ACTIB TRIAL THERAPIST MANUAL FOR REGUL8:
A SELF-MANAGEMENT PROGRAMME FOR IBS

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Assessing Cognitive Behavioural Therapy in Irritable Bowel
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References
Glossary and Abbreviations

ACTIB – Assessing Cognitive Behaviour Therapy in IBS
CBT – Cognitive Behaviour Therapy
DNA – Did Not Attend
HICBT – High Intensity CBT treatment arm
IBS – Irritable Bowel Syndrome
LICBT – Low Intensity CBT treatment arm
SOP – Standard Operating Procedure
Introduction

The aim of this manual is to describe the process of cognitive behavioural therapy (CBT), for people with irritable bowel syndrome (IBS) for the purposes of the Assessing Cognitive Behaviour Therapy in IBS (ACTIB) trial. It provides a description of what should be covered in the CBT sessions. It also covers some of the more subtle issues related to the therapeutic process, which if overlooked could result in non-adherence on the part of the participant.

The present manual will provide direction as to where to find the relevant prompt sheets, therapist records, forms and participant homework sheets. A copy of the patient manual and access to the online programme will also be provided to all therapists. Therapists will be also provided with a ring binder of Standardized Operating Procedures (SOPs), prompt sheets, homework sheets for participants and other handouts that the participants will be given.

It is advisable for therapists to read through a copy of the participant manual. This will allow for an overall understanding of how the programme has been tailored towards those who have IBS. Although the present manual encourages a flexible approach in the formulation of sessions, it will be necessary to have knowledge of the sequence of sessions as conveyed in the participant manual.

The ACTIB trial is a three armed trial consisting of:

- A high intensity therapist delivered CBT (HICBT) programme consisting of 6 hour-long telephone calls with a therapist and accompanied by a 8 chapter participant manual
- A low intensity CBT self-management (LICBT) programme consisting of 8 online sessions and accompanied by 3 half an hour telephone calls with a therapist
- Treatment as usual

This manual is intended to direct therapists delivering both the high and low intensity intervention.
Overview of the ACTIB trial

Short title of trial:
“Assessing Cognitive behavioural Therapy in Irritable Bowel (ACTIB)”

Long title of trial:
“A randomised controlled trial of clinical and cost effectiveness of therapist delivered cognitive behavioural therapy and web-based self-management in irritable bowel syndrome”

The aim of this trial is to determine the clinical and cost-effectiveness of therapist delivered cognitive behavioural therapy and web-based CBT self-management in irritable bowel syndrome. The CBT model of IBS which informs the two treatments being compared has been described in earlier papers1,2,3.

The two treatments will primarily differ on therapist contact time and delivery vehicle (manualised versus web-based). In both therapy arms, medical questions will not be addressed by the therapists and participants will be advised by the research team to seek medical advice if they have medical queries.

High Intensity Cognitive Behavioural Therapy (HICBT)

Participants will be provided with a detailed CBT participant manual containing 8 chapters and including homework sessions. Participants in this arm of the trial will have 6 one hour telephone sessions with a CBT therapist over a 9 week period. They will also receive two one-hour booster sessions at 4 and 8 months post randomisation. More information on scheduling sessions can be found on page 12.

Low Intensity Web-based CBT self-management programme (LICBT)

Participants in this arm will be provided with log on access to Regul8, an interactive, tailored CBT self-management website developed with substantial participant input in a previous trial4. The content of the website is similar to the chapters of the participant manual in the HICBT condition. The main distinction being an interactive element integrated into the website to allow the participants to perform their own self-assessment.

Participants will be advised to start working through the 8 online weekly sessions and homework tasks once randomised and will receive weekly automated email reminders. They will also receive three 30-minute telephone therapy support calls across a 9 week period and two 30-minute booster sessions at 4 and 8 months post randomisation.

Participants will also be able to email the therapist regarding queries about the content of the website programme during the study.

**Treatment as usual (TAU)**

Participants in all three arms will receive TAU, with the control arm being TAU alone. TAU is defined as a continuation of current medications and usual GP or consultant follow-up with no psychological therapy.

The TAU alone participants will have access to the Regul8 website at the end of the trial follow up period.
Following Trial Protocol

The Participants’ Journey
All participants will have gone through rigorous screening by the time they are allocated to treatment. This process will involve the following:

1. Participants will have been recruited either opportunistically at secondary care clinics or via GP practices whereby they will have been invited to take part by letter.

2. Each invite letter will have an ID number. This will become the participant ID number if a participant decides to take part in the study and is eligible.

3. To be included in the study, participants will have to have a diagnosis of IBS according to the ROME III criteria and will need to meet the exclusion criteria below. Participants will be screened for eligibility over the phone by the two research assistants. If eligible participants will provide online consent to continue with the study.

<table>
<thead>
<tr>
<th>Inclusion</th>
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<td>Rome III criteria for IBS diagnosis (see Appendix I for details on these diagnostic criteria).</td>
<td>Unexplained rectal bleeding or weight loss</td>
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<tr>
<td>Refractory IBS with diagnosis of IBS for minimum 12 months.</td>
<td>Inflammatory Bowel Disease</td>
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<td>Coeliac disease</td>
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<td>Colorectal Carcinoma</td>
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<td>No internet access</td>
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<td>Abnormal blood test</td>
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<td>Participation in the MIBS study</td>
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<td>Previous use of CBT specifically for IBS</td>
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<td></td>
<td>Previous access to the MIBS study online self-management programme Regul8</td>
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4. Once the consent is received, the participant will be instructed by email to contact their practice or hospital to make an appointment for a blood test to ensure that they are not anaemic and that there are no signs that their bowel symptoms are due to other illnesses (e.g. Coeliac's disease). Should participants have already had blood taken in the previous three months these results will be obtained from their GP or consultant by the trial team.
5. Once the blood tests are received by the trial team, if eligible, the participant will then be instructed to complete an online baseline questionnaire. This takes around half an hour to complete.

6. After completion of the baseline measures, the participant will be randomised to one of the three conditions.

**Allocation of Participants**

Therapists will be allocated participants who are randomised to the HICBT and LICBT condition. As soon as a participant is randomised to these conditions, a research assistant will notify therapists and it will be decided which therapist the participant is allocated to, based on therapist availability.

Workload, availability and progress of sessions will be discussed in Tuesday morning meetings involving therapists, a research assistant and the therapist supervisor/s.

It is also recommended that therapists enter their planned annual leave and absences in advance. Recording planned leave in their calendars will allow sharing with the research assistant/s and administration staff to augment the participant allocation process.

Once participants are allocated to therapists, a letter should be sent from the therapist to the participant’s GP to inform them of the participant’s involvement in the trial. A template GP letter can be found in Appendix XVII.

**Scheduling Telephone Sessions**

When a therapist is allocated a participant, they will be provided with the date that the participant was randomised. From this date there will be a 12-week period before the participant has to complete the first follow-up questionnaires. The therapist will therefore have a strict 9-week window within which to carry out all treatment sessions. For both conditions there will be two booster sessions at week 16 and week 32 post randomisation.

For more information on scheduling telephone sessions please refer to page 12 or to Standard Operating Procedure (SOP) 1. All SOPs are located in the SOP section of the ring binder.

Participants should be informed that the booster sessions are spaced out to provide an opportunity for them to put into practice what they have learned from their telephone sessions and use of the manual or website (depending on condition). Therapists should convey that these can be used as an opportunity for participants to discuss how they have been progressing, to review and discuss goals as well as problems that they have encountered.

**Logging Treatment Sessions**

All therapists will be issued with a login for an online database to record some brief details about the sessions for statistical analysis purposes.

Initially therapists will be required to register in the database, providing details of their years’ experience as a therapist, their age, and some other demographic details. They will be
provided with a therapist ID and will utilise this and a password to log in each time they record the following details of their sessions with participants:

- Therapist name/ID
- Participant ID
- Due date of session
- Actual date (if it was changed/missed initially)
- Whether the session was missed
- Reason for missed session
- Duration of session
- Date of emails and phone calls to arrange session

It is recommended that therapists enter these details during or directly after the session with participants. Doing so is expected to take less than 5 minutes.

After all sessions for a participant have been entered at the end of therapy (after last booster session), therapists will be required to enter the following information:

- Number of unplanned telephone calls (from participant to therapist for advice)
- Number of telephone sessions attended by partner
- Number of telephone sessions attended by a relative or friend
- Drop out date (if applicable)
- Reasons for drop out (if applicable)
- Rating of participant change (very much better to very much worse)
- Rating of participant adherence to the homework
- Rating of the extent that the participant accepted the model of therapy
- Any other comments

It is advised that therapists familiarise themselves with the information required for the therapy database, particularly the information intended to be gathered at the end of treatment sessions. This is to enable accuracy as much as possible.

A prompt sheet with these variables is contained in Appendix VIII and the full list of variables included in the therapy database is found in Appendix II and III.

Training in utilising the database will be provided by research assistants and further queries can be directed to them. A list of contacts is included in Appendix XIX.

Recording such information should not interfere with therapists’ own note taking in sessions. Prompts for reviewing sessions are available in Appendix VI. These are not compulsory, but therapists may find them useful for structuring notes about the session.

**Recording Treatment Sessions**

All telephone therapy sessions will be recorded for the purpose of assessing treatment fidelity. These will be used for supervision during the study and 10% of the recordings will be analysed once the trial has ended by two independent clinicians. At least two sessions for every therapist and for therapy type will be rated in terms of adherence to the manual or web based approach. The therapeutic alliance between the therapist and participant will also be rated.
All therapists will be provided with a recording device for use in telephone sessions. Therapists should begin recording before participant picks up and state the following:

- Therapist name
- Participant ID
- Session number
- Date

Recordings devices should be passed to the research assistant (Sula Windgassen) after a maximum of three sessions. These sessions will then be uploaded and saved, the recording device wiped and returned to the therapist.

**Unplanned Participant Contact**

Participants are permitted to contact therapists in urgent circumstances in matters regarding therapy. It is made clear by the research team that therapists are not able to issue medical advice. Participants in LICBT may email with queries relating to the online content and where appropriate therapists can provide a short response. For more extensive matters, therapists should communicate to the participant that this may be something that should be discussed in the next telephone session.

For participants in the LICBT condition who may have queries regarding technical issues, they should be referred to Stephanie Hughes sh3r11@southampton.ac.uk (Appendix XIX).

**DNAs**

In some instances participants may not pick up at the time of the scheduled phone call. In these instances therapists should try and call back one to two more times within an appropriate period. If participants still do not pick up, therapists should follow the guidance contained in SOP 2 for DNAs. This is found in the SOP section of the ring binder.

**Adverse and Serious Adverse Events (AE and SAE)**

AEs and SAEs are being assessed by the trial team in questionnaires at 3, 6 and 12 month follow ups. Therefore it will not be necessary for therapists to ask specific questions to ascertain the occurrence of such events. However, should therapists become alerted to an AE or and SAE there are two slightly different processes that therapists should follow.

**Non-serious Adverse Events**

An adverse event covers any event that results in the non-serious deterioration of health of the participant since the beginning of the trial. It does not necessarily have to be associated with or caused by the trial. Therapists will be provided with a Non-serious adverse event log (Appendix XX) to complete should they become aware of any such event. The procedure for logging such event is detailed in SOP 3 for Non-Serious Adverse Events. This is found in the SOP section of the ring binder.

**Serious Adverse Events**

A SAE includes the following events:

- Death
- Life-threatening
- In-patient hospitalisation
- Disability/incapacity
- Congenital anomaly/birth defect
- Deliberate self-harm
- Other medical events requiring intervention to prevent one of the outcomes listed above

Again an SAE does not necessarily have to be associated with the trial, but they always need to be reported. Should one of these events occur therapists should complete an SAE form (Appendix VI) as soon as they become aware of any such event. This form should be sent by email or fax to Gilly O’Reilly within 24 hours. The process of recording and reporting SAEs can be found in SOP 4 for reporting SAEs. This is found in the SOP section of the folder.

Depending on the nature of the SAE, therapists should write to the participants’ GP to inform them of the event. A template letter for this is located in Appendix XXI.

Assessment of Low Mood and Suicide Risk

Some participants may appear to have a particularly low mood and in these cases therapists should consider whether it is necessary to make an assessment of suicidality. Questions regarding such risk may include:

- Have you ever thought about or attempted to kill yourself?
- How often have you thought about killing yourself in the past year?
- Have you ever told someone that you were going to commit suicide or that you might do it?
- How likely is it that you will attempt suicide in the future?
- Do you currently have thoughts about suicide?
- Do you often make plans to end your life?
- What thoughts have you had in relation to suicide?
- Do you have current plans to commit suicide?

Should therapists deem there to be a high risk of the participant attempting suicide, formal assessment of this risk should be made using the questionnaire in Appendix VII. If there is deemed to be a high risk, line managers (Trudie Chalder and Suzanne Roche) should be informed straight away. The trial manager, Gilly O’Reilly should also be informed as soon as possible. An SAE form should only be completed should an attempt on suicide be made. An AE log should be made for suicidal ideation without action.

In the event of a suicide attempt, the GP of the individual will also need to be informed by letter and the information logged on the EPJ. A template GP letter is contained in Appendix XXII.
Understanding IBS

This section aims to help you to understand the basics of IBS. It also illustrates the differences between treatment arms and outlines the CBT approach to IBS.

The following can be found in this section:

- Background information about IBS
- Physiology of IBS and common myths
- Summary of different treatments used in IBS
- A cognitive behavioural model of understanding IBS
- CBT approach to IBS

What is Irritable Bowel Syndrome (IBS)?

Irritable bowel syndrome (IBS) is a condition of the digestive system that occurs in between 10 -20% of individuals at some point in their life. Women are twice as likely as men to be affected by IBS. IBS has also been called spastic colon, mucus colitis, spastic bowel and irritable colon.

The key symptom is recurrent or on-going abdominal pain, which is associated with a disturbance in bowel function.

What are the symptoms?

The symptoms of IBS usually come and go in bouts and can been made worse after eating. The most common symptoms of IBS are:

- Constipation, diarrhoea or alternating bouts of both
- Crampy pain or discomfort
- Gassiness, excessive wind
- Urgent need to open bowels
- Feeling of incomplete emptying of bowels
- Crampy urge to move bowels with no result
- Nausea, acid stomach and vomiting
- Excess passage of mucus
- Changes in the consistency of stools (for example small, hard, round stools to soft, runny stools)

Fatigue is also a common symptom of IBS.

Diagnosing IBS

To be diagnosed with IBS a participant needs to have experienced IBS symptoms for at least 6 months. The key symptom of IBS is abdominal pain, which may be relieved by passing a stool or gas. Participants need to have at least two other IBS symptoms (from list above) in addition to pain to be diagnosed with IBS.

There are no specific medical tests to diagnose IBS. Instead, several tests can be conducted to rule out more serious conditions such as celiac disease, on-going bacterial infections of
the gut and cancer. This usually involves a series of blood, urine and stool tests with a medical examination. In a small number of cases patients may need to have more extensive examinations of the bowel itself to rule out more serious illness.

The present study includes participants who have been diagnosed with IBS according to the ROME III criteria. This requires participants have **at least two of the following IBS symptoms in addition to pain:**

1. More frequent or less frequent bowel movements since the pain/discomfort started.
2. Looser or harder stools since the pain/discomfort started.
3. The pain/discomfort stops after a bowel movement.

More details of the ROME III criteria of IBS are contained in Appendix I. This is the criteria being utilised in the present trial to confirm a diagnosis of IBS in participants. The present trial is seeking to enter only participants with refractory IBS, therefore symptoms will have persisted for a minimum of a year rather than 6 months.

**What is the cause?**

The exact cause of IBS is unknown. However the symptoms are associated with irregularities in the movement of the bowels together with increased bowel sensitivity and altered production of mucus. There is some evidence for stress and viral or infective gastroenteritis as triggers.

IBS may start gradually over time and only become noticeable when the symptoms become severe. It can be triggered by an event such as a viral or infective gastroenteritis (stomach flu) or by a stressful event or by both.

Campylobacter gastroenteritis (which is caused by bacteria in contaminated food and fluids such as undercooked chicken or unpasteurised milk) may cause prolonged symptoms for up to 25% of people. Research has shown that up to 10% of people who have a diagnosis of Campylobacter may warrant a diagnosis of IBS six months after their initial infection. Campylobacter infection releases toxins which leak into the gut wall. These toxins can affect the nerves which stimulate both the muscles in the walls of the intestine and the production of hormones responsible for bowel action. The initial infection can also increase sensitivity in the large intestine. It is important to note that although the infection may trigger these changes, the changes themselves are not due to ongoing infection. Rather in some people the infection appears to set up sensitivity in the bowels.

Some people are more susceptible to bowel symptoms. IBS patients tend to be more sensitive to the feelings of pain and movement within their digestive system. It is possible that this is a hereditary characteristic. Alternatively, as explained above, it may be a reaction to an initial infection.

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Psychological factors and IBS

There is substantial evidence suggesting that psychological factors play an important role in IBS. Stress and anxiety can trigger chemical changes that interfere with the normal workings of the digestive system. Therefore, the stress response can result in physical symptoms. The effect of stress on the digestive system is presented further on page 22.
Physiology of IBS & common myths

Digestive process

To better contextualise symptoms that participants may experience, it is useful to understand the digestive process. The diagram demonstrates the different organs involved in the digestive process and the transit time taken associated with each part of the journey.

Food is digested as it travels through the mouth, continues down the oesophagus, into the stomach, then through the small intestine and the colon and out of the rectum. The nutrients of the food are extracted through the digestive process which includes chewing, chemical action through enzymes and other digestive juices, and absorption. Much of the breakdown and absorption of the nutrients occurs in the small intestine.

The Colon

The large intestine is the part of the bowel that is largely affected in IBS. It is made up of the colon and the rectum.

The colon is:
- 1.5 metres (5 feet) long
- Its main function is to convert liquid waste products passing from the small intestine, into faeces
- This is done by absorbing some of the water through the lining of the colon and through characteristic movements of the muscles in the wall of the colon
• Faeces are made up of dead intestinal organisms and components of food that cannot be digested

The diagram below shows how these different movements help to form and propel the faeces. The movements are created by the combined and coordinated action of circular and longitudinal smooth muscles, coordinated by a network of nerves.

<table>
<thead>
<tr>
<th>Peristaltic contractions</th>
<th>Mass movements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waves of peristaltic contractions propel faeces toward the rectum. Muscles behind food contract, with the muscles in front relax.</td>
<td>Mass movements are strong peristaltic waves that propel faeces relatively long distances about two or three times a day.</td>
</tr>
</tbody>
</table>

**The rectum and anus**

The rectum is at the end of the colon. It is around 12 cm long. It is normally empty until just before a person passes a stool. The rectum lies in the anal canal, which has two valves like structures called sphincters. These keep the anus closed.

Movements in the colon push faeces into the rectum, triggering the reflex to pass a stool. This stimulates the sphincters in the anal canal to relax and allowing the faeces to pass out of the body.

People can assist this reflex to go to the toilet by voluntarily pushing with their abdominal muscles. People can also consciously override the reflex to go to the toilet by tightening their anal muscles.
The physiology behind symptoms in IBS

**Muscular movements in the colon**

Consistent and coordinated muscular movements in the colon are important for normal digestion and passing of stools. In IBS, faecal movement in the colon can either speed up or slow down.

If the motion in the colon is too fast, cramping and diarrhoea may result. Fast movements of faeces into the rectum may also trigger a very strong reflex or urgent need to go to the toilet. If the movements slow down too much constipation may result. This is because slow movements result in too much water being absorbed and consequently a hard and lumpy stool will result. In contrast faecal material passing too quickly will not allow for enough water to be absorbed resulting in a watery and ill formed stool.

Sometimes people with IBS get spasms (rapid muscle contractions) in the colon. This can be caused by lack of coordination in the peristaltic movement. This type of inconsistent movement of the colon muscles can result in the trapping of waste and air in the bowel, which can be extremely uncomfortable. This may cause excessive bloating and/or strange tummy noises.

**Changes in the bacteria in the colon**

There are billions of helpful bacteria in the gut which feed off undigested material and mucus secreted by the cells lining the colon. Through this process the bacteria produce gases. In most cases these gases cause no problem and may be passed from time to time as wind.

In people with IBS the bacterial balance may be altered leading to an increase or build-up of gaseous products. This can lead to symptoms of gassiness and excessive wind. It may also cause reflux and in some cases nausea or vomiting.

**Changes in the mucus in the colon**

Mucus production is important to ease the passage of the stools as it travels down the colon. People with IBS appear to have either too much or too little mucus. This can be noticed when a stool is passed.

The production of mucus is related to the amount of pressure in the bowel. High pressure created by an increase in the contraction segmentation muscular movements in the bowel, result in excess mucus production. Low pressure results in too little mucus. The alteration of mucus can contribute to diarrhoea or constipation in IBS.
The effect of stress

The muscles of the gut are controlled automatically by signals from the brain and nervous system. The brain sends messages to the gut which either speeds up or slows down the motion of the muscles. The colon is usually in movement throughout the day. Food takes several hours or sometimes days to go through this system. A fine balance of motion in the colon is the result of a balance of these two types of messages (speeding up and slowing down) and is necessary in order to keep the contents of the bowel moving forward comfortably.

When a person feels stressed their nervous system becomes more active, resulting in a release of stress hormones such as adrenaline and other physiological changes such as increased heart rate and respiratory rate. These physical changes can sometimes cause radical changes in the activity of the gut. This may cause an increase in spasms or shut down all motion, resulting in diarrhoea or constipation as well as nausea or alternating bouts of all three.

Therefore physical, social or emotional stressors can all result in physical symptoms. For example, you may have had diarrhoea at exam time or constipation when travelling. You may have felt nausea when you experienced a terrible shock or bereavement.
Case study

Joe experiences a severe bout of gastroenteritis (a tummy bug). This infection causes intense bowel pain, extreme diarrhoea and cramping. He loses sleep, stops eating and is unable to work so his normal daily routine is completely disrupted. When Joe feels like eating again, he eats irregularly as his stomach appears to have become sensitive to food and eating often causes tummy cramps and pain. The irregular meals send conflicting messages to Joe’s digestive system, and it stops and starts, causing bouts of diarrhoea and then constipation.

Joe begins to worry about his health, about missing so much work, and about taking care of his family. He feels upset and stressed and this makes his symptoms worse. Joe often feels sick or has diarrhoea in the morning, so he skips breakfast. By lunchtime he is really hungry so he overeats, causing his colon to overreact and start spasming again. He takes a day off work and stays in bed and sleeps during the day, but because of the extra rest finds it hard to sleep that night. He lies awake worrying about what is happening to his health and feels his tummy churning and cramping. Because he has taken a day off, he works extra hard the following day which only serves to increase his stress and make his bowel symptoms worse.

