Hernia Active Living Trial (HALT): A feasibility study of an exercise intervention

FINAL REPORT

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Foreword

I am delighted to be asked to write this foreword for the HALT project for two reasons. Firstly, as the Interim CEO of BRUK the funding charity, I am delighted that the study has produced such positive, informative, initial results. Secondly, as a person who has recently been on the bowel cancer treatment pathway and lived with a temporary ileostomy, I experienced many of the symptoms that the research addresses and truly appreciate the importance of sound advice for ostomates in both the prevention of complications with parastomal bulging as well as its day to day management.

Gill, the steering group and her team of researchers have produced an exemplary piece of initial research that combines the best of quantitative and qualitative collection of data from patients as participants, demonstrating impressive integrated partnership approaches through action research and co-production.

I look forward to hearing about the further development of this study hopefully as an NIHR funded project and to see the growth of Lived Experience Research.

Lynn Dunne
Interim CEO
Direct Line: 02070187771

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1. SCIENTIFIC SUMMARY

1. Background

Parastomal bulging and parastomal hernia, which is a specific type of bulging are common late stomal problems. Studies suggest that ostomates with parastomal bulging are likely to have worse quality of life than those without. The Association of Coloproctology of Great Britain and Ireland 2018 guidelines recommend non-operative management in most cases. An example of non-operative management of parastomal bulging is exercise. One hypothesis is that abdominal exercises counteract a weakness in the abdominal wall from surgery and stoma creation. Another hypothesis is that abdominal and breathing exercises contribute towards strengthening the body core so that there is better control of intra-abdominal pressure.

2. Aims and objectives

The aim of a future effectiveness RCT is to determine whether a structured exercise intervention improves QOL for people living with a parastomal bulge in comparison to healthcare professionals signposting people to written exercise guidance only. The aim of this feasibility study was to address uncertainties relating to the exercise intervention and trial methods. The objectives were:

1. To determine intervention fidelity by assessing if the exercise intervention was delivered as intended by the clinical exercise instructor.
2. To determine intervention adherence by assessing if participants engaged with the exercise programme as intended.
3. To determine intervention acceptability by assessing participants' views about the exercise programme, including its perceived relevance and usefulness in self-managing their parastomal bulge.
4. To determine if the exercise intervention was safe and if the exercises caused participants to feel pain and/or discomfort.
5. To determine eligible patients' consent rate.
6. To determine participants' acceptability of RCT design.
7. To determine participants' acceptability of outcome measures.

3. Design and Methods

In this feasibility study an exercise intervention was developed and then tested in a single-arm trial followed by a feasibility RCT.

Eligibility

Adults 16 years+[a], ≥ 3 months post stoma formation surgery for bowel disease, with a colostomy or ileostomy, who perceived that they had a parastomal bulge were eligible. People already doing core training or with no access to the internet were excluded.

[a] In the UK, for the purposes of research, people 16 years old and over are adults

Recruitment

Social media was used to recruit to the single-arm trial. For the feasibility RCT, patients were recruited from two hospitals.

Data collection

Participants completed an online questionnaire and exercise diary that they accessed via the internet from their own home. A questionnaire was completed by participants at baseline and 12 week follow-up and a diary was completed each week of the 12-week exercise programme. At follow-up, a research assistant conducted a semi-structured interview with participants.

Intervention

The exercise intervention was developed by the research team and the Patient Advisory Group via online meetings and email exchange. Hence, the intervention incorporated expertise about the physiological effects of exercise and theories of behaviour change alongside the lived experience of people with bowel disease, including people with a parastomal bulge. The exercise intervention had three core components:

1. Exercise booklet sent by email to all participants
2. Exercise videos available on a private YouTube channel
3. Exercise sessions delivered online by a clinical exercise instructor

Outcomes

The main outcome of the feasibility study is a decision by an independent Study Steering Committee to proceed or not to an effectiveness RCT. Criteria was set apriori for key trial parameters using a traffic lights system. The following intervention and trial parameters were measured to guide the committee's decision-making:

1. *Intervention fidelity* was assessed by the number of exercise sessions delivered by the clinical exercise instructor and duration. Two instruments were used to assess the extent to which SDT principles were used by the clinical exercise instructors to motivate and support participants – Interpersonal Support in Physical Activity Observational Tool (maximum score=21) and the Basic Psychological Needs in Exercise Scale (maximum score 5).

2. *Intervention adherence* was assessed by the completion rate of the prescribed exercises by participants.

3. *Intervention acceptability* was assessed by free-text comments in the diary about the exercise intervention and by semi-structured interview.

4. *Intervention safety* was assessed by free-text comments in diary about changes with their stoma/parastomal bulge and reports of serious adverse events.

5. *Acceptability of trial parameters* was assessed by eligible patients' consent rate, retention rate and missing data rates.

6. *Acceptability of RCT design* was assessed by using the consent rate and the retention rate as proxy.

7. *Acceptability of instruments to measure outcomes* was explored in the semi-structured interviews conducted with participants at the end of the study and by assessing if any observed changes in the following outcomes flagged concerns about the effect of the exercise intervention: QOL (EQ-5D-5L-5L, Stoma-QOL), Body Image Scale, Patient-Specific Functional Scale, self-efficacy (4 items), physical activity (4 items), and 10 additional questions about parastomal bulging.

Sample size

We intend for QOL to be our primary outcome in the future RCT and in line with Whitehead et al. 2016, a sample size of 20 was considered appropriate.

Randomisation

Participants for the feasibility RCT were randomly allocated to intervention or control groups using a randomisation software package.

Data analysis

Data are reported as percentages, means and standard deviations. For the feasibility RCT, change scores from baseline to follow-up for outcomes were calculated, and an independent sample t-test was conducted with the grouping variable being the control or intervention condition. Qualitative thematic analyses of audio-recorded interviews and focus groups were conducted using the Framework approach.

4. Patient and Public Involvement

A Patient Advisory Group (PAG) was part of deciding that research on exercise intervention for parastomal bulging was important. The PAG was involved in study design, intervention development and preparing the trial materials. Two members of the PAG attended research team meetings to be part of all decision-making about the study.

5. Results

Seventeen participants consented and 13 were referred to the exercise intervention in the single-arm trial; 19 participants were randomised to the intervention or control group in the feasibility RCT.

Qualitative data suggest that participants perceived physical and mental health benefits of the exercise intervention. Perceived physical benefits aligned with the hypothesised benefits of the exercise programme i.e., improved breathing technique, core control and strength. The exercise programme was safe; there were no adverse events. Participants experienced challenges and issues during the exercise programme including pain and discomfort around the stoma but these were within acceptable limits and not all were attributed to the exercise programme.

