using Stata 14.0, multiple primary and secondary analyses were intended as described in detail in the published protocol 13, but due to low participant numbers (see below) and poor return rates for completed outcome data (n=21) these analyses were considered futile.

 **Analysis of qualitative interview data**

The qualitative researcher (TW), two PPI members, two student nurses and the first author (LD) conducted thematic analysis based on the analytical hierarchy of Spencer et al 22. Following transcription and anonymisation of data, several stages ensued:

1. Reading through each transcript by individual team members
2. Identification of early ‘issues of interest’ within each transcript by each team member
3. Sorting of data extracts using tables in Microsoft Word©
4. Team collaboration to discuss issues of interest, identify potential concepts within the data, and agree final themes
5. Development of the final descriptive account

**Results**

**Intervention study**Of the 517 participants from a previous survey who had indicated that they were interested in receiving help for FI, 67 (13.4%) consented to the RCT, and were randomly allocated to either Group 1 (intervention n=35), or Group 2 (control n=32). Of the 67 RCT participants, 36 (53.7%) were female; 26 (38.8%) had UC, 36 (53.7%) had CD, and 3 (4.47%) had IBD-U [Table 1].

In total, 46 participants (67%) were lost to follow-up: 42 did not return outcome data; two were withdrawn due to ineligibility (recruited in error); one had a disease flare (an expected event); and one participant withdrew themselves [Figure 1]. No adverse, serious adverse or unexpected events occurred. Detailed statistical analysis was considered futile due to low participant numbers and poor outcome data completion rates.

Descriptive analysis demonstrated that the most frequently used bowel management strategies were bowel retraining (Group 1: n=6 [20%]; Group 2: n=6 [18.2%]) and pelvic floor exercises (Group 1: n=7 [23.3%]; Group 2: n=6 [18.2%]); participants in the control arm found bowel retraining more difficult to comply with than those in the intervention arm, whilst both groups found pelvic floor exercises moderately easy [Table 2]. Of the self-management strategies suggested, managing stress and anxiety, obtaining a RADAR key (UK initiative giving access to toilet facilities for disabled people), locating accessible toilets in shops, and using pads for protection were considered the most useful [Table 3].

Complete case mean total cost (Standard Deviation) per participant was £376 (£318) for nurse + booklet and £206 (£337) for booklet alone. Low participant numbers prevented detailed health economic analysis.

 **Qualitative Interviews**Sixteen RCT participants who completed the study (five booklet + IBD CNS, 11 booklet only) were interviewed. Two ‘booklet’ interviews were not used due to recording errors; 14 participant interviews (five booklet + nurse; nine booklet only) were analysed. Eleven staff interviews were conducted (two gastroenterologists, two IBD CNS’ who delivered the intervention, three IBD service leads, one research nurse, and three members of the study team).

The interviews (range 22 – 66 minutes; mean 44 minutes) explored patients’ perspectives of the intervention and the failure to recruit to and retain participants in the RCT (staff interviews). Four themes emerged from the analysis: *Challenges in delivering the study*, *Quality and impact of the self-help booklet*, *Being with or without the IBD CNS* and *Looking to the future: developing the booklet and support services.* Findings are presented below supported by verbatim quotes. Participants are identified as Pseudonym: [Intervention (in booklet + nurse arm) or Control (in booklet arm of RCT), IBD CNS, Gastroenterologist, Service Lead, or Researcher].

***Challenges in delivering the study***Despite strenuous efforts, only 67 participants were randomised within the study period. Reasons for failing to recruit and retain participants were many, including high turnover of research staff involved in recruitment and follow-up of participants, and turnover and sickness of clinical staff delivering the intervention. In some cases, although participants were successfully recruited to the intervention arm, there was no IBD CNS available to deliver the intervention:

*‘Everyone was stretched. We had good teams and then key team members left, so it was back to recruitment and training* [of staff]. *So anything from a research point of view was put on pause because we needed to concentrate on our clinical services’ –* Sharon [IBD Services Lead].

Additionally, several high-profile trials for new IBD drugs were launched during the study period and were prioritised by the UK Clinical Research Network which provides research nurses to assist with study recruitment. Simultaneously, across the country, IBD CNS’ were overwhelmed with work for setting up and running new infusion clinics. These, and other unpredictable factors combined to create a ‘perfect storm’ which disrupted the study:

*‘It was about the time when NICE approved some more biologic drugs, and we had major problems with workforce and capacity and our nurses were being sucked completely into trying to sort out the clinical side of patients …so liberating any time at all from the team was incredibly challenging’ –* Helen [Gastroenterologist].