The vicious cycle in IBS

![Diagram of the vicious cycle in IBS]

- **TRIGGER** (Infection, stress or both)
- Changes in bowel function
- Stress / anxiety
- Disruption of social / work life
- More bowel symptoms and worry about health
- Bowel symptoms
- Disrupts daily routine and/or eating habits
Dispelling myths in IBS

There are some common myths about bowel function that many people with IBS may believe. Some of these are listed below:

1. Irregularity is a sign of poor health
2. Not being able to fully evacuate is toxic or dangerous
3. People should pass a stool every day
4. Stools should be a particular shape or form
5. If you feel a sense of incomplete evacuation you must keep straining to pass a stool

Below are some answers to address these common myths.

**How many stools a week are normal?**

There is no single answer to this question. For some people, passing 3 stools per day is normal while for others 3 per week is normal. The important thing is not to get too stressed if you don’t pass a stool on any one day.

**Is constipation harmful to health?**

Whereas constipation can be very uncomfortable, it is unlikely to cause any long-term harm or damage. It does not have toxic effects. The colon is very long and able to store a large amount of faecal matter. The waste products remain in the bowel during constipation and are not reabsorbed into the body.

**What is a normal shaped stool?**

There is no such thing. Stool shape and consistency can alter depending on the motility of the bowel. This is influenced by factors such as mood, change in diet, stress, anxiety and worry, travel or change in environment. Checking stool shape or consistency does not provide a good reflection of the functioning of the bowels. The shape will vary from time to time and this is perfectly normal.

**Should your bowels feel empty after you pass a stool?**

Not necessarily. The feeling of incomplete evacuation is a common symptom of IBS and it does not mean that a stool needs to be passed. The bowel is never completely empty and it is not harmful in situations where a person has not managed to pass a stool or feel as if they are only half done.

Many people respond to the feeling of incomplete evacuation or constipation by spending an excessive amount of time on the toilet straining. This is harmful rather than helpful, as straining often makes people feel desperate and more stressed about their constipation. Feeling uptight will make passing a stool harder as the sphincter muscles in the anus are
meant to relax to allow the faeces to pass out of the body. When tense, the muscles tighten rather than relax. Excessive pushing of the abdominal muscles will have a similar effect.

**When should you go to the toilet?**

When faecal material enters the rectum it triggers a reflex to go to the toilet. It is best to wait until this reflex is felt as this is the body’s natural signal that it is ready to pass a stool. Individuals are then able to use their abdominal muscles to give a slight push to help the process. If it doesn’t happen within a minute or two it is best to get off the toilet and try again later.
# Supplementary Therapies Used in IBS

## Pharmacological Therapy

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Details of therapy</th>
<th>Side effects and/or evidence base</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antispasmodic drug therapy</strong></td>
<td>Used to relax the muscles in the digestive system. Examples of antispasmodic medicines include Mebeverine and therapeutic peppermint oil</td>
<td>Side effects are rare. Antispasmodics are not recommended for pregnant women. Generally found to be effective.</td>
</tr>
<tr>
<td><strong>Laxatives</strong></td>
<td>Used for IBS patients who predominantly suffer with constipation. They make stools denser and softer, allowing for easier passage</td>
<td>Bloating, wind and stomach cramps. Lack of research for use of laxatives in IBS, specifically.</td>
</tr>
<tr>
<td><strong>Anti-motility medicines</strong></td>
<td>Used for IBS patients who predominantly suffer with diarrhoea. Loperamide is commonly used for this and works by slowly contracting muscles in the bowel. This slows the speed at which food passes through the digestive system, providing more time for it to solidify.</td>
<td>Abdominal cramps, bloating, dizziness, drowsiness, skin rash. Not recommended for pregnant women. Loperamide is most frequently studied &amp; accepted as effective with no central side effects.</td>
</tr>
<tr>
<td><strong>Antidepressants:</strong></td>
<td>Two main types of antidepressants are used to treat IBS (below):</td>
<td>Antidepressants have generally been found to be effective in reducing symptoms in IBS.</td>
</tr>
<tr>
<td><strong>Tricyclic antidepressants (TCAs)</strong></td>
<td>Recommended when antispasmodic medicines have not controlled symptoms of pain and cramping. They work by relaxing muscles in the digestive system. TCAs will only provide relief after 3-4 weeks as the body starts to get used to the medication. Amitriptyline is the most widely used TCA</td>
<td>Side effects include dry mouth, constipation, blurred vision and drowsiness. Such side effects should improve within a few days of starting medication and GP should be consulted if side effects become a problem.</td>
</tr>
<tr>
<td><strong>Selective serotonin reuptake inhibitors (SSRIs)</strong></td>
<td>These are an alternative antidepressant. Examples of SSRIs used to treat IBS are citalopram, fluoxetine and paroxetine</td>
<td>Common side effects include blurred vision, diarrhoea or constipation and dizziness.</td>
</tr>
</tbody>
</table>

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## Diets & Probiotics

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Details of therapy</th>
<th>Side effects and/or evidence base</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Fibre Diet</td>
<td>People with IBS may be advised to consume more fibre. This can be in the form of synthetic or natural bulking agents or through increasing consumption of fibrous food.</td>
<td>Increased fibre consumption has been associated with increased flatulence and bloating. Meta-analysis demonstrated that generally only use of isphagula husk is effective for reducing symptoms(^8). No distinction between diarrhoea and constipation predominant IBS.</td>
</tr>
<tr>
<td>Reducing insoluble fibre</td>
<td>Foods that contain insoluble fibre include wholegrain bread, bran, cereals, nuts and seeds (except golden linseeds). Diarrhoea predominant IBS patients may be advised to reduce their insoluble fibre intake.</td>
<td>There is currently very little empirical evidence regarding the increase or decrease of insoluble or soluble fibre.</td>
</tr>
<tr>
<td>Increasing soluble fibre</td>
<td>Foods that contain soluble fibre include oats, barley, rye, fruit, root vegetables, golden linseeds. Constipation predominant IBS patients may be advised to increase their intake of soluble fibre and the amount of water they drink.</td>
<td></td>
</tr>
<tr>
<td>Diet: low FODMAP diet</td>
<td>A low FODMAP diet is one that is low in Fermentable Oligo-, di-, Mono-saccharides and Polys. These are carbohydrates that are rapidly fermented in the gut. The diet involves restricting various foods including those grains, fruits and vegetables that are high in FODMAPs. A dietician is needed for use of the FODMAP, to tailor the diet to different individuals and guide the reintroduction of certain foods.</td>
<td>There is some preliminary research supporting the efficacy of the diet in reducing IBS symptoms. However to date there are few good quality studies providing evidence of successful symptom reduction and improvement of quality of life in IBS. For the purposes of this study, we would encourage participants interested in beginning the low FODMAP diet, to defer doing so until after they have completed the all assessments within the present study.</td>
</tr>
<tr>
<td>Probiotics</td>
<td>Probiotics are organisms such as bacteria or yeast that can be used as dietary supplements to improve digestive health. They are asserted to promote a healthy balance of bacteria in the gut.</td>
<td>There is little risk associated with the consumption of them. Generally the use of probiotics has been found to be effective in reducing IBS symptoms(^8).</td>
</tr>
</tbody>
</table>

General IBS Diet Tips

It is generally suggested that people with IBS should look to maintain a healthy routine of eating. Therapists should encourage participants to follow the advice below in so far as possible:

- Have regular meals and take time when eating
- Avoid missing meals
- Drink at least 8 cups of fluid a day particularly water or non-caffeinated drinks
- Lower amount of alcohol and fizzy drinks
- Reduce intake of resistant starch (often found in processed food)
- Limit fresh fruit portions to 3 a day

For diarrhoea predominant IBS, avoid sorbitol – an artificial sweetener found in sugar free sweets including chewing gum and drinks

Alternative Therapies

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Details of therapy</th>
<th>Side effects and/or evidence base</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypnotherapy</td>
<td>Hypnosis is used to change a person’s unconscious mind’s attitude towards their symptoms.</td>
<td>A review of RCT’s for hypnotherapy in IBS found only 7 papers. There was minimal evidence for change in diarrhoea or constipation symptoms in short or long-term. Effective for change in abdominal pain in short term.</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>Acupuncture is a complementary medicine, in which fine needles are inserted into the skin at specific points along what are called meridians. These are considered to be lines of energy. Acupuncture has been asserted to help symptoms of IBS in providing pain relief, regulating the digestive tract and raising the sensory threshold of the gut.</td>
<td>A 2012 systematic review examining the efficacy of acupuncture compared to credible sham acupuncture found no significant benefit of acupuncture on symptom severity and QoL.</td>
</tr>
</tbody>
</table>

Psychotherapy

The most empirically supported psychotherapeutic treatment for IBS is CBT. Other psychotherapeutic treatments that have been used in IBS and their evidence base according to a 2009 systematic review of psychological therapies in IBS\(^{11}\) are shown in the table below.

<table>
<thead>
<tr>
<th>Therapy Type</th>
<th>Therapy Details</th>
<th>Evidence for Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychodynamic therapy</td>
<td>Aims to explore and confront how a person’s past may unconsciously affect their present beliefs, attitudes and feelings.</td>
<td>There are currently only 2 studies investigating the efficacy of psychodynamic therapy on IBS. It was generally found to be effective but results have not been replicated since 2003.</td>
</tr>
<tr>
<td>Relaxation Training</td>
<td>Aims to reduce stress and anxiety arising from symptoms and other stressors in order to minimize the effects of stress on IBS symptom severity.</td>
<td>No statistical effect on the symptoms of IBS(^{11}). A further two studies have found it to be effective in reducing symptoms, however no difference found up at 3 month follow up in one and results not very big in either studies(^{12,13})</td>
</tr>
<tr>
<td>Multi-component therapy</td>
<td>Consisting of a variety of approaches including stress management, biofeedback and psycho-education.</td>
<td></td>
</tr>
</tbody>
</table>

CBT has the largest amount of studies supporting its efficacy in reducing IBS symptom severity and increasing quality of life (QoL)\(^{15}\). These studies tend to be better designed and controlled, with a larger amount of participants then studies for many other types of alternative therapies. Such effects have also been found in self-management CBT interventions\(^{16}\).


\(^{12}\) Dehkordy, S. K., & Gharamaleky, S. N. (2010). Effects of relaxation and citalopram on severity and frequency of the symptoms of irritable bowel syndrome with diarrhea predominance.. Pakistan Journal of Medical Sciences, 26(1).


Cognitive Behavioural Model of Understanding IBS

The cognitive behavioural model of IBS draws a distinction between factors that precipitate IBS and factors that maintain it.

Predisposing and Precipitating Factors

Susceptibility
Some people are more susceptible to bowel symptoms. IBS patients tend to be more sensitive to the feelings of pain and movement within their digestive system. It is possible that this is a hereditary characteristic.

Personality
People with IBS often report being hardworking, conscientious and having high expectations of themselves. This type of personality may lead to individuals striving very hard to achieve in all they do, leaving little time for pleasure and a sense of pressure.

Stress
Results from the Recovery from Infection Study\textsuperscript{17} showed that people who were under stress and who tended to be perfectionists with an “all or nothing” approach to life, were more likely to have IBS symptoms at three months after the Campylobacter infection.

Infections
Campylobacter gastroenteritis may cause prolonged symptoms for up to 25% of people. Research has shown that up to 10% of people who have a diagnosis of Campylobacter may warrant a diagnosis of IBS six months after their initial infection.

The campylobacter infection releases toxins which leak into the gut wall. These toxins can affect the nerves which stimulate both the muscles in the walls of the intestine and the production of hormones responsible for bowel action. The initial infection can also increase sensitivity in the large intestine. It is important to note that although the infection may trigger these changes, the changes themselves are not due to ongoing infection. Rather in some people the infection appears to produce sensitivity in the bowels.

Perpetuating Factors

Just as there are many factors involved in triggering IBS, there are also many factors that are involved in sustaining it. According to this model, the symptoms of IBS are perpetuated predominantly by unhelpful illness beliefs and coping behaviours. These beliefs and behaviours interact with the participant’s emotional, physiological and interpersonal state/situation to form self-perpetuating vicious cycles of negative patterns of thoughts, emotions, behaviours and symptoms.

Avoidance of activities

People with IBS may avoid activities for fear of making their symptoms worse. Sometimes people stop socialising for reasons of embarrassment. However, stopping doing things on a regular basis can lead to a loss of confidence in being able to do them. For example, they may have stopped seeing friends or doing certain types of exercise, etc. Resuming these activities may provoke fear and lead to further avoidance.

Precaution taking

People with IBS may take precautions when facing certain situations in order to control the symptoms. Some examples of precaution taking are:

- Sitting near the door in a meeting so that the toilet is easily accessible
- Taking tablets for diarrhoea or constipation when leaving the house pre-emptively
- Sitting on the toilet for longer than necessary just in case they get caught short

Over-vigorous activity alternating with resting for long periods

This is also known as “boom or bust” behaviour. People with IBS may tend to expect a lot of themselves and can get over-committed, trying to look after everybody else’s needs before their own. This can cause a boom or bust cycle.

On a good day when IBS symptoms seem to be under control, individuals may over-exert themselves to catch up on things. This inevitably exacerbates symptoms, causing them to slow down or rest completely. The result is that they get behind on their commitments and as soon as they feel a bit better they push themselves really hard to catch up on things again.

Symptom focussing

The symptoms commonly experienced by people with IBS are both distressing and debilitating. They will often pay a lot of attention to their symptoms, which may result in an exacerbation of symptoms and lead to further avoidance.

Life stress

Many people with IBS experience major ongoing life stresses and problems related to the effects of their illness. These may be physical, social or emotional including worries about potential damaging effects of not going to the bathroom every day, social isolation due to reduced ability to socialise or concerns over obligations.

Psychological stress has physiological effects that can affect the severity of IBS symptoms due to the release of certain stress hormones which can disturb normal bodily processes.

Unhelpful thoughts

People with IBS often report having lots of negative thoughts. These may be related to their illness, their symptoms, embarrassment, high standards or self-esteem. Examples include: “I might pass wind in public and embarrass myself” or “I must empty my bowel at least once every other day"
Perfectionism

Just as personality can be a factor in contributing to the development of IBS, it can also be a perpetuating factor. People who are perfectionists are likely to have more difficulty in taking breaks or resting in the day as they feel that they are “wasting” time and “should” be doing something useful. This may lead them to adopt a “boom and bust” approach to activity, which makes it difficult to establish any sort of routine.

Emotional Processing

People experiencing IBS are likely to experience emotions such as embarrassment, shame, fear, anxiety, frustration, anger, depression, sadness or grief. Such feelings are common in most chronic illnesses. These emotions can also produce physiological changes such as changes in bowel function, increased muscle pain, fatigue and impaired memory and concentration.

People with IBS may be inclined to ignore or push away difficult emotions and it is important to assess whether participants have this tendency. It will also be an integral part of therapy to introduce participants to different ways of identifying, accepting and managing emotions. These are discussed on pages 106-117 of the Participant Manual.
A Cognitive Behavioural Approach to Treating IBS

Treatment is focused on addressing the cognitive and behavioural factors that maintain the vicious circle of IBS. This involves the participant becoming aware of and changing unhelpful thoughts about their situation and altering their patterns of behaviour.

Factors that commonly maintain or perpetuate IBS are illustrated in the diagram below.
Aim of Cognitive Behavioural Therapy (CBT)

Treatment aims to help participants reduce and manage their IBS symptoms whilst at the same time improving their quality of life. The therapy consists of education as well as behavioural, cognitive and emotional techniques.

The aim is to improve bowel habits, develop stable, healthy eating patterns, address unhelpful thoughts, manage stress, accept and process emotions, address unhelpful coping behaviours, reduce symptom focussing and prevent relapse.

The main components of this approach are as follows:

- Eliciting the participant's own model of illness to establish how they appraise and cope with their situation.
- Establishing with the participant a shared multifactorial understanding of their illness that takes into account predisposing, precipitating and maintaining factors.
- Using this model as a rationale to implement behavioural, cognitive and lifestyle changes, targeted at reducing the impact of maintaining and predisposing factors.
- Equipping the participant with a variety of appropriate cognitive, behavioural and problem solving skills so that they can continue to make further progress.

Summary of strategies

A variety of cognitive and behavioural strategies will be discussed with participants during their CBT sessions to help them to reduce severity of IBS symptoms and improve their functioning.

Cognitive Strategies

These strategies aim to address unhelpful thoughts and beliefs and may involve agreeing specific behavioural experiments to test out the validity of the participants’ existing beliefs.

Frequent unhelpful cognitions include:

- “I might pass wind in public and embarrass myself” which may lead to an avoidance or reduction in social activities
- “I must empty my bowel at least once every other day” which may lead to 30 minutes spent in the toilet straining
Behavioural strategies

These strategies aim to help participants to a) improve their bowel habits and adopt healthy eating b) establish balanced activity c) improve sleeping patterns. They may involve:

- Reducing straining if constipated
- Establishing healthy bowel habits
- Following a healthy and balanced diet and eating routine
- Establishing a consistent pattern of toileting behaviour
- Graded exposure to situations that may cause anxiety, e.g. socializing
- Graded approach to specified goals
- Working towards a consistent and balanced activity pattern
- Learning to relax

Emotional Processing Strategies

These strategies aim to address difficult emotions and involve finding new ways to deal with these emotions, in addition to taking time to focus on more positive emotions. Strategies may include:

- Developing acceptance and self-compassion
- Learning to express and process emotions (role plays, diary writing)
- Establishing activities that are pleasurable for the participant and calling upon them in times of emotional difficulty
- Utilising physical exercise to “let off steam”
- Developing assertiveness through behavioural experiments and role plays

Problem solving

Problem solving can be used to address worries that may be interfering with the participants’ ability to make progress, e.g. work or relationship issues.
Overview of Trial Procedures

HICBT Treatment Session Overview

Number of sessions
Participants will be offered six one hour telephone sessions within a 9-week period in which they will also be provided with homework tasks. They will also receive two one-hour booster sessions at 4 (16 weeks) and 8 months (32 weeks) after randomisation.

Duration of Sessions
All sessions, including the booster sessions are one-hour long.

Treatment phases
Treatment can be divided into three main phases:

1. Assessment, engagement and treatment planning (Session 1)
2. Active treatment (Sessions 2 to 6)
3. Booster sessions (Sessions 7 and 8)

Booster sessions should be referred to as “booster sessions” rather than “follow-up sessions” in order to promote attendance at these sessions.

Scheduling of sessions
From randomization, participants have 12 weeks within which to receive all treatment sessions. This is because participants will have to complete follow up questionnaires at 12 weeks. The research team will be responsible for ensuring that participants are allocated to therapists to allow for this. However therapists must ensure when scheduling sessions that all six fall into a 9 week period from when they were allocated the participant.

The two booster sessions must occur at 16 and 32 weeks after the participant has been randomized (rather than allocated to the therapist). All therapists will be provided with the dates of each participant’s randomization. Therapists have 3 weeks’ leeway for scheduling the booster appointments.

The scheduling of the treatment sessions can occur at any time within the 9-week period. More information on structuring of the sessions can be found on page 43. The procedure for scheduling appointments with participants can be found in SOP 1 for Scheduling Phone Calls. This is in the SOP section of the folder.

Therapists are advised to schedule all sessions in advance. It may also be helpful to hold the sessions on the same day of the week, at the same time of day should this be possible. This is however, not necessary.

Participants are provided with information when randomized to their treatment condition about what they should expect from treatment. In with this information it is emphasized that
participants should commit to phone calls arranged with therapists and ensure they are in an appropriate environment where they will feel comfortable talking in depth. It is advised that therapists also remind participants of this in the first call and ensure that they are able to apply themselves fully to the session.

DNAs
Therapists should outline the procedure for DNAs in the first session or at the first point of arranging sessions with participants. This will not be part of the treatment time, but treated as administration time and therefore should not cut into assessment in the first session.

DNAs can be re-scheduled as long as it does not mean that treatment falls outside of the 9-week period, which must be adhered to for all participants. Therapists should make clear that advanced notice is generally needed should participants need to cancel. The strict time period for treatment may also be conveyed to participants. As can any further restrictions to flexibility of scheduling appointments that may occur due to part time working hours or upcoming holidays.

Further details on the process for DNAs can be found in SOP 2 for DNAs, in the SOP section of the folder.

LICBT Treatment Session Overview

Number of sessions
Participants will be offered three half an hour telephone sessions within a 9-week period in which they will also have access to the Regul8 website to access course material and interactive homework activities. They will also receive two half an hour booster sessions at 4 (16 weeks) and 8 months (32 weeks) after randomisation.

Duration of sessions
All sessions, including the booster sessions are half an hour long

Treatment Phases
Treatment can be divided into three main phases:

1. Short assessment (main problems, risk assessment), treatment planning, active treatment (Session 1)

2. Active treatment (Sessions 2 to 3)

3. Booster sessions (Sessions 4 and 5)
Scheduling of sessions

The process for scheduling sessions in the LICBT condition is the same as that for those in the HICBT condition as on the previous pages. More information can also be found in SOP 1. The only distinction between the two conditions in the scheduling of sessions is the duration and frequency of sessions to be scheduled; in LICBT only 3 treatment sessions are required within the 9-week period and these sessions are half an hour rather than an hour in duration.

DNAs

The procedure for DNAs in the LICBT condition is the same as that for the HICBT condition as described on the previous page. More details may also be found in SOP 2.
Adhering to Trial Protocol

The present manual should direct therapists to all the information needed to ensure adherence to the trial protocol. Should there be queries regarding any aspect, therapists should use the contact list in Appendix XVIII. This contains details of names, roles and contact details to best inform therapists of who to contact about specific queries.

This therapist manual will be accompanied by a ring binder with a section for SOPs, a section for therapist prompt sheets (PS), a section containing homework sheets (HS) and information/measures provided to participants (PINF).

The table below can be used as a directory for different queries therapists may have.