The results of the study using the apriori criteria and a traffic lights system are presented below:

PARAMETERS	RESULTS	
Number of sessions (maximum=12)	8	Green
Session duration in minutes	48	Green
SDT - Interpersonal Support	20.3	Green
SDT - Basic Psychological needs		
Competence	3.26	Amber
Autonomy	3.44	Amber
Completion rate of prescribed exercises	92%	Green
Adverse events	0	Green
Eligible patients' consent rate	74% single-arm 76% two-arm	Green
Retention rate	47% single-arm 42% two-arm	Red
Missing data rate		
EQ5D Descriptive Score	Single-arm 12.5%; two-arm 0%	Green
EQ5D VAS	Single-arm 0%; two-arm 0%	Green
Stoma-QOL Now	Single-arm 0%; two-arm 12.5%	Green
Stoma-QOL Past Month	Single-arm 0%; two-arm 25%	Amber
Stoma-QOL Work/Social Functioning	Single-arm 37.5%; two-arm 75%	Red
Stoma-QOL Sexuality/Body Image	Single-arm 37.5%; two-arm 62.5%	Red
Stoma-QOL Stoma Function	Single-arm 0%; two-arm 0%	Green
Stoma-QOL Financial Concerns	Single-arm 0%; two-arm 0%	Green
Stoma-QOL Skin Irritation	Single-arm 0%; two-arm 0%	Green
Self-Efficacy	Single-arm 0%; two-arm 12.5%	Green
Physical Activity	Single-arm 0%; two-arm 0%	Green
Do you have pain associated with your bulge/hernia?	Single-arm 0%; two-arm 0%	Green
What size do you consider your bulge/hernia to be?	Single-arm 0%; two-arm 0%	Green
Is your bulge/hernia larger than 5cm diameter?	Single-arm 0%; two-arm 0%	Green
How do you feel about managing your bulge/hernia?	Single-arm 0%; two-arm 12.5%	Green
How do you feel about your body image in relation to your bulge/hernia?	Single-arm 0%; two-arm 0%	Green
How you ever considered surgical repair?		
Are you currently considering surgical repair?	Single-arm 12.5%; two-arm 25%	Amber
	Single-arm 0%; two-arm 12.5%	Green

6. Discussion and conclusions

The exercise intervention is feasible to deliver and acceptable to participants. Self-reported physical benefits aligned with the hypothesised benefits of the exercise programme i.e., improved breathing technique, core control and strength. In a future study, more information about participants' characteristics is required in order to assess if the study and the intervention if implemented in practice, would attract a range of patients who it is designed to benefit. Additional information on for example, ethnicity, level of education, lifestyle behaviours, and internet use would be relevant. Strategies to improve retention need to be included in a future study. Retention strategies could be tested in an embedded pilot RCT of a future effectiveness RCT with clear progression criteria.

2. BACKGROUND

2.1 Prevalence of parastomal bulging

A stoma is an artificial opening on the surface of the abdomen that has been surgically created in order to divert the flow of faeces or urine (Figure 1).

A parastomal hernia (PSH) is defined by the European Hernia Society as 'an abnormal protrusion of the contents of the abdominal cavity through the abdominal wall defect created during placement of a colostomy, ileostomy or ileal conduit stoma.'[1] A parastomal bulge is similarly defined but includes subcutaneous prolapse.[1] It is difficult to differentiate between the two clinically[2] and from a patient perspective lived experience of PSH and parastomal bulge may be indistinguishable. Hence, the importance of a clinical diagnosis is questionable given that a parastomal bulge may be just as debilitating as a clinically diagnosed PSH from a patient perspective. There is no gold standard examination to assess, diagnose and classify PSH.[3] Computerized Tomography (CT) is highly accurate at identifying PSH but is difficult to justify because of cost, and there is risk of radiation exposure.[3] Clinical examination has sensitivity rates between 66% and 94%, and specificity rates are reported to be as high as 100%.[3]

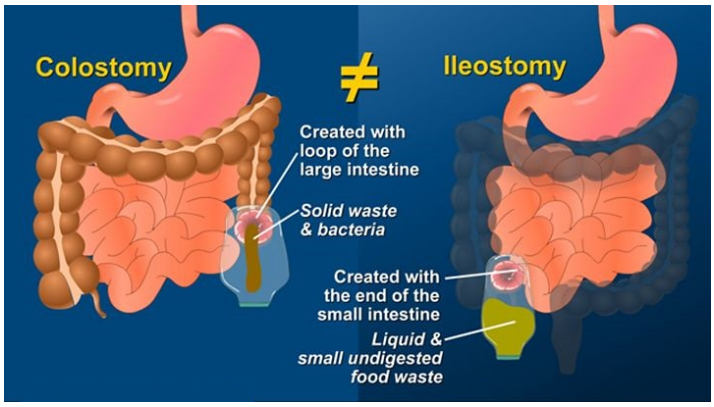


Figure 1: Stoma
Keenan Motley, uploaded Flickr Sept 4th 2020

PSH and parastomal bulging is a common late stomal problem,[4] with prevalence estimates over 30% by 12 months, 40% by 2 years and 50% or higher at longer duration of follow-up[3]. A review of 77 patients undergoing stoma formation at a single UK centre in 2009 found that 20% had a PSH within 16 months follow up.[5] A review of 5019 patients in Denmark found that the incidence of parastomal bulging was 36% within 1 year of stoma formation.[6] A cross-sectional study of 75 patients with an end colostomy operated on between March 1997 and May 2005 at a centre in Spain, found that 33 (44%) had evidence of a PSH on CT at ≥1 years.[7] The majority of these patients were symptomatic (27 versus 6), such as pain or difficulties with stoma appliance and able to identify the moment of clinical appearance of the PSH, which occurred within 8 months of surgery.[7]

In Europe, approximately 700,000 people are living with a stoma, and in the USA, more than 1 million people have a stoma[8]. There is no UK national database of ostomates. A national audit shows that just under 11,500 patients diagnosed with rectal cancer each year have a stoma formed[9] and a UK charity website indicates that each year, around 2000

people with inflammatory bowel disease have a stoma formed.[10] Assuming that half of these people will have a parastomal bulge, this equates to approximately 6,750 people per annum.

2.2 Quality of life

We are aware of only a few studies specifically about quality of life (QOL) in people with a parastomal bulge or PSH. These studies show that QOL and body image are likely to be worse in people who have a parastomal bulge compared to people with a stoma who do not have a parastomal bulge. A Swedish cross-sectional study of 46 (65.7% of the sample) people with a parastomal bulge diagnosed by clinical examination found that QOL was worse in people with a parastomal bulge (measured using Stoma-QOL) compared to 24 people who did not have a parastomal bulge.[11] A Danish cross-sectional study of 1265 patients found that the Stoma-QOL summary and all health domains in SF-36 (general health status, physical and emotional health, daily activities, social activities, pain) were significantly worse in stoma patients with a parastomal bulge compared to those without a parastomal bulge.[12] The study reported that scores for patients with a large parastomal bulge (>10 cm) were significantly worse than for patients with a small bulge in all health domains and summary scores in SF-36 and in the Stoma-QOL summary score, but no differences were found in the Colostomy Impact Score.[12] That size of bulge was significantly associated with QOL may be related to body image, which is a psychological construct that captures the perceptions, emotions, and attitudes a person holds towards his/her own body.[13] A study of 35 patients with colorectal cancer and a stoma found that body image (measured using the Body Image Scale) had a negative effect on quality of life[14] and a Dutch study of 75 (20%) patients who had an incisional hernia after open abdominal surgery (16% as treatment for colorectal cancer) compared to 299 patients who did not have an incisional hernia found that patients with an incisional hernia had significantly worse QOL and lower body image scores.[15]

2.3 Reducing the risk of parastomal bulging

Given the high prevalence of parastomal bulging and the negative impact on QOL, research has focused on understanding modifiable risk factors for parastomal bulging. Potentially modifiable risk factors include stoma formation surgical techniques. One of the larger and more recent studies found that age, colostomy, male gender, alcohol consumption and laparoscopy were associated with an increased risk of parastomal bulging and peristomal mesh and stomas placed through a separate incision were associated with a reduction in risk.[6] The Association of Coloproctology of Great Britain and Ireland (ACPGBI) in 2018 published a position statement about associations between different surgical techniques and parastomal bulging; it concluded that synthetic non-absorbable mesh can be used safely in the short term in the construction of colostomies post rectal surgery and highlighted several on-going studies about surgical techniques that may reduce the risk of

parastomal bulging.[16] It also concluded that suture repair of PSH other than for patients *in extremis* should not be performed and recommended non-operative management of PSH.[16] An example of non-operative management of parastomal bulging is exercise.

