

**Title:** An embedded mixed methods feasibility study evaluating the use of low-intensity, nurse-delivered Cognitive Behavioural Therapy for the treatment of Irritable Bowel Syndrome

## **Abstract**

**Introduction:** This study assessed the feasibility of a nurse-delivered cognitive behavioural therapy (CBT) for the treatment of irritable bowel syndrome (IBS).

**Methods and analysis:** A mixed-method design was used. Twenty participants were randomly allocated to high-intensity CBT ( $n=5$ ), guided self-help ( $n=5$ ), self-help only ( $n=5$ ) or treatment as usual ( $n=5$ ). Ten intervention participants completed semi-structured interviews. Quantitative data were analysed using descriptive statistics; qualitative data were analysed using group thematic analysis.

**Results:** Barriers to the interventions used were negative preconceptions about treatment, factors relating to supporting materials and stigma. Treatment facilitators included therapist-facilitated relaxation, narratives located within self-help materials and social support mechanisms.

**Conclusion:** Further development of the low-intensity interventions in collaboration with service users is required to improve intervention acceptability and relevance.

## Introduction

Irritable Bowel Syndrome (IBS) is a functional gastrointestinal disorder characterised by symptoms such as altered bowel habit, bloating and abdominal pain (Lacy et al., 2016). People with IBS may be troubled by concerns relating to the cause and the effects of their condition (North et al., 2007), report a poor quality of life and often experience work-related absenteeism (Halder et al., 2004). Moreover, IBS places a significant strain on healthcare resources (Canavan et al., 2014 , Longstreth et al., 2003). Psychosocial factors and stress are associated with the onset of the disorder and related to the severity and prognosis of IBS symptoms (Gwee et al., 1996).

CBT is particularly useful for addressing negative thought patterns(North et al., 2007), catastrophizing cognitions and avoidant behaviours (Hunt et al., 2009), and is well supported empirically for IBS (Craske et al., 2011 , Drossman et al., 2003 , Kennedy et al., 2005). A systematic review identified issues regarding the methodological quality and power of related studies (Zijdenbos et al., 2009). The provision of CBT interventions for patients with functional gastrointestinal disorders is lacking in many health care systems and, in the context of our own practice, NHS patients within the UK have no routine access to CBT interventions for the treatment of IBS. The National Institute for Health and Clinical Excellence (NICE), currently recommend referral for psychological therapy for people with IBS who fail to respond to the medical management of IBS (NICE, 2017).

Few studies have evaluated psychological interventions which address concerns regarding treatment provision and intervention accessibility (Lackner et al., 2008). This randomised controlled trial reports on aspects of the feasibility and acceptability of a nurse-delivered, low-intensity (LI) CBT, guided self-help intervention for the treatment of IBS compared to high-intensity (HI) CBT treatment, self-help (SH) without therapist support and a treatment as usual control condition. For IBS patients attending secondary care gastrointestinal clinics, it was envisaged that such an LI-CBT intervention might provide many of the benefits, but be more accessible to participants and more feasible to implement compared to HI-CBT interventions.

## **Methods**

### **Study aim**

To investigate the feasibility and acceptability of LI-CBT interventions for participants with IBS within secondary care gastrointestinal clinics

## **Study objectives**

To develop a tailored nurse-delivered LI-CBT treatment protocol

To examine the number of participants needed to screen in relation to the numbers successfully randomised into the study

To gather reasons why participants may not take part in the trialled interventions

To explore the experience of participants undergoing treatment conditions

To identify barriers and facilitators to the implementation of the trial interventions

## **Study design**

An embedded mixed method design comprising a feasibility randomised controlled trial (RCT) and a nested qualitative component was used (Johnson and Onwuegbuzie, 2004). A criticism of RCTs is the methods potential inability to consider the context of interventions (Tarquinio et al., 2015). It was hypothesised that the collection of qualitative data during the trial would also help identify barriers to the implementation of CBT interventions consistent with the Medical Research Council's guidelines for the evaluation of complex interventions (MRC, 2008). Mixed methods research provides robust and rigorous approaches to research (Anaf and Sheppard, 2007) and creates a richer understanding of phenomena (Creswell and Plano Clark, 2007). A mixed methods research (MMR) approach, underpinned by a pragmatic philosophy, was therefore used to draw from the strengths of both

qualitative and quantitative approaches (Johnson and Onwuegbuzie, 2004). The incorporation of qualitative methods within the RCT ensured that the research was able to consider social experiences and meaning (Denzin and Lincoln, 2000).

## **Participants**

Adults (over 18 years of age) fulfilling Rome III criteria for IBS were included (The Rome Foundation, 2017).

## **Inclusion criteria**

- Documented medical diagnosis of IBS
- Participants with IBS who met Rome III Criteria
- Able to read, write and speak English
- Able to provide written informed consent

## **Exclusion criteria**

- Already receiving psychological therapy or hypnotherapy
- Existing diagnosis of bowel disease based on endoscopic or histologic criteria (i.e. Crohn's Disease, Ulcerative Colitis, coeliac disease)
- Presence or history of structural or surgical diseases of the GI tract (not including appendix or gall bladder surgery)
- Evidence of alcohol or substance misuse
- An established cause for bowel symptoms other than IBS (i.e. medication use)

- The presence of suicidal ideation or self-harm
- Significant psychiatric co-morbidity (such as schizophrenia or bipolar disorder)
- Currently taking part in other research studies

## **Intervention**

The researchers adapted the protocol and SH materials originally developed by Hunt and colleagues (Hunt et al., 2009) at the University of Pennsylvania USA so that treatment could be delivered within a face-to-face, LI format. The intervention comprised of an initial sixty-minute assessment session, with five further thirty-minute treatment sessions over a six-week treatment period working through the following modules with the nurse therapist.

