Participant Information Sheet

Study Title: The effectiveness of an Acceptance and Commitment Therapy (ACT) based psychological intervention on reducing psychological distress in those diagnosed with Gastro-intestinal Dysmotility
Short Title: The PORT Study – ACTing on your GUT feelings

Chief Investigator: **Dr Holly Martin-Smith**

1. Introduction

The Northern Care Alliance NHS Foundation Trust (NCAFT) is a group of four Care Organisations comprising Salford, Oldham, Bury and Rochdale. These organisations operate within the NCAFT and are highly research active.

You are being invited to take part in a study based at Salford Royal Hospital, Northern Care Alliance NHS Foundation Trust (NCAFT). Before you decide, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why have I been invited to take part?

All patients who are diagnosed with gastrointestinal dysmotility (GID) or pseudo-obstruction under services at Salford Royal Hospital and across the Northern Care Alliance NHS Foundation Trust (NCAFT) will be invited to take part in this research.

3. What is the purpose of the research?

Our study aims to assess the effectiveness, feasibility and acceptability of a group based psychological intervention called 'ACTing on your GUT feelings'. This group intervention will be delivered online by a qualified psychologist. We will collect data on psychological, health-related quality of life (HRQOL) and medical outcomes. We will then compare results from those who complete the group intervention to a control group who receive treatment as usual (TAU). This will be the first study to assess whether this group psychological intervention is effective using a standardised therapeutic manual adapted to those diagnosed with GID or pseudo-obstruction. Moreover, it looks at whether delivering a psychological intervention in an online format in a group setting is acceptable and feasible.

4. What is the ACTing on your GUT feelings' group intervention?

'ACTing on your GUT feelings' is a group intervention with a focus on learning to live with difficulties presented by GID or pseudo-obstruction. It will provide participants with an opportunity to meet others who share these difficulties and learn new coping strategies, in a supportive, small group environment. The course involves seven 2-hour sessions on a weekly basis, with a 2 month follow up 'reunion' session. It will require a commitment to attend the online sessions and undertake home-based practice and set personal goals to complete in-between each session. It is a group based on

Acceptance and Commitment Therapy (ACT) a type of Cognitive Behavioural Therapy based on the innovative use of mindfulness and values. The aim of the course is to assist people with GID and pseudo-obstruction to attain a richer, more fulfilling and values driven life despite the impact of their condition.

5. What will happen if I take part?

There are two parts to this study.

Part 1:

If you choose to take part in the study, you will be randomised to one of two study groups.

- The first study group will involve taking part in the online 'ACTing on your GUT feelings' intervention as described above.
- The second study group will not take part in the 'ACTing on your GUT feelings' intervention and will remain on a waiting list for the duration of the study but will be offered the opportunity to access psychological support via the Intestinal Failure Psychology service after the study has finished.

Both groups will be asked to complete a set of questionnaires. The questionnaires will ask you for some demographic information alongside 4 brief questionnaires asking you about your 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). It is expected that these questionnaires will take you between 10-30 minutes to complete. You can choose to complete the questionnaires over the phone, online, via email or in paper format that you can return anonymously by post. We will ask you to complete these at 3 different timepoints.

Both groups will be offered further psychological support if indicated following the end of the study. This support will be individualised based on an assessment with a clinical member of the Intestinal Failure Psychology team and may include individual or group psychological therapy. If no further support is required, both groups will return to receiving their standard care.

Part 2:

If you complete the 'ACTing on your GUT feelings' group intervention and choose to consent to the second part of the study, you will be invited to take part in an individual interview at a convenient time for you. Interviews will be flexible in length but are expected to last between 30-60 minutes. The interviews will take place over the telephone, online or at Salford Royal Hospital if these interviews coincide with other hospital appointments/ admission. During the interview the researcher will prompt discussion around key topics relating to the research aim, but the interview content will also depend upon which topics you wish to raise and discuss.

With your permission, the interviews will be digitally audio-recorded. It will then be transcribed, and the audio-recording deleted. To maintain confidentiality, all identifying information (e.g., names/locations) mentioned within the interview will be removed from the transcript and it will be given a unique non-identifiable ID number. Therefore, the data collected from this interview will remain anonymous. Once the interview has been transcribed the data cannot be withdrawn as the research teams needs to manage their records to ensure the research is reliable. The content of the transcript will then be analysed and will be written up for publication. Anonymous direct quotes may be used as part of the write up.

6. Do I have to take part?

No, taking part is voluntary and it is up to you to decide whether to take part. Any help you give is very much appreciated. If you decide to take part, you are free to withdraw at any time without giving a reason. A decision to withdraw at any time will not affect the standard of any care you receive. If you decide not to take part, you do not have to give a reason. Those who do not give consent to be included in the study will still be able to access the Intestinal Failure Psychology team and standard NHS care and resources.

7. What are the possible benefits of taking part?

Potential benefits would be learning new coping strategies and techniques to manage psychological distress associated with your 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.

8. What are the possible disadvantages and risks of taking part?

We do not anticipate any direct risks or disadvantages of taking part in this study. However, we appreciate that talking about your experiences could be upsetting depending on your experience. If this happens, participants will be offered a break and someone to talk to from the research team. There will be no pressure to continue the programme, questionnaires or interview if you feel you would like to withdraw. We have a distress policy in place that will be implemented if needed and you may be offered access to the intestinal failure psychology service if appropriate. The groups will have rules in place to maintain a safe and supportive online group environment, these include; remaining confidential, try to refrain from using mobiles, showing respect, listening and contributing where it feels comfortable to do so, joining from a secure space where you will not be disturbed and you will also be offered the opportunity to have telephone check ins where you can raise any concerns about any of the above or if anything else arises.

9a. How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information (personally identifiable data) will include your:
- Initials
- NHS number/Hospital ID
- Contact details
- Audio recordings of your voice during interview
- sections of your medical records that are of relevance to the research

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

9b. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. This personally identifiable data will be retained until the last data collection point and then deleted.

9c. Where can you find out more about how your information is used?

You can find out more about how we use your information

a) at www.hra.nhs.uk/information-about-patients/
b) our leaflet available from https://www.ncaresearch.org.uk/patients-public/
c) by asking one of the research team (details below)
d) by contacting the Northern Care Alliance NHS Foundation Trust Data Protection Officer DataProtection.Officer@nca.nhs.uk
e) by viewing the Sponsor's privacy link http://srft.nhs.uk/for-patients/information/privacy-notice-adults/

9. Expenses and payments?

We are unable to pay you for participating in this study. However, travel expenses will be covered if you decide to participate in an interview in person i.e., an extra journey for the interview that you would not normally have made otherwise. We will endeavour to make this interview over the phone or online to minimise any disruption to you.

10. What will happen to the results of the research study?

The final outcomes from the study will be communicated via presentations in scientific meetings and by peer reviewed publications. We will aim to publish the results approximately 12 months after completion of the study. You will not be able to be identified from any report arising from this study. If you are interested, we can give you a report on the findings from the research.

11. Who is organising and funding the research?

The research is organised by the Intestinal Failure research team at Salford Royal Hospital (NCAFT). This study is being funded by PORT (pseudo-obstruction research trust) and Bowel Research UK. Management oversight (Sponsorship) is provided by the Northern Care Alliance NHS Foundation Trust.

12. Who has reviewed this study?

We can confirm that the study has been reviewed and approved by an appropriate NHS Research Ethics Committee, (North West – Greater Manchester East Research Ethics Committee).

13. What if there is a problem?

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 a legal action for compensation against Northern Care Alliance NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you have any complaints about the treatment you have received as part of this study, you can contact the hospital PALs (Patient Advise and Liaison Services) team:

Patient Advice and Liaison Service
Salford Royal Hospital
Northern Care Alliance NHS Foundation Trust
Stott Lane, Salford M6 8HD
Telephone: 0161 206 2003

15. Contact Names and Details for Further Information

If you have any questions about this research, please write to us or call us on 0161 206 5588. Thank you for taking the time to read this information sheet.

Dr Holly Martin Smith
Health Psychologist
Telephone: 0161 206 5588

Thank you for taking the time to read this participant information sheet.
Please do not hesitate to contact the study team as above for any further information or if you have any questions