2.4 Exercise to manage parastomal bulging

Exercise programmes delivered by a clinical exercise specialist are required as part of routine clinical care to support people with a stoma perform abdominal and breathing exercises because most people with a stoma are unlikely to exercise without assistance. This is because studies have highlighted a trend toward inactivity after stoma formation surgery, with fear of PSH being a major deterrent to exercise.[17-19] This feasibility study is about the benefits of exercise for people with a parastomal bulge, and in particular, how exercise can improve QOL.

There is a paucity of prospective data about the natural history and trajectory of parastomal bulging and whether parastomal bulging severity progression can be arrested.[20 21] Uncertainties remain about the role of tensile strength of fascia, skin healing and abdominal wall dysfunction and hernia occurrence after abdominal surgery.[22] One hypothesis is that abdominal exercises counteract a weakness in the abdominal wall from surgery and stoma creation.[23] Abdominal rectus muscle atrophy and midline shift after stoma creation are hypothesized biomechanical mechanisms for parastomal bulging.[24] One of the functions of deep abdominal muscles is to provide support to the abdominal region and the spine by forming a muscle band that tightens like a corset.[25] Following abdominal surgery, the physiology of the abdominal wall is altered with damage to nerve supply and atrophy of the midline muscular wall.[26] Surgery for creating a stoma alters the physiology in the same way and creates a further site of weakness by leaving a hole in the abdominal wall. Evidence indicates that there is muscular atrophy directly below the stoma site, resulting in change of forces and pressure on the abdominal wall.[27]

Another hypothesis is that abdominal and breathing exercises contribute towards strengthening the body core so that there is better control of intra-abdominal pressure. The Association of Stoma Care Nurses highlights intra-abdominal pressure as a risk factor for PSH.[28] Various muscles contribute to a 'synergy of muscles' responsible for generating intra-abdominal pressure – transversus abdominis, the diaphragm, the pelvis floor muscles and the lumbar multifidus and in healthy populations these individual elements co-activate in advance of limb movement.[29] Intra-abdominal pressure is generated through an automatic and simultaneous process of the diaphragm descending and the transversus abdominus and the pelvic floor muscles co-activating. This is why it is hypothesised that the ability to coordinate the postural and respiratory functions will contribute to controlling intra-abdominal pressure which in turn, will reduce the risk of parastomal bulge occurrence and help in the self-management of a parastomal bulge. It follows that any exercise programme

for people with a parastomal bulge would focus on breathing techniques as well as strengthening and utilising the 'synergy of muscles' responsible for generating intra-abdominal pressure. How an exercise intervention is expected to lead to its beneficial effects on people living with a parastomal bulge is presented in Figure 2.

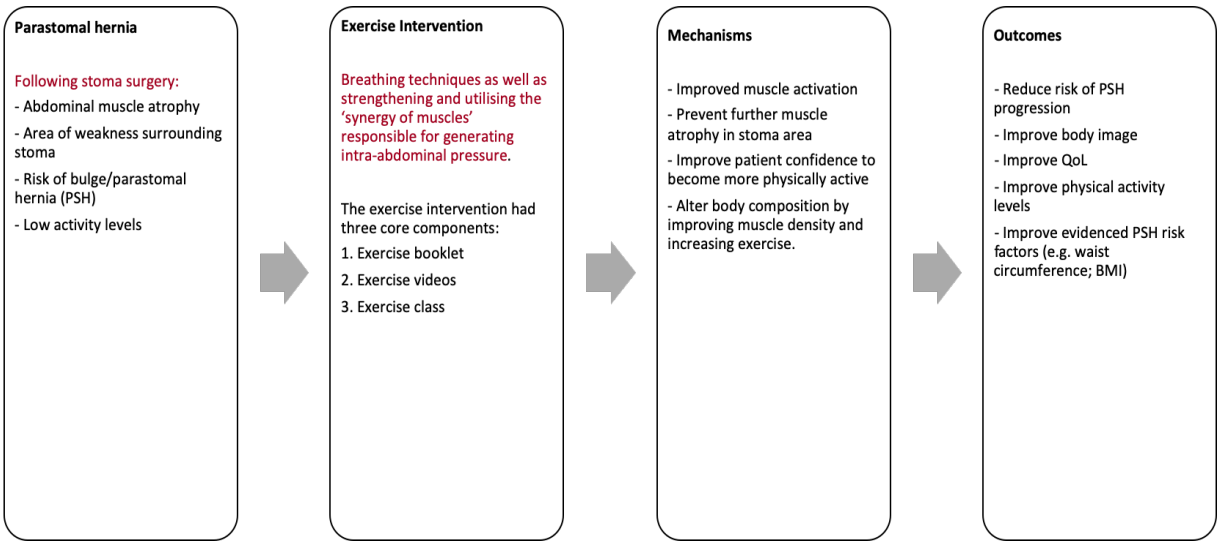


Figure 2: A logic model showing how the exercise intervention might improve outcomes for people with a parastomal hernia

2.5 Intervention development and feasibility studies

Intervention development and feasibility studies often go hand in hand. According to recent published guidance, some of the key principles for intervention development are that the process is iterative, open to change, engages key stakeholders, and is forward looking to future evaluation and implementation.[30] Large-scale, statistically powered randomised controlled trials (RCTs) are increasingly informed by one or more feasibility study that are designed to generate sufficient evidence to make informed decisions by the research team, independent assessors and grant funding bodies about whether an intervention is promising and the research methods can be replicated in a larger multi-centre study.[31] Feasibility studies are preparatory studies for a future randomised controlled trial[32] and are designed to assess predefined progression criteria that relate to uncertainties about the developed intervention (e.g. acceptability, adherence) and study parameters (e.g. consent rate).[33] Ultimately, the goal of feasibility studies is to identify and address potential problems relating to the intervention and trial methods. A key outcome of a feasibility study is a recommendation on whether it is appropriate to proceed to an effectiveness RCT or if further work is necessary to further refine the intervention and methods.[33] The most common reason why previous research teams have concluded that a future RCT was not viable following a feasibility study was patient recruitment.[34] Other reasons for not progressing to a full trial were the intervention, trial design/methods and outcome

measures. Hence, these parameters provide a relevant focus for feasibility studies so that the scientific merit of the potential effectiveness and potential real-world implementation of the intervention can judged alongside an assessment of trial feasibility. It is only then, that an formed decision about whether an intervention is ready to be scaled can be made.[31]

3. AIMS & OBJECTIVES

The aim of a future effectiveness RCT is to determine whether a structured exercise intervention improves QOL for people living with a parastomal bulge in comparison to healthcare professionals signposting people to written exercise guidance only. The aim of this feasibility study was to address uncertainties relating to the exercise intervention and trial methods. The objectives were:

1. To determine intervention fidelity by assessing if the exercise intervention was delivered as intended by the clinical exercise instructor.
2. To determine intervention adherence by assessing if participants engaged with the exercise programme as intended.
3. To determine intervention acceptability by assessing participants' views about the exercise programme, including its perceived relevance and usefulness in self-managing their parastomal bulge.
4. To determine if the exercise intervention was safe and if the exercises caused participants to feel pain and discomfort.
5. To determine eligible patients' consent rate.
6. To determine participants' acceptability of RCT design.
7. To determine participants' acceptability of outcome measures.

