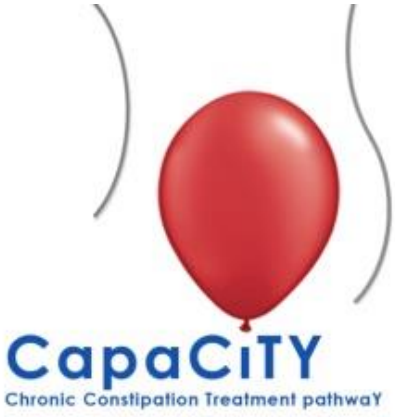
Queen Mary University of London

Insert Trust Logo

Did you know, 1 in 10 people suffers from chronic constipation? To find out more about current treatments we are studying, please read this information sheet.



Chronic Constipation Treatment pathwaY study 1 (CapaCiTY01); is a study comparing habit training and direct visual biofeedback, two specialist treatments for chronic constipation in adults.

Invitation to participate:

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. One of our team will go through the information sheet with you and answer any questions you have. We'd suggest this should take about 15 minutes. We will give you at least a day to make your decision, but you can take as much time as you like. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what it involves. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear.

Part 1: About the research

What is the purpose of the study?

Constipation is a common condition that most people will suffer with at some point in their life. In some people the symptoms can become chronic and severely affect their day-to-day activities.

Chronic constipation is described as someone having symptoms that last for over 6 months and has not responded to simple diet and lifestyle changes and laxatives. The condition can be very difficult to treat even in specialist centres. The treatments available include laxatives, newer drugs, specialist led bowel retraining programmes and surgery. There are also specialised investigations that can be carried out to see if an underlying cause can be found. However, the benefits of these tests are still unclear.

The main aim of this study is to compare two specialist led bowel retraining programmes. The study will look at how well the symptoms of chronic constipation improve with each. In addition, the cost effectiveness of both treatments to the NHS will be assessed, and the helpfulness of investigations in guiding treatment will also be studied. This research is taking place at 10-16 NHS centres across the UK and this study will be 1 of 3 studies taking place over 5 years to develop a treatment pathway for adults with chronic constipation. You may be asked if you wish to participate in more than one study.

Why have I been invited?

You have been asked to take part in this study because you are between the ages of 18 and 70 and have symptoms of chronic constipation.

Do I have to take part?

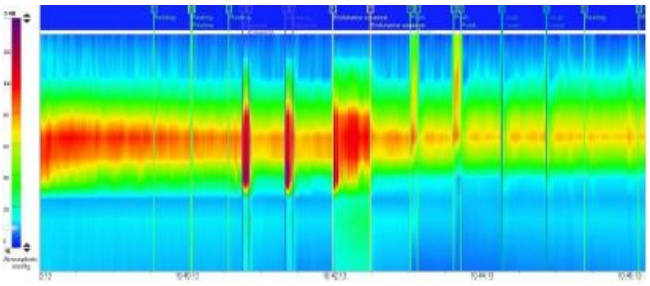
Participation is entirely voluntary. It is up to you to decide to join the study. We will describe the study and take you through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. If you decide not to participate, or withdraw at any time, the standard of care you receive will not be affected.

What will happen to me if I take part?

Your participation in this study will last for up to 12 months after treatment and requires up to 8 visits to the hospital (as outlined below). Each visit will take up to 1 hour. This study is a randomised trial, which means we put people into 3 different groups and give each group a different treatment. The results are then compared to see if one is better than the others. To try to make sure the groups are the same to start with, each patient is put into a treatment group by chance (randomly). This is because sometimes we don't know which way of treating patients is best. Patients have a 1 in 3 chance of going to each of the groups:

Group 1: specialist-led bowel retraining

Group 2: specialist-led bowel retraining with a form of visual prompting (called biofeedback)



Group 3: bowel retraining with or without biofeedback based on the results of specialist investigations (below).

Specialist Gastrointestinal (GI) Physiological Investigations (Group 3 only): If randomly allocated to this group, you will then have a number of more precise tests outlined below, looking at the structure of the lower bowel and back passage, how it works and any abnormalities. This may require 1-2 extra visits to the hospital and waiting times of 4-12 weeks, which is the normal NHS waiting time for these tests. We will endeavour to keep waiting times to a minimum (average 4 weeks). You will not need to repeat these tests if performed in the last 12 months. Two of these tests include X-rays with a very small dose of radiation, equivalent to about 7 months background radiation dose from living in the UK.

1. Anorectal manometry with sensory testing– this includes insertion of a balloon catheter into the back passage to measure sensation and contractions and also your ability to push out the balloon.

2. Evacuating proctogram – A mixture of barium paste and soft solids such as oatmeal is inserted into the rectum, following which you will be asked to sit upon a commode and to push the paste out. The barium shows up on X-Ray, and can thus be seen on a fluoroscope, a kind of X-Ray television. A privacy screen will be placed around the commode so no one is directly watching you (only your X-ray).
3. Gut transit study – measures the movement of food through the stomach and intestines. This requires you to swallow 3 gel capsules (size of a normal antibiotic capsule) filled with markers that will show up on an X-ray. The markers look like white spots or rings in the X-ray pictures, taken 120 hours after swallowing the capsules. You will be required to stop taking laxatives before having this test.