<table>
<thead>
<tr>
<th>Query</th>
<th>Where to look</th>
</tr>
</thead>
<tbody>
<tr>
<td>What happens when I am allocated a participant?</td>
<td>Pgs 11-12, SOP 1, PS1.</td>
</tr>
<tr>
<td>How should I go about scheduling telephone appointments?</td>
<td>Pg 12, SOP 1, Pg 35-34</td>
</tr>
<tr>
<td>What happens if a participant does not pick up?</td>
<td>Pg 14, Pg 34, SOP 2.</td>
</tr>
<tr>
<td>What happens if a participant gets ill during the trial?</td>
<td>Pg 14, SOP 3, SOP 4, Appendix XX, Appendix VI, Appendix XXI, Appendix XXI,</td>
</tr>
<tr>
<td>What do I need to record each session?</td>
<td>Pg 12-13, Appendix II, Appendix VIII</td>
</tr>
<tr>
<td>How do I record sessions?</td>
<td>Pg 13 – 14</td>
</tr>
<tr>
<td>What homework should I set participants?</td>
<td>Pgs 73-93, Appendix IX- XVII</td>
</tr>
<tr>
<td>How should I structure my sessions?</td>
<td>Pgs 73-93, PS 1-4</td>
</tr>
<tr>
<td>What should I address in assessment for HICBT?</td>
<td>Pgs 46-51, 73, PS1</td>
</tr>
<tr>
<td>What should I cover in booster sessions?</td>
<td>Pg 78, PS 5</td>
</tr>
<tr>
<td>What is an adverse event and what should I do when one occurs?</td>
<td>Pg 14, SOP 3, Appendix XX</td>
</tr>
<tr>
<td>What is a serious adverse event and what should I do when one occurs?</td>
<td>Pg 14, SOP 2, Appendix VI, Appendix XXI</td>
</tr>
<tr>
<td>When should I write to GPs?</td>
<td>Pg 12-15, Appendix XVIII, Appendix XXI, Appendix XXII</td>
</tr>
<tr>
<td>What information will the participant have been given?</td>
<td>Pg 11, PINF 1-5, Participant Manual, Regul8 website</td>
</tr>
<tr>
<td>Where can I see the content of sessions on the Regul8 website?</td>
<td>PINF 5, Pgs 92-95</td>
</tr>
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</table>
Supervision

Clinical supervision for discussion of cases will be provided fortnightly in the first half of the trial then monthly in the second half by supervisors employed on the study to ensure quality of therapy and adherence to protocol. The supervision sessions will take place on site at the Maudsley Hospital, London. The format of supervision will be that of group sessions with all therapists on a Tuesday. Should individuals wish further one-to-one supervision, this can be arranged.

Supervision will provide therapists with the opportunity to discuss their participants and to iron out any difficulties that they may be experiencing.

To get the most out of supervision, therapists should prepare for supervision sessions by doing the following:

- Plan in advance what is hoped to be achieved from supervision

- To complete a Review of session record (Appendix IV) after each session to help reflection on sessions and to highlight issues that may need to be discussed in supervision.

- Bring the recordings of all clinical sessions to supervision

- Bring clinical notes to supervision

- Record what has been discussed in supervision in relation to participant(s) on their review of session record.
Knowledge and skills required

As well as a sound knowledge of the physiology, aetiology, epidemiology and available treatments of IBS, a range of skills will be necessary in order to help therapists engage and work collaboratively with the study participants.

**Engagement**

In order to engage the participant in therapy, it is important that the therapist conveys to the participant their belief in the reality of their symptoms and distress. The therapist should be able to demonstrate a sound knowledge of IBS as participants will generally be well informed about their illness and may have had “difficult” experiences with other professionals who may have not taken their problems seriously.

People with IBS may be sensitive to the over-emphasis on psychological factors. It is therefore important right from the start that an integrative model that incorporates physiological factors, e.g. initiating infection, is used. It is important that therapists show respect for their beliefs on the cause(s) of their illness and avoid challenging them as this may provoke strong emotion and will reduce the likelihood of a good therapeutic relationship being established.

In order to maintain participants’ engagement throughout treatment, it will be important to continue using an integrative model and avoid promoting a rigidly dichotomous view of physical and psychological illness.

**Warmth and Empathy**

Empathy is something that is generally applied with all patients without thinking about it. It will be particularly important with this client group in terms of empathizing with the often misunderstood nature of their illness. The group of participants in the ACTIB trial will have refractory IBS, meaning that they will have had a diagnosis for at least a year. Often this will mean that they have undergone many medical examinations, some of which may have been intrusive and will have seen a variety of healthcare professionals.

Often participants will have been given conflicting advice about how to deal with their problems, leading them to a state of confusion and frustration. Some participants will feel under pressure to perform and maintain usual activities but feel that they are competing with their bodies. Others will have become avoidant of many activities that they used to enjoy, in some cases without consciously realizing that they have done so, but feeling low or anxious as a result.

It is therefore very important that therapists convey warmth and empathy straight away in the first session. The assessment provides a good opportunity for participants to tell their story. Often it is the first time that they will have been able to go into detail about all aspects of their problems. Acknowledging the difficulties they have encountered along the way in terms of their illness, whether related to its impact on their life or response from other healthcare professionals, etc., is important.
Getting people to change previous routines can be difficult in a number of ways; the participant may be very fearful of changing the way they do things, fearing worsening of the symptoms. Acknowledging the challenges associated with therapy is key to developing the trust of the participant.

**Sensitivity**

Participants may feel as though their symptoms and diagnosis has been dismissed in the past by previous professionals and worry that therapists may not understand the extent of the impact on their lives. They may also think that therapists will tell them “it is all in their head”. It is worthwhile listening to and trying to use language that is not going to be alienating. In general, it is best to use the language that the participant does to describe their symptoms.

**Collaboration**

Collaboration is an essential skill in working with people with IBS. Up to the point of talking to you, many participants are not likely to have been included in the management of their illness. Many may be unaware of the physiology behind IBS or the rationale behind different medications that they may have used. Therefore they may not have felt able to make informed decisions about managing their illness and may feel helpless with little control. Collaborating throughout treatment will help participants to feel more involved in their treatment and will help them to regain some sense of control.

Therapists will demonstrate a collaborative style during the first session when discussing the individualization the CBT model to their illness. Agreeing an agenda for each treatment session, asking for their input in making suggestions for their homework activity and evaluating previous sessions will help participants to feel valued and included in the treatment process.

**Positive reinforcement**

It is essential to demonstrate positive reinforcement when working with people with IBS. Often, they will be very good at pointing out what they haven’t achieved. It is therefore important to encourage and emphasize what they have achieved. Every session therapists should positively reinforce all of their achievements, however small they may seem, whether it is managing to spend 5 minutes less straining in the bathroom than the previous session, or to go out to a restaurant with friends without taking anti-motility medication.

**Establishing confidence in therapist ability**

Establishing the participant’s confidence in the therapist's ability is integral. This is likely to occur if naturally by utilizing the skills above. Where therapists are not sure or do not know an answer to a question, therapists are more likely to be respected for admitting uncertainty rather than trying to answer in a muddled way.

**Encouraging optimism**

Although it is important to be realistic about the treatment targets that are set with participants, it is important to encourage optimism about the progress made. Participants are more likely to succeed if encouraged to have a positive expectation of therapeutic outcome.
Engaging participants in treatment

Tips for engagement:

- Ask what the participant would like to be called when you first speak.
- Discuss the agenda for the first session and ask the participant whether there is anything that they would like to add to it.
- Show empathy, warmth, sensitivity and understanding during the assessment process (and thereafter).
- Give a clear explanation of the CBT model using the participant's own words and examples.
- Be very positive about participant's attempts to help themselves to overcome their IBS.
- Give participants the opportunity to discuss any fears or worries in relation to CBT.
- Tell the participant that you will look forward to working with them over the coming months.
- Use language that participants will understand.
- Explain that they there is something wrong with the way the bowel is functioning but it is not pathological.
Structuring Treatment Sessions

An overview of the structure of the HICBT and LICBT sessions can be found on pages 72-91 and 96-102. This section provides details of preparing for both HICBT and LICBT sessions with participants generally.

**Discussing what is required of the participant**

At the beginning of sessions therapists should discuss with participants the ways in which they can help themselves to get the most out of CBT. Participants will have received information regarding what is required of them (see participant information section in the folder), however it is best to re-establish this with them over the phone. The following points should be covered with participants as soon as possible.

- To complete all homework tasks on the sheets provided and to have these to hand at the sessions
- To commit to prioritising treatment over the coming months, with a clear understanding that what will help their progress is the changes they make in their lives in-between sessions
- To contact therapists at least seven working days in advance if they are not going to be able to attend an appointment - so that this can be rearranged where possible, within the time specifications of the trial protocol
- To keep therapists informed of any changes in medication, other treatments, etc.
- To participate in setting an agenda each session - so that all of their needs and requirements are met
- To tell therapists should they not be clear on any aspect of the therapy
- To attend the telephone sessions on time and to give advanced warning of cancellation
- To keep cancellations to a minimum due to the restricted time period for treatment to fall within (9 weeks) and restrictions on therapists' availability

**General treatment structuring prompts**

- Read previous session notes before phone session
- Write an agenda on therapist session record (Appendix IV), of what you would like to discuss in the session
- After greeting the participant, discuss the agenda with the participant, asking for further ideas from the participant
- Prioritize the agenda with the participant.
- Remind the participant of the length of the session (1 hour for HICBT and ½ an hour for LICBT).
- Work through the agenda
- Remind the participant when 5-10 minutes are left, if necessary
Write down on the therapist session record anything that you have not managed to discuss in the session, so that it can be prioritized for the next session

Reconfirm the next appointment and check that this is still convenient

**What to include in every session:**

- A review of homework (where applicable)
- General review of impact of symptoms, mood, thoughts and behaviour
- Assess risk if appropriate
- Review of model
- Time to check out the participant’s understanding of any new techniques introduced during the previous session.
- The opportunity to discuss the participant’s reactions to the previous session and any issues that you did not have time to discuss
- An opportunity to discuss any other issues (other problems that may have come up in the previous week or two weeks)
- Time to plan homework
Assessment Issues

In the HICBT condition, therapists will provide a full assessment within the constraints of a 60 minute telephone session. Time for scheduling further appointments will not be included in the allocated treatment time, but will count as administrative time.

In the LICBT condition, participants will have conducted their own assessment through the information and interactive tasks provided on the Regul8 website. This section will focus on providing assessment for those in the HICBT condition.

At the time of assessment participants should already have read chapters 1 and 2 of the participant manual, covering the physiology of IBS and introducing the CBT model of IBS. Their understanding of the CBT approach to IBS is likely to still be limited and participants may still harbour concerns or misgivings about the approach.

The main challenge to assessment will be the time constraint of 60 minutes. Additional time can be spent on the scheduling of sessions and will not count as therapy time. It is advised to do this at the end of the session.

Below is a template of an assessment format that therapists may wish to use for initial guidance. There is also a first session prompt sheet for HICBT and LICBT in the prompt sheet section of the folder. Further details on what to cover in the first session with participants in the LICBT condition can be found on pages 96 and 99.

Assessment format

Therapists should take note of:
- Participant ID & name
- What the participant likes to be called
- Age of participant
- Date of session
- Duration

Details of the participant ID, date of session, booster sessions, etc. will be stored in the therapy database (see Appendix II and III).

Main problem
Although IBS may have been diagnosed, it can be useful to open the assessment with a question such as “What is the main problem for you.” This gives the participant the opportunity to encapsulate the whole problem before you break it down into small components. It may also reveal problems other than IBS that will also be important to assess.

Physical symptoms (frequency, intensity, duration)
It is important to ask participants for a complete list of symptoms. They may report constipation, diarrhoea or both; abdominal pain or discomfort; excessive wind; urgent need to open bowels; feeling of incomplete emptying of bowels; crampy urge to move bowels with
no result; acid stomach, nausea, vomiting; excess passage of mucus; changes in the consistency of stools (for example, hard and round stools to soft, runny stools). They may also report fatigue or other somatic complaints.

**Other symptoms**

Sleep complaints are common. Ask whether they have difficulties in getting to sleep, or waking in the night (the participant will explore their sleep patterns in Chapter 7 of the participant manual). Participants may also suffer from problems with concentration, memory, headaches, pain in their muscles and libido.

**Restricted/modified activities**

Ask participants about each of the areas below.

**Work:** If they are working, is it impaired in any way? They may miss work days because of their symptoms. They may feel embarrassed because they need to go to the loo more frequently than other colleagues. Have they been able to get support from work? For example, they gave him/her an office near the toilets.

**Social:** How has this changed? Establish whether their social network has changed, whether they go out as much as before or friends visit instead.

**Sport:** Do they exercise regularly? How has this changed?

**Home:** Check out what has changed. Can they cook, clean, care for the children, etc.? Is there someone helping them with this? Have they had any dietary changes for any reasons?

**Personal relationships:** If they are in a one to one relationship, how has this changed? It can sometimes be that the relationship gets stronger, on the other hand it can cause strain on both partners. Do they have an active sex life with their partner and how intimate are they? Does this change with the fluctuation of symptoms?

**Family relationships:** The dynamics can change within the family. People can feel very guilty about not doing as much with their family or for their family as they used to do. They may also feel upset that their family does not seem to understand their physical complaints and may at times make them feel like they are overreacting or that it is in their head.

**Toileting behaviours and idiosyncratic beliefs about going to the toilet.**

- How many times do they go to the loo per day/week?
- How much time do they spend in the bathroom every time they go?
- Do they strain when going to the toilet even when they haven’t experienced the reflex to go?
- Do they check their stools regularly?
- What are their main concerns about diarrhoea/constipation?
- Have they had accidents in the past? How many? Where? When?
- How long do they sit on the toilet on each occasion?

Common myths are also listed on pages 24-25

**Onset**

Therapists should obtain as much information as possible about what was happening around, and just before, the time of onset. Caution must be taken with the type of questions that you ask, as a participant who feels that their illness is directly caused by food poisoning
may feel that therapists are trying to “psychologise” the illness with questions such as “was there anything stressful happening in your life at the time of onset?” This could be rephrased as “was there anything different going on in your life at the time?” or “Tell me about your life just before you became ill.”

Some participants will have a clear onset associated with an illness such as gastroenteritis, food poisoning, stressful event. If this is the case, find out how they managed in the days and weeks after the illness began. Did they try to keep going despite their illness? Also what kind of management/medical advice did they get at the time?

Course and fluctuations of illness since onset
At the time that participants are having their first session, they will have had their illness for at least a year and in some cases, many years.

Find out what the illness has been like since it started. Have there been marked fluctuations (periods of feeling reasonably well and periods of intense symptoms, usually called flare-ups); or has their illness gradually got worse/better? Find out about any particular life events, e.g. other illnesses, etc. Again briefly touch on advice and diagnosis during this period, as it’s often an important factor in onset/maintenance.

Coping strategies
Participants will have often tried a variety of ways of coping with their symptoms. It is useful to enquire about what methods they have tried in the past as well as what strategies they are currently using, as this information may help to shed light on maintaining factors.

Useful questions may be:

- What do you do when you are constipated? E.g. do you spend a long time in the bathroom straining before going to work? Do you manually evacuate?

- What do you do when you have diarrhoea? E.g. Do you avoid social events or look for the bathroom as soon as you get to a place? Do you take anti-diarrhoeal medication before leaving home?

- Is there anything that you avoid for fear of making your symptoms worse? Have you tried other coping strategies in the past?

- It is also useful to find out the reason for using particular strategies, e.g. were they given advice to take anti-diarrhoeal medication? Did someone tell them it is healthy to go to the bathroom once a day? Etc. Establish the effect that they think that their strategies are having on their symptoms.

A further list of coping strategies and behaviours that you may like to ask about can be found in the session1 HICBT prompt sheet in the prompt sheet section of the folder.

Modifying factors
Some people with IBS may note specific things that make them feel better and/or worse. It is a useful question to ask as it can be useful for eliciting illness management beliefs. Holidays or exercise are examples of things that people with IBS report as being helpful. Busy work schedules can make people with IBS feel worse.

They may feel that eating specific types of food, alternative medicines or certain activities may have an effect on their symptoms.
Overall impact of illness on your life

Although therapists will have detailed information about the specific effects of IBS on the participant’s life, asking them about the overall impact will give insight into their attitude towards it.

Although many people will say things such as “It’s stopped me doing what I want to do”; some people will be more optimistic and say things such as “It’s made me much more aware of how busy I am”. They often find it cathartic to summarise the impact of their illness.

Opinions/attitudes of important others

Ask about the opinion and attitudes of people that are close to them. Find out about their friends’ attitudes, have they lost friends? Are friends supportive? What are work colleagues/employers like? How about family members?

Establish the level of support they get (too much/ too little). For example, they may be struggling to keep their head above water in a household where no-one helps.

Mental state

Therapists should aim to get an overview of the participants’ mood, energy, enjoyment, self-worth, capacity for suicidal thoughts, guilt, hope, future predictions. It will be important to touch on whether participants suffer with anxiety- major worries/preoccupations, panic attacks or depression.

Low mood and anxiety are common in IBS. Many participants will report feelings of frustration about the unpredictability of their symptoms.

Some questions:

- Do you feel discouraged or depressed?
- Are you satisfied with your relationships?
- Do you get enough emotional support from your partner?
- Do you have any financial worries?

An opening question such as “It sounds as if IBS has changed your life quite a lot, how does this make you feel?” is appropriate. This will then lead you into more specific questions about enjoyment, self-worth, etc.

A sensitive inquiry about suicidal thoughts is essential where participants’ mood appears particularly low i.e. “Have things ever been so bad that you have felt like ending your life?” Further details about processes for participants assessed to be a high suicide risk are found on page 15.

When someone has been ill for a long time they may have stopped doing many of the things that they used to do. There may be some anxiety related to their avoidance of certain situations. It is important to establish what, if any, phobic anxiety problems they have which may be targeted in future sessions.

Questions could include “Are there any situations in which you feel tense?” “Are there any situations that you tend to avoid because they would make you feel uncomfortable”, e.g. going out to dinner. “When you have been in those (specified) situations, have you noticed any symptoms that come on suddenly, e.g. diarrhoea”. For participants who have noticed acute symptoms, discuss further to establish whether or not they have suffered from panic attacks.
Current treatment/management of this problem

Establish whether participants are currently treating their IBS with the use of particular medicines, diets, alternative therapies or activities. Therapists should ascertain what they perceive the effect of these measures has been on their symptoms.

Past Medical History & Previous treatments

A brief overview of their medical history is necessary to establish concurrent or previous problems. It is useful to note any similar episodes of illness, treatments and outcome. Participants may have seen a variety of health professionals and have tried a number of treatments. All the participants in this trial will have refractory IBS, which means that they still have ongoing symptoms after 12 months despite being offered appropriate medications and lifestyle advice.

It is important to find out what they have tried and its effect, e.g. antidepressants. It is also at this point that you may establish the attitude of other professionals to their problems.

Psychiatric history (dates, treatments, therapies, etc.)

Enquiries should be made about whether they have ever seen a professional in relation to depression, anxiety or any other problems of this nature. Treatment dates and effects should be noted. If they have had a history of depression, careful enquiry and details of past suicidal ideas/Attempts should be noted.

Other problems/issues

Before moving on to discussing the participant's own beliefs about their illness and the treatment explanation, it is useful to ask whether there are any other issues or problems that you haven't discussed over the course of the assessment. It is unlikely that participants would come up with something new at this point, but may repeat a problem that they have already mentioned, e.g. a phobic anxiety or relationship problems.

It would be important to clarify whether you will be able to address any additional problems (other than IBS) during their CBT sessions. If you cannot address an additional problem, it would be important that you inform the participant of where they may be able to receive help. Alternatively you could liaise with the appropriate agency/GP.

Beliefs about the cause of the illness and why it is persisting

It is useful to identify the participant's beliefs about the cause of their IBS and what is contributing to keeping it going before you discuss the IBS specific CBT model.

Questions may include “What do you think has caused your illness?”, “Do you consider that there may be any other factors that have contributed to your illness?” and “What do you think is causing your symptoms now?” Therapists should listen to what they say without passing judgement. At this point therapists may link certain cognitions with behaviours that the participant has conveyed engaging in. E.g. fearful cognitions may be linked with avoidant behaviours.
Treatment explanation using CBT model

Please see page 30 of this manual and section two of chapter two “Making the link between symptoms, behaviours and thoughts” from the Participant manual.
Background History

To a large extent a comprehensive background history will be obtained in aspects of the assessment as detailed on pages 46-51. Again the time constraints of a 60 minute first session, means that therapists should attempt to make the information gathering process as succinct as possible.

The points contained below contain the main important aspects of background that therapists should try to gather. Rather than investigating past issues, therapists should try and look at present background factors that may influence the participants’ engagement in CBT.

Pre-morbid personality and lifestyle

It is important to ask about their personality as this information may be helpful in determining some of the cognitive work that you do with your participant. For example someone who describes themselves as a hard worker or a perfectionist, may hold beliefs such as “To be successful, I have to work hard all of the time” and may require more work on taking regular breaks and challenging their beliefs than someone who describes themselves as a laid-back sort of person!

It is useful to find out what participants do currently in terms of sport, social life etc. and how this may compare with what they feel they would like to do. It should also be established how many units of alcohol the participant drinks per week and whether they take any illicit drugs.

Current situation (housing, cohabiting, work, benefits, interests)

Inadequate housing, financial difficulties due to not working or reduced hours may be factors that are contributing to the maintenance of the person’s IBS. If they are not working, do they want to return to their previous job? Knowing about their current interests/hobbies may be helpful when you come to discuss targets for treatment.

Future plans (work, moving house, starting a family etc.)

It is important to note any significant future plans as it may have an effect on treatment. This can also be useful in highlighting what the participant feels their IBS holds them back from doing and achieving.
Explanation of the Cognitive Behavioural Model

Individualizing the CBT model

Discussing the CBT model and giving an individualised rationale is very important in terms of demonstrating an understanding of the participant’s problems. Ways of doing this may involve discussing individualised vicious circles or using a three systems model (interaction between coping behaviours, beliefs and symptoms). Information gathered during the assessment can be utilised when offering an explanation of how the problems may have evolved. Check every so often with the participant that what you are discussing fits with their experience. Encourage the participant to contribute to the discussion.

Triggers

It is helpful to divide the triggers into 3 sections (social, physical, emotional) and to go through them together. People with IBS may report a bout of gastroenteritis at the onset and may feel that this is the most important factor. It is important to write down the physical trigger first of all. Gradually work through all of the factors that the participant mentioned around the time of onset, e.g. working hard, life events, being very physically active, etc. Personality factors such as having high expectations or feeling stressed or anxious may also be added.

Maintaining Factors

Once you have agreed on the precipitating factors which have led to the IBS symptoms, you should move on to the maintaining factors. It is useful to summarise what the participant has told you. For example, having important meetings at work causes the participant worry and anxiety. The participant may spend time worrying about what could go wrong during meetings (e.g. having to rush to the toilet in the middle of it). This adds to their anxiety which causes more diarrhoea and bloating than usual.

If participants have ongoing problems at home, e.g. financial worries, a sick relative etc, then it is important to include these factors. Fears, unhelpful thoughts, frustrations that you have elicited from assessment should also be included, e.g. “I’m never going to get well”, “I can’t control my symptoms”, etc.

