ISRCTN11791740 https://doi.org/10.1186/ISRCTN11791740

# CapaCiTY study 1-chronic constipation treatment pathway

**Submission date**
15/07/2015

**Recruitment status**
No longer recruiting

**Registration date**
16/07/2015

**Overall study status**
Completed

**Last Edited**
01/08/2025

**Condition category**
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Some degree of constipation affects nearly everyone at some stage in their life. However, some people suffer chronic (long term) symptoms that seriously impair their quality of life and which require medical intervention (treatment). Doctors use the term 'chronic constipation' to describe patients who have had symptoms for a long time (more than 6 months) and fail to respond to basic measures e.g. simple laxatives. This problem can affect 1 in 50 people, especially women and it can be remarkably difficult to treat effectively, even in specialist units. Current approaches include various new and old drugs, nurse-led bowel retraining programmes, bowel irrigation using special catheter systems, and a variety of surgical operations that may have variable, and sometimes very poor, results. While there is current optimism that the situation for such patients will improve with several new treatments being developed (drugs and medical devices), there is a lack of professional guidance as to which patients should be offered which treatments and when. Further, the value of certain specialist (expensive and invasive) investigations to better understand the underlying cause of the constipation is also unclear. In a resource-constrained NHS, doctors and patients need to have confidence that new and sometimes expensive therapies are cost-effective and that the old ones actually work. The aim of this research is test the effectiveness and cost-effectiveness of nurse led habit training (HT) and nurse led biofeedback training (HTBF) as a treatment for chronic constipation.

Who can participate?
Patients aged 18-70 with chronic constipation.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 receive HT treatment. This involves giving each patient a leaflet covering normal bowel function, what causes constipation, advice on diet and fluid intake, how to get into a good bowel habit, posture, and defaecatory dynamics (what happens when a person moves their bowels) and pelvic floor exercises as appropriate. Those in group 2 receive HTBF treatment. All patients in group 2 receive the same leaflet as group 1 but are also given direct visual feedback during defaecatory dynamics coaching. A quarter of all patients taking part are also randomly selected to receive specialist radio-physiological tests to see whether they are suffering from a functional defecation disorder. For each treatment, the researchers collect detailed data on the

effectiveness of reducing symptoms, patient acceptability and cost to the NHS .. Armed with this information, it will be possible by the end of the research to put all this evidence into an NHS guidance document, which can be used nationally as a treatment pathway to give the right care to the right patient at the right time.

What are the possible benefits and risks of participating?
The risks of participation are considered very low. The interventions proposed are those already offered to patients in specialist centres throughout the UK and internationally. The only difference conferred by participation is that these interventions will be randomly allocated and very carefully assessed. All interventions are safe. Patients receiving specialist investigations will undergo two X-ray procedures. The combined dose of radiation from these procedures is equivalent to less than 7 months annual background radiation dose from living in the UK. Further, these investigations would be carried out in routine clinical practice in many centres for patients with CC.

Where is the study run from?
Approximately ten NHS trusts in England.

When is the study starting and how long is it expected to run for?
July 2014 to June 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Natasha Stevens
n.stevens@qmul.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Mrs Shiva Taheri

### Contact details
Barts and The London School of Medicine and Dentistry
Centre for Neuroscience and Trauma
Blizard Institute
2 Newark St
London
United Kingdom
E1 2AT
+44 (0)20 7882 6031
s.taheri@qmul.ac.uk

# Additional identifiers

### Protocol serial number

17784

# Study information

### Scientific Title
Randomised trial of habit training vs. habit training with direct visual biofeedback in adults with chronic constipation

### Acronym
CapaCiTY01

### Study objectives
To determine:
1. Whether a complex specialist-led intervention (pelvic floor retraining using biofeedback) is more effective than standardised habit training
2. Whether outcomes of such specialist-led interventions are improved by stratification to complex or standardised therapy based on prior knowledge of anorectal and colonic pathophysiology

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
London City and East, 06/12/2014, ref: 14/LO/1786