Visit 1: Initially you will have a medical history taken and a physical examination including a brief examination of your back passage (if not already performed) and be given questionnaires and a diary to complete. You will then be randomly assigned to one of the three groups (please see figure 2 below).

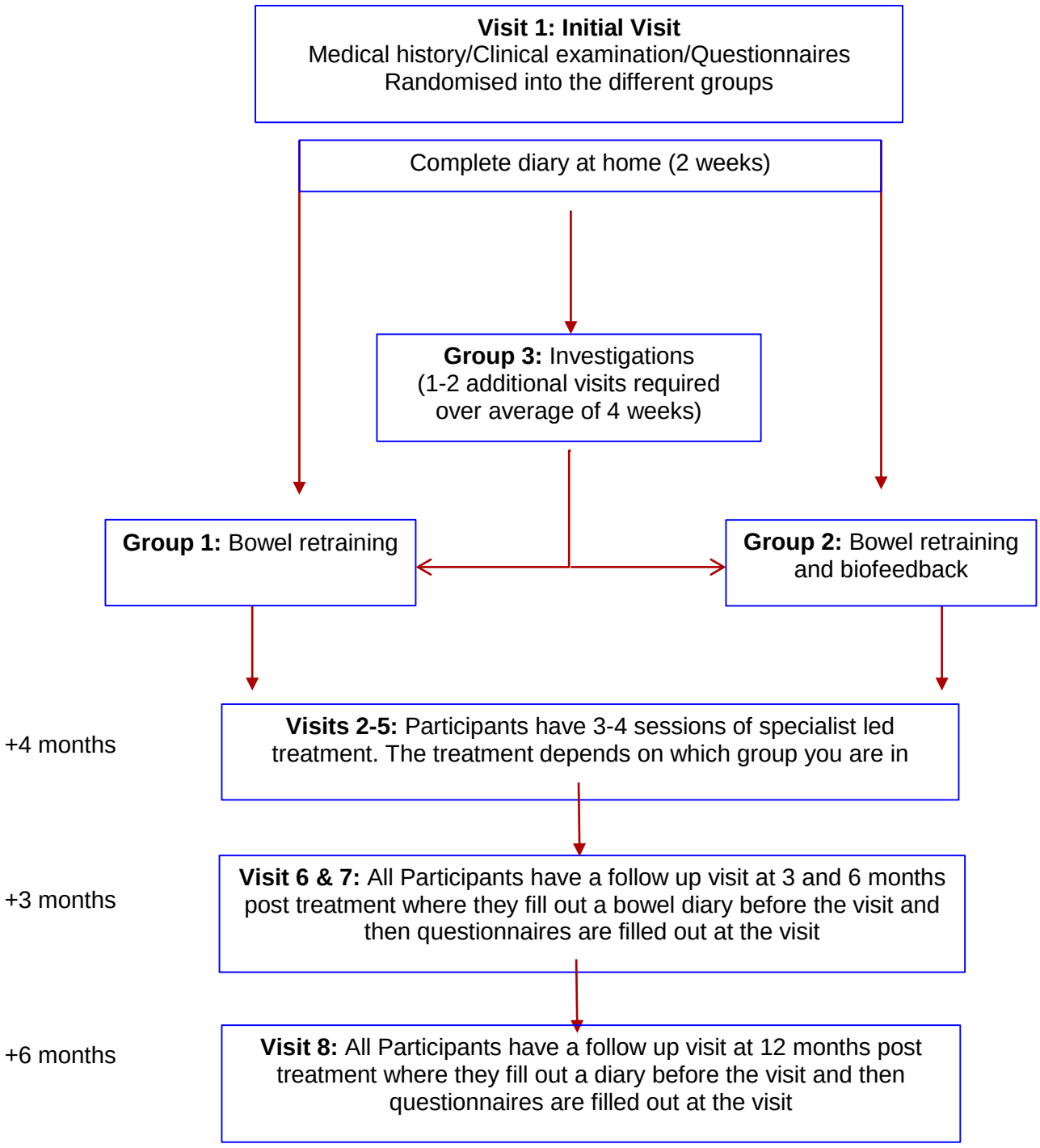
Visit 2-5: You will receive a maximum of 4 treatment visits at monthly intervals. Both groups will have general bowel retraining; this involves looking at, and correcting where necessary, behaviours around going to the toilet, including stopping laxatives. Initially a baseline assessment will be taken followed by advice on how and when to go to the toilet, as well as any suggested lifestyle changes that can be made. Life style changes can include your fibre intake or how much fluid you drink. Some sessions may be done over the phone if this is your wish, but the first and last will be face to face.

One group will also have a procedure known as biofeedback, which is used to train your muscles. A small catheter and balloon, connected to a computer, is inserted into your back passage. As you tighten or relax your muscles, these changes can be seen on a computer screen. Visualising this information with the aid of a specialist will help you learn to use the correct muscles. We understand the procedure may cause some embarrassment, however, your dignity will be maintained at all times as much as is possible. The techniques you learn can then be practiced at home.