4. METHODS

The feasibility study was conducted in line with a published a priori protocol[35] and Statistical Analysis Plans. Some changes to the study were made as a consequence of the Covid-19 pandemic (Appendix 1).

4.1. Design

In this feasibility study an exercise intervention was developed and then tested in a single-arm trial followed by a feasibility RCT.

4.2. Participants

Eligibility criteria for participants

Adults 16 years+[b], ≥ 3 months post stoma formation surgery for bowel disease (e.g., inflammatory bowel disease, colorectal cancer), with a colostomy or ileostomy, who perceive that they have a parastomal bulge (i.e. individual self-assessment) or who have a clinical diagnosis of a PSH were eligible.

People who are already doing core training (e.g., Pilates, yoga) were excluded because they clearly do not need the support of an exercise intervention in order to engage in exercise likely to be of benefit to their self-management of a parastomal bulge. People who did not have access to the internet were excluded because the intervention was delivered online by video conferencing and exercises were expected to be performed in a participant's own home rather than, for example, a gym. For the single-arm trial, people who had a previous hernia repair were excluded but this was amended during the feasibility RCT.

Some exercise intervention studies include cardiovascular disease risk as an eligibility criterion because it is advisable that persons at moderate risk of cardiovascular disease undergo medical examination prior to starting a vigorous exercise programme.[36] The exercise intervention developed in this feasibility study did not involve vigorous exercise and therefore no health screening of potential participants was required.

How participants were identified and consented

Two recruitment methods were used that would target the population of interest i.e., people who would use the exercise intervention were it to be implemented in the real-world.

Social media was used to recruit to the single-arm trial. An advertisement about the study was disseminated by members of the Patient Advisory Group and by relevant stoma

[b] In the UK, for the purposes of research, people 16 years old and over are adults

charities (Ileostomy and Internal Pouch Association, Colostomy UK) on both Facebook, and Twitter. Contact details of a research assistant were provided, along with brief eligibility criteria. This allowed anyone who was interested in taking part to see if they were eligible and to contact the research team directly. We anticipated that people recruited by this method would be highly self-motivated to exercise. Recruitment using this method was carried out from 5th May 2020 to 10th May 2020 through social media advert for the single-arm trial. Due to the Covid-19 pandemic, referrals to the exercise intervention did not begin until 14th August 2020 due to NHS R&D departments putting a stop to all non-essential research.

For the feasibility RCT patients were recruited from two hospital trusts between 7th April – 7th August 2021. Patient recruitment from a large metropolitan teaching hospital was conducted by research nurses who identified a list of patients who had a bowel stoma and sent out an invitation letter and the Participant Information Sheet. Interested patients then got in touch directly with a research assistant via email or telephone who then conducted eligibility screening with the patient. Patient recruitment from an acute district hospital was conducted by the clinical colorectal team at the hospital who completed screening for eligible patients from their outpatient list and sent out invitation letters to potentially eligible patients. The patient was instructed to contact a research assistant directly by email or telephone if they were interested in taking part, who then conducted eligibility screening with the patient.

Data collection

Three methods were used to collect data from participants – questionnaire, diary and semi-structured interview. Participants completed an online questionnaire and exercise diary that they accessed via the internet from their own home. The questionnaire was completed at baseline and follow-up (i.e. pre- and post-intervention) and the diary was completed each week of the 12-week exercise programme. At follow-up, a research assistant (JM, WG) conducted a semi-structured interview with participants by telephone or video conference.

4.3. Intervention

The exercise intervention was developed by the research team and the Patient Advisory Group via online meetings and email exchange. Hence, the intervention incorporated expertise about the physiological effects of exercise (see section 2.4) and theories of behaviour change alongside the lived experience of people with bowel disease, including people with a parastomal bulge.

The exercise intervention had three core components:

1. Exercise booklet sent by email to all participants
2. Exercise videos available on a private YouTube channel

3. Exercise sessions delivered online by a clinical exercise instructor

Depending on participant ability, safety, and time commitments, they could use the booklet and/or watch the exercise videos and/or have a one-to-one exercise session with a clinical exercise instructor once a week for 12 weeks. Each component is described below.

We developed an **intervention booklet** that was sent by email to participants. In the booklet, exercises were described narratively and shown pictorially. The images were drawn by Susan Meer, a member of the Patient Advisory Group. The booklet was designed by Scott Clifford who was also a member of the Patient Advisory Group.

The exercises illustrated and described in the booklet were expected to be completed at home by participants. These exercises were chosen by the research team and were based on the Australian Physiotherapy and Pilates Institute methods programme.[37] The exercises focussed on breathing techniques as well as activating and utilising the 'synergy of muscles' to focus on control and engagement of the muscle groups.

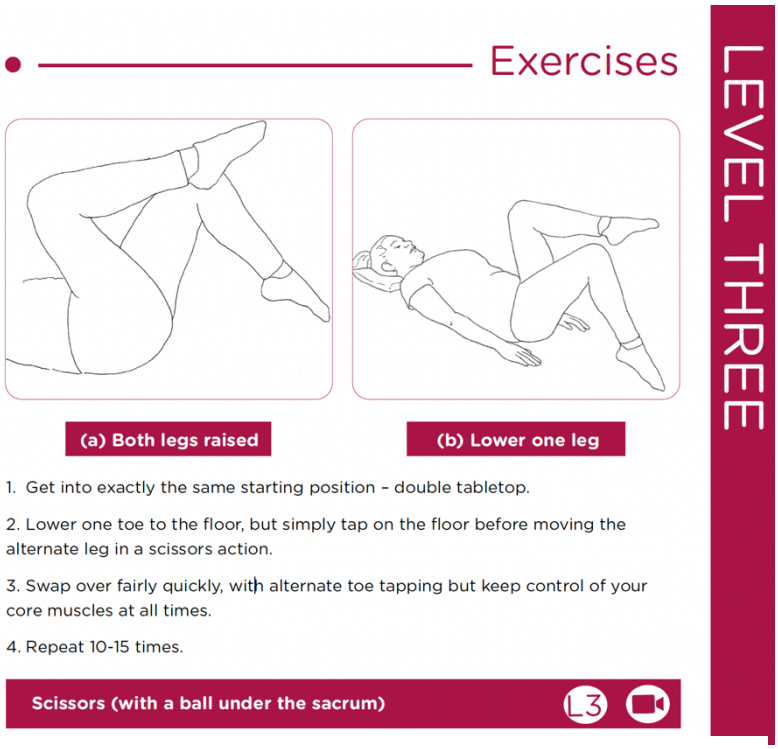


Figure 3: HALT Booklet 'scissors' Level 3

There were 3 levels of exercise with level 1 being the easiest. For example, in level 1, the 'scissors' exercise involved lifting each leg off the floor independently and one at a time while one foot remains on the floor; in level 3 the 'scissors' exercise involved lifting both legs off the floor with knees at 90 degrees and then tapping the floor with the toe but keeping the opposite leg in the fixed 'table top' position (as seen in Figure 3).

In the booklet, there was a hyperlink to a private **YouTube video channel** so that participants could watch how each exercise was correctly performed. In each video, Andrea Robson, a member of the Patient Advisory Group, performed each exercise while being

given verbal instructions by Sarah Russell, a clinical exercise instructor who runs the Ostomy Studio. There were 13 exercise videos in total. The videos were produced by a production company and were filmed in the Ostomy Studio.

