ISRCTN15207595 https://doi.org/10.1186/ISRCTN15207595

Hernia active living trial: HALT

Submission date
11/07/2019

Recruitment status
No longer recruiting

Registration date
20/02/2020

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A stoma is an opening on the abdomen that can be connected to either your digestive or urinary system to allow waste (urine or faeces) to be diverted out of your body. People living with a stoma can go on to develop a bulge or hernia at the site of the surgery. Reported rates of these parastomal hernias are as high as 40% 2 years after surgery. Attempts to repair the hernia using surgery have been disappointing with hernia recurrence in 30-76% of patients. Other types of intervention are needed to manage the symptoms, and quality of life issues that come with having a parasttomal hernia.
This is a feasibility trial so we will not be focusing on outcomes. The trial will recruit enough patients to gain knowledge of the number of patients who complete the intervention, and how patients feel about the intervention. We will also be looking at the following measures: the size of the bulge/hernia; abdominal composition (e.g muscle, fat ratios); quality of life; body image; physical activity levels; and Body Mass Index (which is a risk factor for parastomal hernia). Any changes in these measures will be reported, but they will not be classed as significant until a larger trial is undertaken.

Who can participate?
Patients who have a stoma and have been diagnosed with a parastomal hernia.

What does the study involve?
This intervention aims to provide a theoretically based physical activity intervention to improve core control, and strengthen the abdominal wall at a site of potential weakness. The hypothesis is that this intervention will reduce the risk of the hernia/bulge progressing, and that there will be an improvement in the appearance of the hernia, and have an effect of patient quality of life and body image.

What are the possible benefits and risks of participating?
This is a low risk study of a physical activity intervention as the main component. We do not anticipate any safety issues while carrying out the study. The intervention will concentrate on core training which involves small movements which will be described in detail and closely monitored by a clinical exercise specialist. There is a small risk of post-exercise soreness when learning new movements and activities. This is normal, and will subside within 24-48 hours. Patients will be made aware that they may experience some muscle soreness when first trying the exercises.

The exercises involved all have 4 levels of progression/difficulty and will be prescribed based on individual circumstances and abilities.
The exercises have been chosen based on guidelines issued by the American College of Sports Medicine (ACSM) in 2019 for patients living with an ostomy (stoma). They have also been informed by the Australian Physiotherapy and Pilates Institute (APPI) and have been discussed with our patient advisory group for appropriateness.

Where is the study run from?
University of the Highlands and Islands, UK.

When is the study starting and how long is it expected to run for?
March 2020 to June 2021

Who is funding the study?
Bowel Disease Research Foundation (via funding from Ileostomy and Internal Pouch Association and The Kingston Trust) (UK)

Who is the main contact?
Prof. Gill Hubbard
gill.hubbard@uhi.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Gill Hubbard

ORCID ID
http://orcid.org/0000-0003-2165-5770

Contact details
Dept. of Nursing and Midwifery, University of the Highlands and Islands, Centre for Health Science, Old Perth Road
Inverness
United Kingdom
IV2 3JH
+44 (0)1463 279815
gill.hubbard@uhi.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269384

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
1576GH, IRAS 269384

Study information

Scientific Title
A feasibility study of a physical activity intervention to improve quality of life in people with a bulge/parastomal hernia.

Acronym
HALT

Study objectives
To assess the feasibility of a physical activity intervention in people living with a stoma who have a bulge or parastomal hernia. We will evaluate the feasibility and acceptability of the key trial parameters. The main outcome is the decision by an independent Study Steering Committee whether to proceed to a full randomised controlled trial of the intervention. The hypothesis for a full RCT is that the intervention will improve core control and activation for patients with an area of potential weakness on the abdominal wall, thus reducing the risk of hernia progression. Increases in physical activity will improve hernia/ bulge appearance, and body image, thereby overall quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/02/2020, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; nosres@nhs.net), ref: 20/NS/0007

Study design
Feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised feasibility study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stoma, parastomal hernia

Interventions
A theoretically informed 12 week physical activity intervention with a clinical exercise specialist. Control group will receive usual care.

Intervention Group - The intervention will involve participants having 12 (1 per week) consultations with an exercise instructor. Professional associations for exercise specialists, such as the UK Chartered Institute for the Management of Sport and Physical Activity acknowledge that pre-exercise screening is an important part of the duties of an exercise specialist. Hence, the instructor will use the Physical Activity Readiness Questionnaire (PARQ) long version so that she can prescribe an individualised exercise programme for each participant, taking account of medical history and current health status. Participants will be prescribed 4 different types core training exercises with 4 levels of progression. These exercises are based pm the Australian Physiotherapy and Pilates Institute methods programme. Over the 12 week programme, there will be gradual progression in the prescribed frequency (number of times to perform the exercises that week), intensity (rate of exertion to perform the exercise that week) and duration (minutes to perform these exercises). The exercises will conform with the new guidelines issued by American College of Sports Medicine for people with an ostomy appliance.

Participants will receive a weekly physical activity consultation from an exercise instructor in-person, telephone and by video conferencing.

The intervention is of 12 weeks duration. Each participant will receive a weekly consultation. The duration of each weekly consultation is likely to vary; based on our previous study the average range is likely to be 15 - 45 mins (min 5;max 120; median 35) .
Control Group – Will receive usual care and signposted to information about physical activity guidance provided by relevant UK charities including Ileostomy and Pouch Association, and Colostomy UK. Control group participants will undergo the same baseline and follow up measures as the intervention group.

Intervention Type
Other

Primary outcome measure
Decision to proceed with a full-scale RCT of the intervention. An independent steering group committee will recommend whether the findings support the progression on to a fully powered trial.

Secondary outcome measures
At baseline (T0) and post-intervention 12weeks (T1):
1. Diagnosis and classification of PSH measured using clinical examination
2. Muscle activation measured using electromyography (EMG)
3. Body composition:
3.1. Waist circumference (cm)
3.2. BMI (kg/m^2) measured using TANITA scales (weight) and Stadiometer (height)
4. Patient reported outcomes:
4.1. QoL measured using Stoma-QoL and EQ-5D
4.2. Body image measured using the body image scale
4.3. Physical functioning measured using the patient specific function scale

5. Physical Activity measured using the Actigraph GT3X+ accelerometer
6. Psychological determinants of physical activity measured using:
6.1. Basic psychological needs in exercise scale
6.2. Exercise self-efficacy questionnaire

Overall study start date
01/09/2019

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Stoma and diagnosed with a parastomal hernia, or has a bulge at the stoma site
2. >12 weeks post surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Previous parastomal hernia repair
2. Urostomy

Date of first enrolment
01/03/2020

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Highland
Raigmore Hospital
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of the Highlands and Islands

Sponsor details
Executive Office
Ness Walk
Inverness
Scotland
United Kingdom
IV3 5SQ
+44 (0)1463 279000
ro@uhi.ac.uk

Sponsor type
University/education

Website
https://www.uhi.ac.uk/en/

ROR
https://ror.org/02s08xt61

Funder(s)

Funder type
Charity

Funder Name
Bowel Disease Research Foundation

Alternative Name(s)
BDRF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol for this trial will be submitted for open publication as encouraged by the health research authority (HRA).
Future analysis and results will be prepared into manuscripts, which will be submitted to appropriate peer-reviewed journals.

Intention to publish date
01/05/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/09/2020	30/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		03/07/2023	04/07/2023	Yes	No