Visits 6-8: You will then be followed up initially 3 months after treatment and then after 6 and 12 months. At these follow up visits you will be asked to complete further questionnaires and diaries. Each diary will take a couple of minutes to complete at the end of each day for two weeks. The Questionnaires should take 10-20 minutes in total to complete.

You may also be approached to take part in one to one interviews. This is up to you to decide separately to this part of the study. If you are interested, your contact details will be used by Kings College London researchers to give you further information and you will be consented to take part at a later date.

Figure 2: Participant flow chart



What will I have to do?

If you choose to be part of this study, it is important for you to:

- Attend your visits on the scheduled dates
- Complete your diaries and questionnaires.
- Follow the instructions you receive during the visits

Expenses and Payments

If you decide to take part you will be reimbursed for your expenses incurred with the extra visits to hospital. This will be £60 given out over the course of the study (e.g. £20 on completion of visit 1, visit 6 and visit 8).

What are the possible disadvantages, risks and side effects of taking part?

The study involves procedures that are done routinely in normal care and have been done daily in specialist centres for up to 30 years. Two of the routine tests use X-rays. We are all exposed daily to 'Background Radiation' that comes from natural sources all around us. The X-rays you could receive during the tests are equal to less than 7 months of background radiation and considered minimal risk. You will not be able to choose which treatment you receive. As there will be use of X-rays, it is very important to let the research team know if there is any likelihood that you are pregnant. For this reason you may be asked to perform a pregnancy test and will be excluded from the study if you are pregnant or trying to get pregnant. Women entering the study will also be asked to use proven methods to prevent pregnancy throughout the course of the study. Women must advise the research team if they become pregnant or would like to start trying to become pregnant. If this happens you will be withdrawn from the study treatment but may continue to complete diaries and questionnaires if you like.

What are the possible benefits of taking part?

We cannot promise the study will help your constipation however; the information we get from this study will help inform future treatment of people with chronic constipation.

What happens when the research study stops?

If you require further treatment you will return to being looked after in the regular clinic. With your permission, we would like to be able to use the data collected in this study for future research of a similar nature. All future research will require ethical review and approval and your data will remain confidential.

What if there is a problem?

Any complaint about the way you have been dealt with during the clinical trial or any possible harm you might suffer will be addressed. The detailed information concerning this is given in Part 2 of this information sheet.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes part 1.

What if relevant new information becomes available?

If new information becomes available about the treatments being studied or the way in which we are planning to conduct the study, you will be notified so that you have an opportunity to re-consider your involvement. This is very unlikely to occur but if it does the researcher will discuss this with you and ask you to sign a document confirming the changes were explained and you have agreed to either continue or withdraw and return to routine care.

What will happen if I don't want to carry on with the study?

You are free to drop out of this study at any time by notifying the study nurse or doctor and without having to give a reason. This would not affect the care you receive. If you withdraw from the study any information collected up to that point will still be used but no further information will be collected. You may also be given the option to withdraw from treatment but continue to complete questionnaires and diaries if you wish. If you become unable to complete the study you will be withdrawn but the data collected up until then will still be used.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Please insert local investigator contact details here). If you remain unhappy and wish to complain you should contact the Patient Advice and Liaison Service (PALS) <insert local Pals contact here>

We do not expect you to suffer any harm or injury as a result of this research. Bowel retraining is safe & has no side effects. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action against the sponsor Queen Mary, University of London, but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?

If you consent to take part in this study, Doctors, nurses and other personal involved in the study may need access to your medical records and test results. The records obtained while you are in this study will remain strictly confidential at all times. The information will be held securely on paper and electronically under the provisions of the 1998 Data Protection Act. Your contact details and data relevant to your participation in the study may be passed to members of the central research team at Queen Mary University of London. Your contact details will be shared with investigators from King's College to arrange your interviews. Your identifiable data will not be passed to anyone else outside the research team or the Sponsor, who is not involved in the trial.

You will be allocated a unique participant number, consisting of the study number, a hospital code and a number given in order of enrolment. This code will

be used to identify you on all trial forms. Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

In line with the regulations, at the end of the study your data will be securely archived for a minimum of 20 years. Arrangements for confidential destruction will then be made.

Will my GP be informed of my involvement?

Your GP, and other doctors treating you, will be notified that you are taking part in this study.

What will happen to the results of the research study?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask your study doctor after the study has ended. A lay summary of the results will also be provided to the study participants at the end of the study and published on the bowel and cancer research website at www.bowelcancerresearch.org

Who is organising and funding the research?

The sponsor, who is responsible overall for this study is Queen Mary, University of London. The research is being funded by the Department of Health through the National Institute for Health Research (NIHR).

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your safety, rights and wellbeing. This study has been reviewed and approved by London City and East Research Ethics Committee.

Further information and contact details

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved.

Principal Investigator

Name *add name*

Tel. Number: *add Tel. number*

Your Researcher/

Specialist Nurse/

Research Fellow/

Clinical Scientist *delete as appropriate*

Name *add name*

Tel. Number: *add Tel. number*