An example of a more detailed vicious circle is overleaf.
Vicious Cycle in IBS

**LIFE CIRCUMSTANCES**
- Stress
- Major life events
- Busy lifestyle

**PHYSICAL**
- Infection
- Food poisoning

**PSYCHOLOGICAL**
- Perfectionistic traits
- Anxiety
- Depression
- Suppressing emotions

**IBS SYMPTOMS**
Abdominal pain/cramping/discomfort, altered form/frequency in the passage of stools – diarrhoea and/or constipation

**MAINTAINING FACTORS:**
- Restrictive diet
- Change in patterns of eating
- Reduction of exercise
- Use of constipating medications/laxatives
- Checking for nearest toilets
- Asking for reassurance about IBS
- Avoiding social situations
- Avoiding making plans in case IBS flares up
- Unhelpful toileting behaviours – excessive straining, checking, manual evacuation, excessive wiping
- Monitoring sensations in stomach excessively
- Avoidance of staying away from home overnight in case of flare ups
- Avoiding exercise due to symptoms

- Unhelpful patterns of activity – active avoidance, consistent under-activity, boom/bust
- Cognitive style – thinking errors
- Perfectionistic traits - cognitive/behavioural patterns
- Difficulties with emotional processing
- Difficulties managing stress
- Poor sleep hygiene
Rationalising the CBT Model with Participants

Below are some ways to address concerns and queries about the rationale for CBT in IBS:

- CBT is a pragmatic approach which is helpful in a variety of illnesses, including diabetes and cancer. There is a wealth of research demonstrating its efficacy for reducing symptom severity and increasing quality of life. There is also previous research demonstrating the efficacy of CBT in IBS (see page 29).

- CBT aims to help people to become an expert in managing their problems, including physical problems and provides individuals with new coping and problem solving techniques.

- When participants begin to change certain behaviours they can expect a temporary increase in symptoms but this is perfectly normal as their body adapts to change. E.g. As a participant may increase their rates of exercise, they may notice that they need to pass a stool more frequently or soon after beginning exercise. This is likely to happen as the body begins to get used to the additional activity. Another example would be of a participant who slowly reintroduces avoided foods and starts to experience some bloating or pain. Again this is an adjustment as the body starts to readapt to the intake of a previously avoided food.

- Elicit the participant’s own expectations and doubts about CBT and address these directly.

- Provide examples of the strategies that may be used so that the participant obtains an idea of what they will be doing in the coming weeks. A hypothetical practical example of how changing one aspect in the CBT vicious cycle can affect other aspects positively.

- For participants who are attempting to alter their eating or toileting behaviour, positively reinforce their attempts and say that you will be helping them to build on what they are already doing.

- Highlight that CBT is an integrative approach taking into account physiological factors as well as psychological, emotional and behavioural factors.

- Refer participants to page 13 of the participant manual, in which it explains how the gut is affected by the brain.

Helping Participants to Manage Their Symptoms

The overall aim of CBT is to help people to become an expert in managing their symptoms. Strategies to facilitate participants managing their own symptoms autonomously include:

- Giving clear explanations about the CBT model and rationale for treatment so that participants can quickly learn about what may be maintaining their IBS

- Repeating rationale for CBT to reinforce the model and to increase the participant’s level of understanding

- Checking the participants’ understanding when discussing new strategies

- Encouraging participants to evaluate the progress that they have made since the last session and in light of this information ask them to make suggestions for new goals
• Agreeing set-back plans before participants are discharged so that they are aware of potential triggers and feel confident in managing a flare-up of symptoms.

Involving a relative, friend or significant other as a co-therapist

Participants sometimes find it helpful to have a significant other, relative or friend to act as a co-therapist. It can provide them with support and encouragement, particularly when they are experiencing difficulties with their programme. Participants sometimes like to have a co-therapist who is very involved, e.g. someone with whom they can discuss their progress and any problems on a daily basis. Others prefer to have a co-therapist who is less involved, e.g., they may want to talk to them about their progress on an informal basis, once a week.

Some participants want to do therapy without the help of a relative or friend, or do not have anyone that they feel is suitable. In the present trial, it is not likely that many participants will opt to involve someone else in treatment. However, therapists should facilitate this where participants express a wish to do so.

Co-therapists may wish to be present on telephone sessions, using speaker phone, or they may wish to support the participant outside of sessions.

For participants who do want to have a co-therapist:
• Ask the participant to suggest that the “co-therapist” reads the Participant Information Sheet (see page 39) for where to find this. This document contains information about CBT for IBS and the structure of the sessions.

If a co-therapist is to be involved then it is useful to:
• Find out how much contact they have with the participant, i.e. see them once a week, live with them etc.
• Discuss with the participant how they would like their co-therapist to help them (the amount of support given by a co-therapist will vary on a number of factors, e.g. time available to co-therapist, requirements of the participant, etc).
• Discuss practical ways that they can help the participant, e.g. encouraging them to engage in social activities.
• Discuss the importance of giving the participant praise for all of their efforts, e.g. filling in diaries, etc. (where co-therapist attends a telephone session)
• Discuss the possibility that the participant may notice a temporary increase in their symptoms. Reassure the co-therapist that this is quite normal when someone is focusing on their symptoms in the beginning of therapy (where co-therapist attends a telephone session).
Setting Long-Term Targets in CBT

Before setting targets

- Inform participants that setting targets will provide them with a clear direction and focus during CBT

- Make the clear distinction between shorter term goals set in therapy and long term targets. Targets are the things that the participant would like to be doing in the longer term rather than something they want to achieve immediately

Setting targets

- It is important that the participant has different types of targets to work towards to make their life as balanced as possible: Targets should include pleasurable activities as well as activities such as work and chores etc.

- Targets should be realistic and achievable, rather than representing a wish list

- Be wary of the participant being too ‘driven’ or ‘ambition orientated’ when setting targets. If their target seems too ambitious, it is important to discuss reasons why they may not be a good idea. For example, people with IBS tend to expect a lot of themselves. They often get over committed and try and look after everybody else’s needs before their own. Discuss the possibility that this may have been partly responsible for them becoming ill in the first place.

- Inform the participants that they will be able to change their targets once their initial ones have been achieved

- It is important that all targets are specific in terms of:
  - The behaviour that they wish to perform (activity)
  - How often they would like to carry out the behaviour (frequency)
  - The length of time to be spent on the behaviour (duration)

After target setting

- Once targets have been agreed, you and the participant can both write them down on the long-term target record (Appendix XVII). The participant can then keep their copy in their treatment manual and therapists can keep your copy in the notes

- The participant may break down each target into manageable steps by either following the guidelines in their manual, or in a session with the therapist.
Behavioural Experiments

Behavioural experiments can be beneficial in helping participants to test out their negative cognitions and constructing and testing new more adaptive perspectives.

There are two broad types of behavioural experiments that can be used at various stages of therapy. One type is based on hypothesis testing, i.e. “is it true that…?” and the other is based on discovery, i.e. “What would happen if…”

**Hypothesis Testing**

Hypothesis-testing experiments can be used to test the validity of a particular unhelpful cognition (negative prediction). For example, “if I do not pass a stool, my abdominal pain will get worse”. “If I eat this now, I will have diarrhoea”. They can also be used to support evidence for a more adaptive cognition. For example, “If I regularly eat breakfast, my pains will gradually decrease”.

**Discovery**

Discovery experiments can be used when participants are unclear about the processes maintaining a problem, or about what might happen if they acted in a different way. These experiments can help in the development of the formulation, in designing treatment strategies and in creating and refining new perspectives. For example, a participant may be unclear about what may happen if they change what they are doing at the beginning of their course of CBT.

**Examples of situations where behavioural experiments may be used**

Behavioural experiments may be loosely introduced in the first session. The participant may feel wary about the whole CBT approach. One way of dealing with the ambivalence is to view the approach as an experiment and wait to see what happens over a period of time.

Behavioural experiments may also be used to test out the validity of the participant’s existing “unhelpful” thoughts. They may then be used to strengthen new, “helpful” thoughts.

**Examples of behavioural experiments in IBS**

There a few different types of behavioural experiments that can be used to help participants to test their negative cognitions and construct more adaptive perspectives. These include active experiments, gathering information from other sources and direct observation. Examples of behavioural experiments which may be used in IBS are below.

In active behavioural experiments the participant will deliberately think or act in a different way in the “problem” situation. For example, participants may have previously spent a lot of time sitting on the toilet straining to pass a stool when they felt they “should” pass one. You may ask them to refrain from straining and only go to the toilet when they feel the physical urge to go. They should be encouraged to note what happens, and reflect on the implications for their thinking and behaviour in the longer term.
In certain situations where the participant feels that an experiment is going to be difficult, it can be useful to use role play where this is possible over the phone. For example, if the participant has difficulty in telling new acquaintances that they suffer with IBS, this may be due to a fear of disclosure prompting a negative response such as disgust, embarrassment or complete rejection. Role play could be used to practice how to tell new acquaintances in different ways, which may lead the participant to increase their confidence in tackling this problem should it arise in day-to-day life.
Managing Potential Difficulties

Before embarking on CBT with participants, it is useful to think about potential difficulties that you may encounter during your sessions. We have listed possible problems that you may come across with some suggestions of how to deal with them.

Difficulties with engagement

Participants may have difficulty engaging with therapy for a variety of reasons. We have already outlined factors that help engagement, but it is worth considering particular engagement problems and how to manage them.

Fixed physical attribution of illness

Participants who hold a fixed physical attribution of their illness are likely to have difficulties engaging with a therapy that they feel is going to be looking at their “behaviour” and “thought” patterns. Examples of a physical attribution may include permanent damage being caused from physiological dysfunction, damage from taking too many medications, an unalterable disease, etc.

If participants are insistent that there is an ongoing “physical” problem, it is rarely helpful to directly challenge them on this point. It is important that you acknowledge that their illness is real but its effects can be reversed by the way they manage it. The way that you present the rationale for treatment will be particularly important otherwise they may feel that you are trying to “psychologise” the illness. It is particularly helpful if they are sceptical about this approach, to describe a model of illness, to look at all the factors that may have triggered it and be involved in maintaining it. Participants often feel reassured when they are informed that CBT helps people with a wide range of health problems including cancer, chronic pain and diabetes. It can be helpful for this group of participants to try to view aspects of CBT as an experiment.

Example Dialogue

The following dialogues may help to engage participants in therapy:

Session 1

Therapist: Up to now, you have been trying to manage your IBS by responding to your symptoms by doing a number of things e.g. avoiding certain foods that make your symptoms worse and through specific toileting behaviour (e.g. straining or avoiding things for fear of accidental soiling). However, from what you have said, it seems that this hasn’t really worked and in fact your work/social life still appears to be affected quite markedly. Does that sound right?

Participant: Yes

Therapist: Although what you have been doing to help yourself seems logical, your IBS has not improved. Would you agree?

Participant: I have tried to do things in so many ways over the years and don’t really seem to have got anywhere, so yes I suppose I agree with you.
Therapist: What I am proposing, is that I try to help you to do things in a slightly different way, i.e. (use specific examples from assessment of participant) that you establish a routine of eating at regular times of day and only identifying the nearest toilet and using it when you have the urge to go, with a set time of how long you remain on the toilet without passing a stool. This will help to regulate your digestive system, allowing it to adapt to a routine and produce stools when appropriate for your digestive system. What do you think about that? Would you be prepared to give it a go with my help?

Participant: I’m a bit worried. What if I feel like I need to go, but can’t? What if I really feel pain and bloated but can’t pass a stool? Surely not waiting for me to pass a stool will make me feel worse?

Therapist: I understand that what I am proposing may seem worrying to you. However, how would you feel about starting with very small goals? I would suggest in the first instance that we look at your responses to symptoms in an average week. I would suggest that you fill in a symptom and action diary for the next week and that you bring them ready for your next appointment. So for the next week you will not be doing anything different, except filling in your diaries. Would that be ok?

Participant: Yes, that’s reasonable.

Therapist: Good. Then when you come for your next appointment, we can discuss how we move forward from here, is that ok?

Participant: Yes.

Resistance to changing current approaches to symptom management

As the participants in the current trial will have a diagnosis of refractory IBS, they are likely to have developed ingrained habits in coping with their IBS which they may be hesitant to change. Some of these approaches to symptom management may be avoidant types of behaviour whilst others will be the over-reliance on medications. It is important in these instances to refer back to the physiology of IBS and the digestive system, referring participants to parts in the participant manual or website with diagrams. This will help in providing a rationale that the participant may be more willing to accept in terms of altering their behaviour.

Session 2

In this session, you will be agreeing a routine of behavioural management of symptoms of diarrhoea and/or constipation. Common myths will be discussed. The importance of healthy, regular eating and not being overly focused on elimination is covered. Participants may have difficulty accepting a programme that contradicts their normal pattern of dealing with symptoms. The following dialogue may help with this.

Therapist: Last time we agreed that we would go through your diary and agree how we would move forward, is that ok with you?

Participant: Yes
Therapist: Before we do that, would you say that the past week was fairly typical for you?

Participant: I would say that it was reasonably typical for me

[If the week was not typical at all, you need to decide whether the participant can give you enough information to decide on their first programme. If not, you will need to ask the participant to complete diaries for a further week in order to get a more accurate picture to enable you to write a programme]

Therapist: Well, thank you for completing your symptom diary so diligently. All this information will really help us to move forward. We’re going to take a look at some of your responses to your symptoms and see how you might do things differently and establish a routine of regular eating, toileting and activities that will work for you. Would that be ok?

Participant: But what if I don’t feel like eating at set times What if I feel really bad when I am meant to eat something. Surely that will just make me feel worse and won’t be good for me?

Therapist: Would you be willing to give it a try to see what happens? It seems that at this moment you are predicting that you would feel worse. Why don’t we agree to test it out to see what happens and look at it as a type of experiment? During our next phone session we can discuss how you got on with it. If you are eating regularly, adopting a slightly different approach to managing your bowel symptoms and approaching activities a little differently, you may gradually find that you have less time when your symptoms are really severe. Also, if you develop a more regular eating pattern, your body is likely to start getting used to it. Obviously, it will take a little while for your body to get used to doing things in a different way and you may find a slight increase in your symptoms initially. However, once your body gets used to a different routine, the symptoms will hopefully subside.

Participant: I’m willing to try it, as there does not seem to be much of an alternative

Therapist: Good.

Feeling that a physical cause has been missed and wanting further investigations

Some participants may not hold a specific belief about what is wrong with them, but feel that despite many investigations, something has been missed. They may feel that they want to continue having investigations or try a variety of treatments until they are cured. Again, it is important to empathise with their situation, but to encourage them to hold off having further investigations until after they have completed the course of CBT. All participants will continue with medical treatment as usual, however this will not be likely to involve investigative procedures at this stage. Furthermore, in order to have been accepted into the trial participants will have undergone a comprehensive screening to ensure that they are not suffering with a more serious diagnosis such as inflammatory bowel disease or cancer.
Example Dialogue

Participant: I am feeling uncomfortable, I really cannot believe that all my tests are clear. I feel sure that something has been missed. I think I might go to my GP just one more time to ask him if there are any other tests that I could have.

Therapist: I can understand that with feeling the way you do, you feel something has been missed. However, what I am proposing to do is to help you to understand why you feel as bad as you do and also to see if we can help you to feel a bit better in the process. Would that be ok?

Participant: But what if something has been missed that could easily be rectified?

Therapist: As part of this trial you have had blood tests which have excluded many of the more serious potential causes of your symptoms. It therefore seems unlikely that someone would be able to detect an obvious cause of your problems. Although I can see the temptation of seeking further clarification of your problems, in reality what can happen is that you end up feeling more confused. I believe that your symptoms are part of a bigger picture and I would like to spend some time discussing my thoughts on this matter with you. Would you be willing to do that?

Participant: Well, I suppose it wouldn’t do any harm!

Therapist: What I suggest that we do is to write down what we know about your illness, including your symptoms, what was happening at the time you became ill and ways that you have been managing to deal with your illness to date. This information may help us to look at factors that may have triggered it and factors that may be involved in keeping it going. I hope this will help us to make some sense of your illness together before we move on to discussing ways of overcoming it. Would you give my suggestion a go?

Participant: Yes

Therapist: Great. Then maybe that would be a good place to start this session. [Direct them to get a paper and pen]

Non-compliance with diary keeping

Participants may not be very compliant with keeping their diaries; some of the reasons for this are listed below:

- Not sticking to the agreed programme
- Not enough time to keep them properly e.g. busy with work and/or home life
- Forgetting to fill them in for a couple of days and therefore feel that there is no point in starting them again
- Find them boring
- Requiring too much extra time to complete
As diary keeping is an integral part of CBT, the issues surrounding non-diary keeping and the importance of keeping diaries must be discussed with them. The following discussion aims to highlight the point.

**Example Dialogue**

**Therapist:** Now we have agreed the agenda for today’s session, I wonder whether we could start by discussing your diary?

**Participant:** We can do, but I haven’t written much on them

**Therapist:** Oh, why is that?

(What you say will depend on the participant’s reason for not completing the diaries, but pointing out the importance of completing diaries is important at this stage. This should be done with sensitivity as the participants may feel guilty about not completing them).

**Not sticking to the agreed programme**

**Example Dialogue**

**Participant:** There didn’t seem to be much point. I haven’t done much that we agreed at my last appointment, therefore there wasn’t an awful lot to write down.

**Therapist:** I think that it would be useful for us to talk about why you did not manage to do what we agreed. There are often lots of reasons for not sticking to the agreed programme, particularly when you just start it, but it’s important that we try to iron out the difficulties so that it seems more manageable for the next week/two weeks. When we have done that, maybe we can recap the importance of completing diaries. We had lots to talk about at the last session and I may have not clarified their importance, would that be ok?

(You should then establish exactly what the participant has done, what they haven’t done and their reasons. E.g., was the programme realistic? Did life-events get in the way? Etc. You should then problem solve to ensure that they are more likely to manage their agreed programme before the next session).

**Not enough time to keep the diaries properly, e.g. if they are working**

**Example Dialogue**

**Participant:** I have had a really busy two weeks and just haven’t had time to fill them in. I have done the odd day when I’ve remembered, but I’m afraid they look rather bare.
Therapist: Well, I am glad that you have managed to write something down. Maybe we can
start by looking at what you have written down and then talk about how you can fit keeping
your diaries into your schedule, would that be ok?

(You should then problem solve the difficulties of diary keeping. Maybe agree times to write
things down, have a reminder note in work diary, keep the diaries in a place where they can
be easily seen or writing down less, etc. Establish whether keeping the diaries is in fact
helpful. Maybe suggest that the participant uses the target achievement record, which
requires less detail, instead.)
Forgetting to fill them in for a couple of days and therefore feel that there is no point in starting them again

Example Dialogue

**Participant:** I managed to keep them for a few days and then forgot for a couple, so I didn’t feel that there was any point in starting again.

**Therapist:** It sounds as if you managed well for the first few days. I wonder if it would be useful for us to look at what you have managed to complete and then to talk about why you might have forgotten to complete them.

(You should then discuss the reasons for the participant forgetting to complete them, e.g. were they too busy? Did they have difficulties with the programme? Clarify the importance of keeping diaries and problem-solve ways of remembering to keep diaries.)

Participant feels too embarrassed/ashamed to discuss or write down their difficulties/symptoms

Example Dialogue

**Participant:** I’m just finding this really difficult to think about, let alone write down or talk about. I mean, what if someone found the dairy!? I’m finding the sessions really hard, I find it really hard to talk about the symptoms.

**Therapist:** Often when people have these symptoms, they become really good at hiding them from others, and sometimes this means we can start to feel ashamed by them. This is especially true of the symptoms that we maybe feel are very private, such as changes in our toileting habits. I understand that what we’re looking at together then can feel really hard to openly discuss, and it may feel difficult for you to write some things down.

Over the course of our sessions, we often find that this starts to get a lot easier, and it may make you feel more able to be more open with other people in your life. For now, is there any way we could make this easier? For example, you could put down ‘d’ in the diary, instead of using the full word ‘diarrhoea’.

(Establish exactly which aspects the participant finds most uncomfortable. Is it talking about them that is hard, or writing things down which they don’t want to do, or both? Is it the language choices? Think about switching terminology to something the participant feels more comfortable with. Is there a way of making the diary more secure if they are concerned about someone seeing/finding it?)
High Intensity Treatment Session Plans

The following section is intended to provide a flexible outline for therapists to help structure sessions. It is not intended to be strictly prescriptive and therapists are encouraged to formulate their own structure based around the initial assessment session with the participant.

The treatment session plans provide information on how sessions may correspond with sections of the participant manual that the participant may be working through. However, the participants are also advised to work through the manual in a way that suits them and not necessarily in chapter order.

Scheduling of treatment sessions should ideally be arranged in advance all at once. The table below is an example resource for therapists to use when scheduling their sessions with participants in the HICBT condition.

**HICBT week scheduling table**

<table>
<thead>
<tr>
<th>Week</th>
<th>Session Number</th>
<th>Date</th>
<th>Time</th>
<th>Session Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1 (therapist allocated participant)</td>
<td></td>
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<td></td>
<td>Treatment period</td>
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<td>Week 2</td>
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<td>Week 3</td>
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<tr>
<td>Week 10 - 15</td>
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<td></td>
<td>Follow-up period</td>
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<tr>
<td>Week 16 (4 months)</td>
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<tr>
<td>Week 13 - 23</td>
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<tr>
<td>Week 32 (8 months)</td>
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The first 6 treatment sessions can occur at any point within the first 9 weeks of a participant being allocated to a therapist. Ideally participants will have had time to work through sessions 1 and 2 of the Participant Manual before the first telephone session.

At week 12 post randomisation, participants will have to fill out questionnaires to measure any change in symptoms and impact on life. Consequently it is important for therapy sessions to remain within 9 weeks of allocation of a participant.

The two booster sessions should occur at week 16 and week 32 post randomisation. Therapists will be provided with the date of randomisation of each participant. There will be a three-week leeway for scheduling the booster sessions.
# Overview of Participant Manual Content

Below is a summary of each chapter in the Participant Manual. This may be useful to help adapt the telephone sessions to the personal needs of each participant.