- An introduction to IBS
- Relaxation training
- The cognitive model of stress management
- The cognitive model of IBS and behavioural experiments
- Managing avoidance using exposure
- Diet and IBS

## **Comparators**

The nursing intervention was compared to: a) a HI-CBT intervention over eleven treatment sessions, delivered by an HI therapist, b) a six module CBT

based SH workbook as a stand-alone intervention without therapist support and c) a treatment as usual (TAU) control condition consisting of routine medical care based upon best practice guidelines.

Within the HI intervention, the psychotherapist delivered treatment to participants based upon a treatment protocol developed from the work of Toner (Toner et al., 2000). Treatment consisted of eleven treatment sessions at weekly intervals. The first of these sessions was two hours in duration allowing for comprehensive assessment, with subsequent sessions lasting up to one hour. Within the SH intervention, participants were issued the same six module SH treatment workbooks as utilised within the LI nursing intervention. In order to identify if additional benefits arising could be attributed to the involvement of the nurse within LI-CBT, the SH workbooks were used as a stand-alone intervention in order to facilitate direct comparison between the two groups. There was therefore no involvement of the nurse therapist during participant's exposure to the SH intervention.

### **Intervention fidelity**

The interventions delivered within this study were audio recorded and 10% were monitored for compliance to study protocol. Therapists also completed a report form confirming interventions were delivered as intended. No breaches of study protocol were reported on case report forms returned by therapists during the conduct of the study. The monitoring data for the LI-

CBT sessions confirms that treatment was delivered as intended, although within HI-CBT treatment, some inconsistencies with the follow up of homework activities was noted. There were no major deviations from protocol.

## Outcomes

The following quantitative measures were completed by participants by mail at 12 weeks and 26 weeks' post randomisation.

### IBS Symptom Severity

GSRS-IBS consists of 13 items with five symptom sub-domains including: abdominal pain, bloating, diarrhoea, constipation and satiety. Participants were asked to record the previous 7 days' symptoms indicating responses on a 7-point Likert scale. Mean item scores (between 1 and 7) are calculated for each of the five sub domains. Two-hundred-and-thirty-four participants were involved in Wiklund and colleagues psychometric evaluation of GSRS-IBS (Wiklund et al., 2003). The internal consistency reliability was high, ranging from 0.74 (pain) to 0.85 (satiety). The associations between similar constructs in the GSRS-IBS and the various HRQL scores supported the GSRS-IBS construct validity.

### Quality of Life

IBS-QOL consists of 34 self-report Likert scales specific to IBS. IBS-QOL also makes possible the analysis of eight sub domains which include: dysphoria, interference with activity, body image, health worry, food avoidance, social reaction, sexual factors and relationships. IBS-QOL has undergone two

rigorous evaluations, the first demonstrating high reproducibility and internal consistency (Patrick et al., 1998), the second longitudinal construct validity (Drossman et al., 2000).

### Anxiety and Depression

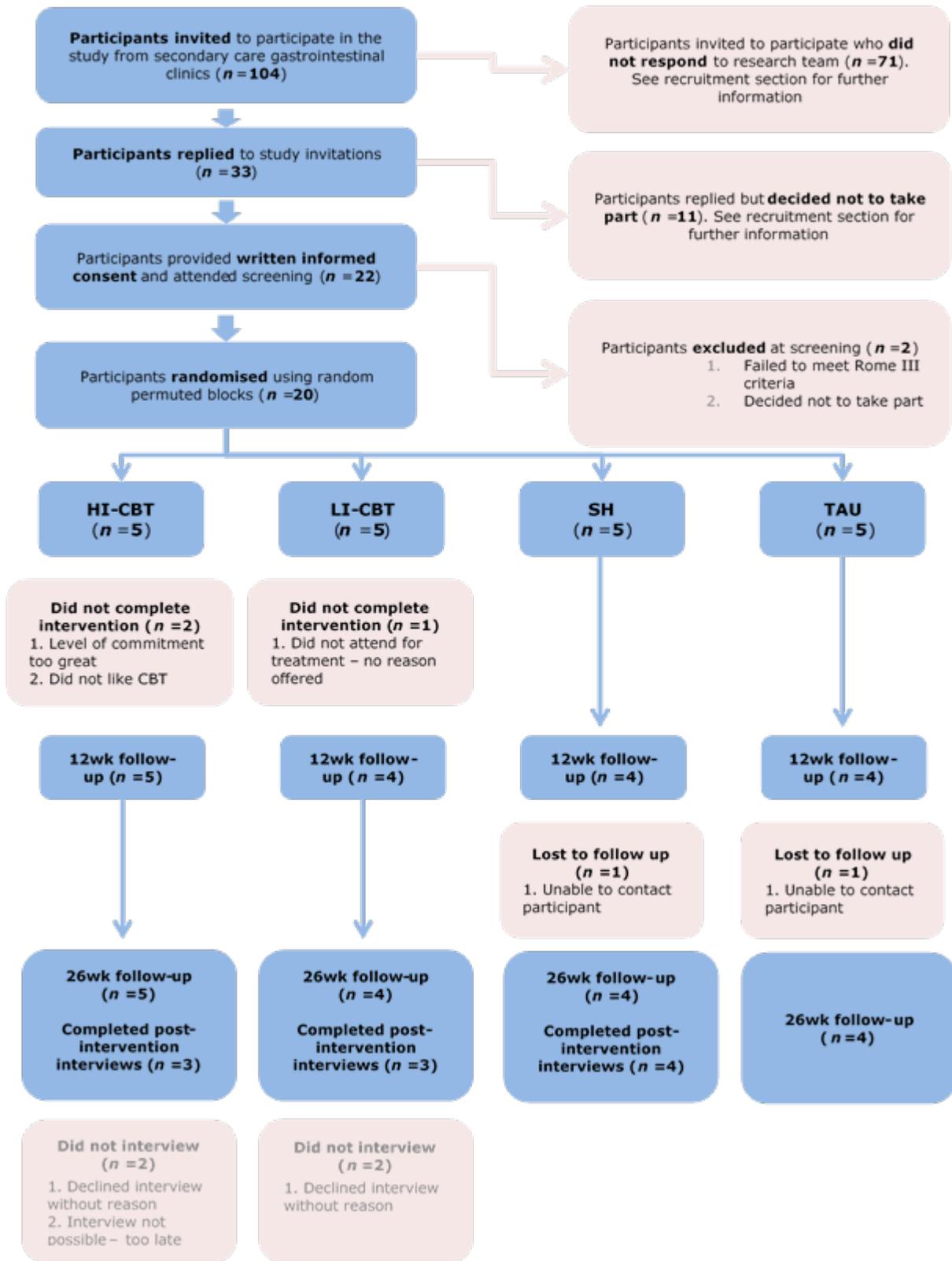
Levels of depression were measured with PHQ-9 (Kroenke et al., 2001), and anxiety using GAD-7 (Löwe et al., 2008). Both measures consist of 9 and 7 item self-report Likert scales respectively indicating depression and anxiety severity scores. PHQ-9 has a sensitivity of 88% and a specificity of 88% for major depression (Kroenke et al., 2001). PHQ-9 scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively. PHQ-9 has been validated for the screening of depression in community (Nease and Maloin, 2003), secondary outpatient (van Steenbergen-Weijenburg et al., 2010) and prenatal care settings (Sidebottom et al., 2012). With receiver operating curves of  $n = 127$ ; 0.930, the PHQ-9 is a valid tool for establishing levels of depression among adults from a variety of medical populations (Rathore et al., 2014). GAD-7 is validated for measuring levels of general anxiety disorder among general populations (Löwe et al., 2008). With a threshold score of 10, GAD-7 has a sensitivity of 89% and specificity of 82% for generalized anxiety disorder (Williams, 2014). Like PHQ-9, GAD-7 has been validated in recent studies when utilised for screening within primary care (Mohd Sidik et al., 2012), perinatal care (Zhong et al., 2015) and applied to complex medical problems such as MS