Participants were offered a **1-to-1online clinical exercise session** with a clinical exercise instructor. Before the first session, participants completed a self-screening form (Physical Activity Readiness Questionnaire – PAR-Q) to determine any possible health risks. They also completed some relevant medical history questions directly linked to their stoma, their surgery, and their parastomal bulge. In this feasibility study, the intervention was delivered separately by two clinical exercise instructors who both held a Register of Exercise Professional Level 4 cancer rehabilitation qualification and had previously supported clinical populations, including people with a stoma, to engage in exercise, including Pilates. Participants could arrange to meet once a week online over a period of 12 weeks (if required) for 15-45 minutes with an instructor. During the session, the instructor would show a participant how to perform a specific exercise and then observe them doing the exercise. The instructor would prescribe an exercise programme for the participant for the following week based on the participant's level of competence. The instructor drew on the core principles of Self-Determination Theory (SDT) to motivate and support participants to practice the prescribed exercises each week. According to this theory, conditions that support a person's basic psychological needs, which is their need for 'autonomy,' (feeling of being the origin of behaviour), 'competence' (feeling of being effective) and 'relatedness' (feeling of being understood and cared for by others), foster the most volitional and intrinsic forms of motivation for initiation and long-term maintenance of exercise.[38]

There was in-built flexibility so that the intervention could be tailored to address the unique needs of each participant. The intervention could vary as follows:

- what participants used (booklet, video, exercise session),
- when during the week and day participants did the exercises in their own home,
- what exercises they did, how many times a week, how many repeats of each exercise during each session, at what level and how long for,
- how many online 1-to-1 sessions participants had with the clinical exercise instructor during the 12-week programme,
- how long the 1-to-1 session lasted, what exercises were discussed and how the instructor engaged with the participant (i.e. what was said and done).

4.4. Outcomes

The main outcome of the feasibility study was a decision by an independent Study Steering Committee to proceed or not to an effectiveness RCT using the following traffic light system to guide decision-making (Table 1). Members of this group were: *Professor Anna Campbell*, Professor in clinical exercise science, Edinburgh Napier University and Director of CanRehab, *Professor Thomas Pinkney*, colorectal consultant surgeon and Director of the Birmingham Surgical Trials Consortium and the Birmingham Centre for Observational and Prospective Studies, and *Professor Shaun Treweek*, Professor of Health Services Research, University of Aberdeen and lead for Trial Forge. The group met with the research team and funder representatives in a 2 hour meeting to discuss study findings.

Table 1: Criteria for progression to an effectiveness RCT

PARAMETERS	GREEN	AMBER	RED
INTERVENTION PARAMETERS			
Intervention fidelity			
Number of sessions (maximum=12)	Mean ≥8/12	>6	<6
Session duration in minutes	Mean ≥30	>15	≤15
SDT - Interpersonal Support *(maximum score=21; higher score=higher fidelity)*	Mean score ≥16	>14	<10
SDT - Basic Psychological needs *(maximum score=5; higher score=higher fidelity)*	Mean score ≥4	≥3	<3
Intervention adherence			
Completion rate of prescribed exercises	Mean score ≥80%	>60%	<50%
Intervention acceptability			
Exercise acceptability for self-managing parastomal bulge assessed qualitatively by free-text comments in diary & interview	-	-	-
Intervention safety			
Challenges and changes to stoma/parastomal bulge during exercise assessed qualitatively by free text in diary	-	-	-
Adverse events	Mean score ≥1%	≥3%	≥5%
TRIAL PARAMETERS			
Eligible patients' consent rate	≥30%	>20%	<20%

Retention rate	≥60%	>50%	<50%
Missing data rate	≤20%	≤40%	>40%
DECISION	NO CHANGES	MODIFY	MODIFY/STOP

Outcomes used to assess the feasibility and acceptability of the intervention were as follows:

Intervention fidelity

Intervention fidelity was defined as the extent to which the intervention was delivered as intended by the clinical exercise instructor. Quantitative measures of fidelity were the number of exercise sessions delivered by the instructor and duration. To collect this information, the clinical exercise instructor recorded for each participant the number of online consultations and duration, and the exercise prescription. Based on our previous study of a physical activity intervention for people with stoma, we estimated that the mean number of consultations would be 10 and mean duration approximately 35 minutes.[39] Two instruments were used to assess the extent to which SDT principles were used to motivate and support participants:

1. Four online consultations were recorded by the clinical exercise instructors (3 by 1 instructor and 1 by the other instructor) with participants' permission and two researchers (GH, CT) assessed these using the Interpersonal Support in Physical Activity Observational Tool.[40] The tool assesses four domains with 21 items: autonomy support by 7 items (e.g., *enhancing self-worth*), involvement by 2 items (e.g., *demonstrating affection*), structure by 4 items (e.g., *encouraging questions*) and controlling by 8 items (e.g., *over authoritative*). A total score was summed, with a higher score indicating higher intervention fidelity.
2. Participants receiving the intervention completed the Basic Psychological Needs in Exercise Scale,[41] which is an 11-item self-report questionnaire. Participants rate each item on a 5-point scale from 1 (*I don't agree at all*) to 5 (*I completely agree*). Items assess participants' need fulfilment for autonomy, competence and relatedness. In line with SDT, the satisfaction of these needs results in higher levels of behavioural self-determination that in turn, is reflected by higher levels of, for example, intrinsic motivation (e.g., finding exercise enjoyable) and identified regulation (e.g., considering exercise outcomes to be personally important). The relatedness subscale was not relevant to this intervention and was not reported.

Intervention adherence

Intervention adherence was defined as the completion rate of the prescribed exercises by participants. Participants used the online diary to record each week the extent to which they completed the exercises prescribed by the instructor. At the end of each week, participants answered the following question: '*How much of your prescribed exercises did you complete this week? When answering this question think about your success in relation to the prescribed frequency, intensity and duration.'* There were five response options: all of it 100%, most of it (75%), about half of it (50%), some of it (25%), none of it (0%).

Intervention acceptability

The acceptability of the intervention was investigated by free-text comments in the diary and during a semi-structured interview. Participants we given the opportunity to comment in the diary on how they *'felt doing the exercises e.g. any challenges, any issues or changes with your stoma/hernia, did you find it enjoyable?'* The interview schedule is available in Appendix 2 and included for instance, experiences of the intervention and benefits and barriers of exercise.

Intervention safety

Participants used the diary to report any challenges or any changes with their stoma/ parastomal bulge during their participation the exercise programme. Serious adverse events (AEs) were reported as part of the ethical conduct of the study. A standard SAE form was completed by the clinical exercise instructors if required.

Outcomes used to assess the feasibility and acceptability of trial parameters were as follows:

Eligible patients' consent rate

Eligible patients' consent rate was defined as the number of patients who were sent a letter and Participant Information Sheet about the study by the hospital clinical team who then went on to consent to participate in the feasibility RCT. Based on our previous study of a physical activity intervention for people with stoma, we estimated a 30% consent rate.[39] It is not possible to calculate a consent rate for recruiting participants by social media in the single-arm trial because how many people saw the advertisement about the study is unknown; hence, only the number of people recruited via this method is reported.