### Study design
Randomised; Interventional; Design type: Not specified, Treatment

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Topic: Primary Care, Gastroenterology; Subtopic: Gastroenterology, Gastroenterology; Disease: All Diseases, All Gastroenterology

### Interventions
Participants are randomly allocated to one of three groups:

3-4 treatment sessions every 4 weeks (+/- 1 week)
Each session lasts 45-60min

1. Habit training (HT)
A written information leaflet covering normal bowel function; causes of constipation; diet and fluid advice; getting into a good bowel habit, posture, defaecatory dynamics and pelvic floor exercises where relevant. Plenty of optimism, encouragement and personal attention.

2. Habit training with Biofeedback (HTBF)
Each session will incorporate all features of HT intervention (above) but also include direct visual biofeedback using a portable high resolution anal manometry system and balloon catheter connected to a computer monitor during defaecatory dynamics coaching. The outcome of each session will note the ability to expel the balloon, generate propulsion, increase rectal pressure, relax the anal canal, and ability to sense the balloon at lower or higher volumes over successive sessions

3. INVEST
A quarter of patients will be randomised to receive specialist radio-physiological tests to diagnose functional defecation disorder. Based on the results of these tests, they will receive habit training or habit training with biofeedback as described above.

### Intervention Type
Behavioural

### Primary outcome(s)
Response to treatment defined as a 0.4 point [changed from 1-point on 10/05/2016] (or greater) reduction in PAC-QOL score at 6 months post end of treatment)

### Key secondary outcome(s))
Added 10/05/2016:
1. Binary responses to treatment defined as either a 0.4-point (or greater) reduction in PAC-QOL score
2. Binary responses to treatment defined as either a 1-point (or greater) reduction in PAC-QOL score
3. PAC-QOL: individual domains and total score (as continuous variables)
4. PAC-SYM score: individual domains and total score (as continuous variables)
5. A two week patient diary (for 2 weeks prior to each assessment) to record bowel frequency and whether each evacuation was 'spontaneous and / or complete'
6. Journal will also capture concurrent medication, health contacts, time away from normal activities (including work) since the patient's last visit
7. Generic QOL: EQ-5D-5L descriptive system and EQ-VAS
8. Patient Health Questionnaire-9 (PHQ-9)
9. Generalized anxiety disorder questionnaire (GAD7)
10. Global patient satisfaction / improvement score (VAS) and whether they would recommend each treatment experienced to other patients
11. Potentially modifiable cognitive and behavioural psychological variables shown to predict onset and perpetuation of other functional bowel symptoms: negative perfectionism, avoidant and 'all or nothing' behaviour subscales of the behavioural response to illness questionnaire (CC-BRQ), and Brief illness perception questionnaire BIPQ (CC)
12. Qualitative interviews to assess patient and researcher experience and acceptability of the interventions

Measured at 3, 6, 12 months post end of treatment

### Completion date
30/06/2020

# Eligibility

## Key inclusion criteria
1. Age 18-70 years
2. Patient self-reports problematic constipation
3. Symptom onset > 6 months prior to recruitment
4. Symptoms meet American College of Gastroenterology definition of constipation
5. Constipation failed treatment to a minimum basic standard (NHS Map of Medicine 2012 (lifestyle AND dietary measures AND =2 laxatives or prokinetics) tried (no time requirement)
6. Ability to understand written and spoken English (due to questionnaire validity)
7. Ability and willingness to give informed consent

The study will use the American College of Gastroenterology definition of constipation (which is reasonable, simple and extensively published): unsatisfactory defaecation characterized by infrequent stool, difficult stool passage or both for at least previous 3 months. This avoids the more complex Rome definitions (which are likely to change with Rome IV in 2015).