(Terrill et al., 2015). The GAD-7 produces a score between 0-21. Scores of 5, 10 and 15 represent mild, moderate and severe anxiety respectively (Spitzer et al., 2006).

### **Recruitment and sample selection**

Potentially eligible clinic patients were identified by a member of their care team and were given participant information packs. Patients expressed interest in becoming study participants by the return of a reply slip. Posters were also deployed on clinic and hospital notice boards. Authors suggest that 12 participants per group should be sufficient for calculating the mean and variance which can be used to determine full scale trial sample sizes (Julious, 2005), although there is no consensus on the sample size which should be recruited to feasibility studies. A pragmatic decision was therefore made to randomise 60 participants across four treatment conditions. Participants from the three intervention conditions were invited to participate in post-intervention interviews. As recommended within the consolidated standards for the reporting of trials (CONSORT, 2012), figure 1 demonstrates the flow of participants throughout the study period.

# Figure 1: Feasibility Study Flow Chart



## **Randomisation and blinding**

The principle investigator (AD) screened all participants and randomised eligible participants using an online randomisation system (see [www.sealedenvelope.com](http://www.sealedenvelope.com)). Participants were randomised across the four treatment conditions using random permuted blocks. All quantitative, post intervention outcome data were successfully collected by a research assistant blind to participant allocation.

## **Patient and public involvement**

A patient advisory group (PAG) was involved in the design of the study and review of study documents from the outset. The PAG highlighted potential barriers to the recruitment and selection of participants and helped shape the materials used within the nurse-delivered and SH interventions through peer review processes.

## **Ethical issues**

Participants were made aware of the potential identification of clinical anxiety and/or clinical depression during recruitment and selection. The participants' hospital care team and general practitioner were notified where a moderate to severe level of anxiety or depression was detected. The study was granted a favourable ethical opinion by the Nottingham 2 Local Research Ethics Committee (REC ref: 13/EM/0428). Host organisation approval was sought from the host NHS Trust. All participants taking part in this study provided written informed consent. All participants identified as ineligible for randomisation during the screening process completed a baseline data set

and this marked the end of their participation. All randomised participants could continue taking part until the completion of the 26 week follow up.

## **Results**

### **Analysis of quantitative data**

Quantitative data were entered into SPSS version 22 for analysis. Only descriptive statistics were generated to describe the range of data collected. No attempts were made to produce inferential data which was beyond the remit of feasibility.

### **Qualitative data thematic analysis**

Ten participants took part in the post-intervention interviews; three from the HI treatment regimen, three from LI and four from the SH intervention. The average interview duration for each of the interview groups was 47 minutes for the HI treatment participants, 41 minutes for LI participants and 30 minutes for those from the SH intervention.

Knowledge claims which arise from the conduct of qualitative research should be powerful and convincing (Kvale, 1996). The qualitative methods were therefore designed to be justifiable and sufficient to demonstrate substantial rigor and quality (Ballinger, 2006). The consolidated criteria for reporting qualitative research (CORE-Q), is a 32-item checklist for ensuring quality and rigor when reporting empirical research using interviews and

focus groups (Tong et al., 2007). The proposed qualitative methods were therefore consistent with the standards listed within the CORE-Q checklist.