Acceptability of RCT design

Eligible patients' consent rate and the retention rate were used as proxy measures of the acceptability of RCT design. The retention rate was defined as the number of consenting participants who completed baseline and follow-up measures. Based on our previous study

of a physical activity intervention for people with stoma, we estimated a 60% retention rate.[39]

Acceptability and data availability of outcome measures

The acceptability of instruments to measure outcomes were explored in the semi-structured interviews conducted with participants at the end of the study. Data availability refers to the amount of data available for analyses. In a future statistically powered RCT, only complete data (i.e., individually paired baseline and follow-up data for the primary outcomes) will be included in the analyses. In this feasibility study, we therefore assessed the amount of complete data for the following outcomes:

Quality of life: In a future effectiveness RCT, we intend QOL to be the primary patient-report outcome. This outcome provides us with the patient perspective of the intervention's direct clinical benefit and is a primary end-point that is considered important to patients.[42] To our knowledge, there are no bespoke instruments for assessing parastomal-related QOL or for body image in this patient group. There are, however, generic QOL and body image instruments and several stoma-specific QoL tools[43] that we assessed in this feasibility study.

The generic QOL instrument that we used was the European Quality of Life-5 Dimensions (EQ-5D-5L), which is a common measure of health-related QOL.[44] It is divided into two sections: the EQ-5D index and the EQ thermometer. The EQ-5D index assesses health across five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ thermometer is a single 20-cm vertical visual analogue scales with a range of 0 to 100, where 0 is the worst and 100 is the best imaginable health and is completed by the user for their current health. Descriptive data from the five dimensions of the EQ-5D part 1 can be used to generate a health-related QOL profile for the participant, created from the 1–5 scale for each question. This can be further divided into participants reporting 'problems' or 'no problems', combining some of the subscales. Part 2 is scored from 0 (worst health state imaginable) to 100 (best health state imaginable). The score from part 2 can be used to track changes in health, on an individual or group level, over time. Simulation-based estimates (mean score) of the minimal important difference (MID) of the EQ-5D-5L index score in 6 countries (including England) were generally between 0.037 and 0.069, which are similar to the MID estimates of other preference-based QoL measures[45] The MID (mean and standard deviation) for England was 0.037 ± 0.008.

Stoma-related QOL was measured using the Stoma- QOL,[46] which was deemed acceptable for use by participants in our previous study.[39] It is a 21-item questionnaire; 19 items covering the 5 domains of work/ social functioning, sexual/body image, stoma function, financial concerns, and skin irritation are scored using a 5-point Likert-type frequency scale, and 2 items measure overall life satisfaction and are scored from 0 to 100, with 0 being the

worst possible score and 100 being the best score. To our knowledge, no recommended MID estimates have been published for this instrument.

Body image: The Body Image scale[47] was used for assessing body image. It was chosen because it has been validated in ostomy patients.[48] It is a 10-item questionnaire with items scored using a 4-point rating scale that was developed to assess the affective (e.g., feeling self-conscious), behavioural (e.g., difficulty in looking at the naked body) and cognitive (e.g., satisfaction with appearance) aspects of body image in cancer patients.

Physical functioning: The Patient-Specific Functional Scale (PSFS) focuses on the patient's opinion of their function in order to provide clinicians with a reliable and valid self-reported outcome measure.[49] The patient lists up to five activities that are limited by their condition (in this feasibility study, parastomal bulge) for which they are seeking treatment (in this feasibility study, the exercise programme). For each activity, patients use a continuous rating scale (0 to 10) with a lower score indicating that they are unable to perform the activity, to indicate the extent to which they are able to carry out the activity. The total score is the sum of the activity scores divided by the number of activities listed. It takes an average of 4 minutes to complete. It is used in clinical practice and research to assess if there is a meaningful change in functional status that has occurred over time. The MID has been evaluated for certain conditions and is between 2 and 3.[49]

Self-efficacy: The Exercise Regularly Scale[50] was adapted to assess self-efficacy. There were four items: (1) 'How confident are you that you can do gentle exercises to strengthen your abdominal muscles? (2) How confident are you that you can do aerobic exercises such as walking and cycling (3) How confident are you that you can exercise without it causing problems with your stoma? (4) How confident are you that you can exercise without it causing problems with your parastomal hernia/bulge? All items were rated from 1 (Not at all confident) to 10 (Totally confident).

Physical activity: This was measured through 4 self-report questions asking how many times in the past week participants had been physically active inside and outside the home and typical duration in minutes. Total time of physical activity was calculated for both inside and outside activities over the past week and then summed for a total time. This measure was adapted from a single-item physical activity measure[51].

Alongside these instruments, we also included the following 11 additional questions about parastomal bulging:

1. How soon after surgery did you notice your bulge/hernia?
   Less than 3 months/ 3-6 months/ 6-12 months/ 12-24 months/ more than 24 months
2. Do you get pain associated with your bulge/hernia?

Yes/No

If Yes how bad is the pain on a scale of 1-10?

3. Does your pain affect any of the following? Select ALL that apply
   Being active or participating in your hobbies/ Completing your day to day activities/ Lifting items you find heavy/ Doing your job
4. What size do you currently consider your bulge/hernia to be?
   Very small/ Small/ Medium/ Large/ Very large
5. Is your bulge/PSH larger than 5cm diameter (a tennis ball is around 6cm)?
   Yes/No
6. Do you use any of the following to help manage your bulge/hernia? Please select ALL that apply:
   Support garments/ Exercises/ Dietary management or restriction/ Other
7. On a scale of 0-10 how well do you feel you are managing your bulge/hernia at the moment
   0 being not managed at all; 10 being very well managed
8. How do you feel about your body image in relation to your parastomal bulge?
   0 – not at all happy – 10 completely happy
9. Does your bulge/hernia affect any of the following? Please select ALL that apply.
   Your stoma output/ your bag adherence/ Other bag issues/ The food you eat/ Other
10. Have you ever considered a surgical repair for your bulge/hernia?
    Yes/No
11. Are you currently considering a surgical repair for your parastomal bulge?
    Yes/No

4.5 Sample size

The 'right' sample size for feasibility studies should be informed by the anticipated contexts under which the planned future RCT will be conducted.[31] This feasibility study therefore assessed the feasibility of recruiting people with a parastomal bulge in a large teaching hospital primarily serving a large urban population, a general hospital serving a small urban and remote and rural population and via social media. These recruitment methods would yield a representative target population for the planned future RCT. Moreover, in the future RCT, we intend for QOL to be our primary outcome and in line with Whitehead et al., a sample size of 20 was considered appropriate.[52]

4.6 Randomisation

Participants for the feasibility RCT were randomly allocated to intervention or control groups by a research assistant using MinimPy which is a free randomisation software package to manage the process of minimizing the difference among trial groups with respect to pre-selected categorical factors i.e. site. Participants were randomised on a 2:1 basis, intervention to control.

4.7 Data analysis

Data was analysed using SPSS v26. The rates of eligibility, retention, and follow-up were reported as percentages, as were the missing data rates for each outcome of interest. Means and standard deviations for the single arm trial and the feasibility RCT were calculated and presented. For the single arm trial outcomes were analysed through a paired t-test of baseline and follow-up data. For the feasibility RCT change scores from baseline to follow-up were calculated and an independent sample t-test was conducted with the grouping variable being the control or intervention condition. Due to the small numbers in this study and the objectives being primarily feasibility only 95% confidence intervals are reported.

Participants were asked to record their weekly exercise in an anonymous online diary. They recorded the level of exercises they have been asked to work at, how many days a week the exercises had been prescribed, how long they should be exercising for, and how much of the prescribed activity they had completed. These data were collated and presented with frequencies, and percentages. Qualitative thematic analyses of audio-recorded interviews and focus groups were conducted using the Framework approach [53].