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Content</th>
<th>Homework</th>
</tr>
</thead>
</table>
| **Chapter 1: Irritable Bowel Syndrome explained.** | What is Irritable Bowel Syndrome?  
- How do you diagnose IBS?  
- Is IBS a serious disease?  
- How common is IBS?  
- What causes the symptoms?  
  The digestive system  
- Anatomy and physiology  
- Changes in the digestive system in IBS  
  What causes Irritable Bowel Syndrome  
- How does IBS start?  
- The role of the nervous system in the digestive process  
- The stress response  
- A vicious cycle of stress and symptoms  
  Summary | None |
| **Chapter 2: Assessment of your symptoms** | Review of chapter 1  
- Reflective questions  
- Short summary of chapter 1  
  Symptom management: the 6 steps of symptoms management  
  Making the link between symptoms, behaviours and thoughts  
- Diagram and example  
  Assessing the impact of IBS in your life  
  Self-monitoring  
- Some problems you may experience with self-monitoring  
  Self-monitoring diary  
- Instructions and example of diary  
  Summary | Symptom diary |
### Chapter 3: Managing your Irritable Bowel symptoms

<table>
<thead>
<tr>
<th>Review of chapter 2</th>
<th>Keep record of achieved daily goals for:</th>
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</thead>
<tbody>
<tr>
<td>- Reflective questions</td>
<td>Managing diarrhoea:</td>
</tr>
<tr>
<td>- Short summary of chapter 2</td>
<td>Managing constipation:</td>
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<td></td>
<td>Eating</td>
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<tr>
<td>Short introduction to setting goals</td>
<td></td>
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<tr>
<td>Managing diarrhoea</td>
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<tr>
<td>- Fear and diarrhoea</td>
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<tr>
<td>- Going to the toilet immediately when you feel the urge</td>
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<td>- Strengthening your anal muscles</td>
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<tr>
<td>- Tightening your anal muscles</td>
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<td>- Medication and diarrhoea</td>
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<td>- Checking behaviours</td>
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<td>Managing constipation</td>
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<tr>
<td>- Dispelling some myths</td>
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<td>- Reduce straining</td>
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<tr>
<td>- Should I use medication to help my constipation?</td>
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<tr>
<td>- Examples of goals</td>
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<td>Eating patterns and stress</td>
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<tr>
<td>- Change in diet and IBS</td>
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<tr>
<td>- Adjusting your diet routine when you have IBS</td>
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<tr>
<td>- Food intolerances and troublesome foods</td>
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<tr>
<td>- Reintroducing avoided foods</td>
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<tr>
<td>- Examples of goals</td>
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<tr>
<td>Summary</td>
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<tr>
<td>Goal sheet: Managing symptoms and eating</td>
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</tbody>
</table>

### Chapter 4: Exercise and activity

<table>
<thead>
<tr>
<th>Review of chapter 3</th>
<th>Keep record of achieved daily goals for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Reflective questions</td>
<td>Managing diarrhoea:</td>
</tr>
<tr>
<td>- Short summary of chapter 3</td>
<td>Managing constipation:</td>
</tr>
<tr>
<td>Revisiting your goal sheet</td>
<td>Eating</td>
</tr>
<tr>
<td>Exercise patterns and goal setting</td>
<td>Exercise and activity patterns</td>
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<tr>
<td>- NICE guidelines for exercise</td>
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<tr>
<td>- Examples of goals</td>
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<td>Patterns of activity</td>
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<tr>
<td>- Assessing your own activity pattern</td>
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<tr>
<td>- Boom or boost</td>
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<tr>
<td>- Avoidance</td>
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<tr>
<td>- Boom or boost and Avoidance</td>
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<tr>
<td>- Special considerations for each type of activity pattern</td>
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<tr>
<td>Summary</td>
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<tr>
<td>Goal sheet: Exercise and activity</td>
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<tr>
<td>Chapter 5: Identifying thought patterns</td>
<td>Chapter 6: Alternative thoughts</td>
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<tr>
<td>Review of chapter 4</td>
<td>Review of chapter 5</td>
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<tr>
<td>• Reflective questions</td>
<td>• Reflective questions</td>
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<tr>
<td>• Short summary of chapter 4</td>
<td>• Short summary of chapter 5</td>
</tr>
<tr>
<td>Revisiting your goal sheet</td>
<td>Revisiting your goal sheet</td>
</tr>
<tr>
<td>Identifying unhelpful thoughts</td>
<td>Identifying alternative thoughts</td>
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<tr>
<td>• Common thinking errors</td>
<td>• Step 1: Weighing up the evidence</td>
</tr>
<tr>
<td>Thoughts and high personal expectations</td>
<td>• Step 2: Don't expect to do everything perfectly</td>
</tr>
<tr>
<td>• Unhelpful aspects of perfectionism</td>
<td>• Step 3: Avoid focusing on your symptoms</td>
</tr>
<tr>
<td>• Negative thoughts and perfectionism</td>
<td>• Step 4: Coming up with alternatives</td>
</tr>
<tr>
<td>Example of thought record</td>
<td>Example of alternative thought record</td>
</tr>
<tr>
<td>Summary</td>
<td>Alternative thought record sheet</td>
</tr>
<tr>
<td>Thought record sheet: recording negative thoughts</td>
<td>Goal sheet: Alternative thoughts</td>
</tr>
<tr>
<td>Goal sheet: Identifying thought patterns</td>
<td>Complete the thought record</td>
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<td>Keep record of achieved daily goals for:</td>
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<td>Managing diarrhoea;</td>
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<td>Managing constipation;</td>
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<td>Eating;</td>
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<td></td>
<td>Exercise and activity patterns</td>
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<td></td>
<td>The participant will focus on the areas relevant to him/her</td>
</tr>
</tbody>
</table>
### Chapter 7: Learning to relax, improve sleep and manage stress

- **Review of chapter 6**
  - Reflective questions
  - Short summary of chapter 6
- Revisiting your goal sheet
- Revisiting your thought record
- **Learning to relax**
  - The importance of relaxation
  - Breathe easy (diaphragmatic breathing, relaxation training)
  - Important tips when learning relaxation
  - Setting goals for relaxation
- **Improving your sleep**
  - Erratic sleep patterns
  - Stress and sleep
  - Worry and sleep
  - Sleeping too much
  - Important general tips
  - Setting goals for improving sleep
- **Tips for managing stress**
  - Determining control
  - Reframing experiences
  - Learning how to say no
  - Prioritising
  - Looking after yourself
  - Reward yourself
- **Goal sheet: Learning to relax, improve sleep, and manage stress & emotions**

### Chapter 8: Processing emotions, managing flare-ups and maintaining improvement

- **Review of chapter 7**
  - Reflective questions
  - Short summary of chapter 7
- **Accepting and processing emotions**
- **Strategies for symptom flare-ups**
- **Long term goal setting**
- **Long-term goal sheet**
- **Final summary**

- Complete the alternative thought record
- Keep record of achieved daily goals for:
  - Managing diarrhoea;
  - Managing constipation;
  - Eating;
  - Exercise and activity patterns;
  - Learning to relax, improving sleep

The participant will focus on the areas relevant to him/her.
Overview of Structure HICBT Session Plans

**Session 1**

- Set agenda
- Initial assessment
  - Main problem
  - Physical symptoms
  - Restricted/modified activities
  - Toileting behaviours and idiosyncratic beliefs
  - Onset
  - Course and fluctuations of illness since onset
  - Coping strategies
  - Modifying factors
  - Opinions/attitudes of important others
  - Mental state
  - Current treatment/management of this problem
  - Previous treatments for this problem (with effect)
  - Past medical and psychiatric history
  - Beliefs about the cause of the illness and why it is persisting
- Treatment explanation using CBT model
- Background History (personal and family)
  - Pre-morbid personality and lifestyle
  - Current situation (housing, living with, work, benefits, interests)
  - Future plans (work, moving house, starting a family etc.)
- Physiology of IBS
- Stress response and cycle of stress and symptoms
- Making the link between symptoms, behaviours and thoughts
  - Develop an individualised CBT model of IBS
  - Discuss an individualised rationale, addressing any participant queries about the CBT approach
- Discuss the possibility of the participant having a friend or relative to act as a co-therapist
- Outline the number of sessions and check agreed dates/agree the next 5 session dates
- **Homework**: Read Chapters 1 and/or 2 if not done already. Self-monitoring of symptoms (see Appendix IX). Read Chapter 3.
Session 2

A typical session 2 may follow a similar format as below. The treatment session may also correspond with content covered in Chapter 3 of the Participant Manual.

- Set agenda
- Review CBT model and the rationale for treatment
- Review symptom diary and symptom self-assessment, discussing links between symptoms, thoughts and behaviour
- Elicit personal model of CBT, identifying maintaining factors
- Review CBT model as a way of testing out their beliefs that certain behaviours will result in worsening of symptoms
  - Establish present toileting behaviour & safety behaviours and set goals related to these
  - Discuss longer-term targets for treatment and record them
  - Discussion around how to set goals/why we will set goals
- **Homework:** Goal setting around the avoidance of certain foods (if applicable) or toileting behaviour – goal sheet in Chapter 3 (see Appendix X). Read Chapter 4
Session 3

A typical session 3 may follow a similar format as below. The treatment session may also correspond with content covered in Chapter 4 of the Participant Manual.

- Set agenda

- Review the participant’s understanding of the model in light of information they read for homework and adjusting their behaviour to meet their goals

- Discuss progress and problems with their first activity

- Re-set goals around managing diarrhoea/constipation, and eating patterns according to success over the last week.

- Discuss strategies for dealing with problems arising and re-examine participant’s beliefs regarding common myths in IBS

- Review existing patterns of exercise and activity (boom/bust)

- Check participants’ understanding of how extremes of activity and/or avoidance can maintain symptoms.

- Agree goals for exercise and activity pattern

- Homework: Complete goal sheet for patterns of activity and exercise (see Appendix XI). Read Chapter 5 of the Participant Manual. Complete the thought record sheet before next session with therapist.
Session 4
A typical session 4 may follow a similar format as below. The treatment session may also correspond with content covered in Chapter 4 of the Participant Manual.

- Set agenda
- Carry out mid-way evaluation in order to review their understanding of the model of treatment, their overall progress and any problems, etc.
- Review progress with activity programme/shorter term and longer term goals
- Encourage participant to suggest own ideas for their activity programme from now on
- Discussion around thinking errors
  - Can the participant identify with any of these?
- Review identification with perfectionist traits
  - Is this something the participant views are a contributing/maintaining factor for their symptoms and is this an area they wish to work on?
- **Homework:** Carry out thought diary to spot thinking errors (see Appendix XII for Thought Record). Continue to record whether they completed their goals for Chapter 5 (see Appendix XIII). Read Chapter 6 of the Participant Manual. Complete the Alternative thought record before the next session with the therapist (Appendix XIV).
Session 5
A typical session 5 may follow a similar format as below. The treatment session may also correspond with content covered in Chapter 6 of the Participant Manual.

æ Set agenda
æ Continue to review homework and work towards potential targets
æ Discuss any potential blocks that are making it more difficult for the participant to make progress
  o Problem solving
  o Resources that may help overcome these problems.
æ Review of thought diary
  o Has the participant spotted any patterns to their thoughts/symptoms?
  o Have they been able to record their thoughts?
æ Introduction of thought challenging and generating alternative thoughts.
æ Be aware of how the participant may avoid social situations due to embarrassment
æ Continue cognitive work;
  o Review illness beliefs in light of any changes that they have made.
  o Conceptualise any regular themes/schema and discuss ways of challenging them.
æ Agree new behavioural goals if previous ones have been achieved.

Homework: Continue to generate alternative thoughts using the thought challenging process (see Appendix XIV for Alternative thought record). Continue to record whether they completed their goals for Chapter 6 (see Appendix XV). Read Chapters 7 and 8 and complete goals for Chapter 7 (see Appendix XVI)
Session 6

A typical session 6 may follow a similar format as below. The treatment session may also correspond with content covered in Chapter 7 and 8 of the Participant Manual.

• Set agenda
• Continue to review homework
• Continue discussion on changing activities in order to work towards targets
• Review model and discuss what has been learned
• Offer the client to re-visit anything they have not understood or feel some additional support around would be helpful.
• Goal setting around sleep, managing stress, relaxation and processing emotions (or salient issues addressed in previous sessions)
• Plan for future by discussing how to maintain gains and make further lifestyle changes
  o Agree some long term targets and goals to help reach these
  o Discuss what participant would like to achieve by next session
  o Problem-solve potential issues
  o Discuss how to deal with future setbacks/flare ups.
• Homework: Continue to record whether they completed their goals for Chapters 7 and 8. Work towards any additional goals for relaxation, stress, emotional processing and/or sleep
• Agree two further session dates for around week 16 and week 32 from randomisation

Booster sessions 7-8

• Set agenda
• Evaluate progress since discharge appointment, particularly focussing on targets
• Discuss problems that have occurred and how they have dealt with them
• Problem solve any outstanding problems
• Review their understanding of the model
• Agree further targets and goals (see Appendix XVII for Long-term goal sheet)
HICBT Session Prompts

Therapists will be able to refer participants to sections of the manual before, during and after the session. Therefore it will not be necessary to cover all areas in depth. Furthermore, exactly what is covered in each session will be dependent on the assessment and formulation carried out by the therapist.

Session 1

- Timeline of IBS
  - Events at time of onset: stressful life events, emotional distress and/or suppression, busy or challenging period, initial illness, change in pattern of activity or exercise

- CBT model of IBS with particular emphasis on the physiology; covering link to the ANS and enteric nervous system as per chapter 1 of participant manual.

- Eliciting participant’s beliefs and coping behaviours
  - Beliefs they may hold:
    - People think they’re strange because of how frequently they go to the bathroom/stomach noises/accidentally passing gas
    - Can’t function when they have bowel symptoms/frustrated by them/having them interferes with how good they feel about themselves/affect concentration
    - Feel out of control of symptoms
    - Embarrassed about symptoms/ worried about symptoms interfering with work/social events
    - Want to go home whenever feel discomfort/ worry about not getting to bathroom in time
    - Feel it is normal to empty bowels at least once a day and abnormal to do so less
    - Nothing helps bowel symptoms
  - Behaviours they may engage in:
    - Eating specific foods/avoiding others
    - Straining to open bowels / Going to the toilet more often than need to pass stools
• Checking stools for abnormalities

• Avoiding exercise when have stomach pains

• Wearing baggy clothes when stomach feels bloated

• Avoiding social events/ making plans

• Carrying items in case of accidents (wet wipes/sanitary towels/spare underwear)

• Taking medication to manage symptoms

• Avoiding sex in case of embarrassment

• Safety behaviours (checking for the nearest toilet)

• Avoid staying away from home overnight

• Constant attention to symptoms and/ or stomach

• General background history

  • Tendencies towards perfectionism

  • Activity patterns/exercise patterns

  • Anything that may be relevant – although time on this kept brief due to time constraints of assessment

• If there is time, you can start making the link between symptoms, behaviours, and thoughts and elicit the personal model of the participant. This can be also done in following sessions.
Session 2

- Review CBT model and the rationale for treatment
  - Elicit the understanding of the participant and address any concerns that they have regarding the applicability e.g. through approaching CBT as an experiment

- Elicit personal model of CBT, identifying perpetuating factors
  - Perpetuating factors may be behaviours such as:
    - Avoidance behaviours
    - Safety behaviours
    - Fixation on symptoms
    - Over reliance on medications
  - Perpetuating factors may also be cognitive
    - Fears of embarrassment
    - Negative patterns of thinking e.g. mind reading
    - Perfectionist beliefs
    - Unhelpful beliefs re IBS symptoms. Here important to dispel myths such as the following: irregularity is a sign of poor health, being unable to pass a stool is toxic or dangerous, stools should be passed every day, stools should be a particular shape or form, a sense of incomplete evacuation means that you must keep straining to pass a stool

- Review symptom diary, looking at links between symptoms, thoughts and behaviour
  - Highlight where thoughts may have had effect on symptoms e.g. emotional suppression may be associated with a flare up, fear of embarrassment may cause feelings of nausea
  - Where possible normalising symptoms and the links between these and thoughts and behaviours

- Review CBT model as a way of testing out their beliefs that certain behaviours will result in worsening of symptoms

- Establish present toileting behaviour & safety behaviour and set goals related to these
  - Example goals for toileting behaviour may be:
É To use the toilet only when I have a definite urge to pass a stool

É To hold on for one minute when I feel the urge before going to the toilet. Each week I will increase this by a further one minute

É To practice clenching my anal muscles – 10 repetitions three times a day

É To visit the cinema (or other activity) without using the toilet for one hour before

É To spend no longer than 5 minutes straining on the toilet and to reduce this by a minute per week

Example goals with regards to medication:

É To go out for a social evening this week without taking anti-diarrhoea tablets

É To take antispasmodic medication daily as prescribed

É To avoid taking medication for constipation that stimulates the anal reflex

É TO use a small amount of bulking agent when I get a severe bout of constipation (defined as…). When the constipation is relieved to stop taking the medication.

Example goals for checking behaviours are:

É I will not check my stool for abnormalities this week

É I will not check where the toilets are when I go out for dinner until I have the urge to go to the toilet

Example goals for eating behaviour:

É To eat two slices of wholegrain toast for breakfast each morning

É To eat 3 meals a day at regular intervals

É To chew food slowly and thoroughly

É To drink 6-8 cups of liquid daily, including fruit and vegetable juices and water

É Eat foods every day such as fruit, vegetables, bread and cereals to ensure sufficient fibre.

É To decide which avoided foods should be reintroduced, pick one and slowly reintroduce the food into the diet – specifying the frequency and amount of food to be eaten

Discuss longer-term targets for treatment and record them
0 Longer term goals should be realistic and achievable
0 They should have clear focus and direction
0 There should be different types of targets to work towards making their life as balanced as possible
0 Targets are things that the participant would like to be doing in the longer term rather than immediately
Session 3

- Review the participant’s understanding of the model in light of information they read for homework and adjusting their behaviour to meet their goals

- Review self-monitoring diaries and discuss progress and problems with their first activity programme

- Discuss strategies for dealing with problems arising and re-examine participant’s beliefs regarding common myths in IBS. Problems arising could be:
  - Fixed physical attribution of illness
  - Wary of changing behaviours
  - Feeling a physical cause has been missed and wanting further explanations
  - Non-compliance with diary keeping
  - Not sticking to diary keeping
  - For such issues see page 60-66

- Review existing patterns of exercise and activity
  - Boom/bust
  - Consistent over activity
  - Consistent underactivity

- Agree goals for exercise and activity pattern
  - Examples of goals for exercise may be:
    - To start going to the gym for 20 minutes twice a week and to increase this to three times a week in three weeks’ time
    - To walk three times a day for 15 minutes. To upgrade these walks by 5 minutes per week so that by the end of the programme they are walking for 30 minutes each time
  - Example goals for activity pattern outlined in pages 57-61 in Participant Manual

    This is a list of goals set by someone who was doing too much:
    - Leave work on time to go home at least twice a week
    - Have two evenings at home per week when working
    - Go swimming once a week
    - Be in bed by 11.00 pm during the week
Prioritise tasks that have to be done at the beginning of the week (Sunday PM) and eliminate tasks that do not have to be done.

This is a list of goals set by someone who had limited their activity substantially over time:

- Get up at 8.30 every day
- Walk for 10 minutes, 3 times daily (11 am, 2.30, 5 pm).
- Rest for an hour in the chair in the morning and afternoon
- Do not catnap during the day
- Do 15 minutes housework in the morning and afternoon
- Go to bed at 10.00 pm.
Session 4

- Carry out mid-way evaluation in order to review:
  - Understanding of the model of treatment
  - Overall progress
  - Any problems being encountered

Here cognitions should be explored and problem solving carried out if necessary.

- Common thinking errors (please refer to pages 66 to 72 of the Participant Manual for more details). Common thinking error examples tailored to IBS can be found in Appendix XXIII.
  - “Shoulds”
  - Black and White Thinking

The tendency to think in black and white or in absolutes is another common thinking error. These thoughts often contain a ‘never’ or ‘always’ statement.

- Catastrophising

Catastrophisers often jump to conclusions about future events and imagine the worst possible outcome.

  - Overgeneralising
  - Predicting the Future
  - Eliminating the Positive
  - Mind Reading

- High expectations and unhelpful aspects of perfectionism (please refer to pages 70-72 of the Participant Manual for more details). High expectations and unhelpful aspects of perfectionism examples tailored to IBS can also be found in Appendix XXIII

  - Negative thoughts and perfectionism
Session 5

- Continue to review homework and work towards potential targets

- Discuss any potential blocks that are making it more difficult for the participant to make progress, e.g. problem solving, or resources that may help them to overcome these problems.

- Continue cognitive work;
  0 Review illness beliefs in light of any changes that participants have made
    - For example behavioural experiments may have shown participants that they aren’t likely to have a toileting accident if they don’t get to a toilet straight away
    - They may not have experienced any consequences when reintroducing once avoided foods into their diet
    - They may notice that feelings of incomplete evacuation subside soon after their visit to the toilet, once they have reduced their straining behaviour

- Conceptualise any regular themes and discuss ways of challenging them.
  - Challenging negative thoughts by weighing up the evidence (how else could I interpret what has happened?/ Do some of the facts contradict what I am thinking?)
  - Am I just focusing on the negative aspect of the situation?
  - Am I seeing the picture in black and white?
  - Am I expecting the worst or catastrophising?
  - What is truly the worst thing that can happen in this situation?
  - Am I trying to predict the future or read other people’s minds?
  - Am I jumping to conclusions based on a previous experience?

- Agree new targets if previous ones have been achieved
Session 6

- Continue to review homework
- Continue discussion on changing activities in order to work towards targets
  - In the context of their successes/failures
  - May choose to continue with targeting 1 type of behaviour e.g. toileting behaviours and move on to eating behaviours when comfortably reached goals
  - Frame attempts as positive
- Addressing worries, stress and anxiety associated with IBS
  - Relaxation techniques; diaphragmatic breathing; relaxation CDs
  - Improving sleep
  - Managing stress
- Processing emotions.
  - Step 1: Identifying Our Emotions.
    - Identifying positive and negative emotions.
  - Step 2: Developing acceptance.
    - What do we mean by acceptance?
    - How do I accept my emotions?
  - Step 3: Managing emotions.
    - Expressing emotions.
    - What if I can’t talk about my feelings?
    - Managing specific emotions:
      - Setting goals for managing emotions.

Please read pages 106-117 of the Participant Manual for more details on the “Processing emotions” section.

- Review model and discuss what has been learned
- Plan for future by discussing how to maintain gains and make further lifestyle changes
- Discuss how to deal with future setbacks
  - Strategies for flare ups
• Reducing self-blame and focusing on positive steps to be taken to solve the problem

• Handling the situation in a similar way to which the participant would be likely to handle with a friend or family member

• Flare ups of IBS common at times of stress – planning for stressful times

• Revisiting past successful methods of coping with flare ups
Low Intensity Treatment Session Plans

The following is intended to provide a flexible outline for therapists to structure sessions. It is not intended to be strictly prescriptive and therapists are encouraged to formulate their own structure based around the initial assessment session with the participant.