The qualitative element of the study aimed to capture knowledge which was located in the minds and personal experiences of others (Nespor and Barylske, 1991). Interview methods permitted the exploration of these experiences and the subsequent textual portrayal of the phenomena (Patterson and Williams, 2002). Interview questions were used by the interviewer to seek clarification, illustration and further exploration regarding important issues (Parahoo, 2006). The interview questions were structured around the need to identify barriers to the use of psychotherapy amongst patients with IBS and to explore experiences that participants might have when receiving the trial interventions. The interview schedule consisted of open ended questions which allowed participants to freely express their feelings and experiences.

Interviews were conducted as per ethical approval by a co-investigator (EH) who was not connected to the delivery of interventions. Interviews took place within facilities located within a digestive diseases research centre. The interviewer had a background in the delivery of LI psychological interventions for common mental health problems. Interview recordings were transcribed verbatim by AD and analysed as per the thematic framework analysis described by Ritchie and Spencer (Ritchie and Spencer, 1994). In

order to improve the rigour during the analysis and guard against investigator bias, a group analysis approach was used to analyse the interview data (Gunaratnam, 2009). Both the investigator (AD) and the interviewer (EH) analysed the interview transcripts under the supervision of an experienced qualitative researcher. The data were analysed and themes identified within the data as follows.

1. The researchers became immersed in the data by exploring the richness, depth and diversity. AD transcribed audio data for analysis which were verified by the interviewer (EH).
2. The analysts independently produced a draft thematic framework. This involved the identification and assembly of key issues, concepts and themes which could be used to reference the range of data. The two analysts then jointly agreed upon the thematic framework.
3. The thematic framework was applied to the interview transcripts and charts were built to build a picture of the data.
4. The analysts jointly compared the perceptions, accounts, and experiences within the data and identified the key themes.

The four main themes identified during framework analysis consisted of; the participant's initial perceptions of treatment, the experience of executing therapeutic tasks, practical considerations for engagement and the participants perceived utility of treatment. Further themes were identified

which did not relate directly to the objectives of the study, these will be reported elsewhere.

### **Recruitment, retention and participant characteristics**

One hundred and four patients were approached with details regarding the study. Overall, 33 expressions of interest were received, which equates to a response rate of 34.4%. Ethical approval was therefore sought to ask participants who chose not to take part in the study their reasons for not doing so. The following table (table 1) lists the responses from a small sample (n=10) of participants who were contacted to discover the factors affecting their decision not to participate. As per ethical approval, participants were under no obligation to provide this information and identifiable data were not collected.

**Table 1: Reasons for participants not wishing to express further interest in research upon invitation to the study**

<b>Patient</b>	<b>Reasons offered for not expressing further interest</b>
1	Level of commitment too great
2	Generally of no interest
3	Does not have the time/symptoms resolved
4	Personal circumstances (immediate family unwell)
5	Too busy to take part

6	Does not want to make stress levels worse
7	Well controlled on new medicines
8	Too busy to take part
9	Receiving therapy via community services
10	Too busy to take part

Of the 33 participants who responded to the invitations, 22 attended screening for enrolment to the study. Table 2 shows the reasons why some patients who originally expressed an interest in participating in the study decided not to take part.

**Table 2: Reasons for participants who expressed further interest in research not taking part in the study**

<b><u>Patient</u></b>	<b><u>Reasons for not taking part</u></b>
1	Does not want to take part due to holidays
2	Moved abroad
3	Proximity issues and difficulty travelling to trial centre
4	Too busy to take part
5	Unable to make contact with respondent
6	Unable to make contact with respondent
7	Too busy to take part
8	Too busy to take part due to university work
9	Did not attend screening due to personal problems
10	Unable to make contact with respondent
11	Unable to read or write in English (excluded)

Table 3 presents the characteristics of the twenty participants who were screened and found to be eligible to participate in the study in accordance with the inclusion and exclusion criteria.

**Table 3: Participant demographic data**

		<b>Treatment condition</b>				
		<b>HI-CBT</b>	<b>LI-CBT</b>	<b>SH</b>	<b>TAU</b>	<b>Total</b>
		(n = 5)	(n = 5)	(n = 5)	(n = 5)	(n = 20)
<b>Female, n (%)</b>		<b>5 (100)</b>	<b>4 (80)</b>	<b>4 (80)</b>	<b>4 (80)</b>	<b>17 (85)</b>
<b>Age (years), Mean (S.D.)</b>		<b>56.6</b>	<b>40.0</b>	<b>37.2</b>	<b>44.0</b>	<b>44.5</b>
		(14.4)	(18.9)	(18.5)	(15.7)	(17.4)
<b>Age diagnosed with IBS (years), Mean (S.D.)</b>		<b>47.8</b>	<b>37.4</b>	<b>31.4</b>	<b>32.8</b>	<b>37.4</b>
		(10.9)	(18.6)	(12.1)	(13.6)	(14.5)
<b>Rome criteria, n (%)</b>	IBS-C	<b>0 (0)</b>	<b>1 (20)</b>	<b>1 (20)</b>	<b>0 (0)</b>	<b>2 (10)</b>
	IBS-D	<b>3 (60)</b>	<b>2 (40)</b>	<b>2 (40)</b>	<b>2 (40)</b>	<b>9 (45)</b>
	IBS-M	<b>2 (40)</b>	<b>2 (40)</b>	<b>2 (40)</b>	<b>3 (60)</b>	<b>9 (45)</b>
<b>IBS onset associated with infective episode, n (%)</b>		<b>0 (0)</b>	<b>3 (60)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>3 (15)</b>
<b>Previous received psychotherapy, n (%)</b>		<b>1 (20)</b>	<b>0 (0)</b>	<b>1 (20)</b>	<b>0 (0)</b>	<b>2 (10)</b>
<b>Antidepressant use, n (%)</b>		<b>2 (40)</b>	<b>0 (0)</b>	<b>2 (40)</b>	<b>2 (40)</b>	<b>6 (30)</b>
<b>Ethnic origin, n (%)</b>	White British	<b>4 (80)</b>	<b>5 (100)</b>	<b>5 (100)</b>	<b>5 (100)</b>	<b>19 (95)</b>
	White other	<b>1 (20)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>1 (5)</b>
<b>Household income, n (%)</b>	< £15000	<b>0 (0)</b>	<b>1 (20)</b>	<b>1 (20)</b>	<b>0 (0)</b>	<b>2 (10)</b>
	£15000-£19999	<b>0 (0)</b>	<b>2 (40)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>2 (10)</b>
	£20000-£29999	<b>2 (40)</b>	<b>1 (20)</b>	<b>1 (20)</b>	<b>2 (40)</b>	<b>6 (30)</b>
	£30000-£39999	<b>2 (40)</b>	<b>0 (0)</b>	<b>1 (20)</b>	<b>0 (0)</b>	<b>3 (15)</b>
	£40000-£49999	<b>0 (0)</b>	<b>0 (0)</b>	<b>1 (20)</b>	<b>1 (20)</b>	<b>2 (10)</b>
	£60000-£69999	<b>0 (0)</b>	<b>1 (20)</b>	<b>1 (20)</b>	<b>2 (40)</b>	<b>4 (20)</b>
	£70000-£99999	<b>1 (20)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>1 (5)</b>
<b>Marital status, n (%)</b>	Divorced or separated	<b>1 (20)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>1 (20)</b>	<b>2 (10)</b>
	Living as married	<b>1 (20)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>0 (0)</b>	<b>1 (5)</b>
	Married	<b>3 (60)</b>	<b>1 (20)</b>	<b>1 (20)</b>	<b>3 (60)</b>	<b>8 (40)</b>
	Single	<b>0 (0)</b>	<b>3 (60)</b>	<b>4 (80)</b>	<b>1 (20)</b>	<b>8 (40)</b>