IBD CNS’ were supportive of the study, but generally do not have research time built into their contracts and simply did not have capacity to recruit participants and deliver the intervention:

‘*It’s really, really difficult when you’re trying to do full time IBD clinical work’ –* Linda [IBD intervention Nurse].

Multiple personnel changes combined with pressure amongst research staff to recruit participants to other studies may also have affected fidelity to the eligibility screening for the RCT, resulting in participants with less of a problem (and therefore less likelihood of demonstrable improvement) being recruited. Despite clear guidance regarding study involvement in the participant information sheet for the RCT, some patients recruited to the intervention arm were reluctant to attend additional hospital appointments with the IBD CNS; others, who had wanted help and consented to take part in the RCT later reported that fecal incontinence was not their primary disease-related concern, which likely affected their engagement with the study. Whether these difficulties reflected inadequate detail in the participant information sheet for the study, poor preparation and understanding of what was being consented to during recruitment, or whether both were adequate but not understood by participants is not clear.

There was difficulty obtaining completed outcome data from participants. Despite reminders and encouragement from research nurses, only 21 complete sets of outcome data were received. Despite patient consultation during development, and clear instructions for completion, the questionnaires used as outcome measures in the RCT were reported to be too long and repetitive:

*‘There was a question about the burden on patients with long questionnaires and the PPI* [team] *was consulted and they said, ‘No, this is a really engaged population and it shouldn’t be a problem.’ But I think perhaps a wider range of patient representatives who more accurately reflected the IBD community might have been helpful’ -* Madeline [Research Team Member]

***Quality and impact of the self-help booklet***The booklet was received positively for its style and approach; patients appreciated that it was accessible and well-written, and addressed FI in a direct manner:

‘*It wasn’t skirting around [the issue]; it talked about it sensibly and openly … you have to be open about it and it was the first thing I had ever read that was like that*’ Veronica [Intervention].

Staff concurred, stating that it helped them structure a conversation around FI with patients:

‘*It prompts you to ask the questions … I think that’s the main thing, because a lot of the time, we don’t always ask the relevant questions regarding fecal incontinence’* Louise [Service Lead].

Many patients found the practical tips, websites, contacts for support, products to help manage or contain poor control, and reminders of techniques to improve bowel control, useful:

‘*The ‘holding on’ and the psychological aspect that the booklet talks about was the most helpful*’ Michelle [Control].

The UK national key system for access to public toilets for disabled users, availability of maps to locate local toilets, and the quick toilet access card from Crohn’s & Colitis UK were also helpful:

 ‘*The ‘Can’t Wait’ card – I didn’t know about that … so I joined up to that organisation so I could get that*’ Ryan [Control].

Others appreciated learning about bowel anatomy and physiology, and the optimum position for effective defecation:

‘*It was learning basic techniques. One doesn’t normally think that the best way to evacuate one’s bowels is to raise your legs*’[referring to advice to sit on the toilet with knees raised if evacuation was incomplete]*.* Jack [Control].

Nurses also commented on the beneficial information:

‘[The booklet*] brought up things that I think patients hadn’t necessarily thought about or hadn’t realised the impact that these would have on their incontinence*’ Trudy [IBD Nurse].

Whilst the booklet was helpful for some, it did not meet everyone’s needs:

‘*Most people would have found there were parts of* [the booklet] *that fitted them better than other parts, maybe*’ Sarah [Intervention].

Other patients who reported that they already knew much of the advice presented in the booklet, still found it helpful:

‘[The booklet] *had an awful lot of things that I already knew and I’d already worked out. But it was a really good reminder of things*’ Bethany [Intervention].

Some of the IBD CNS who delivered the intervention noticed a lack of engagement amongst some participants:

‘*Some people were difficult to engage, particularly if they didn’t think it was all that relevant or helpful. There was a gentleman who came in and just flicked through the booklet and basically said, “There’s nothing in here that I don’t already know, so I don’t really see the point*”’ Lauren [IBD CNS].

Some patients, regardless of the group they were in, appeared to have benefitted from taking part in the study. The booklet, and the specialist nurse support, provided helpful reminders and tips. Patients reported a positive impact from psychological self-talk (the act or practice of talking to oneself, either aloud or silently to promote mental positivity), being able to access public toilets more easily, and pelvic floor exercises:

*‘The key helps, holding on helps, and doing [pelvic floor] exercises*’ Jill: [Control].

