Twitter @HALT_trial

Changes due to COVID-19 pandemic

Item	Original protocol	Amended
Recruitment	Recruitment through clinical care teams at Leeds and Highland sites, plus social media.	Social media only.
Consent	Participant to be provided with patient information sheet (PIS) prior to meeting research team. Then informed consent to be taken in person with wet ink signature.	PIS to be emailed, and informed consent to be collected online using the same form with the same content. All informed consent procedures will still be adhered to.
Activity Diary	Paper activity diary to be provided by research team and completed each week by participant.	Online completion only.
Outcome measures	Physical activity measured through accelerometer device given to, or posted to participant.	Physical activity measure added to online questionnaire.
	Body Composition was to be taken by measuring body mass index (BMI).	Cannot be measured – removed.
	Parastomal hernia classification was to be completed by a clinician.	Cannot be done – removed *
Face to face interviews	End of intervention interviews were to be completed face to face	Interviews will now be completed via video call or telephone depending on individual preference.

***** The clinical team at Raigmore hospital are in the process of developing a guide for participants to measure and classify their own hernia/bulge. This is an exciting development from the changes we have had to enforce due to the COVID pandemic.

Project summary

This trial is currently recruiting.

The Hernia Active Living Trial (HALT) is an exercise intervention for people living with a stoma. Parastomal hernia can occur at the site of the stoma and is commonplace after surgery, with up to 40% occurrence 2 years after surgery. Surgical repair results for parastomal hernia have been disappointing with recurrence rates reported between 30-76%. People living with a parastomal hernia have identified physical activity as a top research priority in relation to their quality of life. The trial aims to assess the feasibility and acceptability of the intervention and trial parameters to develop a full scale RCT. We hypothesise that the intervention will increase core muscle activation and stability across the abdominal wall at a site of potential weakness (the stoma) and reduce the risk of parastomal hernia progression, we are including quality of life measures. The project is being led by Professor Gill Hubbard. We have developed a 12-week Pilates style exercise intervention, with recruitment planned at 2 sites; NHS Highland and Leeds Teaching Hospitals NHS Trust with our research colleagues at Leeds University. The intervention will be delivered by our clinical exercise specialist, Sarah Russell, who will provide weekly video calls to support participants.

Intervention and Patient Involvement

The intervention has been developed with input from clinical teams, exercise physiologists, and with patients. The project has a very active 15-member patient advisory group (PAG) and we have had their input for many of the project areas, including questionnaire design, the content of the intervention, and the patient information sheet (PIS). A member of our PAG team has developed our PIS with their design and graphics background to a high end product we are proud to offer our potential participants. Another talented member of our PAG has provided us with beautiful illustrations of the exercises we will be using (Image 1), which will be used to create an exercise booklet to compliment the videos we have produced (Image 2). Another member of our PAG very kindly volunteered to be involved in filming the exercise videos for us. The PAG input has been invaluable, and the research team provides regular feedback on how their input has shaped the details of the project, and the changes we make along the way based on their feedback.