	Widowed	<b>0</b> (0)	<b>1</b> (20)	<b>0</b> (0)	<b>0</b> (0)	<b>1</b> (5)
<b>Education, n (%)</b>	Grammar sch/college	<b>1</b> (20)	<b>2</b> (40)	<b>3</b> (60)	<b>2</b> (40)	<b>8</b> (40)
	Primary school	<b>0</b> (0)	<b>0</b> (0)	<b>1</b> (20)	<b>0</b> (0)	<b>1</b> (5)
	Secondary school	<b>2</b> (40)	<b>0</b> (0)	<b>0</b> (0)	<b>2</b> (40)	<b>4</b> (20)
	Technical/professional	<b>1</b> (20)	<b>1</b> (20)	<b>0</b> (0)	<b>0</b> (0)	<b>2</b> (10)
	University degree	<b>1</b> (20)	<b>2</b> (40)	<b>1</b> (20)	<b>1</b> (20)	<b>5</b> (25)
<b>Smoking status, n (%)</b>	Currently smoking	<b>0</b> (0)	<b>0</b> (0)	<b>2</b> (40)	<b>1</b> (20)	<b>3</b> (15)
	Never smoked	<b>5</b> (100)	<b>4</b> (80)	<b>3</b> (60)	<b>2</b> (40)	<b>14</b> (70)
	Previously smoked	<b>0</b> (0)	<b>1</b> (20)	<b>0</b> (0)	<b>2</b> (40)	<b>3</b> (15)
<b>Alcohol consumption U/week, mean (S.D.)</b>		<b>2.0</b> (2.9)	<b>9.3</b> (13.6)	<b>0</b> (0)	<b>5.7</b> (6.1)	<b>4.3</b> (7.9)

Eighty five percent of the participants randomised to the feasibility study were female; there were no males in the HI-CBT treatment condition. The mean age of participants was 44.5 years (S.D. = 17.4) which was similar within the LI-CBT, SH and TAU conditions. Participants in the HI-CBT intervention were slightly older with a mean age in years of 56.6 (S.D. = 14.4). The sample represents an equal mix of participants with IBS-D and IBS-M type IBS, and 10% were found to have IBS-C consistent with Rome III criteria. No participants were found to have IBS-U. The average age of participants diagnosed with IBS was 37.4 years (S.D. = 14.5), which was similar within the LI-CBT, SH and TAU conditions. Participants in the HI-CBT intervention were slightly older when diagnosed with IBS, with a mean age in years of 47.8 (S.D. = 10.9). Thirty percent of the sample was using anti-depressant medications at the time of baseline data collection, and 15% had previously been exposed to psychological interventions.

Sixty percent of participants within the LI-CBT treatment condition associated the onset of IBS with an episode of infectious gastroenteritis. The mean level of alcohol consumption was 4.3 units per week (S.D. = 7.9). The SH sample did not report weekly alcohol consumption. The sample consisted mainly of white-British participants (95%) with only one participant from a white-other ethnic origin. The sample had a household income, ranging from £<15'000 to £99'999, with 30% of the sample having a household income of £20'000 -

£29'999. Eighty five percent of the sample did not report smoking on enrolment.

Figure 1 shows the flow of participants through the study. One participant was lost at twelve weeks follow up within the LI-CBT, SH and TAU treatment conditions, reasons for which were not volunteered by participants. The remaining participants continued to complete the twenty-six week follow up. Of the thirteen potential participants selected for post intervention interviews, three declined participation: two of whom did not provide further information, one was unable to participate as study closure and data analysis had already begun owing to time constraints.

### **Gastrointestinal symptoms**

Table 4 describes changes within the four treatment conditions in relation to overall symptom profiles as measured with GSRS-IBS.

