

Participant Information Sheet

ACTIB (Assessing Cognitive behavioural Therapy in Irritable Bowel): A randomised controlled trial of clinical and cost effectiveness of therapist delivered cognitive behavioural therapy and web-based self-management in irritable bowel syndrome

Chief Investigator: Dr Hazel Everitt, Clinical Lecturer in General Practice, University of Southampton

Please read this information carefully before deciding to take part in this project. If you are happy to participate please return the reply slip in the FREEPOST envelope that is enclosed with this letter.

What is the project about?

We are a group of researchers based at the Department of Primary Medical Care at the University of Southampton and the Institute of Psychiatry, at King's College London undertaking studies into the management of Irritable Bowel Syndrome (IBS)

Why have I been chosen?

You have received this letter because you have consulted your GP in the last 12 months about IBS or you are currently seeing a consultant about your symptoms.

Do I have to take part?

Participation in the project is entirely voluntary. It is up to you to decide whether to take part. You are able to withdraw at any time without giving a reason. If you decide to withdraw or not to take part in this study this will not affect the standard of care you receive.

What will happen to me if I take part?

If you decide you would like to take part we would ask you to return the reply slip at the bottom of the attached letter to the study team. You can also email them directly or contact them by phone using the details at the end of this sheet.

A member of the team will then go through some questions with you to make sure that you are suitable to take part in the study. If you are eligible to take part you will then be asked to have a blood test to make sure you are not anaemic and that there are no signs that your bowel symptoms are due to other illnesses.

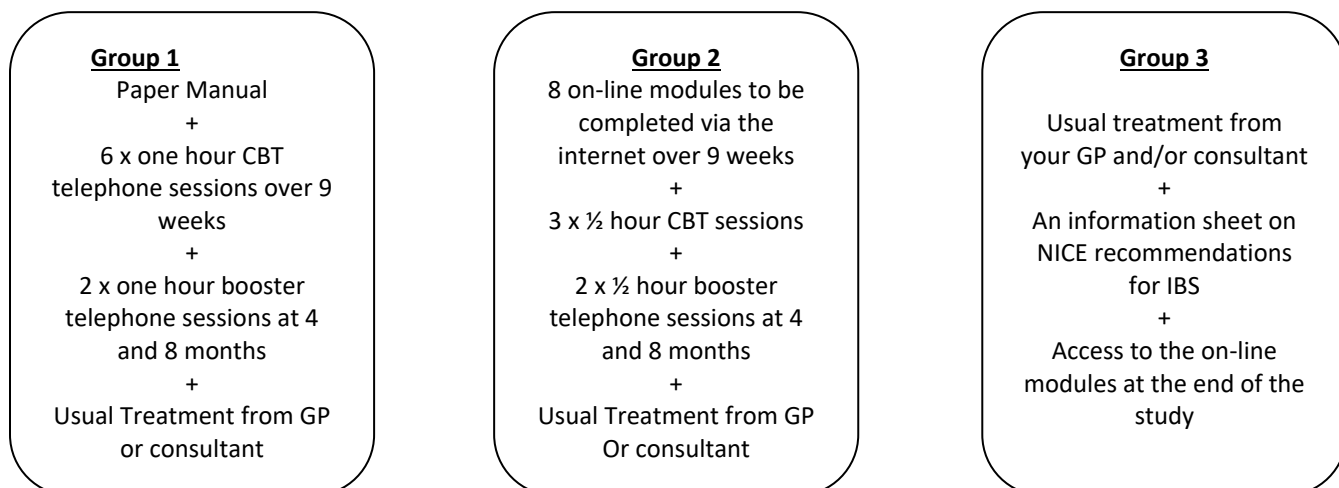
The blood test is a straightforward, safe procedure but may cause some minor discomfort and you may notice some slight bruising which should subside in a couple of days. The blood will be sent for analysis to the Pathology Laboratory at Southampton General Hospital.