However, many already managed their bowel issues with medication and lifestyle adjustments, for example by eliminating foods which triggered urgency, and reducing stress. These factors, and the variability of bowel control issues during variations in IBD disease activity, meant they could not specifically link any changes to the intervention alone.

***Being with or without the IBD CNS***

Whether or not patients were randomised to receive IBD CNS support may have influenced their engagement with the study. The additional support from the nurse was welcomed:

‘*I find it more encouraging to share face-to-face. If it’s just a booklet, you’re just reading it with your own thoughts. If you’ve got questions, you can’t answer them*’ Bethany [Intervention]

Some in Group 2 (booklet alone) regretted not having the additional support:

‘*I’d actually like to talk to someone because I’m the sort of person who would prefer a face-to-face talk about it, even if it’s just for reassurance*’ Jill [Control].

Meeting with the IBD nurse face-to-face was considered motivational:

‘*If you know you’re going to an appointment, that tends to bring things to mind and you don’t [ignore them]. And you carry on doing the [pelvic floor] exercises, whereas if I had just had the booklet and not seen anybody, possibly I would have just let those things slip*’ Sarah [Intervention].

This perspective was echoed by some in the control group, who stated that being responsible to someone other than themselves may have motivated them to work more diligently through the booklet, adding an element of discipline:

‘*When you sit in front of someone and have to answer to them … I would have made sure I was doing it*’ Jack [Control]

Intervention nurses also saw the benefit of face to face sessions:

‘*I was disappointed for one or two people* [allocated to the control group] *who I thought would benefit from having face-to-face input rather than just the booklet*’ Trudy [IBD CNS].

However, some patients in the booklet only group were happy to work through the booklet alone, feeling that they didn’t need additional help.

 **Looking to the future: developing the booklet and support services**

*Booklet development*
The booklet was welcomed by those who perceived the content as relevant. There were different interpretations of the meaning of ‘incontinent’ with this variously being understood as having ‘an accident’ occasionally, or never having control over one’s bowels. Even though they reported experiencing incontinence, some people seemed reluctant to apply the word to themselves, perhaps due to the taboo around the term:

‘*The booklet seemed like it was really for those who were having lots of incontinence issues. I only get caught out occasionally*’ – Robin [Control].

Whilst several participants reported having had ‘accidents’ recently, they didn’t necessarily consider themselves ‘incontinent’. Changing the language of the self-management booklet might improve engagement by patients who have bowel control issues, but do not view this as “incontinence”.

Many patients voiced a need for self-help support with online materials which could be accessed when convenient rather than repeated hospital visits which add to the already onerous burden of IBD care, a reluctance also noticed by clinicians:

*‘They often didn’t want to come up to have thirty minutes with the nurse outside of the clinic appointment, and therefore we found it difficult to get their three or four sessions in over those three months. Most patients didn’t have their full number of sessions’*Peter [Gastroenterologist].

Participants also made suggestions for additional booklet content, including advice about regular sleep patterns, exercising, dietary supplements, cognitive behavioural therapy, meditation / mindfulness and IBD support groups.

*IBD support services*IBD CNS capacity issues, adapting the intervention according to local clinical availability and continued education across the multidisciplinary team (MDT) were reported as essential to be able to successfully integrate the intervention within IBD clinical services:

*‘To get [the intervention] completely as a part of standard consultation, I think there’s probably a few more steps* [including] *education because it’s such a big MDT to educate’* Helen [Gastroenterologist].

**Discussion**
Although the available data is limited and analysis descriptive, bowel retraining and pelvic floor exercises may show promise as effective strategies for helping people with IBD-related bowel control issues. IBD CNS may be crucial to encouraging and maintaining engagement with interventions but facilitating this in the current over-stretched climate of the UK NHS is a challenge.

A recent review of RCTs publicly-funded by the UK health technology programme suggests that just over 50% of included trials achieved the target recruitment23, with factors such as ‘*the optimum structure, staffing and organization for the conduct of large and small trials*’ being influential23; The ability of research nurses to recruit to studies and IBD clinical nurse specialists to deliver research interventions to patients in the UK NHS is limited by time and staff capacity. Our study was running at a time of huge expansion across the UK IBD service for infusion of new biologic drugs, which took priority. Active case-finding for FI should be within remit for all members of the multi-disciplinary team, but unless hospitals have a dedicated continence service addressing bowel as well as urinary issues, the responsibility for delivering any intervention would lie with the IBD CNS. These specialist practitioners are already under considerable pressure24, with a rapidly-expanding job description and increasing demands on their time25 perhaps limiting their capacity to engage with and deliver patient-focused interventions within clinical services. The implications of the failure to recruit to the RCT are apparent – with insufficient data, the effectiveness of non-invasive methods for managing FI in IBD cannot be demonstrated.