**Table 4: Participant GSRS-IBS overall scores and change from baseline to 26 week follow up**

		<b>Treatment condition</b>			
		<b>HI-CBT</b>	<b>LI-CBT</b>	<b>SH</b>	<b>TAU</b>
<b>Table 4</b>		( <i>n</i> = 5)	( <i>n</i> = 5)	( <i>n</i> = 5)	( <i>n</i> = 5)
<b>Baseline</b>	Mean	50.4	51.2	49.2	38.6
	S.D.	14.7	11.8	11.2	10.8
<b>12 weeks</b>	Mean	34.2	39.0	45.2	45.4
	S.D.	12.2	11.47	19.2	14.0
<b>26 weeks</b>	Mean	33.2	37.8	42.0	47.4
	S.D.	11.4	9.6	15.1	19.5
<b>Change</b> (baseline to 26 weeks)	Mean	<b>-17.2</b>	<b>-13.4</b>	<b>-7.2</b>	<b>8.8</b>
	S.D.	9.2	11.5	10.5	10.6

Participants within the HI-CBT and LI-CBT treatment conditions experienced a mean overall reduction in total symptom scores by -17.2 (S.D. = 9.2) and -14.4 (S.D. = 11.5) respectively between baseline and 26 weeks. The SH treatment condition resulted in a mean reduction of symptom scores by -7.2 points (S.D. = 10.5). Participants with the TAU condition experience a mean increase in symptom scores of 8.8 (S.D. = 10.6).

## Anxiety and depression

Tables 5 and 6 show that participants within the HI-CBT condition experienced improvements in both anxiety and depression.

**Table 5: Degree of change in GAD-7 mean scores  
Treatment condition**

	<b>HI-CBT</b> ( <i>n</i> = 5)	<b>LI-CBT</b> ( <i>n</i> = 5)	<b>SH</b> ( <i>n</i> = 5)	<b>TAU</b> ( <i>n</i> = 5)
Baseline	7.8	6.8	9.8	9.2
S.D.	3.1	5.3	5.6	4.8
26 weeks	4.8	5.0	7.4	7.8
S.D.	5.0	4.0	6.0	5.5

**Table 6: Degree of change in PHQ-9 mean scores  
Treatment condition**

	<b>HI-CBT</b> ( <i>n</i> = 5)	<b>LI-CBT</b> ( <i>n</i> = 5)	<b>SH</b> ( <i>n</i> = 5)	<b>TAU</b> ( <i>n</i> = 5)
Baseline	10.2	8.4	11.2	13.0
S.D.	5.5	6.6	6.3	6.6
26 weeks	6.8	6.8	9.2	11.6
S.D.	7.4	7.5	6.9	5.8
Change	<b>-3.4</b>	<b>-1.6</b>	<b>-2.0</b>	<b>-1.4</b>
S.D.	2.1	4.0	3.4	3.4

Participants within the HI-CBT condition experienced a mean change in depression of -3.4 points (S.D. = 2.1) compared to -1.6 (S.D. = 4.0) within LI-CBT, -2.0 (S.D. = 3.4) within SH and -1.4 (S.D. = 3.4) within TAU. These data demonstrate that all participants experienced some reduction in GAD-7 and PHQ-9 scores at 26 weeks, with the greatest reductions noted within the HI-CBT treatment condition.

### **Quality of life**

IBS-QOL scores improved by a mean of 23.1 (S.D. = 17.2) points for HI-CBT, 24.1 (S.D. = 23.5) for LI-CBT and by 9.9 (S.D. = 19.1) for the SH condition at 26 week follow up. Participants within the TAU condition experienced a deterioration in quality of life with a mean score reduction of -3.8 points (S.D. = 9.1).

**Table 7: Degree of change in overall IBS-QOL mean scores**  
**Treatment condition**

	<b>HI -CBT</b> (n = 5)		<b>LI -CBT</b> (n = 5)		<b>SH</b> (n = 5)		<b>TAU</b> (n = 5)	
	<u>Mean</u>	<u>S.D.</u>	<u>Mean</u>	<u>S.D.</u>	<u>Mean</u>	<u>S.D.</u>	<u>Mean</u>	<u>S.D.</u>
<b>Baseline</b>	50.3	20.1	47.9	18.2	40.4	22.0	56.0	20.0
<b>26 weeks</b>	73.4	23.1	72.1	12.5	50.3	31.5	52.2	23.7
<b>Change</b>	<b>23.1</b>	17.2	<b>24.1</b>	23.5	<b>9.9</b>	19.1	<b>-3.8</b>	9.1

### Initial perceptions of treatment

SH participants were mostly disappointed with the treatment arm they had been allocated, some of whom clearly stated that they would have preferred a therapist-led course of treatment. These views were reinforced by some participants receiving HI-CBT who also felt that they would have been disappointed with the TAU or SH treatment conditions. There was also doubt regarding the likely benefits of treatment among the SH group prior to intervention delivery. Amongst the three intervention conditions, participants described how their motivation to participate in CBT treatments was driven by the failure of conventional medical therapy or because CBT was perceived as a *'last resort'*. There was also some evidence that contradictory advice received from medical professionals had some bearing on the initial perceptions of treatment. This was particularly evident when participants detected ambiguity amongst professionals regarding the cause of IBS.

## Experience of therapeutic task execution

Participants described relaxation techniques as useful in the day-to-day management of their IBS. Some participants struggled with their ability to implement relaxation techniques which appeared to relate to the mode of treatment. Participants receiving SH found the interventions much more difficult to implement than those within delivered therapies. Therapist-facilitated relaxation within HI-CBT (the therapist physically doing the relaxation activities alongside participants) was highly valued by participants. Furthermore, constructive feedback from therapists increased confidence in some participant's ability to correctly execute relaxation techniques.