### LICBT week scheduling table

<table>
<thead>
<tr>
<th>Week</th>
<th>Session Number</th>
<th>Date</th>
<th>Time</th>
<th>Session Type</th>
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<tbody>
<tr>
<td>Week 1 (therapist allocated participant)</td>
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<td>Treatment period</td>
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<td>Week 2</td>
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<td>Week 10 -15</td>
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<td>Follow-up period</td>
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<tr>
<td>Week 16 (4 months)</td>
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<td>Week 13- 23</td>
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<td>Week 32 (8 months)</td>
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Participants in the LICBT condition will receive 3 rather than 6 phone calls in the treatment period and these will be half an hour rather than an hour in length. Participants in this condition will also receive two booster calls, also half an hour in length. These should occur at weeks 16 and 32 post randomisation. Therapists will be provided with the date of randomisation of each participant. There will be a three-week leeway for scheduling the booster sessions.
The first 3 treatment sessions can be scheduled at any point within the first 9 weeks of a participant being allocated to treatment. Ideally participants will have had time to work through sessions 1 and 2 of the website before the first telephone session.

At 12 weeks post randomisation the participant will complete follow-up questionnaires to assess any change in symptoms and impact on life. Consequently it is important for therapy sessions to remain within 9 weeks of allocation of a participant.

Participants will be working through the 8 session online CBT website within this 9-week period. They are encouraged to order the sessions at their own discretion, however during phone calls, therapists may direct them to specific sessions to prioritise for the next session. Homework for participants is all contained on the website.
Overview of Regul8 Website Content

<table>
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<tr>
<th>Session 1</th>
<th>Part 1</th>
<th>Welcome and Introduction to the website</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>What is IBS?</td>
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<td></td>
<td>- Symptom self-assessment checklist</td>
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<td>- Their own causes of IBS checklist</td>
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<td>- Diagnostic criteria</td>
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<td>- IBS as a syndrome not a disease</td>
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<td>The digestive system</td>
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<td>- Movement of food through the digestive system</td>
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<td>- Physiology of the bowel</td>
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<td>- How IBS affects bowel co-ordination</td>
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<td></td>
<td>- The ABC of IBS symptoms: Abdominal pain, Bloating, and Change in Bowel Habit</td>
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<td>Assessment of their symptom severity score</td>
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<td>Part 2</td>
<td>Introduction to link between stress and symptoms</td>
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<tr>
<td></td>
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<td>- Fight and flight response</td>
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<td>- Identify their own stressors</td>
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<td></td>
<td>- Short questionnaire to identify their stress levels</td>
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<td>- Vicious cycle of stress and IBS</td>
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<td>Homework</td>
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<tr>
<th>Session 2</th>
<th>Part 1</th>
<th>Review of session 1 – reflective questions</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>The six steps of symptom management</td>
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<td>Linking thoughts, behaviours, emotions and symptoms</td>
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<td>Personal model created</td>
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<td>- Includes Behaviours, thoughts, emotions selection</td>
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<td></td>
<td>Part 2</td>
<td>Introduction to symptom self-monitoring</td>
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<tr>
<td>Homework</td>
<td></td>
<td>Symptom-monitoring diary for a week – rating of abdominal pain, stress, diarrhoea (accidents), constipation, eating habits (size and frequency of meals) and changes in behaviours related to symptoms.</td>
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<tr>
<th>Session 3</th>
<th>Part 1</th>
<th>Review of session 2 – reflective questions</th>
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<td>Review of symptom diary</td>
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<td>Review of personal model</td>
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<td>Managing symptoms:</td>
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<td>- IBS medications</td>
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<td>Selection of their bowel habits</td>
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<td>Managing diarrhoea &amp; goal setting:</td>
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<td>- Habits self-assessment</td>
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<td>- Advice for each selected habit</td>
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<td>- Anal muscle strengthening</td>
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<td>- Tightening anal muscles to override reflex</td>
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<td>- Limiting use of medications</td>
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<td>- Checking stools</td>
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<td>- Avoidance</td>
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<td><strong>Managing constipation &amp; goal setting:</strong></td>
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<td>- Myths self-assessment</td>
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<td>- Irregularity of stool passage</td>
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<td>- Toxicity of stools</td>
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<td>- Shape and form of stools</td>
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<td>- Incomplete evacuation</td>
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<td>- Reducing straining</td>
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<td>- Increased consumption of fibre</td>
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<tr>
<td><strong>Part 2</strong></td>
<td><strong>Eating patterns and stress</strong></td>
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<td>- Importance of routine</td>
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<td>- Healthy eating and balanced diet (rather than specific diets)</td>
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<td>- Increasing soluble fibre</td>
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<td>- NICE recommendations on diet and IBS (optional link)</td>
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<td><strong>Reintroducing avoided foods</strong></td>
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<td><strong>Goal setting</strong></td>
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<td><strong>Goal sheet</strong></td>
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<tr>
<td><strong>Homework</strong></td>
<td><strong>Completion of goals and goal progress record – specify what, when and how</strong></td>
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<td><strong>Session 4</strong></td>
<td><strong>Part 1</strong></td>
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<td><strong>Review of session 3 – reflective questions</strong></td>
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<td><strong>Review of goal sheet</strong></td>
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<td><strong>Setting new goals, if needed</strong></td>
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<td><strong>Review of IBS symptoms &amp; current symptom severity score</strong></td>
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<td><strong>Stress and symptoms assessment</strong></td>
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<td><strong>Review of personal model</strong></td>
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<td><strong>Exercise:</strong></td>
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<td>- Why exercise is good for IBS</td>
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<td>- NICE recommendations</td>
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<td>- Exercise self-assessment</td>
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<td>- Goal setting to increase exercise, if needed</td>
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<td>- Exercise timetable, if needed</td>
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<td><strong>Part 2</strong></td>
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<td><strong>Introduction to patterns of daily activity</strong></td>
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<td><strong>Activity-symptom self-assessment</strong></td>
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<td>- Boom or bust cycle</td>
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<td>- Avoidance cycle</td>
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<td><strong>Goal setting</strong></td>
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<td></td>
<td>- Tips for setting goals for each activity pattern</td>
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<td></td>
<td><strong>Goal sheet</strong></td>
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<tr>
<td><strong>Homework</strong></td>
<td><strong>Completion of goals and goal progress record</strong></td>
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</tbody>
</table>
| Session 5 | Part 1 | Review of session 4 – reflective questions  
| Review of goal sheet  
| Setting new goals, if needed |
| Part 2 | Review of personal model  
| Introduction to unhelpful thinking  
| Link between thinking, perfectionist thinking and symptoms  
| Additional information on perfectionism  
| Common unhelpful thoughts self-assessment  
| Unhelpful thinking styles  
| Unhelpful thinking and perfectionism/high personal expectations  
| Introduction to recording thoughts  
| Example thought record addressing their Personal Model |
| Homework | Completion of goals and goal progress record  
| Thought record |

| Session 6 | Part 1 | Review of session 5 – reflective questions  
| Review of goal sheet  
| Setting new goals, if needed  
| Review of thought record – reflective questions |
| Part 2 | Review of personal model  
| Introduction to thought challenging  
| The 4 steps to find alternative thoughts:  
| 1. Weighing up evidence  
| 2. Don’t expect to always do things perfectly  
| 3. Avoid focusing on your symptoms  
| 4. Try and come up with alternatives  
| Alternative thought record – interactive examples |
| Homework | Completion of goals and goal progress record  
| Alternative thought record |

| Session 7 | Part 1 | Review of session 6 – reflective questions  
| Review of goal sheet  
| Setting new goals, if needed  
| Review of alternative thought record  
| Impact of alternative thoughts on IBS symptoms |
| Part 2 | Review of personal model  
| Learning to relax:  
| - Importance and benefits of relaxation  
| - Diaphragmatic breathing (video tutorial)  
<p>| - Progressive muscle relaxation (recording) |</p>
<table>
<thead>
<tr>
<th>Session 8</th>
<th>Part 1</th>
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<tr>
<td>Review of session 7 – reflective questions</td>
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<tr>
<td>Review of goal sheet</td>
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<tr>
<td>Setting new goals, if needed</td>
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<tr>
<td>Review of alternative thought record</td>
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<tr>
<td>Impact of alternative thoughts on IBS symptoms</td>
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<tr>
<td>Processing emotions:</td>
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<tr>
<td>- Positive emotion self-assessment</td>
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<td>- Positive emotion suppression</td>
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<tr>
<td>- Negative emotion self-assessment</td>
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<tr>
<td>- Impact of negative emotion</td>
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<tr>
<td>Development of acceptance:</td>
<td></td>
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<tr>
<td>- 3 minute acceptance recording</td>
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<tr>
<td>- Beach ball analogy</td>
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<td>Managing emotions:</td>
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<td>- Verbal expression</td>
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<tr>
<td>- Writing</td>
<td></td>
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<tr>
<td>Managing sadness, grief &amp; loss</td>
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<tr>
<td>- Goal setting, if needed</td>
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<tr>
<td>Managing anger or frustration</td>
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<td>- Being assertive</td>
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<tr>
<td>- Goal setting, if needed</td>
<td></td>
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<tr>
<td>Managing fear, anxiety and embarrassment</td>
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<tr>
<td>- Goal setting, if needed</td>
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<tr>
<th>Part 2</th>
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<tbody>
<tr>
<td>Review of IBS symptom severity</td>
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<tr>
<td>Long-term goal setting</td>
</tr>
<tr>
<td>Managing symptom flare-ups - strategies</td>
</tr>
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<thead>
<tr>
<th>Homework</th>
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</thead>
<tbody>
<tr>
<td>Completion of goals and goal progress records</td>
</tr>
<tr>
<td>Alternative thought record</td>
</tr>
<tr>
<td>Long-term goals for the next 4 months (until the first booster session)</td>
</tr>
</tbody>
</table>
Overview of Structure LICBT Session Plans

**Telephone session 1**

Participants should be directed to complete Sessions 1 (understanding your IBS) and 2 (assessing your symptoms) on the website before the first phone call. These can be done back to back or at different times according to what suits the participant.

- Set agenda

- Checking practicalities of completing web-based programme - any technical issues to problem solve or make a note to refer on to research assistant

- Therapist should check the understanding of the participant of the physiology of digestive system and/or IBS and provide more explanation if needed

- Therapist should ask participant to talk through their own personal model i.e. what the computer generated from their self-assessment and any bits they feel may have been left out. This will include
  
  - Exploring thoughts, behaviours and feelings
  - Exploring the link between these

- Suggestions of how to make best use of the programme in relation to their personal model (barriers/thoughts/problematic behaviours specific to the participant)

- Agree or outline sessions to be completed online by participant before next phone call. Would usually be in sequence presented by computer programme unless behaviours appear to be less of an issue for the individual.
Telephone session 2
This may tend to focus on behaviour change and goal setting.

As participants will be working through the website in an order that they choose, phone calls will be based around the sessions that the participants have previously completed. Therapists should:

- Set agenda
- Check any difficulties with programme and/or homework and problem solve
- Check any queries the participant has regarding CBT programme
  - Addressing queries over relevance for participant (i.e. use of psychological programme in physical symptoms, etc.)
  - Issues arising relating to symptoms (e.g. how these may initially get worse when changing behaviours, etc.)
- Explore participants’ reflections on material they have worked on to date, particularly any new insights they have gleaned. This may include insights from their symptom diaries or any of the other self-assessments related to maintaining behaviours
- A key theme may be to look at goals set by participant and suitability of these. Are they aiming too high or are their goals not structured enough. Goals may relate to managing constipation or diarrhoea, developing consistency in diet, exercise or reducing avoidance or all-or-nothing behaviours
- Agree salient sessions to be completed before next phone call session.
Telephone session 3

This may focus on thought records, stress management or processing emotions.

æ Set agenda

æ Summarise key issues discussed from last session, including goals agreed. Ascertain progress made

æ Discuss thoughts or reflections participants may have so far and explore issues arising, problem solving where necessary

æ Establish what the participant would like to focus on in the session, suggesting one or two are prioritised if multiple topics are presented

æ If the participant hasn’t progressed with the programme or has major problems with the content – explore reasons for this and how it may best help to use current session

æ If thoughts have been identified as key issue it may be helpful to ask participant to go through their thought record to cross check understanding and help come up with alternatives

æ If stress or expressing emotions is the key explore which strategies they have decided to focus on and where to progress with these

æ If participant is fairly concrete in their thinking it may be best to stay with Identifying any new relevant goals and encourage achievement on existing goals

æ At end of session - talk about creating longer term targets

æ Identify possible challenges that face the participant in continuation of the programme and how these may be addressed.
LICBT Session Prompts

This check list will help to guide the telephone sessions you will engage participants in as part of the LICBT arm of the trial. You may find it helpful to print a copy to tick off as you go. The check list contains a list of the most important things to cover during each session.

Participants will likely complete the Regul8 programme in a sequential order. However, for some participants, you may decide to alter the ordering in response to their personal model. Session 1 is likely to be very similar for most participants. However, sessions 2 and 3 may be different depending on which order participants are working through the programme. Whilst this checklist is designed as a useful prompt for each of the sessions, please remember to be flexible around the online sessions, goals and homework the participant has completed between telephone sessions.

Telephone Session 1
Week 2

Likely to focus on sessions 1 & 2 of the Regul8 programme (Understanding IBS and Assessing your symptoms).

<table>
<thead>
<tr>
<th>Ask how they are going with the website.</th>
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<table>
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<tr>
<th>Any arising technical difficulties have been addressed (either problem-solved during the call or referred to a research assistant).</th>
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<table>
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<tr>
<th>Have they managed to work through the Regul8 sessions 1 &amp; 2?</th>
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<table>
<thead>
<tr>
<th>If YES: Excellent! What did they get out of sessions? Do they fully understand the physiology of IBS?</th>
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<table>
<thead>
<tr>
<th>If NO: Explore reasons. Do they know when they will plan to do this? Arising difficulties in completing the sessions have been problem-solved with the participant</th>
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<table>
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<tr>
<th>Has the participant completed their own personal model?</th>
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<thead>
<tr>
<th>Ask them to talk you through what they have in the model – checking for understanding of maintenance factors. Probe areas where you feel issues may have been left out or where there seems to be misunderstandings</th>
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<table>
<thead>
<tr>
<th>An agreement has been made on which of the sessions will be most helpful for the participant in relation to their own maintenance factors (highlighted in the personal model)</th>
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<table>
<thead>
<tr>
<th>A plan has been made for which sessions the participant will complete before the telephone session 2</th>
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<table>
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<tr>
<th>The participant has scheduled time during the week to complete the next online Regul8 sessions</th>
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<table>
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<tr>
<th>The participant knows when their next telephone session will be</th>
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</table>
Telephone Session 2

Week 4
Likely to focus on sessions 3 and 4 of Regul8 – Managing symptoms and Exercise and activity.

Ask how they are going with the website

Any arising technical difficulties have been addressed (either problem-solved during the call or referred to a research assistant)

Have they managed to work through the Regul8 sessions (usually 3 and 4) ?

If YES: If YES: Excellent! What did they get out of sessions?
Any arising problems have been problem-solved, and goals have been re-set

If NO: Do they know when they will plan to do this?
Arising difficulties in completing the sessions have been problem-solved with the participant

Any concerns the participant has about the use of the CBT model have been discussed (notably concerns about using a psychological model to manage physical symptoms)

Any concerns about a worsening of symptoms have been addressed (symptoms commonly get slightly worse when the goals are first embarked upon)

**Participants’ understanding of behavioural maintenance factors has been checked in relation to any of the symptoms below:**

1. Managing diarrhoea:

2. Managing constipation:

3. Unhelpful eating patterns:

4. Exercise:

5. Unhelpful patterns of activity:

The participant has a list of goals they would like to work on, and suitability and realism of goals has been checked with the patient

A plan has been made for which sessions the participant will complete before telephone session 3

The participant knows what their homework tasks are and when their next telephone session will be
Telephone Session 3

Week 7

Likely to focus on sessions 5, 6, 7 and 8 – Unhelpful thinking, Managing Stress and Processing Emotions

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Ask how they are going with the website</td>
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<tr>
<td>Any arising technical difficulties have been addressed (either problem-solved during the call or referred to a research assistant)</td>
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<tr>
<td>Have they managed to work through the Regul8 sessions (usually 5 to 8)? Homework review has been completed – has the participant completed the agreed sessions and the goals?</td>
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<tr>
<td>If YES: Excellent! What did they get out of sessions?</td>
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<tr>
<td>Any arising problems have been problem-solved, and goals have been re-set</td>
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<tr>
<td>If NO: Arising difficulties in completing the sessions have been problem-solved with the participant</td>
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<tr>
<td>Any major struggles with completing the programme or the content have been explored:</td>
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<tr>
<td>Decide how best to use the session. May be worth suggesting you focus on thoughts as this is often the bit most patients find challenging.</td>
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<tr>
<td>If thoughts on agenda - Discuss thought record and progress in relation to this. Ask about examples of unhelpful thoughts to talk through over the phone. Talk through any misconceptions if evident e.g. confusing feelings and thoughts or help elicit thoughts if they are struggling. If only have IBS thoughts in record – perhaps explore perfectionist thoughts as well.</td>
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<tr>
<td>Check if they were able to come up with alternatives and explore these together. Help them come up with others or clarify the thought challenging process</td>
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<tr>
<td>If they want to focus on stress management – explore issues like time out, doing rewarding activities. Discuss implementing the relaxation techniques. Explore any difficulties with these.</td>
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<tr>
<td>Can also focus on emotional processing and help facilitate goals and discussions in this area. May include some role play over the phone to practice talking about emotions.</td>
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<tr>
<td>If they haven’t progressed with the programme or have major problems with the content – explore reasons for this and how it may best help to use current session</td>
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<tr>
<td>Do they have a list of long-term goals they would like to work on until the first booster session?</td>
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<tr>
<td>If YES: The suitability and realism of these goals have been checked with the participant</td>
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<tr>
<td>If NO: They have been encouraged to work through until the end of the programme and to set long-term goals</td>
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<tr>
<td>They know what their homework tasks are</td>
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<tr>
<td>Any problems or concerns about continuing the programme independently have been problem-solved with the participant</td>
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<tr>
<td>The two booster sessions at weeks 16 and 32 have been scheduled</td>
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**Booster Session 1**

**Week 16**

| Ask how they are doing – what they would like to focus on today. |
| Have they managed to continue with the programme and complete their long-term goals? |
| Discuss which strategies they are still using to manage symptoms. Which of these are working and if they are not – explore how the ‘tools’ can be maximized or perhaps change tack and focus on others. |
| May decide to set new goals of expand on current goals. Focus can be on behaviours, emotions or thoughts. |
| Any major struggles with completing the programme or the content may need to be explored. Motivation of participant to continue programme explored (re-examining relevance of their personal model) |
| Ask about flare-ups and if they have occurred – how they are managing these. |
| If any problems or concerns about working on the self-management programme independently problem-solved with the participant |
| The last booster session at week 32 has been scheduled |

**Booster Session 2**

**Week 32**

| Ask about general progress or lack of it – how things in general |
| Agree what they would like to focus on – can be revision of any of the session or general overview. |
| Examine what participant what gains they feel they have made since starting the programme. Relate back to long term goals |
| How much their IBS interferes with their life compared to previously? Is there much change? Room for more? |
Eating Patterns & IBS

Change in diet and IBS

The symptoms of IBS often upset dietary habits. During a bout of symptoms, some people find that only certain foods are palatable. Others find it difficult to eat at all while experiencing their symptoms. Following an infection such as campylobacter, it may seem impossible to get back to a normal diet.

Self-management for IBS requires a good look at dietary habits. Participants will be directed to look at their dietary patterns in terms of times of day that they eat, frequency and size of meals.

Eating at different times of the day each day and missing out meals on certain days are factors that can make IBS worse. Constantly fluctuating diet will lead to fluctuating pain and discomfort. This is because the bowel will be unable to develop a good routine as it cannot predict food intake.

Adjusting diet routine in IBS

Special diets have been shown to be of little benefit for IBS. It was thought for example that a high fibre diet was beneficial, but recent studies have shown that a normal amount of fibre in a healthy diet is sufficient. Certain diets recommend avoiding specific types of food and they make strong claims about the benefits that IBS patients can get from them. However, the evidence that these diets reduce IBS symptoms in the long-term is not strong enough and further large studies are needed.

The best approach for IBS is to eat a healthy and balanced diet. This means eating a balance of fibre, protein, carbohydrates and fat. Consistency of eating pattern should also be made. For example, three meals a day at regular times will help the body get in a rhythm of digestion. This means that if a person skips breakfast due to time constraints or symptoms in the morning, they should consider a goal such as eating one or two pieces of toast each morning. Even a small breakfast is better than no breakfast at all.

It is also best to avoid eating on the run. When food is chewed carefully, it mixes well with the saliva and the digestive process is able to begin already through the enzyme activity in the saliva. Eating at a consistent slower pace at each meal also provides the digestive system with a degree of predictability.

If possible it is also worth trying to have similar sized meals. When people eat very little during the day and then have a large meal at night, it tends to overload the digestive system.
National Institute for Clinical Excellence (NICE) for diet and nutrition:

1. Have regular meals and take time to eat.
2. Avoid missing meals or leaving long gaps between eating.
3. Drink at least eight cups of fluid per day, especially water or other non-caffeinated drinks, for example herbal teas.
4. Restrict tea and coffee to three cups per day.
5. Reduce intake of alcohol and fizzy drinks.
6. Eat five portions of a variety of fruit and vegetables each day, in place of foods higher in fat and calories.
7. It may be helpful to limit intake of high-fibre food (such as wholemeal or high-fibre flour and breads, cereals high in bran, and whole grains such as brown rice).
8. Reduce intake of “resistant starch” (starch that resists digestion in the small intestine and reaches the colon intact), which is often found in processed or re-cooked foods.
9. People with diarrhoea should avoid sorbitol, an artificial sweetener found in sugar-free sweets (including chewing gum) and drinks, and in some diabetic and slimming products.
10. People with wind and bloating may find it helpful to eat oats (such as oat-based breakfast cereal or porridge) and linseeds (up to one tablespoon per day).
11. Eat as little as possible of: fried foods, drinks and confectionery high in added sugars, other food and drinks high in fat and sugar, such as some take-away and fast foods.

Suggested goals for developing a healthy bowel routine:

1. Eat two slices of whole grain toast for breakfast each morning.
2. Eat 3 meals a day at regular intervals.
3. Chew food slowly and thoroughly.
4. Drink 6-8 cups of liquid daily, including fruit and vegetable juices and water.
5. Eat foods every day such as fruit, vegetables, bread and cereals to ensure sufficient fibre in diet.

Food intolerances and troublesome foods

Some people with IBS do show food intolerances, but many researchers are not really sure why. The most common intolerances are to dairy and wheat products.

Some participants may have gained advice from a dietician and chosen to rule out problem foods, slowly reintroducing them to monitor the effect on their symptoms. While this can be
helpful, these methods will not completely eliminate the IBS symptoms as though foods can worsen symptoms, they are not the sole cause of them. In addition, if foods are avoided then re-introduced, it will take time for the bowel to adjust to the change. In the adjustment phase more extreme bowel movements or abdominal discomfort may be triggered.