5. PATIENT AND PUBLIC INVOLVEMENT

The Patient and Public Involvement (PAG) was led by Lesley Booth, Public Involvement lead at Bowel Research UK. Relationships between the academic researchers and the members of the PAG were well-established because the patient and public involvement for this feasibility study was a continuation from a previous study carried out by the research team.[39] Two member of the PAG (Lesley Booth, Bowel Research UK and Caroline Bramwell, Ileostomy and Internal Pouch Association) attended all research team meetings to contribute to the management or running of the study. The PAG have given valuable feedback about the content of the intervention, and about the lay language being used in public facing documentation (e.g. patient information sheet and Social media advert). The PAG have also shared their range of expertise with the designing of the HALT trial logo and Participant Information Sheets (Ben Hinx and his daughter), designing the exercise booklet (Scott Clifford) producing artwork to illustrate the exercises (Susan Meer), being the demonstrator for our exercise videos (Andrea Robson), and being on hand for any queries to help develop the project with patients at the core of the work. The PAG will continue to assist with lay summaries and disseminating the findings from this work. The research team are exceptionally grateful for their time and support.

6. RESULTS

6.1 Consent and retention rates

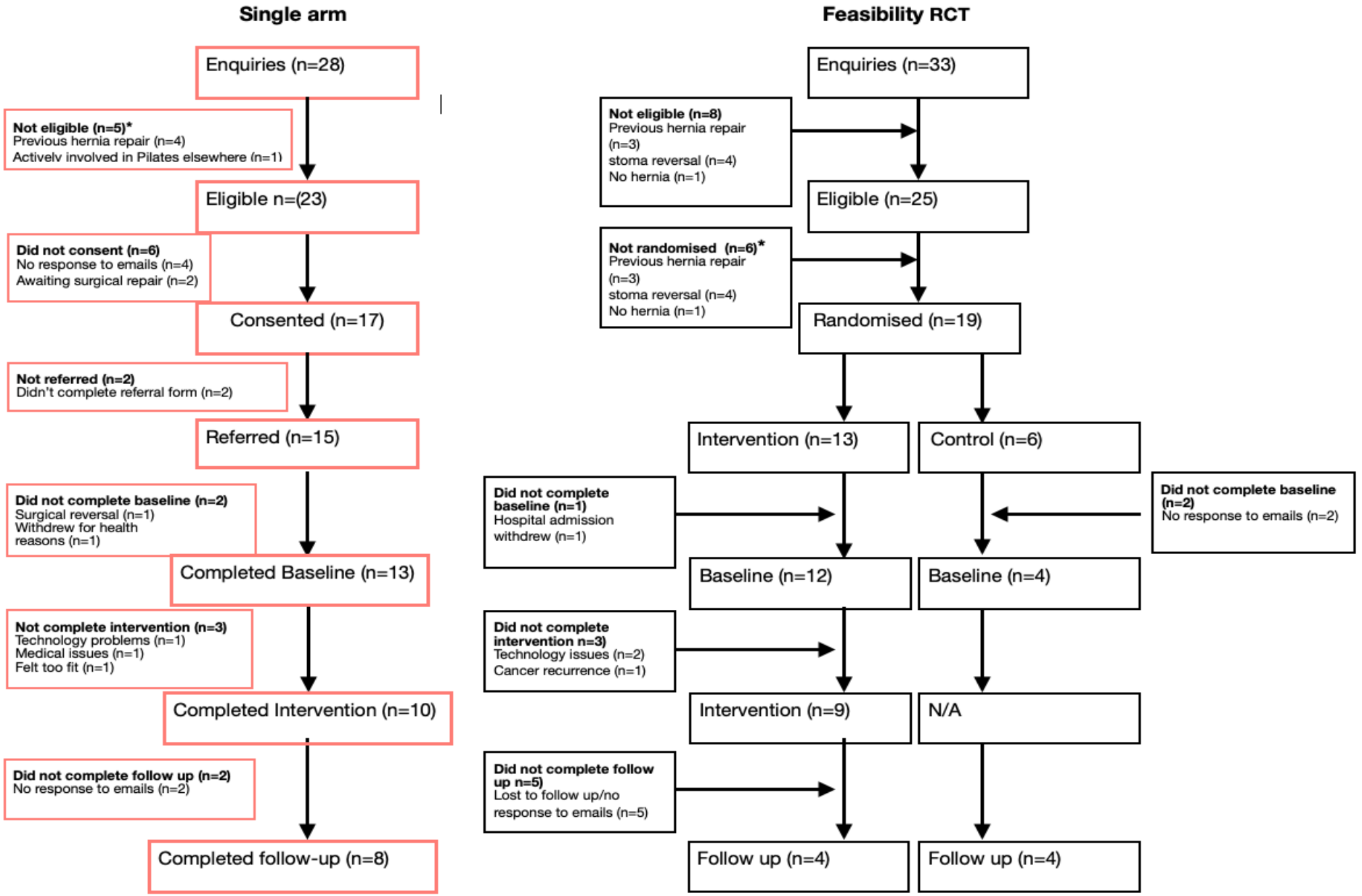
Figure 4 displays the recruitment flowchart for both the single-arm trial and feasibility RCT.

For the single arm trial, which recruited participants by social media, 28 people enquired about the study over a period of 5 days, of which 23 (82%) were eligible to take part. Seventeen eligible participants consented to the study i.e. 74% eligible patient consent rate and of these, 15 were referred to the clinical exercise specialist. Thirteen participants completed baseline measures and 8 of these completed follow-up measures i.e. 47% retention rate. Of the 15 intervention referrals, 10 (66%) participants completed the intervention.

For the feasibility RCT, 33 people enquired about the study over period of 13 weeks, of which 25 (76%) were eligible to take part, and 19 (i.e. 76% eligible patient consent rate) were randomised to the intervention or control group. Sixteen participants completed baseline measures, and 8 completed follow up measures i.e. 42% retention rate. Of the 13 intervention referrals, 9 (69%) participants completed the intervention.

For the feasibility RCT, the hospital that recruited participants directly through the clinical care team resulted in all participants being confirmed as eligible by the research assistant, and 80% being randomised. The hospital that recruited participants via research nurses resulted in 55% of participants being confirmed as eligible by the research assistant, and 70% of those eligible being randomised. Personal communication with the research nurses suggests that it was difficult to screen for eligibility using electronic patient records.

Figure 4: Participant recruitment flowchart (* See Eligible patients consent rate section)



6.2 Participant characteristics

Characteristics are summarised in Table 2. Across the single-arm and feasibility RCT, 19 (53%) were female, the age range was 25 to 75 years, 12 (33%) were diagnosed with bowel cancer, 20 (56%) had a colostomy. There were differences between participants recruited by social media and hospital; notably, people recruited by social media were younger and more people recruited by hospital had bowel cancer. The fourth column in Table 2 describes the sample from our previous study of a physical activity intervention for people with a bowel stoma.[39] The current study recruited more males and more people with a colostomy compared to the previous study.

