ISRCTN79959493 https://doi.org/10.1186/ISRCTN79959493

The effectiveness of an acceptance and commitment therapy based psychological intervention on reducing psychological distress in those diagnosed with gastro-intestinal dysmotility

Submission date 10/01/2023	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/01/2023	**Overall study status** Stopped	
Last Edited 17/12/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Gastrointestinal dysmotility (GID) describes an array of disorders which affect the movement of contents through the intestinal tract. At the severe end GID can lead to symptoms of pain, cramps, bloating, difficulty maintaining weight, constipation, diarrhoea, nausea, vomiting and malnutrition. It is often a cause of people needing long-term home intravenous feeding, known as home parenteral nutrition (HPN). Owing to the symptoms and treatment, it has been found that living with GID can have a significant detrimental impact on a person's quality of life (QOL) and psychological wellbeing. A recent study reported that there is an increasing need for psychosocial support. However, there is limited data on what type of therapeutic modality or more so what component of the psychological intervention is most effective in the GID population. Acceptance and Commitment Therapy (ACT) has been found to be beneficial for psychological wellbeing in many other chronic conditions including IBD and applied in a group format. This study aims to assess the effectiveness, feasibility and acceptability of a group-based psychological intervention called 'ACTing on your GUT feelings'.

Who can participate?
Patients aged over 18 years with GID

What does the study involve?
Participants will be randomly allocated to either the treatment group where they will attend seven 2-hour weekly sessions with an 8-week follow-up 'reunion', or a Treatment As Usual (waiting-list control) group. Both groups will be asked to complete a set of questionnaires. The questionnaires will collect demographic information and assess psychological wellbeing (anxiety and low mood), health-related quality of life and psychological flexibility (the ability to stay

present with and adapt to the challenges of life). Medical outcomes will also be collected. All outcomes and questionnaires will be collected before and after the intervention. Participants will also be invited to attend interviews to discuss their views and experiences.

What are the possible benefits and risks of participating?
Potential benefits would be participants learning new coping strategies and techniques to manage psychological distress associated with their health condition, and also helping to improve quality of life in general. Another possible benefit of taking part would be meeting others with shared experiences of the same health condition in a supportive, small group environment. The researchers do not anticipate any direct risks or disadvantages of taking part in this study. However, they appreciate that talking about personal experiences could be upsetting and support from the research team will be available to all participants as well as the option to withdraw from the study at any time.

Where is the study run from?
Northern Care Alliance NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2022 to October 2023

Who is funding the study?
1. Bowel Research UK
2. Pseudo Obstruction Research Trust (PORT) (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
315811

Central Portfolio Management System (CPMS)
54458

Study information

Scientific Title
The effectiveness of an acceptance and commitment therapy based psychological intervention on reducing psychological distress in those diagnosed with gastro-intestinal dysmotility

Acronym
The PORT Study – ACTing on your GUT feelings

Study objectives
An acceptance and commitment therapy (ACT) group intervention will reduce psychological distress and increase health-related quality of life and psychological flexibility relative to a waiting list (treatment as usual) control condition in patients diagnosed with gastro-intestinal dysmotility.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 23/12/2022, North West- Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048306; gmeast.rec@hra.nhs.uk), ref: 22/NW/0364

Primary study design
Interventional

Study design
Randomized; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastro-intestinal dysmotility

Interventions
Potential participants will be invited into the study by invitation letter with an opt-in reply. Those interested will be given a participant information sheet explaining the rationale for the study and they will have the opportunity to ask questions before giving their consent to take part. Participants who are interested in taking part in the study will also have an assessment to ensure suitability for the group intervention. Those who require other mental health support /not suitable will be provided with information on how to access other available support. They will also be asked to complete several baseline questionnaires. Demographics: age, sex, marital status, ethnicity, and employment, previous/current psychology input, Psychological outcomes: Patient Health Questionnaire (PHQ-9) and General Anxiety Disorder (GAD-7) to assess depression and anxiety; Acceptance and Action Questionnaire (AQII) to assess psychological flexibility; previous psychology input, QOL: Short form 36 (SF36) Medical: gastrointestinal/HPN complications, HPN requirements, hospital readmissions, length of admissions, sick days, opioid use, and anti-depressant use. Once recruited, participants will be randomly allocated to either group intervention or waitlist control by random number sequence allocation. This will be a single-blind study design as participants will know whether they had been allocated to the group or not. Participants allocated to the group intervention will be put into a group of 9-10 people. The ACT intervention will be carried out in an online format over a period of 8 weeks with each session lasting approximately 2 hours. The intervention will utilise a standardised therapy manual based on ACT-based interventions but adapted to the patient population. It will cover a different topic each week but ultimately work on the ACT principles of becoming more open with emotions, aware of the present moment and engaged in working towards values important to them. Attendance will be recorded for the acceptability and feasibility part of the study and all group participants will be asked to complete a feedback form for each session attended of the intervention to assess effective components. A select number of those would also take part in a qualitative semi-structured interview based on their experiences of the group and the acceptability and feasibility of the intervention. Interviews will be expected to last about 1 hour. All participants regardless of the randomly allocated group will complete post-intervention measures.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety is measured using the Generalised Anxiety Disorder (GAD7) questionnaire at baseline, week 7 and week 15
2. Depression is measured using the Patient Health Questionnaire (PHQ9) at baseline, week 7 and week 15
3. Psychological flexibility is measured using the Acceptance and Action Questionnaire (AQII) at baseline, week 7 and week 15
4. Health-related quality of life (HRQoL) is measured using the RAND 36-item Health Survey 1.0 (SF-36) at baseline, week 7 and week 15

Key secondary outcome(s)
1. Demographics (age, sex, marital status, ethnicity, employment, diagnosis, duration of diagnosis and previous psychology input) are measured using a questionnaire at baseline
2. Medical outcomes (gastrointestinal/HPN complications, HPN requirements, hospital readmissions, opioid use, anti-depressant use) are measured using access to medical records at baseline and week 15

Completion date
31/10/2023

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Has a diagnosis of GID
2. Age 18 years or above
3. Is fluent in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
6

Key exclusion criteria
1. Insufficiently well to give consent or to take part
2. Currently receiving or due to start psychological therapy at another service or privately
3. Difficulties such that they are currently in receipt of ongoing input from secondary care mental health services
4. Substantial substance abuse difficulties
5. Severe and/or chronic mental health problems such as personality disorders where the interpersonal difficulties themselves are the required focus of an intervention
6. A learning disability, at such a level that specialist skills would be required to deliver an intervention

Date of first enrolment
07/03/2023

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

England

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Sponsor information

Organisation
Northern Care Alliance NHS Foundation Trust

Funder(s)

Funder type
Charity

Funder Name
Bowel Research UK

Alternative Name(s)
Bowel Research United Kingdom, BRUK

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Pseudo Obstruction Research Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2	28/11/2022	18/01/2023	No	Yes
Protocol file	version 2	28/11/2022	18/01/2023	No	No