It is important to encourage participants not to get too obsessed with diet as eating habits can become ruled by the fear that the symptoms may return. Depending on what symptoms they’re experiencing, they may find it helpful to trial the exclusion of wheat bran and lactose BUT stress that they should consult with a doctor before doing this. Drastically changing diets may mean that the participant doesn’t get the nutrients that they require.

**Reintroducing avoided foods**

Some people with IBS try to eliminate foods that seem to aggravate their symptoms. Whereas it is a good idea to drink alcohol and caffeine in moderation, it should not be necessary to eliminate them entirely. The goal of the programme is to increase the participants’ options in lifestyle through the management of their symptoms, rather than to place restrictions on them.

If participants monitor foods too closely, they may attribute their symptoms to food when they are actually being triggered by other factors such as anxiety or change in diet. This process could cause participants to needlessly eliminate many foods which are nutritionally valuable or enjoyable.

Furthermore, cutting foods can cause further problems, when a person happens to eat them due to a craving or occasion. Because the stomach will not be used to the food, it may cause unnecessary sensitivity. A good alternative is to eat such foods little and often to allow the stomach to adjust to them.

Steps to reintroduce avoided foods:

1. The first step towards reintroducing avoided foods is to decide which food would be a good starting point to try and face. These may be foods that participants would like to eat such as chocolate or food that would be good for the participant to eat.
2. If participants are avoiding a number of different foods, they should deal with one at a time.
3. Participants should slowly reintroduce the food into their diet. It is important to specify the frequency and amount of food to be eaten e.g. allowing one small chocolate bar a week
Exercise & IBS

It is important to complete regular exercise to maintain health, which can be hard for people with busy lifestyles. Setting specific goals in this area can help. If participants already exercise on a regular basis, they should strive to keep that schedule consistent, bearing in mind the goal of moderation.

However if participants have stopped exercising because of their symptoms or time constraints, or they have never had a regular schedule of exercise, then this is an important aspect to be encouraged.

Participants should be advised that the word “exercise” does not necessarily mean gym membership and marathons and that in reality it can be a lot easier and more available. Research has shown that as little as 30 minutes of continuous aerobic exercise such as walking, three times a week can be beneficial to health. Even this small amount of exercise can improve fitness and the quality of sleep.

Exercise can also impact on a person’s sense of well-being. The “fight or flight” response to stressful situations prepares the body for physical action that is rarely engaged in. This is because stressors nowadays tend to be more emotional or mental stresses. Aerobic exercise is important for well-being because it increases heart rate and breathing, which increases the delivery of oxygen to the muscles, allowing them to work efficiently. This can flush the adrenaline and other stress hormones that may have accumulated over the day, out of the body. It also stimulates many of the “feel-good” hormones, including those which provide a sense of well-being and natural pain relief.

The National Institute for Clinical Excellence (NICE), have provided the following guidance for exercise:

There are different types of physical exercise:

- Vigorous intensity exercise: swimming, jogging, aerobics, football, tennis, gym, cycling.
- Moderate intensity exercise: pilates, yoga, tai chi.
- Low intensity exercise: walking.

To stay healthy, adults aged 19-64 are recommended to do:

1) At least 150 minutes (2 hours and 30 minutes) of moderate-intensity aerobic activity such as cycling or fast walking every week, AND muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders and arms).

OR

2) 75 minutes (1 hour and 15 minutes) of vigorous-intensity aerobic activity such as running or a game of singles tennis every week, AND muscle-strengthening activities
on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders and arms).

OR

3) An equivalent mix of moderate- and vigorous-intensity aerobic activity every week (for example 2 30-minute runs plus 30 minutes of fast walking), AND muscle-strengthening activities on 2 or more days a week that work all major muscle groups (legs, hips, back, abdomen, chest, shoulders and arms).
### Appendix I - ROME III Criteria

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>If Never, skip remaining questions</th>
</tr>
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</table>
| 1. In the last 3 months, how often did you have discomfort or pain anywhere in your abdomen? | 0 Never  
1 Less than one day a month  
2 One day a month  
3 Two to three days a month  
4 One day a week  
5 More than one day a week  
6 Every day | If Never, skip remaining questions |
| 2. For women: Did this discomfort or pain occur only during your menstrual bleeding and not at other times? | 0 No  
1 Yes  
2 Does not apply because I have had the change in life (menopause) or I am a male | If Never, skip remaining questions |
| 3. Have you had this discomfort or pain 6 months or longer?            | 0 No  
1 Yes | |
| 4. How often did this discomfort or pain get better or stop after you had a bowel movement? | 0 Never or rarely  
1 Sometimes  
2 Often  
3 Most of the time  
4 Always | |
| 5. When this discomfort or pain started, did you have more frequent bowel movements? | 0 Never or rarely  
1 Sometimes  
2 Often  
3 Most of the time  
4 Always | |
<p>| 6. When this discomfort or | 0 Never or rarely | |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>Scale</th>
</tr>
</thead>
</table>
| 1. pain started, did you have less frequent bowel movements?            | 1 Sometimes 
2 Often 
3 Most of the time 
4 Always |
| 7. When this discomfort or pain started, were your stools (bowel movements) looser? | 0 Never or rarely 
1 Sometimes 
2 Often 
3 Most of the time 
4 Always |
| 8. When this discomfort or pain started, how often did you have harder stools? | 0 Never or rarely 
1 Sometimes 
2 Often 
3 Most of the time 
4 Always |
| 9. In the last 3 months, how often did you have hard or lumpy stools?    | 0 Never or rarely 
1 Sometimes 
2 Often 
3 Most of the time 
4 Always |
| 10. In the last 3 months, how often did you have loose, mushy or watery stools? | 0 Never or rarely 
1 Sometimes 
2 Often 
3 Most of the time 
4 Always |
| **Alternative scale:**                                                   |                                                                      |
| 0 Never or rarely                                                       | 1 About 25% of the time                                                |
| 2 About 50% of the time                                                 | 3 About 75% of the time                                                |
| 4 Always, 100% of the time                                              |                                                                      |
C1. Irritable Bowel Syndrome

Diagnostic Criteria*
Recurrent abdominal pain or discomfort** at least 3 days/month in last 3 months associated with two or more of criteria #1 - #3 below:

Pain or discomfort at least 2-3 days/month (question 1>2)
For women, does pain occur only during menstrual bleeding? (question 2=0 or 2)

1. Improvement with defecation
Pain or discomfort gets better after BM at least sometimes (question 4>0)

2. Onset associated with a change in frequency of stool
Onset of pain or discomfort associated with more stools at least sometimes (question 5>0), OR
Onset of pain or discomfort associated with fewer stools at least sometimes (question 6>0)

3. Onset associated with a change in form (appearance) of stool
Onset of pain or discomfort associated with looser stools at least sometimes (question 7>0), OR
Onset of pain or discomfort associated with harder stools at least sometimes (question 8>0)

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis
Yes. (question 3=1)

**"Discomfort" means an uncomfortable sensation not described as pain.
In pathophysiology research and clinical trials, a pain/discomfort frequency of at least two days a week is recommended for subject eligibility.
Pain or discomfort more than one day per week (question 1>4)

Criteria for IBS-C
(question 9>0) and (question 10=0)

Criteria for IBS-D
(question 9=0) and (question 10>0)

Criteria for IBS-M
(question 9>0) and (question 10>0)

Criteria for IBS-U
(question 9=0) and (question 10=0)
### Appendix II – Variables of the Therapy database (MACRO)

Variables to be recorded **during/after each session:**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Arm</strong></td>
<td>Key for responses: Therapist led CBT=1; Regul8 website=2</td>
</tr>
<tr>
<td><strong>Date of randomisation</strong></td>
<td>Date</td>
</tr>
<tr>
<td><strong>Name/ID of therapist</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Due date session 1</strong></td>
<td>Date</td>
</tr>
<tr>
<td><strong>Session 1 - actual date</strong></td>
<td>Date</td>
</tr>
<tr>
<td><strong>Session 1 - missed</strong></td>
<td>Key for responses: Yes/No</td>
</tr>
</tbody>
</table>
| **Comments/Reasons for not attending** | Key: Reasons for non-attendance:  
- **FU** – IBS flare-up  
- **UW** – unwell (other reason)  
- **WC** – work commitment  
- **FC** – family commitment  
- **PH** – phone problem  
- **UK** – unknown **OTHER**: please specify. |
| **Duration of session 1** | In minutes |
| **Email 1 to arrange session 1 - date** | Date |
| **Email 2 to arrange session 1 - date** | Date |
| **Telephone call to arrange session 1 - date** | Date |
| **Due date session 2** | Date |
| **Session 2 - actual date** | Date |
| **Session 2 - missed** | Key for responses: Yes/No |
| Comments/Reasons for not attending | Key: Reasons for non-attendance:  
| FU – IBS flare-up  
| UW- unwell (other reason)  
| WC – work commitment  
| FC – family commitment  
| PH – phone problem  
| UK – unknown OTHER: please specify. |
| --- | --- |
| Duration of session 2 | In minutes |
| Completion of homework | Key for responses: Completed, Not completed, Partially completed. Space for comments. |
| To what extent have you engaged with your homework during the last week? | 0 to 100 where 0 is NOT AT ALL and 100 is TOTALLY |
| Email 1 to arrange session 2 - date | Date |
| Email 2 to arrange session 2 - date | Date |
| Telephone call to arrange session 2 - date | Date |
| Due date session 3 | Date |
| Session 3 - actual date | Date |
| Session 3 - missed | Key for responses: Yes/No |
| Comments/Reasons for not attending | Key: Reasons for non-attendance:  
| FU – IBS flare-up  
| UW- unwell (other reason)  
| WC – work commitment  
| FC – family commitment  
| PH – phone problem  
<p>| UK – unknown OTHER: please specify. |
| Duration of session 3 | In minutes |
| Completion of homework | Key for responses: Completed, Not completed, Partially completed. Space for comments. |</p>
<table>
<thead>
<tr>
<th>To what extent have you engaged with your homework during the last week?</th>
<th>0 to 100 where 0 is NOT AT ALL and 100 is TOTALLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email 1 to arrange session 3 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Email 2 to arrange session 3 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Telephone call to arrange session 3 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Due date session 4</td>
<td>Date</td>
</tr>
<tr>
<td>Session 4 - actual date</td>
<td>Date</td>
</tr>
<tr>
<td>Session 4 - missed</td>
<td>Key for responses: Yes/No</td>
</tr>
<tr>
<td>Comments/Reasons for not attending</td>
<td>Key: Reasons for non-attendance:</td>
</tr>
<tr>
<td></td>
<td>FU – IBS flare-up</td>
</tr>
<tr>
<td></td>
<td>UW - unwell (other reason)</td>
</tr>
<tr>
<td></td>
<td>WC – work commitment</td>
</tr>
<tr>
<td></td>
<td>FC – family commitment</td>
</tr>
<tr>
<td></td>
<td>PH – phone problem</td>
</tr>
<tr>
<td></td>
<td>UK – unknown OTHER: please specify.</td>
</tr>
<tr>
<td>Duration of session 4</td>
<td>In minutes</td>
</tr>
<tr>
<td>Completion of homework</td>
<td>Key for responses: Completed, Not completed,</td>
</tr>
<tr>
<td></td>
<td>Partially completed. Space for comments.</td>
</tr>
<tr>
<td>To what extent have you engaged with your homework during the last week?</td>
<td>0 to 100 where 0 is NOT AT ALL and 100 is TOTALLY</td>
</tr>
<tr>
<td>Email 1 to arrange session 4 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Email 2 to arrange session 4 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Telephone call to arrange session 4 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Due date session 5</td>
<td>Date</td>
</tr>
<tr>
<td>Session 5 - actual date</td>
<td>Date</td>
</tr>
<tr>
<td>Session 5 - missed</td>
<td>Key for responses: Yes/No</td>
</tr>
</tbody>
</table>
| Comments/Reasons for not attending | Key: Reasons for non-attendance:  
| | FU – IBS flare-up  
| | UW – unwell (other reason)  
| | WC – work commitment  
| | FC – family commitment  
| | PH – phone problem  
| | UK – unknown OTHER: please specify.  
| Duration of session 5 | In minutes  
| Completion of homework | Key for responses: Completed, Not completed, Partially completed. Space for comments.  
| To what extent have you engaged with your homework during the last week? | 0 to 100 where 0 is NOT AT ALL and 100 is TOTALLY  
| Email 1 to arrange session 5 - date | Date  
| Email 2 to arrange session 5 - date | Date  
| Telephone call to arrange session 5 - date | Date  
| Due date session 6 | Date  
| Session 6 - actual date | Date  
| Session 6 - missed | Key for responses: Yes/No  
| Comments/Reasons for not attending | Key: Reasons for non-attendance:  
| | FU – IBS flare-up  
| | UW – unwell (other reason)  
| | WC – work commitment  
| | FC – family commitment  
| | PH – phone problem  
| | UK – unknown OTHER: please specify.  
| Duration of session 6 | In minutes  
| Completion of homework | Key for responses: Completed, Not completed, Partially completed. Space for comments.  
| To what extent have you engaged with your homework during the last week? | 0 to 100 where 0 is NOT AT ALL and 100 is TOTALLY  

<table>
<thead>
<tr>
<th>Email 1 to arrange session 6 - date</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email 2 to arrange session 6 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Telephone call to arrange session 6 - date</td>
<td>Date</td>
</tr>
<tr>
<td>Due date booster call 1</td>
<td>Date</td>
</tr>
<tr>
<td>Booster call 1 - actual date</td>
<td>Date</td>
</tr>
<tr>
<td><strong>To what extent have you continued using the strategies you learned during treatment?</strong></td>
<td>0 to 100 where 0 is NOT AT ALL and 100 is VERY MUCH</td>
</tr>
<tr>
<td>Booster call 1 - missed</td>
<td>Key for responses: Yes/No</td>
</tr>
</tbody>
</table>
| **Comments/Reasons for not attending** | Key: Reasons for non-attendance:
- FU – IBS flare-up
- UW – unwell (other reason)
- WC – work commitment
- FC – family commitment
- PH – phone problem
- UK – unknown OTHER: please specify. |
| Duration of booster call 1 | In minutes |
| Email 1 to arrange booster call 1 - date | Date |
| Email 2 to arrange booster call 1 - date | Date |
| Telephone call to arrange booster call 1 - date | Date |
| Due date booster call 2 | Date |
| Booster call 2 - actual date | Date |
| **To what extent have you continued using the strategies you learned during treatment?** | 0 to 100 where 0 is NOT AT ALL and 100 is VERY MUCH |
| Booster call 2 - missed | Key for responses: Yes/No |
### Comments/Reasons for not attending

<table>
<thead>
<tr>
<th>Key: Reasons for non-attendance:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FU</strong> – IBS flare-up</td>
</tr>
<tr>
<td><strong>UW</strong> – unwell (other reason)</td>
</tr>
<tr>
<td><strong>WC</strong> – work commitment</td>
</tr>
<tr>
<td><strong>FC</strong> – family commitment</td>
</tr>
<tr>
<td><strong>PH</strong> – phone problem</td>
</tr>
<tr>
<td><strong>UK</strong> – unknown <strong>OTHER</strong>: please specify.</td>
</tr>
</tbody>
</table>

### Variables to be recorded at the **end of therapy**:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of unplanned telephone calls</strong></td>
<td>Number</td>
</tr>
<tr>
<td><strong>Number of telephone sessions attended by partner</strong></td>
<td>Number</td>
</tr>
<tr>
<td><strong>Number of telephone sessions attended by a relative, friend</strong></td>
<td>Number</td>
</tr>
<tr>
<td><strong>Overall, how much has the participant changed since the start of the study?</strong></td>
<td>Key for responses: Very much better, Much better, A little better, No change, A little worse, Much worse, Very much worse</td>
</tr>
<tr>
<td><strong>How well has the participant adhered to treatment?</strong></td>
<td>Key for responses: Completely, Very well, Moderately well, Slightly, Not at all</td>
</tr>
<tr>
<td><strong>To what extent did the participant accept the model of therapy?</strong></td>
<td>Key for responses: Completely, Very well, Moderately well, Slightly, Not at all</td>
</tr>
<tr>
<td><strong>Other comments</strong></td>
<td>Free text</td>
</tr>
</tbody>
</table>
Variables to be collected when a participant drops out:

<table>
<thead>
<tr>
<th>Drop-out from therapy - date</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comments/Reasons for dropping out</strong></td>
<td>Key: Reasons for dropping out:</td>
</tr>
<tr>
<td></td>
<td><strong>FU</strong> – IBS flare-up</td>
</tr>
<tr>
<td></td>
<td><strong>UW</strong> - unwell (other reason)</td>
</tr>
<tr>
<td></td>
<td><strong>WC</strong> – lack of time for work commitments</td>
</tr>
<tr>
<td></td>
<td><strong>FC</strong> – lack of time for family commitments</td>
</tr>
<tr>
<td></td>
<td><strong>PH</strong> – phone problem</td>
</tr>
<tr>
<td></td>
<td><strong>UK</strong> – unknown <strong>OTHER</strong>: please specify.</td>
</tr>
</tbody>
</table>
Appendix III – Trial session record

The information in this sheet will need to be recorded during/after each session. Points 1 to 8 can be recorded in the MACRO database directly. Points 9 to 14 do not need to be logged into the MACRO database.

1. Participant number:
2. Date of session:
3. Session number:
4. Attended/cancelled/DNA:
5. Attended by partner/relative/friend (if Yes, please specify):
6. Duration of session:
7. Other contact between sessions (email, etc):
8. Question about engagement: To what extent have you engaged with your homework during the last week? 0 to 100 where 0 is NOT AT ALL and 100 is TOTALLY
9. Agenda

10. Session content

11. Homework plans

12. Points for discussion for next session

13. Action to be taken by therapist (e.g. contact GP)
Appendix IV – Review of session record

Participant number:  
Date:  
Session number:  

For supervision purposes, it would be helpful if you could complete this record after each of your treatment sessions.

<table>
<thead>
<tr>
<th>What went well?</th>
<th>Were there any difficulties?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Questions to raise in supervision

Feedback/advice from supervision

119
## Appendix V – Withdrawal / Drop-Out Report Form

Please complete at the point of withdrawal/drop-out or at the last study visit.

<table>
<thead>
<tr>
<th>1</th>
<th>Date of withdrawal / Release from ACTIB Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day / Month / Year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2</th>
<th>Who has taken the decision for this patient to drop-out of the trial?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Investigator</td>
</tr>
<tr>
<td>2</td>
<td>Patient</td>
</tr>
<tr>
<td>3</td>
<td>Therapist</td>
</tr>
<tr>
<td>4</td>
<td>Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2b</th>
<th>If other, please specify</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[text]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Has the patient withdrawn from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Treatment</td>
</tr>
<tr>
<td>2</td>
<td>Whole trial (including follow up)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4</th>
<th>Primary reason for withdrawal / release from Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient no longer meets IBS criteria (i.e. misdiagnosis not recovery)</td>
</tr>
<tr>
<td>2</td>
<td>Patient has withdrawn consent</td>
</tr>
<tr>
<td>3</td>
<td>Patient has a psychiatric diagnosis that excludes them from the trial</td>
</tr>
<tr>
<td>4</td>
<td>Patient is not able to commit time to therapy sessions</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>5</td>
<td>Patient is not able to commit time to questionnaires</td>
</tr>
<tr>
<td>6</td>
<td>There are contra-indications to the patient receiving trial treatments</td>
</tr>
<tr>
<td>7</td>
<td>Poor adherence to treatment</td>
</tr>
<tr>
<td>8</td>
<td>Deterioration of pre-existing medical condition</td>
</tr>
<tr>
<td>9</td>
<td>Patient lost to follow up</td>
</tr>
<tr>
<td>10</td>
<td>Adverse event (complete SAE form)</td>
</tr>
<tr>
<td>11</td>
<td>Protocol non-compliance (significant deviation from protocol)</td>
</tr>
<tr>
<td>12</td>
<td>Other</td>
</tr>
</tbody>
</table>

4b  If other, please specify [text]

6. Permission given to use data collected prior to drop out (tick all that apply)

<table>
<thead>
<tr>
<th>6a</th>
<th>Use of all data denied</th>
<th>1</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>777</td>
<td></td>
<td>Not available or not applicable</td>
</tr>
<tr>
<td></td>
<td>888</td>
<td></td>
<td>Not done</td>
</tr>
<tr>
<td></td>
<td>999</td>
<td></td>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6b</th>
<th>Patient lost to follow up (moved, died etc.)</th>
<th>1</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>777</td>
<td></td>
<td>Not available or not applicable</td>
</tr>
<tr>
<td></td>
<td>888</td>
<td>999</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>-----</td>
<td>-----</td>
<td></td>
</tr>
<tr>
<td>Permission to use data up to release</td>
<td>Not done</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>Permission to continue to collect follow-up data</td>
<td>1</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>777</td>
<td>Not available or not applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>888</td>
<td>Not done</td>
<td></td>
</tr>
<tr>
<td></td>
<td>999</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>Permission to use data up to release</td>
<td>6c</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permission to continue to collect follow-up data</td>
<td>6d</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix VI – Serious Adverse Event Form

ACTIB
Assessing Cognitive behavioural Therapy in Irritable Bowel

Serious Adverse Event Report Form

Instruction
In case of a Serious Adverse Event (SAE), please complete this form and fax to 023 80522299 within 24 hours and telephone/email Gilly O’Reilly 023 80241066 actibstudy@soton.ac.uk 07887517663

<table>
<thead>
<tr>
<th>Study ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

ddmmyyy

Please tick one
Initial report
Follow up report (one month)

Description of SAE………………………………………………………………………………………………………

Description of Treatment …………………………………………………………………………………………………

<table>
<thead>
<tr>
<th>Date Onset SAE ddmmyyyy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stop Date SAE ddmmyyyy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

SAE Classification

Death
Life-threatening
□ In-patient hospitalisation
□ Disability/incapacity
□ Congenital anomaly/birth defect
□ Deliberate Self harm
□ Other medical events requiring intervention to prevent one of the outcomes listed above

**Relationship to Study**

□ None
□ Remote
□ Possible
□ Probable
□ Definite

**Subject Outcome**

□ Resolved
□ Resolved with sequelae
□ Ongoing

Investigators Name ..................................................

Investigators Signature ..............................................

Date .................................................................
Appendix VII - The Suicide Behaviours Questionnaire –Revised (SBQ-R)


Patient Name ______________________________ Date of Visit ___________________

Instructions: Please check the number beside the statement or phrase that best applies to you.