The intensity of HI-CBT treatments and the depth and breadth of treatment could be problematic and preparation for therapy was recommended by participants. These issues were not a feature of the SH or LI-CBT approaches, although some lower intensity treatment approaches were considered by participants as *'too superficial'* or not of sufficient intensity for addressing complex problems. Many of the participants valued the prospect of face to face therapy which may in turn impact initial perceptions of treatment and participants' ability to correctly execute tasks. Executing therapeutic tasks such as relaxation exercises was difficult for participants experiencing dyslexia, although such issues were overcome with therapist intervention or family support.

## Practical considerations for engagement

Lack of therapist input was particularly problematic for SH participants and was considered essential by participants within the LI-CBT and HI-CBT forms of treatment. Participants specifically suggested that face to face contact with therapists was highly valuable. Social support or interaction was useful for some participants when implementing treatment related activities, whilst others chose to remain autonomous and carry out their activities alone describing a reluctance to “burden” friends or family with IBS related issues. Where participants received treatment from a therapist, the personality of the therapist had the potential to influence the execution of therapeutic tasks for some participants, and a ‘*good personality*’ was seen as a facilitator to building an effective therapeutic relationship. An additional benefit for participants receiving lower-intensity treatment was the self-help materials, which they considered were a valuable resource. There was some concern that the materials could be difficult to tailor to individual circumstances, although the presence of narratives or real-life scenarios within the material improved the applicability of the material as described by some participants.

There was a strong emphasis on the need for therapist delivered treatment to be sufficiently flexible to fit around working patterns and other activities. These issues were particularly important for participants in employment. HI-CBT participants suggested documentation within the HI-CBT intervention could have been improved. Participants suggested that the number of

sessions and session duration should be tailored to meet individual needs and remain flexible rather than rigidly applied in accordance to treatment protocols.

### **Perceived utility of treatment**

A number of participants felt that their knowledge relating to IBS improved over the course of the study. Generally, participants developed confidence in the notion that IBS may be related to stress or heightened states of arousal. Where participants perceived treatment to be useful, the interventions enabled some participants to accept and recognise the role of stress relating to IBS symptoms and reduce doubt they had about the accuracy of IBS diagnoses. Relaxation was eventually considered a particularly useful intervention component for some participants who originally reported difficulty executing relaxation tasks once their therapist had addressed these difficulties. However, there were other participants who did not report experiencing symptom reduction from utilising relaxation techniques. Whilst some participants described symptom improvement, others described treatment benefits associated with improved coping mechanism and the wider application of interventions to other aspects of life.

### **Discussion**

This study aimed to investigate the feasibility and acceptability of nurse-delivered LI-CBT for IBS. A tailored nurse-delivered CBT treatment protocol

was developed and the number of participants needed to screen in relation to the numbers successfully randomised were examined. The qualitative data was collected to explore the experience of participants undergoing treatment conditions and to identify barriers and facilitators to the implementation of the trial interventions.

The participants within this study were successfully recruited directly from secondary care gastrointestinal outpatient clinics within a large university teaching hospital. The conversion rate to response was approximately 34% when methods were used to invite participants to take part via postal return. A total of 104 participants were required to be approached to achieve 22 screening visits and 20 randomisations. The conversion rate from participants approached to randomisation was 20.8%. Future recruitment programs utilising the same methods should therefore consider that around 100 patients will need to be approached to achieve  $n = 20$  within the clinical setting where the feasibility study took place. Explanations for participants not taking part were explored although it is not clear whether the clinical research element (i.e. completion of questionnaires) or the required commitment to therapy (12 hours if randomised to HI-CBT) deterred potential participants, or whether some other unforeseen phenomena was responsible.

Contacting participants to identify issues relating to taking part was much more difficult than anticipated. For example, it was not possible to contact participants with whom the investigator had no direct contact, and it is likely that some intent-to-please bias may have influenced the responses obtained from participants by the investigator. It is for these reasons that few data were collected relating to reasons for not taking part. It is possible to infer that higher recruitment into this feasibility study may have changed the data observed, although there is little in the way of guidance for researchers conducting feasibility studies regarding sample size.

Within the SH intervention, some of the participants who were interviewed in the post-treatment phase reported disappointment regarding the lack of therapist interaction and felt that some therapeutic tasks contained within the SH materials were difficult to execute due to a lack of therapist guidance. They also had preconceptions about the utility of treatment relating to doubt that the SH intervention would help their IBS. It is therefore not surprising to observe that both HI-CBT and LI-CBT interventions may have had a greater impact on QOL and symptom severity than SH. However, the SH modules utilized in the study were not originally developed to serve as a stand-alone intervention and were used alongside therapist feedback and interaction via the internet (Hunt et al., 2009). The LI-CBT intervention is therefore more closely related to the original intervention developed by Hunt and colleagues

and in the original format appeared to have a positive effect on symptom severity and health-related QOL.

Furthermore, since the original evaluation and development of this intervention, the format has now been expanded upon to form a stand-alone self-help treatment aimed at improving symptom Severity, HRQOL, and Depressive symptoms (Hunt et al., 2014). The SH book has also since been published (Hunt, 2016). In relation to the findings within the qualitative data here, some of the major additions and expansions to the SH book included clinical vignettes and examples intended to personalize the text and help patients apply it to their own lives. The Improving Access to Psychological Therapies (IAPT) service now lists the book among their recommended manuals for the management of IBS (IAPT, 2017).

Participants within the SH condition reported marginally greater improvements in depression (PHQ-9) and anxiety (GAD-7) scores than those receiving therapist delivered LI-CBT, which seems counterintuitive considering the SH participants' disappointment regarding the lack of face-to-face interaction.