Participation in RCTs is known to be burdensome, with factors such as disappointment when randomized to the control (placebo) arm, and over-demanding follow-up contributing to that burden26. The qualitative findings of this study certainly bear these issues out, with participants reporting that being in Group 1 (IBD CNS +booklet) was, or would have been, more motivating for them, and clinicians commenting that participants did not want to attend hospital for the required study visits.

Bowels and incontinence are taboo topics27,28 in many conditions, including IBD29,30, and talking about incontinence is, understandably, difficult for patients31. Our qualitative findings suggest that the word ‘incontinent’ was unpopular amongst RCT participants, with many denying FI and preferring to talk about ‘urgency’ or ‘leakage’. Using this language in clinical practice, and re-naming the booklet as ‘*Managing Bowel Control in Inflammatory Bowel Disease*’ may appeal to more people who would welcome help but do not consider themselves ‘incontinent’.

Patient and Public Involvement is now an expectation in publicly-funded research in the UK32 although Staley33 argues that ‘*the impact of (PPI) involvement in any particular project is somewhat unpredictable*.’ The level of experience of both the research team in working with PPI, and the panel members, may contribute to this unpredictability. The research team on this study were proficient at working with PPI panels to design, facilitate and deliver research studies. Yet despite PPI input, participants reported at interview that the questionnaires used as outcome measures in the RCT were too long and repetitive. Our experience suggests that research teams should be cautious of only consulting with ‘expert’ PPI members, who may be more committed and enthusiastic than the ‘typical’ member of the target population. Ensuring PPI teams have a mix of experienced and novice members may give a more realistic view of what participants may be willing to do regarding interventions and outcome measures in future studies and go some way towards mitigating against the unpredictable impact of their involvement.

More work is needed to determine acceptable interventions for addressing FI in IBD. Non-invasive interventions such as dietary modification, medication and biofeedback are effective in the general population34, while anal sphincter repair, and sacral and tibial nerve stimulation have been shown to improve FI but studies were small and uncontrolled35. Future controlled studies which target underlying causes, including loose stool and psychological factors, are recommended35, although modes of delivery which avoid over-burdening both patients (with additional hospital visits) and clinical staff (with additional workload) are required. Our experiences have informed a larger programme of study to develop and deliver an on-line self-management intervention for people with IBD

**Strengths and limitations**

The failure of the study to recruit to the RCT was a major limitation, preventing collection of sufficient data to answer the research question through complete analyses. Statements regarding generalisability and interpretation are also inappropriate. There was robust PPI involvement in study design and delivery, but the perspectives of the very experienced panel perhaps skewed the assessment of appropriate burden for participants. We cannot report on fidelity to the intervention although we had planned to conduct two initial “test” sessions with each IBD CNS to gauge competence and 3-4 follow up visits at random during patient consultations for this purpose.

We recognised that training the IBD CNS’ to deliver the intervention could potentially influence delivery of usual IBD care. We emphasized during training the importance of attempting not to influence usual care for the Group 2 (booklet alone) participants and wherever feasible, for another team member to see these patients in consultations. In reality, the IBD CNS were very busy managing acute aspects of IBD and it is unlikely that they would have had the time to spontaneously provide more intensive input for FI, to Group 2 participants.
The robust processes adopted during team analysis of qualitative data and team agreement on final themes added credibility to findings.

**Conclusions**

The RCT data were not analysed due to low participant numbers. Recruitment was affected by several operational and system-wide factors beyond the control of the study team. Outcome data collection appears to have been too onerous for participants. It is not possible to report whether any perceived improvements arose from the intervention alone, or if the increased cost of contact with the IBD CNS is offset by improvement in patient outcomes. Participants’ and clinicians’ experiences provide insights into study design and delivery, which have since informed a subsequent intervention study. Given the fast pace and complexity of modern life, future interventions should be designed around technologies which enable remote access. The motivational function of the IBD CNS appears essential, and online materials would need to include access to professional help, but a ‘one-size fits all’ approach may not work.

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**Figure Legends**

**Figure 1: CONSORT flow diagram**