## Participant type(s)
Patient

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
18 years

## Upper age limit
70 years

## Sex
All

## Key exclusion criteria
The study interventions necessitate the exclusion of major causes of secondary constipation. In detail:
1. Significant organic colonic disease (red flag symptoms e.g. rectal bleeding prior investigated); IBD; megacolon or megarectum (if diagnosed beforehand) [the study will provide a useful estimate of the prevalence of such cases in referral practice]; severe diverticulosis/stricture /birth defects deemed to contribute to symptoms (incidental diverticulosis if known not an exclusion).
2. Major colorectal resectional surgery
3. Overt pelvic organ prolapse (bladder, uterus, rectum) or disease requiring obvious surgical intervention
4. Previous pelvic floor surgery to address defaecatory problems: posterior vaginal repair, STARR and rectopexy; previous sacral nerve stimulation
5. Rectal impaction (as defined by digital and abdominal examination: these form part of the NHS Map of Medicine basic standard)
6. Significant neurological disease deemed to be causative e.g. Parkinson’s, spinal injury, multiple sclerosis, diabetic neuropathy (not uncomplicated diabetes alone)
7. Significant connective tissue disease: scleroderma, systemic sclerosis and SLE (not

hypermobility alone)
8. Significant medical comorbidities and activity of daily living impairment [based on Bartell index in apparently frail patients, Bartell index <=11]
9. Major active psychiatric diagnosis [schizophrenia, major depressive illness and mania]
10. Chronic regular opioid use (at least once daily use) where this is deemed to be the cause of constipation based on temporal association of symptoms with onset of therapy; all regular strong opioid use
11. Pregnancy or intention to become pregnant during study period
12. Previous nurse-led bowel management
13. Severe visual impairment sufficient to prevent visual biofeedback
Urinary pregnancy testing will be made available to women of child-bearing potential at eligibility assessment and advice will be given to all women regarding need to prevent pregnancy during the study intervention period. Serum pregnancy testing will be mandatory for women of childbearing potential randomized to the INVEST group based on the NHS 10 day rule

### Date of first enrolment
26/03/2015

### Date of final enrolment
30/06/2018

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
### Queen Mary University of London
National Bowel Research Centre
Blizard Institute
Abernethy Building
2 Newark Street
London
United Kingdom
E1 2AT

### Study participating centre
### Homerton University Hospital NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

**Study participating centre**
**Barts Health NHS Trust**
The Royal London Hospital
Whitechapel Rd
London
United Kingdom
E1 1BB

**Study participating centre**
**St Marks Hospital at The North West Hospitals NHS Trust**
London
United Kingdom
HA1 3UJ

**Study participating centre**
**University College Hospitals NHS Foundation Trust**
London
United Kingdom
NW1 2BU

**Study participating centre**
**Guy's and Thomas' NHS Foundation Trust**
London
United Kingdom
SE1 7EH

**Study participating centre**
**Sandwell and West Birmingham NHS Trust**
Birmingham
United Kingdom
B71 4HJ

**Study participating centre**
**University Hospital Southampton NHS Foundation Trust**
Southampton
United Kingdom
SO16 6YD

**Study participating centre**

**University Hospital Leicester NHS Foundation Trust**
Leicester
United Kingdom
LE1 5WW

**Study participating centre**
**Sheffield Teaching Hospital NHS Foundation Trust**
Sheffield
United Kingdom
S5 7AU

**Study participating centre**
**Poole Hospital NHS Foundation Trust**
Poole
United Kingdom
BH15 2JB

**Study participating centre**
**North Bristol NHS Foundation Trust**
Bristol
United Kingdom
BS10 5NB

**Study participating centre**
**Shrewsbury and Telford Hospital NHS Trust**
Shrewsbury
United Kingdom
SY3 8XQ

# Sponsor information

**Organisation**
Queen Mary University of London

**ROR**
https://ror.org/026zzn846

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository held by the Barts and the London Pragmatic Clinical Trials Unit, Queen Mary University of London.

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/11/2021 | 27/10/2022 | Yes | No |
| Protocol article | protocol | 24/03/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | A study within a trial (SWAT) of clinical trial feasibility and barriers to recruitment in the United Kingdom – the CapaCiTY programme experience | 15/11/2024 | 01/08/2025 | Yes | No |
| Participant information sheet | | | 11/05/2016 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |