Study Protocol

Version 2.0 (28.11.22)

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

Sponsored by:

NHS
Northern Care Alliance
NHS Foundation Trust
Salford I Oldham I Bury I Rochdale

Funded by:

Pseudo Obstruction Research Trust
Reg Charity No. 1114217
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BOWEL RESEARCH UK
Let's end bowel cancer and bowel disease

IRAS ID: 315811

Sponsor ID: 22GAS09-S

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Name (please print): Date: ...../...../.....

Position:

Chief Investigator:

Signature:

Name (please print): Date: 28/11/22

Contents

1. Study Summary

To assess the effectiveness, feasibility and acceptability of an Acceptance and Commitment Therapy (ACT) based psychological intervention delivered in a group format by a qualified psychologist on psychological measures (distress, psychological flexibility, Health-related Quality of Life (HRQOL)), and medical outcomes (described in section 6) when compared to a control group who will receive treatment as usual (TAU) within a patient group with a diagnosis of Gastrointestinal Dysmotility (GID). A further description of the results of those with Chronic intestinal pseudo-obstruction (CIPO) against those non-CIPO will also be included to see whether the preliminary effectiveness or needs differ between these two groups.

The ACT intervention will be carried out in an online format and consist of 7 weekly sessions followed by an 8-week follow up with each session lasting approximately 120 minutes. An online format will be utilised due to the logistics – an online format will allow all participants to attend, taking into consideration the COVID pandemic and geographical location of patients in our service being a national centre for patients needing home parenteral nutrition (HPN). All patients will be followed up and asked to complete feedback forms after each session to assess effective components of the intervention. A subset of patients will also be invited to take part in a qualitative interview based on their experiences of the intervention. Patient experts from the Pseudo Obstruction Research Trust (PORT) and our patient focus group will be invited to be involved in aspects of the study such as the study design, development of the therapeutic manual, recruitment, and dissemination of the study's results.

At the time of writing and to our knowledge this will be the first study to assess whether a group psychological intervention is effective using a standardised therapeutic manual adapted to those diagnosed with GID. Moreover, it looks at whether delivering psychological interventions in an online format in a group setting is acceptable and feasible with this patient population and in the NHS environment. Outcomes from this study will not only shape future psychological interventions but also promote psychological support for this cohort of patients who have expressed wanting this service. If group interventions are proven to be effective, it will mean that patients may have more rapid access to psychological intervention rather than inevitable long waiting lists for individualised psychological support. In addition, the group intervention can be adapted for further gastrointestinal conditions in the future.

2. Project Team

2.1 Study team

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2.2 Sponsor contact information

Northern Care Alliance NHS Foundation Trust has accepted the responsibilities of Sponsorship for the study. The sponsor's representative is Professor Steve Woby.

Study Sponsor:	Northern Care Alliance NHS Foundation Trust
Sponsor Reference:	22GAS09-S
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2.3 Funding

We achieved external funding from PORT/Bowel Research UK. This is a £49, 994.20 grant over 18 months. There will be no further funding to cover the cost of this study.

2.4 Organisational Structure and Responsibilities

Chief Investigator:

Design and conduct of study
Preparation of protocol and revisions
Recruitment of participants
Organising study meetings
Reviewing progress of the study and agreeing to changes in the protocol if necessary
Oversight of patient safety by conducting regular meetings with study team
Publication of study reports
Study budget holder
Responsible for data management plan

Sub-investigator:

Design and conduct of study
Preparation of protocol and revisions
Recruitment of participants
Organising study meetings
Reviewing progress of the study and agreeing to changes in the protocol if necessary
Oversight of patient safety by conducting regular meetings with study team
Publication of study reports
Study budget holder
Responsible for data management plan

3. Background Information and Rationale

Gastrointestinal dysmotility (GID) has no universally accepted definition but it is a broad term that encompasses a spectrum of disorders where there is dysregulation or disruption of the complex enteric neuromuscular co-ordination necessary for motility of food through the gastrointestinal tract [1, 2]. At the severe end of the spectrum, disruption to GID can lead to intractable gastrointestinal symptoms (pain, cramps, bloating, difficulty maintaining weight, constipation, diarrhoea, nausea, vomiting, malnutrition) [1,2], and is a recognised cause of people needing long term home intravenous feeding, known as home parenteral nutrition (HPN) [1-6]. GID can be separated into sub-types of Chronic intestinal pseudo-obstruction (CIPO) and non-CIPO; the latter is characterised by symptoms representative of intestinal occlusion despite no physical obstruction being present. A study found that the CIPO sub-type of GID is associated with higher HPN dependency, higher incidence of bacterial overgrowth and more surgical intervention compared to those with a non-CIPO sub-type of GID [7].

It has been found that the quality of life (QOL) and psychological wellbeing of those diagnosed with a GID is impacted due to the management of gastrointestinal symptoms and treatment for maintaining nutrition and body weight [8]. There is significant evidence detailing the effect of GID and, where required, HPN on daily life and psychosocial outcomes due to the inability to eat normally, loss of independence, lifestyle change and control of bodily functions [9-11] with many experiencing a difficult journey from symptom onset to getting a diagnosis of GID, which impacted upon their psychological wellbeing along the way [12].

A recent study reported that there is increasing awareness of the psychological impact of severe GID diagnoses and the roles of psychosocial support, with clinical psychologists becoming an integrated part of the multidisciplinary care for these patients [13]. Vasant et al [14] surveyed clinicians' perspectives on the management of patient's diagnosed with severe GID and found that clinicians felt that psychological therapies were the second most useful intervention after treatment for bacterial overgrowth. Studies in other gastrointestinal conditions have used various psychological interventions including gut hypnotherapy [15], mindfulness [16], cognitive behaviour therapy (CBT) [17], and solution focussed therapy [18] with mixed effects on psychological, QOL and medical outcomes. However, there is little to no data on what type of therapeutic modality or more so what component of the psychological intervention is most effective in the GID population.

Recently a study found that an Acceptance and Commitment Therapy (ACT) intervention was effective in reducing psychological distress in those diagnosed with IBD [19]. ACT has also been found to be beneficial for psychological wellbeing in many other chronic conditions [20] and works on the principle

that rather than try to modify or eliminate negative thoughts or feelings, it encourages individuals to accept that adverse experiences exist whilst simultaneously fostering a commitment to move toward values that have been identified and adopted by the individual [21].

4. Aims of the proposed research

4.1 Primary Objective:

To assess the effectiveness, feasibility and acceptability of an online ACT based psychological intervention on psychological measures (distress, psychological flexibility, QOL and medical outcomes (described below in section 6) when compared to a control group who will receive treatment as usual (TAU).

4.2 Secondary Objective:

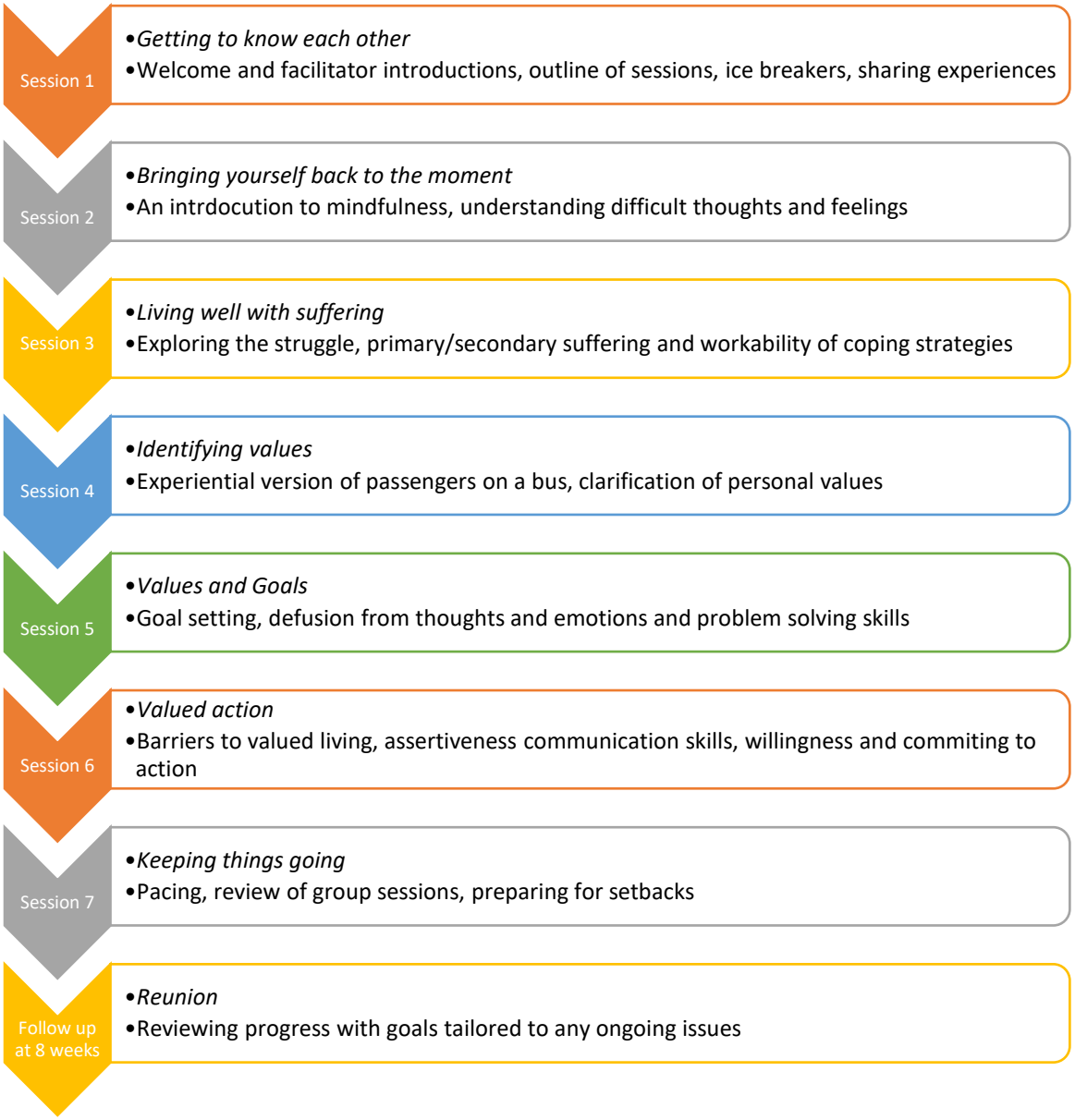
The study aims to recruit people with a diagnosis of GID, with a description of the results of those with CIPO against those non-CIPO to see whether the effectiveness or needs differ between these two groups.

5. Study Design

This study will be a pilot randomised controlled trial (RCT) with patients diagnosed with gastrointestinal dysmotility. Assessment of QoL of intestinal failure (IF) patients is very complex as IF is not only affected by the HPN treatment itself but also by the underlying disease and frequency of hospital readmissions. Therefore, a range of data will be collected including demographic characteristics, psychological outcomes, and medical outcomes, collected at different timepoints to allow for analysis (further detail is provided section 7.6 below).

Blinding of investigators or participants will not be possible in this study as participants and investigators will know whether participants had been allocated to the group or not. Participants allocated to the group intervention will be put into a group of 9-10 people. There will be maximum five rounds of the group intervention over the study period to meet sample size. The intervention is adapted from the Better Living with Illness group protocol [22] based on ACT. The group will be delivered over 7 weeks in weekly two-hour sessions, with a follow up 'reunion' at 8 weeks. A treatment manual has been adapted by the chief investigator who has received specialist training in ACT and previous experience of running this intervention online to people with long-term conditions. Each session utilises experiential exercises and metaphors to cover core ACT processes. Worksheets and guided mindfulness meditation exercises will be recommended to facilitate learning and encourage home practice. The intervention also covers problem solving skills, pacing, assertiveness skills and goal setting as they are important features of living with a long-term condition such as GID. An overview of the content of group sessions is provided in figure 1.

Figure 1, Session content of group



Attendance will be recorded to assess recruitment and retention 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. Feedback will not be incorporated as the study progresses to retain intervention consistency for each participant as close as possible.

The study will utilise a mixed-methods design using quantitative standardised psychometric questionnaires to address psychological and quality of life outcomes, as well as a qualitative approach. The study will use face-to-face or telephone semi-structured interviews to explore participants experiences and views on the feasibility and acceptability of the intervention. These interviews will take place at one time point after the group intervention.

6. Detailed Plan of Investigation

6.1 Recruitment procedure

The proposed recruitment strategy will involve screening the database at Salford Royal Hospital, Northern Care Alliance NHS Foundation Trust (NCAFT) for potentially eligible patients with gastrointestinal dysmotility. This search will be conducted by the research team working on the study and subsequently participants that fit the eligibility criteria will be sent a letter, approved by ethics, introducing them to the study and outlining what would be involved. Participants may also be approached during their HPN clinic appointment. A follow-up courtesy call 2-3 weeks after sending the letter may also be made by a member of the research team.

A telephone screening assessment will then be arranged with all interested participants for the therapeutic group programme to assess for suitability, to conduct a brief psychological assessment and check they meet inclusion criteria. During this phone call the research study will be discussed including the rationale in line with details provided on the participant information sheet and patients will have the opportunity to ask questions.

If after this telephone screening assessment with a clinical team member they meet inclusion criteria, and wish to continue, the research team will arrange a convenient time to obtain informed consent, via a consent form. Participants will be given a minimum of 24 hours to decide whether or not to take part. In some circumstances the participant may be asked to complete consent over the telephone. For example, in situations where to protect the safety of the participant and staff, it is not appropriate to bring the participant into a clinical setting for the consent process (e.g. during the COVID-19 pandemic). Participants will be randomised (using random number sequence methods) into one of two groups; the ACT intervention programme, or a control group receiving treatment as usual where they will not receive the psychological intervention during the study. Letters will be sent to GPs of all patients taking part in the study.

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.

All participants who provide consent will be asked to complete questionnaires at 3 timepoints (T1- baseline/pre-treatment; T2- week 7/post-treatment & T3 – 8 week-follow-up). These will be completed via paper, online, over the phone or email. The questionnaires will not have personal identifiable information on them but will be pseudonymised with a study participant number, of which only members of research team will have access to.

The second part of the study will involve semi-structured interviews performed by a suitably qualified member of the research team with training or experience to perform qualitative interviews. For the qualitative element of the study, participants will be able to register interest in the qualitative study and receive additional information about this part. Interviews will be conducted at a mutually agreeable time between the moderator conducting the interviews and the participant. If possible, they will try to accommodate this with their routine appointments at Salford Royal Hospital to make it easier for the participant to take part or alternatively over a video consultation.

6.2 Inclusion Criteria:

1) Has a diagnosis of Gastrointestinal Dysmotility

2) Age 18 years or above

3) Is fluent in English

6.3 Exclusion Criteria:

The participant may not enter the study if ANY of the following apply:

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 on-going 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.

6.4 Screening for eligibility

As per current clinical practice within a psychology service, a telephone assessment will be conducted by the assistant psychologist or qualified psychologist (both members of the research team), with all participants to screen for eligibility to ensure that the person meets the inclusion/ exclusion criteria, and equally importantly to conduct a brief psychological assessment. A screening tool is not used but decisions are based on clinical judgement (as is clinical practice) owing to answers given to questions about their condition, an assessment of risk, expectations and goals and level of commitment/engagement. This assessment means we will be well placed to judge whether our intervention is suitable, and we can sign post and inform GPs if other services are better placed to meet potential participants' needs. We will of course, in line with good clinical practice, continue to monitor participants' needs throughout the course of the intervention.

6.5 Ineligible and non-recruited participants

People who are ineligible or not recruited will have access to the existing array of NHS services.

6.6 Study duration

The proposed project duration is expected to be 18 months from first receiving funding from PORT and Bowel Research UK. The start date for the study will be as soon as ethics and local C&C has been granted. The ACT intervention will occur in total over a 15-week period (7 weekly sessions plus an 8 week-follow up) with each session lasting approximately 120 minutes and it is expected to take between 25 minutes to complete the questionnaires. The final study visit for the group intervention

will be 31/05/2022. The qualitative interview phase of the study is expected to take participants between 30-60 minutes and interviews will be conducted once a participant has completed the intervention. All interviews will be conducted by October 2023. Writing up the results of this study is expected to be complete within 12 months after study end. Approximate end date 31/10/2023. Following this no further data collection will take place i.e. the last patient will have completed their last visit.

6.7 Consent procedure

Participants will be approached via letter of invitation or telephone call by a member of the research team. They will be sent a Participant information sheet (PIS) and Informed Consent Form (ICF) and then if interested in participating they can contact the study team or will have a follow up phone call to see if they are interested. If they would like to be involved, they will receive a screening/telephone assessment as described above. If they meet inclusion criteria and wish to continue they may either be invited to meet or have a telephone call with an appropriately delegated member of the study team to allow the participant to ask questions, go through the consent procedure, and be informed of their right to withdraw at any stage. If consent is via telephone, the researcher will use a telephone script/consent form to ensure the process is documented appropriately. The contact will include a clear verbal explanation of the study (e.g., by talking through the PIS and the sections of the ICF). Only when the potential participant has had the opportunity to ask questions and had these answered satisfactorily, will they be asked to verbally confirm consent to participate. The telephone consent will be documented by the researcher/consent taker. Where possible, this consent process will be conducted in the presence of a witness e.g. another CRN practitioner or independent member of the clinical team.

If consent is collected face to face, a clear explanation of the study will be provided as above, the participant will be provided with time to ask any questions and once satisfied will be asked to complete the consent form.

6.8 Outcome measurement

Several outcome measures and data will be collected:

- Demographic characteristics and background information such as: age, sex, marital status, ethnicity, employment, diagnosis, duration of diagnosis and previous psychology input. This will be gathered by asking participants to complete a brief questionnaire once they have consented to take part in the study.
- Psychological outcomes collected through multiple pseudonymised self-reported questionnaire:
    - Generalised Anxiety Disorder Assessment (GAD-7) [23] to assess anxiety
    - Patient Health Questionnaire (PHQ-9) [24] to assess depression
    - Acceptance and Action Questionnaire (AQII) [25] to assess psychological flexibility.
    - The RAND 36-item Health Survey 1.0 (SF-36) [26] to assess health-related quality of life (HRQoL).

  These items will be measured at baseline (T1/pre-treatment); session 7 (T2/post treatment), and 8 weeks follow-up (T3/2-month follow-up).
- Medical outcomes:
    - Gastrointestinal/ HPN complications

- HPN requirements
- Hospital readmissions
- Opioid use
- Anti-depressant use

Medical outcomes will be collected accessing medical records at baseline and post follow up

A feedback evaluation questionnaire will also be used to measure the feasibility and acceptability of ACT intervention.

6.9 Withdrawal criteria

Participants will be allowed to withdraw from the study at any point. We will not collect any further data from this participant. However, data collected up to the point of withdrawal will be included in the analysis

7. Regulatory and Ethical Considerations

7.1 Study conduct

- The study will be conducted in accordance with the UK Policy Framework for Health and Social Care Research and other applicable guidance.

- The study will not commence until all regulatory approvals are in place, which will include Health Research Authority (HRA) Approval, Research Ethics Committee (REC) Approval and confirmation from local Research and Development that the Trust has capacity and capability to carry out the research.

7.2 Monitoring and audit

- The study will be subject to the standard procedures for monitoring and auditing of studies by the sponsor.

- Any changes to the protocol will be agreed with the sponsor prior to submission to NHS research ethics committee for review with the exception of where urgent safety measures apply.

- All staff working in the study will have completed appropriate training to undertake the duties delegated to them by the principal investigator such an ICH-GCP.

7.3 Protocol deviations

- Any deviations to the protocol will be reported to the sponsor within 24 hours of the occurrence to allow an impact assessment to be completed.

- Consideration will be given to the nature of the deviation, its causes, and the potential impact on the study.

- Where necessary, a deviation from the protocol may lead to an amendment to the protocol

7.4 Study progress reports

The PI and research team will submit progress reports to the Sponsor and funder: PORT & Bowel Research UK as requested and prior to submission to NHS REC, in accordance with the terms and condition of the study approval.

7.5 Stopping rules

Although no adverse events are anticipated, and it is not anticipated that the study will be stopped prior to its intended end-date. However, the study will be halted if:

- New information comes to light which means that the aims of the study are futile
- Safety issues come to light regarding the intervention
- Resources to conduct the study are no longer available
- Abuse of group guidelines, group guidelines include but are not exclusive to; 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 participants will not be disturbed and participants will also be offered the opportunity to have telephone check ins where they can raise any concerns about any of the above or if anything else arises. Clinical judgements will also be made.
- If the study fails to recruit less than 10% of invited participants after 6 months of recruitment

8. Record keeping and data management

All information obtained from study participants will be treated as confidential and will comply with the requirements of the General Data Protection Regulations 2018 and the NHS Code of Confidentiality. All data collected will be stored on a secured (password protected) database with access available only to the chief investigator and study team responsible for handling and processing the relevant data. Any personal identifiable information will be stored separately from any interview content to ensure it remains anonymous. Study participants will never be identified by name when data or information are published or presented in the future.

9. Statistical analyses and data handling

Quantitative analysis

Descriptive statistics will be included for all psychological and medical outcomes. Further analysis is summarised in the table:

Objective	Method to measure this
Acceptability	The percentage of all patients randomised to the intervention arm minus deaths that complete the 2-month follow up. This will be compared to the percentage of controls (minus deaths) that complete the 2-month follow up. Completion will be defined as attendance at least 3 out of the 8 sessions. True completion will be defined as the number of participants who completed the whole intervention (all 8 sessions).
Feasibility	For those in the intervention group only: The results of the feedback evaluation questionnaire given after every intervention session.

Effectiveness	The preliminary effect of the intervention will be estimated using the estimated mean difference between trial arms at post-treatment and 2 months follow up, adjusted for baseline scores, from analysis of covariance (ANCOVA). The analysis will be conducted using Stata 14 and an alpha level of 5%. This will be completed for all psychometric measures. Results of the subgroup analysis will be described, comparing those with Chronic intestinal pseudo-obstruction (CIPO) against those non-CIPO to see whether the effectiveness or needs differ between these two groups.

Qualitative analysis

Qualitative interview audio recordings will be transcribed verbatim and all identifying information will be removed. Data will be analysed using reflexive thematic analysis [27-29). Thematic analysis will include data familiarisation, initial coding, and sub-theme formation, and theme labelling.

10. Dissemination of Results and Publications

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. The study and results may be promoted and publicised more widely via the Sponsor Trust's Research & Innovation website and on the PORT charities website.

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