The findings which suggest participants valued face-to-face contact with a therapist are of interest, since these issues are currently debated within the literature. For example, the results of a recent study suggest that therapists

rate face-to-face therapy as a more therapeutic experience than other types of treatment such as internet based therapy where such contact is absent (Bengtsson et al., 2015). Authors also suggest that psychological interventions delivered on the telephone present a variety of challenges, including a lack of control over environments, potential breaches of confidentiality and difficulty developing therapeutic alliance without face-to-face support (Brenes et al., 2011). Researchers have also found that therapists achieved successful working alliances faster and more readily during face-to-face therapy (Bengtsson et al., 2015). Nonetheless, interventions underpinned by technology such as internet and telephone may increase access to evidence based interventions (Mohr et al., 2012). Despite this, internet therapy has been described as impersonal, non-genuine and inhibitory (Bendelin et al., 2011).

Some participants described the benefits of relaxation techniques which, when implemented successfully, helped participants to manage symptoms during daily life events and activities. Relaxation was evaluated particularly positively when facilitated by the therapist. The aim of including relaxation techniques within the multi-component interventions trialled within this study was to reduce sympathetic nervous system arousal which may be responsible for the exacerbation of IBS symptoms and maintenance of underlying psychopathology such as anxiety and higher states of arousal. In this context, relaxation utilised in conjunction with other psychological

therapy components was predicted to reduce levels of psychological distress by promoting a physiological state in opposition to how the body reacts under stressful situations (Brent et al., 2009). These observations are also in keeping with the biopsychosocial models of IBS. Perhaps the most relevant findings in relation to the qualitative data were those themes which elucidate the potential barriers and facilitators to the implementation of the trialled interventions.

The aim of this research was to explore factors relating to the feasibility of nurse delivered, LI-CBT interventions for the treatment of IBS. The quantitative data collected during this study suggests that LI-CBT may benefit patients with IBS in terms of the outcome measures captured during the feasibility study. However, the data gathered also potentially indicates that the changes brought about by the three interventions may relate to treatment intensity and dose, although there is insufficient data from this study on which to firmly base these assumptions.

Overall, the qualitative data suggests that LI-CBT was accepted by participants as a useful form of treatment for IBS within secondary care gastrointestinal clinics. This is perhaps further supported by the QOL deterioration of participants within the TAU condition of the study. The qualitative data has helped to provide a novel and valuable insight into the use of these various CBT interventions within gastrointestinal nursing

practice. The findings of the qualitative data may therefore improve the acceptability and suitability of the LI-CBT intervention if the identified facilitators and barriers to treatment are considered during future intervention development and testing.

Despite the inability of the study to draw conclusions about the efficacy of the trialled interventions, the study does have some implications for gastrointestinal nursing practice. Nurses working within gastroenterology should consider the access that patients have to psychological interventions within their specialities, particularly considering the recommendations afforded by NICE for patients with chronic, treatment-refractory symptoms. Most importantly, this paper further highlights the importance of psychosocial aspects of presentations which should be carefully considered during nursing assessment and the evaluation of care for patients, particularly those with functional gastrointestinal problems such as IBS.

### **Strengths and limitations**

This study provides an insight into the use of LI-CBT interventions when implemented during a feasibility study within gastrointestinal clinics. The recruitment difficulties identified during the conduct of this feasibility study highlight some of the challenges faced by researchers when conducting complex studies within clinical settings. Nonetheless, for future research studies to be successful, these recruitment issues need to be further

explored and addressed. Despite attempts to gather reasons for non-participation, it is still possible that the lack of recruitment to the study may be indicative of a lack of acceptability of the modes of treatment.

The shortfall of participants recruited into this study may have implications for the data collected, namely the small sample size. A novel, nurse-delivered intervention has been trialled within gastrointestinal clinical practice which has been developed in close collaboration with service users. The qualitative data collected suggests further improvements to the LI-CBT intervention may be required to enhance the quality of nurse-delivered LI-CBT. The methods utilised within this feasibility are robust and have been scrutinised through extensive peer review. In particular, the mixed-method study design has generated data which makes a novel contribution to our understanding of how CBT interventions may be perceived by trial participants. Such methods are likely to be worthwhile within future research studies.

## **Conclusion**

The data generated during this study would suggest that nurse delivered, LI-CBT may be a feasible mechanism for CBT intervention delivery within secondary care outpatient gastroenterology. Significant difficulties in recruitment were experienced throughout the duration of this study which may render further investigations unfeasible if problems with recruitment are not addressed. Themes generated from the qualitative data have highlighted a variety of barriers and facilitators to the implementation of CBT treatment

approaches as implemented during the conduct of a clinical trial. Participants struggled with the autonomy required to complete SH interventions, with most participants valuing face-to-face interaction with a therapist.

Facilitators to the implementation of the interventions included the successful implementation of relaxation techniques and the explicit use of narratives within SH materials to enable participants to self-identify with the text. Participants also felt that preparation may improve engagement with therapy and improve the acceptability of CBT interventions for IBS.

This study was situated within the feasibility and pilot remit of the Medical Research Council's guidelines for the evaluation of complex interventions (MRC, 2008). Although this study adds knowledge in relation to the potential barriers and facilitators to the successful implementation of the trialled interventions, the significant difficulties in recruiting participants to the feasibility trial suggest that further feasibility and piloting work is required to overcome these barriers if a large scale RCT is to be feasible at a single study centre. Further development of these lower-intensity interventions in collaboration with service users is required and may improve the acceptability and relevance of the interventions within future studies.

**Ethics and dissemination:** A favourable opinion for this research was granted by the Nottingham 2 Research Ethics Committee.

**Registration details:** ISRCTN: 83683687 (<http://www.controlled-trials.com/ISRCTN83683687>)

**Permissions** *An adapted version of the Irritable Bowel Syndrome self-help intervention originally developed by Melissa Hunt at the University of Pennsylvania was used during this study, as permitted under a research license issued by the University of Pennsylvania, Philadelphia, USA*

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