1. Have you ever thought about or attempted to kill yourself? (Check only one)

☐ 1. Never
☐ 2. It was just a brief passing thought
☐ 3a. I have had a plan at least once to kill myself but did not try to do it
☐ 3b. I have had a plan at least once to kill myself and really wanted to die
☐ 4a. I have attempted to kill myself, but did not want to die
☐ 4b. I have attempted to kill myself, and really hoped to die

2. How often have you thought about killing yourself in the past year? (Check only one)

☐ 1. Never
☐ 2. Rarely (1 time)
☐ 3. Sometimes (2 times)
☐ 4. Often (3-4 times)
☐ 5. Very Often (5 or more)

3. Have you ever told someone that you were going to commit suicide, or that you might do it? (Check only one)

☐ 1. No
☐ 2a. Yes, at one time, but did not really want to die
☐ 2b. Yes, at one time, and really wanted to die
☐ 3a. Yes, more than once, but did not want to do it
☐ 3b. Yes, more than once, and really wanted to do it

4. How likely is it that you will attempt suicide one day? (check only one)

☐ 0. Never
☐ 1. No chance at all
☐ 2. Rather unlikely
☐ 3. Unlikely
☐ 4. Likely
☐ 5. Rather likely
☐ 6. Very likely
### SBQ-R Scoring

**Item 1: taps into lifetime suicide ideation and/or suicide attempts**

<table>
<thead>
<tr>
<th>Selected response 1</th>
<th>Non-Suicidal sub-group</th>
<th>1 point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selected response 2</td>
<td>Suicide Risk Ideation sub-group</td>
<td>2 points</td>
</tr>
<tr>
<td>Selected response 3a or 3b</td>
<td>Suicide Plan sub-group</td>
<td>3 points</td>
</tr>
<tr>
<td>Selected response 4a or 4b</td>
<td>Suicide Attempt sub-group</td>
<td>4 points</td>
</tr>
</tbody>
</table>

**Total Points**

**Item 2: assesses the frequency of suicidal ideation over the past 12 months**

<table>
<thead>
<tr>
<th>Selected Response:</th>
<th>1 point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>1 point</td>
</tr>
<tr>
<td>Rarely (1 time)</td>
<td>2 points</td>
</tr>
<tr>
<td>Sometimes (2 times)</td>
<td>3 points</td>
</tr>
<tr>
<td>Often (3-4 times)</td>
<td>4 points</td>
</tr>
<tr>
<td>Very Often (5 or more times)</td>
<td>5 points</td>
</tr>
</tbody>
</table>

**Total Points**

**Item 3: taps into the threat of suicide attempt**

<table>
<thead>
<tr>
<th>Selected response 1</th>
<th>1 point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selected response 2a or 2b</td>
<td>2 points</td>
</tr>
<tr>
<td>Selected response 3a or 3b</td>
<td>3 points</td>
</tr>
</tbody>
</table>

**Total Points**

**Item 4: evaluates self-reported likelihood of suicidal behaviour in the future**

<table>
<thead>
<tr>
<th>Selected Response</th>
<th>0 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>0 points</td>
</tr>
<tr>
<td>No chance at all</td>
<td>1 point</td>
</tr>
<tr>
<td>Rather unlikely</td>
<td>2 points</td>
</tr>
<tr>
<td>Likelihood</td>
<td>Points</td>
</tr>
<tr>
<td>------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Unlikely</td>
<td>3</td>
</tr>
<tr>
<td>Likely</td>
<td>4</td>
</tr>
<tr>
<td>Rather Likely</td>
<td>5</td>
</tr>
<tr>
<td>Very Likely</td>
<td>6</td>
</tr>
</tbody>
</table>

Sum all of the scores circled/checked by the respondents. The total score should range from 3 to 18

**Total Score:**

Total SBQ-R: a cut-off of ≥7 indicating suicide risk
Appendix VIII - Prompt sheet for Telephone calls: Information to be logged each session

☑ Due date of session
☑ Actual date
☑ Whether the session was missed
☑ Reason for missed session
☑ Duration of session (minutes)
☑ Date of emails and phone calls to arrange session

After all sessions for a participant have been entered therapists will be required to enter the following information:

☑ Number of unplanned telephone calls (from participant to therapist for advice)
☑ Number of telephone sessions attended by partner
☑ Number of telephone sessions attended by a relative or friend
☑ Drop out date (if applicable)
☑ Reasons for drop out (if applicable)
☑ Rating of participant change (very much better to very much worse)
☑ Rating of participant adherence to the homework
☑ Rating of the extent that the participant accepted the model of therapy
☑ Any other comments
## Appendix IX - Self-monitoring symptom sheet

<table>
<thead>
<tr>
<th>Pain and Stress Ratings</th>
<th>Diarrhoea</th>
<th>Constipation</th>
<th>Meals</th>
<th>Behaviour changes because of symptoms</th>
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</thead>
<tbody>
<tr>
<td>0 - 10</td>
<td>Number of times (T)</td>
<td>Number of attempts (a)</td>
<td>Missed (ms)</td>
<td>Small (s)</td>
</tr>
<tr>
<td>None - Severe</td>
<td>Accidents (A)</td>
<td>Time straining (t)</td>
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<td></td>
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</tbody>
</table>

### Monday
- Pain =
- Stress =
- T =
- A =
- a =
- t =

**Breakfast:**
- time______

**Lunch:**
- time______

**Dinner**
- Time______

### Tuesday
- Pain =
- Stress =
- T =
- A =
- a =
- t =

**Breakfast:**
- time______

**Lunch:**
- time______

**Dinner**
- Time______
<table>
<thead>
<tr>
<th></th>
<th>Pain</th>
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<th>a</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wednesday</strong></td>
<td></td>
<td></td>
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<td>Breakfast: time</td>
<td>Lunch: time</td>
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<td>Stress</td>
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<td><strong>Thursday</strong></td>
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<td>Breakfast: time</td>
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<tr>
<td>Pain</td>
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<td>Breakfast: time</td>
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<td>Pain</td>
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<td>Day</td>
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<td>Time</td>
<td>Activity</td>
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<td>Time_____</td>
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</table>
### Appendix X- IBS Goal Sheet For Chapter 3: Managing your Symptoms and Eating

Write your goals in the column provided for each section. If a section does not apply to you, leave it out. In the columns marked Monday – Sunday, tick if you have achieved the goals, or cross if you did not manage to meet your target. If a goal is set for only a few days a week, leave the other days blank and tick or cross on the chosen day(s).

**Managing Diarrhoea:**

<table>
<thead>
<tr>
<th>Goals</th>
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<th>Fri</th>
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**Managing Constipation:**

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**Eating:**

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</table>
Appendix XI- IBS Goal Sheet For Chapter 4: Exercise and Activity

Write your goals in the column provided for each section. If a section does not apply to you, leave it out. In the columns marked Monday – Sunday, tick if you have achieved the goals, or cross if you did not manage to meet your target. If a goal is set for only a few days a week, leave the other days blank and tick or cross on the chosen day(s).

**Managing Diarrhoea:**

<table>
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<th>Goals</th>
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**Managing Constipation:**

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**Eating:**

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<th>Goals</th>
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**Exercise and Activity Patterns:**

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</table>
### Appendix XII- Thought Record: Chapter 5

<table>
<thead>
<tr>
<th>Date</th>
<th>Situation</th>
<th>Feeling</th>
<th>Negative thought</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>What I was doing</td>
<td></td>
<td><em>What I was thinking (in detail)</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>(Any thinking errors?)</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Situation</th>
<th>Feeling</th>
<th>Negative thought</th>
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134
Appendix XIII - IBS Goal Sheet Chapter 5: Identifying your thought patterns

Write your goals in the column provided for each section. If a section does not apply to you, leave it out. In the columns marked Monday – Sunday tick if you achieved the goals or cross if you did not manage to meet your target. If a goal is set for only a few days a week, leave the other days blank and tick or cross on the chosen day(s).

**Managing Diarrhoea**

<table>
<thead>
<tr>
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**Managing Constipation**

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**Eating**

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**Exercise and activity patterns**

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Appendix XIV - Alternative Thought Record: Chapter 6

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<th>Situation</th>
<th>Feeling</th>
<th>Negative thought</th>
<th>Alternative thought</th>
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<tbody>
<tr>
<td></td>
<td>What I was doing</td>
<td></td>
<td>What I was thinking</td>
<td>Plus rating of the unhelpful thought (0-100%)</td>
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<td>Plus rating of the new thought (0-100%)</td>
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</table>
Appendix XV - IBS Goal Sheet For Chapter 6: Alternative thoughts

Write your goals in the column provided for each section. If a section does not apply to you, leave it out. In the columns marked Monday – Sunday tick if you achieved the goals or cross if you did not manage to meet your target. If a goal is set for only a few days a week, leave the other days blank and tick or cross on the chosen day(s).

### Managing Diarrhoea

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### Managing Constipation

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Appendix XVI - IBS Goal Sheet For Chapter 7: Learning to relax, improving sleep and managing stress

Write your goals in the column provided for each section. If a section does not apply to you, leave it out. In the columns marked Monday – Sunday tick if you achieved the goals or cross if you did not manage to meet your target. If a goal is set for only a few days a week, leave the other days blank and tick or cross on the chosen day(s).

**Learning to relax, improving sleep**

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**Changing Activity Patterns**

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**Managing Diarrhoea and/or constipation**

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**Diet and Exercise**

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Appendix XVII - Long-term goal sheet: Chapter 8

1. Goal: _____________________________________________________

Steps:
   a. _______________________________________________________
   b. _______________________________________________________
   c. _______________________________________________________
   d. _______________________________________________________

2. Goal: _____________________________________________________

Steps:
   a. _______________________________________________________
   b. _______________________________________________________
   c. _______________________________________________________
   d. _______________________________________________________

3. Goal: _____________________________________________________

Steps:
   a. _______________________________________________________
   b. _______________________________________________________
   c. _______________________________________________________
   d. _______________________________________________________
Appendix XVIII – GP Letter Intro to Trial

[SLaM Header]

[Therapist address and contact]

[Date]

Dear [GP Name]

Re: [Participant name] participation in the ACTIB (Assessing Cognitive Therapy in Irritable Bowel) trial

I am writing to inform you that [participant name] has consented to take part in the ACTIB trial and has been randomised to the [high intensity CBT / low intensity CBT condition]. This involves [6/3] telephone sessions with myself over the course of the next 9 weeks along with use of a CBT [manual/website] tailored for use in IBS patients.

The participant has been advised to procedure with usual medical care.

You will be contacted by myself should any serious adverse events occur. If you require more information about the trial you can contact the two members of the trial team I have included below.

Best Wishes

[therapist name]

Research Assistant: Sula Windgassen Tel: 0203 228 3557 Email: sula.1.windgassen@kcl.ac.uk

Research Assistant: Alice Sibelli Tel: 0207 188 0179 Email: alice.sibelli@kcl.ac.uk
# Appendix XIX – Contact List

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Location</th>
<th>Email</th>
<th>Phone Number</th>
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<tbody>
<tr>
<td>Dr Hazel Everitt</td>
<td>Chief Investigator</td>
<td>Southampton</td>
<td><a href="mailto:H.A.Everitt@soton.ac.uk">H.A.Everitt@soton.ac.uk</a></td>
<td>0238 024 1052</td>
</tr>
<tr>
<td>Dr Gilly O'Reilly</td>
<td>Trial Manager</td>
<td>Southampton</td>
<td>G.O'<a href="mailto:Reilly@soton.ac.uk">Reilly@soton.ac.uk</a></td>
<td>0238 024 1066</td>
</tr>
<tr>
<td>Prof Rona Moss-Morris</td>
<td>LICBT Therapist Supervisor</td>
<td>London, Guy's Hospital</td>
<td><a href="mailto:rona.moss-morris@kcl.ac.uk">rona.moss-morris@kcl.ac.uk</a></td>
<td>020 7188 0180</td>
</tr>
<tr>
<td>Prof Trudie Chalder</td>
<td>HICBT Therapist Supervisor</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:Trudie.chalder@kcl.ac.uk">Trudie.chalder@kcl.ac.uk</a></td>
<td>0207 848 0406</td>
</tr>
<tr>
<td>Stephanie Hughes</td>
<td>Research Assistant/technical &amp; web support</td>
<td>Southampton</td>
<td><a href="mailto:sh3r11@southampton.ac.uk">sh3r11@southampton.ac.uk</a></td>
<td>023 8052 2286</td>
</tr>
<tr>
<td>Alice Sibelli</td>
<td>Research Assistant/therapist allocation &amp; qualitative interviewer</td>
<td>London, Guy's Hospital</td>
<td><a href="mailto:Alice.sibelli@kcl.ac.uk">Alice.sibelli@kcl.ac.uk</a></td>
<td>027 188 0179</td>
</tr>
<tr>
<td>Sula Windgassen</td>
<td>Research Assistant/data manager &amp; participant follow up coordinator</td>
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<td><a href="mailto:Sula.1.windgassen@kcl.ac.uk">Sula.1.windgassen@kcl.ac.uk</a></td>
<td>0203 228 3557</td>
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<tr>
<td>Dr Flis Bishop</td>
<td>Qualitative Lead, University of Southampton</td>
<td>Southampton</td>
<td><a href="mailto:f.l.bishop@soton.ac.uk">f.l.bishop@soton.ac.uk</a></td>
<td>02380 599020.</td>
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<tr>
<td>Dr Mary Burgess</td>
<td>CBT therapist</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:Mary.Burgess@slam.nhs.uk">Mary.Burgess@slam.nhs.uk</a></td>
<td>020 3228 5075</td>
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<tr>
<td>Dr Antonia Dittner</td>
<td>Clinical Psychologist</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:Antonia.Dittner@slam.nhs.uk">Antonia.Dittner@slam.nhs.uk</a></td>
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<tr>
<td>Dr Caroline Stokes</td>
<td>Clinical Psychologist</td>
<td>London, Denmark Hill</td>
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<tr>
<td>Barbara Bowman</td>
<td>CBT therapist</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:Barbara.Bowman@slam.nhs.uk">Barbara.Bowman@slam.nhs.uk</a></td>
<td>020 3228 82986</td>
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<tr>
<td>Suzanne Roche</td>
<td>CBT therapist</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:Suzanne.Roche@slam.nhs.uk">Suzanne.Roche@slam.nhs.uk</a></td>
<td>020 3228 83112</td>
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<tr>
<td>Morufat Raji</td>
<td>Therapist Administrator</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:Morufat.Raji@slam.nhs.uk">Morufat.Raji@slam.nhs.uk</a></td>
<td>0203 228 3362</td>
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<tr>
<td>Andrea Bardsley-Ball</td>
<td>Therapist Administrator</td>
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<td><a href="mailto:Andrea.Bardsley-Ball@slam.nhs.uk">Andrea.Bardsley-Ball@slam.nhs.uk</a></td>
<td>0203 228 5075</td>
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<tr>
<td>Dr Robert Logan</td>
<td>Gastroenterologist</td>
<td>London, King's College Hospital</td>
<td><a href="mailto:robert.logan@nhs.net">robert.logan@nhs.net</a></td>
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<tr>
<td>Dr Nicholas Coleman</td>
<td>Gastroenterologist</td>
<td>Southampton, Southampton General Hospital</td>
<td><a href="mailto:Nicholas.Coleman@suht.swest.nhs.uk">Nicholas.Coleman@suht.swest.nhs.uk</a></td>
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<tr>
<td>Dr Sabine Landau</td>
<td>Statistician</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:sabine.landau@kcl.ac.uk">sabine.landau@kcl.ac.uk</a></td>
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<tr>
<td>Nick Magill</td>
<td>Statistician</td>
<td>London, Denmark Hill</td>
<td><a href="mailto:nicholas.magill@kcl.ac.uk">nicholas.magill@kcl.ac.uk</a></td>
<td>020 7848 0323</td>
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## Appendix XX Non-Serious Adverse Events Log

This log is to be completed for all adverse events reported by the participant. Serious Adverse Events should be reported using the SAE report Form. When complete fax to the research team 023 80522299 or email to g.o’reilly@soton.ac.uk

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<th>Start date of AE</th>
<th>Stop date of AE (if known)</th>
<th>Description of Adverse Event</th>
<th>Was the event related to trial treatment</th>
<th>Has participant withdrawn from trial follow-up</th>
<th>Please rate the severity of the event</th>
<th>Any medication or therapy taken as a result</th>
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Dear [GP Name]

Re: ACTIB Trial Serious Adverse Event Notification [Participant name]

I am writing to inform you that during the course of [his/her] involvement in the ACTIB trial receiving [High intensity CBT over the phone OR low intensity web-delivered CBT], [participant name] has suffered a [SAE type].

This is [not] thought to be related to their involvement with the trial and [participant name] will [not] be continuing to participate in the trial. I shall notify you should these circumstances change.

Best Wishes

[therapist name]
Dear [GP Name]

Re: ACTIB Trial [Low Mood]/ [Suicide Risk]/ [Suicide Attempt] [Participant name]

I am writing to inform you that during the course of [his/her] involvement in the ACTIB trial receiving [High intensity CBT over the phone OR low intensity web-delivered CBT], [participant name] has recently been deemed to [have a particularly low mood] OR [be a potential suicide risk] OR [have made an attempt at suicide].

This is [not] thought to be related to their involvement with the trial. [Participant name] will [not] be continuing to participate in the trial as it is not deemed appropriate in the present circumstances. I have informed [participant] that I will be contacting you and have recommended that [he/she] makes an appointment.

Best Wishes

[therapist name]
Appendix XXIII: Negative Thought Patterns

Below are the negative patterns of thinking as described in the Participant manual and referred to on page 86 of the therapist manual.

- **“Shoulds”**

  Many thoughts include the word ‘should’. The word ‘should’ implies that there is a standard or fixed rule that must be followed. It can apply to us or to others. We may continually feel that others ‘should’ act in a certain way. We also may spend quite a lot of time telling ourselves how we ‘should’ be acting.

  This can get us into thinking problems as it fills us with expectations of others and ourselves that are: 1) probably not possible and 2) leave us feeling disappointed or upset. The problem with ‘should’ thoughts is that they are often not attainable in reality and so they leave us constantly upset at the violation of them.

- **Black and White Thinking**

  The tendency to think in black and white or in absolutes is another common thinking error. These thoughts often contain a ‘never’ or ‘always’ statement. As IBS is an ongoing problem, it is not uncommon for people to start to think about their illness in terms of “always having it” or “never getting better”.

  Other examples may occur in other areas of your day-to-day life. You may think, “I am never on time”, however, chances are that you will be on time, at least some of the time! You may have thoughts such as “I always mess things up”. This type of thought is not only highly unlikely, but also powerfully underlies feelings of insecurity or low self-esteem. There are few absolutes in the world, so the use of never or always is seldom warranted.

  We may also have these thoughts about other people such as “she never considers how I might be feeling”. Realistically, never and always are rarely appropriate when thinking about others or ourselves.

- **Catastrophising**

  As you can see from the long list of examples, catastrophising is a very common thinking error. This is the tendency to think the worst about things. Catastrophisers tend to get things out of proportion which often leads to unnecessary feelings of anxiety, panic or distress. For instance, Sally starts to worry when her husband is five minutes late from work, convinced that he has been in an accident. When he arrives home safe and sound thirty minutes later, she has made herself feel sick with worry.
Catastrophisers often jump to conclusions about future events and imagine the worst possible outcome. For example, John has been told that his IBS is not a life-threatening condition. However, he is convinced that the doctor is saying that because he doesn’t know what’s wrong with him. John thinks that the doctor probably doesn’t know what is wrong because he has a rare form of terminal cancer.

- **Overgeneralising**

When we overgeneralise, we come to conclusions based on one experience or aspect of a situation. For example, Joan thinks, “I’ve tried changing my daily routine before, it didn’t work then, why should it work now”.

- **Predicting the Future**

Without realising it many of us have negative thoughts about future events. If we think we are going to feel bad we often land up doing so. However, none of us can really predict what is going to happen in the future.

- **Eliminating the Positive**

It is often easy to dwell on the bad aspects of experiences and to ignore or forget about the good aspects. For instance, Jeremy’s boss gives him some feedback about his work. Most of this is very positive but he tells Jeremy that he needs to be a bit more assertive in meetings. Jeremy goes home thinking that he is doing a terrible job. In this situation Jeremy has ignored the fact that most of the information is positive and has only focused on the negative.

- **Mind Reading**

We constantly make assumptions about what others are thinking about us. These assumptions are usually negative, such as “Because my house is a mess, they must think I am a lazy housekeeper.” The truth of the matter is most people are too concerned about the impression they are making on you to have time to pass judgements. Some people are very critical but it is worth thinking about whether these people’s opinions need to matter that much to us.

- **High expectations and unhelpful aspects of perfectionism (please refer to pages 70-72 of the Participant Manual for more details).**

  - **Unhelpful aspects of perfectionism:**

If you are a perfectionist you may be unhappy with your work unless it is exceptional, or with your house unless it is immaculately clean. You may spend so much time on achieving your high standards that there is not much time left over for more pleasurable activities. You may feel that you, or others, are never good enough which may lead you to be overly critical. You may feel anxious about the things that you do in case the result is not perfect. This can take out the enjoyment of doing things.
In addition, perfectionists can sometimes be intimating to others. People around you may be unable to achieve your high standards and feel inadequate in comparison. They may feel that you are critical of what they do because it is not as good as what you can or think you can achieve.

0 Negative thoughts and perfectionism:

Perfectionism can trigger negative thoughts when we hold ourselves accountable to unreasonable and unrealistic standards. There are a number of irrational beliefs, which are related to perfectionism. These beliefs can generate ongoing negative thoughts about ourselves and the people around us.

The irrational beliefs include: “People around me must love and approve of me.” In fact it is impossible to please all the people in your life. Even those who love you may be turned off by some of your behaviours and qualities. This doesn’t mean that they do not care for you. It just means that there are certain things about you that they don’t like as much. Similarly, there will be things about the people you love that turn you off at times.

0 Underlying irrational beliefs:

1. I must be unfailingly competent in everything I undertake. It is impossible to be competent at everything you do. The price you pay for this belief is self-blame if you fail, lowered self-esteem and a fear of failing if you try something new. This belief also leads you to push yourself too hard to meet these self-imposed standards.

2. If I don’t go to great lengths to please others they will reject me. Interestingly, if we try to please others all the time we often fail to do so. If you allow the real you to show, a positive response from someone relates to the real you and you don’t need to worry about letting your guard slip or doing the wrong thing. If you constantly try to please others you may find you have very little time left over for yourself.

3. If people disapprove of me, it means I am wrong or bad. It is impossible for everyone to like you just the same, as it is impossible for you to like everyone around you. This belief sparks chronic anxiety and is based on an unrealistic expectation of people’s response to you.

4. My worth as a person depends on how much I achieve or produce. A more rational assessment of your worth would depend on your capacity to enjoy things in life and to make the most of opportunities presented to you.
References