As part of this study, you will continue to receive treatment as usual from your doctor as you normally do and can continue using any medication that you currently find helpful. However, you will also have the opportunity for additional treatment which has been shown to reduce IBS symptoms in previous studies. You won't be able to choose which treatment as a computer system will allocate you to one of three groups at random (see box diagram below for details). People in group 1 will receive a manual about managing their IBS as well as six one hour sessions with cognitive behavioural therapist (CBT) over the telephone over a 9 week period with two one hour extra telephone sessions at 4 and 8 months to see how they are doing. Sessions will be scheduled at times that suit you. We will endeavour to use the same therapists for you throughout your participation in the trial.

People in group 2 will have access to a self-management website for IBS consisting of 8 on-line modules to complete in their own time on the internet over 9 weeks. In addition, they will receive

three half hour support sessions with a CBT therapist over the telephone. These will be followed up with two half hour booster telephone sessions at 4 and 8 months to see how people are doing.

People in group three will initially just receive an extra information sheet about their conditions. However at the end of the study they will be given access to the IBS self-management website.



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Both the therapy manual and the self-management on-line programme are designed to help you manage your IBS and consists of 8 sessions or 'modules' to work through over a nine week period. The website group (group 2) will do this largely on their own. Each module takes around 30-45 minutes to complete. The therapy group (group 1) will do this in conjunction with a therapist.

Examples of the type of material covered in the modules are:

- Understanding your IBS symptoms
- Assessing your symptoms,
- Managing Symptoms and Eating, Exercise and Activity
- The role of thoughts and emotions in IBS
- Managing Stress and Sleep
- Managing Flare-ups and
- The Future.

During your participation of the study we will ask you to fill in an on-line questionnaire at the start and 3, 6, 12 and 24 months to assess your IBS symptoms and ask you about how you are feeling and how you believe your quality of life is.

You will also be asked to keep a simple log of homework tasks to be completed.

At the end of the study, we will also check your GP notes to see how many appointments you have had for your IBS in the 12 months before you came into the study and for the 12 months after you entered the study.

We will also ask a small number of people who enter the study if they would like to take part in an interview which should last between 30 and 60 minutes about how it was taking part in the study and any useful feedback they can give us about the study. You will have the option to agree to this or not and it is entirely up to you to decide.

Are there any benefits in my taking part?

Previous studies suggest that your IBS symptoms will be helped by the therapist or the self-management programme, however we cannot guarantee change in your symptoms. Your information will help us gain more knowledge regarding the website programme and the therapist treatment used in the trial, the cost of each and whether we should offer either of these routinely to people with IBS.

Will my participation be confidential?

All information that you provide will be strictly confidential. You will be identified by an ID number and the information you provide will be stored in locked filing cabinets or a password protected computer. The study will fully comply with the Data Protection Act and University policy on conducting research studies.

Your GP will be informed that you are participating in the study, so that they are aware that you are receiving additional support for your IBS. The self –management website is a secure website and any information you provide on the website is only accessible to you and select people in the research team.

Who is organising the funding?

The study is funded by the NHS as part of the National Institute of Health Research (NIHR) Health Technology Assessment (HTA) funding stream.

Who is managing the study?

The study is being sponsored by the University of Southampton who will monitor the study regularly to make sure that everything is being done as agreed at the start. The Berkshire Research Ethics committee has reviewed the study and are happy for it to go ahead (Reference: 13/SC/0206).

What happens if something goes wrong?

If you have complaints about the way your illness was managed, this study will not affect your normal rights to pursue a complaint within the NHS in the normal way.

If you were to have any concern or complaint about this project you can contact the head of Research Governance at the University of Southampton – Diana Galpin, University of Southampton, Highfield Campus, Southampton, SO17 1BJ Telephone: 023 8059 5058D.Galpin@soton.ac.uk

Where can I get more information?

If you have any questions about this research after reading this information sheet please contact the Trial Manager Gillian O'Reilly, Primary Care and Population Sciences, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST. Telephone 02380 241066 email actibstudy@soton.ac.uk

