

CapaCiTY study 1-chronic constipation treatment pathway

Submission date 15/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/10/2022	Condition category Digestive System	<input type="checkbox"/> 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

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Study website

<http://www.blizard.qmul.ac.uk/capacity.html>

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See additional files

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 measure

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)

Secondary outcome measures

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

Overall study start date

01/07/2014

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

Sample Size: 394: . Allocation ratio to intervention groups as follows Habit training (147): Habit training with biofeedback (147): INVEST (100)

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

England

United Kingdom

Study participating centre

Queen Mary University of London

National Bowel Research Centre
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Study participating centre

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Study participating centre

Barts Health NHS Trust

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Study participating centre

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Study participating centre

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Sponsor information

Organisation
Queen Mary University of London

Sponsor details
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Sponsor type
University/education

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

Publication and dissemination plan

The results from this trial and others in the chronic constipation programme will be disseminated as follows:

1. In appropriate peer review scientific and/or medical journals.
2. Feedback directly to participants, GPs and participating Trusts.
3. Via charity links with bowel and cancer research charity
4. Public dissemination via our study website.
5. Through networks such as the Primary Care Society for Gastroenterology and CCGs To school children via Centre of the Cell 'Gut Feeling' and 'Poo Racer' games and educational tools www.centreofthecell.org
6. To the NIHR and development of NICE guidelines
7. A 2 day international meeting entitled 'Current perspectives in chronic constipation' will be hosted at QMUL

Intention to publish date

01/07/2020

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?
Participant information sheet	protocol		11/05/2016	No	Yes
Protocol article		24/03/2017		Yes	No
Results article		01/11/2021	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No