Table 2: Baseline characteristics of participants

Variable		n=36 (%)	n=18 (%)	n=18 (%)	n=30 (%)
		Total sample	Social media	Hospital	Previous trial
Gender	Male Female	19 (53%) 17 (47%)	10 (56%) 8 (44%)	9 (50%) 9 (50%)	8 (27%) 22 (73%)
Age (years)		Mean 58 (min 25: max 75)	Mean 54 (min 25: max 71)	Mean 64 (min39: max 75)	Mean 52 (min24: max 77)
Diagnosis	Bowel cancer Crohn's Diverticulitis Ulcerative Colitis Other	12 (33%) 1 (3%) 7 (19%) 7 (19%) 9 (25%)	2 (11%) 1 (6%) 5 (28%) 3 (17%) 7 (39%)	10 (56%) 0 2 (11%) 4 (22%) 2 (11%)	13 (43%) 7 (23%) 1 (3%) 9 (30%) 0
Type of stoma	Colostomy Ileostomy	20 (56%) 16 (44%)	10 (56%) 8 (44%)	10 (56%) 8 (44%)	8 (27%) 22 (73%)

6.3 Missing data rate

The rate of missing data for the outcome measures can be found in Table 3. This shows that most of the outcome measures are well completed by the participants with the majority having no missing data. However, measures of Stoma-QOL for the Work/Social Function and Sexuality/Body Image subscales show high rates of missing data with complete missing data for the control group on the work/social function subscale. There is also a high level of missing data for the control group on the question of ever having considered surgical repair for their bulge/hernia.

Table 3: Missing data rate for the outcome measures

Outcome measure	Missing data rate %		
	Single arm trial (n=8)	Feasibility RCT	
		Control (n=4)	Intervention (n=4)
EQ5D Descriptive Score	12.5	0	0
EQ5D VAS	0	0	0
Stoma-QOL Now	0	25	0
Stoma-QOL Past Month	0	25	25
Stoma-QOL Work/Social Functioning	37.5	100	50
Stoma-QOL Sexuality/Body Image	37.5	75	50
Stoma-QOL Stoma Function	0	0	0
Stoma-QOL Financial Concerns	0	0	0
Stoma-QOL Skin Irritation	0	0	0
Self-Efficacy	0	25	0
Physical Activity	0	0	0
Do you have pain associated with your bulge/hernia?	0	0	0
What size do you consider your bulge/hernia to be?	0	0	0
Is your bulge/hernia larger than 5cm diameter?	0	0	0
How do you feel about managing your bulge/hernia?	0	0	25
How do you feel about your body image in relation to your bulge/hernia?	0	0	0
How you ever considered surgical repair?	12.5	50	0
Are you currently considering surgical repair?	0	25	0

The feasibility study was not powered to detect statistical significance however, it is useful to see the data to assess if the distribution of responses were within a typical range.[54 55] The data can be found in Appendix 3 and show that baseline and follow up distributions were within a typical range for the EQ-5D descriptive score.

6.4 Intervention fidelity

The maximum number of exercise sessions available to participants was 12. Table 4 shows that participants received on average 8 sessions, lasting on average 48 minutes. Feedback

from the exercise instructors were that some participants did not require more than 8 sessions and therefore did not continue after the eighth session.

Table 4: Average number of sessions, and duration of participant intervention

Participants n=17	Mean	Median	Range
Average number of sessions per participant	8	7	5-12
Average duration of session [mins]	48	48	31-62.5

The clinical exercise instructors delivered the exercise sessions in accordance with the principles of SDT. Both researchers (GH, CT) gave a maximum score of 21 for three video exercise sessions using the Interpersonal Support in Physical Activity Observational Tool. One researcher scored the fourth video session as 21 and the other researcher gave a score of 16. The total score was therefore 163 out of 168, giving an average score of 20.3.

The data for the Basic Psychological Needs in Exercise Scale found that for the Competence subscale mean scores increased from 2.98 (SD: 1.02) to 3.26 (SD: 0.88) and for the Autonomy subscale mean scores increased from 2.95 (SD: 1.03) to 3.44 (SD: 1.17) from baseline to follow-up.

6.5 Intervention adherence

Data taken from participant online diaries shows how much of the prescribed exercise participants had completed on any given week. The online diary was used by 15 participants. 92% of the exercises prescribed were completed (completion was defined as >75% of the exercise prescription given).

6.6 Testing online group exercise sessions

A group-based exercise session was offered to 8 participants as part of the feasibility RCT. Four participants took up this offer. Feedback from the exercise instructor was that participants initially agreed to take part in a group session but stated a preference for one-to-one sessions instead. During the group sessions participants developed at different rates and needing varying levels of input and guidance, making an online session more difficult to deliver. The experiences of participants of these sessions are reported below in the section on the qualitative interviews.

6.7 Intervention safety

No serious adverse events were reported. Eight participants provided 13 comments in the diary about challenges and issues with the stoma/parastomal bulge during the exercise programme (Table 5). Not all challenges and issues were attributed to the exercise

programme. The exercise programme was perceived by participants to have caused some discomfort and pain but equally, some stoma/parastomal bulge issues were not perceived as linked to the exercise programme but were perceived to make exercising difficult.

Table 5: Comments in diary that highlight challenges, pain and discomfort

Participant	Comment
ID29	Single leg bridge pulls on base of spine a little but not excessively
ID29	Exercises were tough this week, but more to do with being on-call for work and getting calls in the very early hours whilst still working normal hours. This compounded with a lack of sleep due to the position of my colostomy bag made this week on the whole quite challenging
ID11	Some soreness in my right upper rib, that was it but improving
ID12	Stoma quite painful this week
ID07	Took it easier as pulled a muscle lifting some sacks of coal and my abdomen didn't feel right, so eased off the tabletop exercise moves as core area felt 'strained'
ID04	Having really bad pains in my pelvis, back and hernia
ID07	One or two adhesion type pains in left (non-hernia) side
ID04	Challenge with hernia constant pain with it
ID02	I didn't do as much this week as I think I did one slightly wrong last week which caused some additional pain
ID02	Stoma also a little swollen this week but I don't think it's linked
ID05	Second day mild discomfort in my groin, disappeared by day four
	My lower back is feeling fatigued when doing the exercises which says to me I still have a bit of stabilisation work to do
ID22	Hernia hurts and feel sick but can feel a difference in doing the exercise

6.8 Qualitative Interviews

Twelve interviews were conducted with participants in the single-arm (n=8) and feasibility RCT (in n=4 intervention, and 1 control group). Thematic analysis was completed by three researchers (WG; JM; GH). The identified themes and sub-themes are illustrated in Table 6.

Table 6: Common themes from participant interviews

Theme	Sub-theme
Reasons for joining	Self-management
	Helping others
	Avoiding surgery
Benefits for being involved	Positive physical changes
	Instructor support

	Behaviour changes
	Mental Health improvements
Barriers	Health issues
	Time constraints
	Own perceptions
Intervention content	Technology
	Exercises
	Group sessions

Reasons for being involved

The majority of participants decided to sign up for the trial to help them self-manage their parastomal bulge:

"If I can find a way of managing that hernia so it doesn't get any worse in a more proactive way" (ID02)

"If this is something that's going to help me deal with that, because the help you get, I mean, the help I get from my stoma nurses is unbelievable, but there was never anything that was specifically about how to make it… how I could make it better" (ID03)

"Oh, this looks like it might be a good idea, if I can do some exercises, maybe that will do something for the hernia." So that was my thinking behind it, and that was why I applied to do it, yeah" (ID08).

Participants also suggested that their involvement in the trial was also an opportunity to help other people with a parastomal bulge:

"Well, if it helps someone out, yeah, no problem…… yeah, okay, I'll help out if you want, yeah, no problem." But then actually it turns out I got quite a lot from it" (ID29)

"So, I thought I've got nothing to lose by giving it a go and seeing if, you know, if what… I'll try it, and if it helps somebody else then brilliant" (ID05)

One participant joined the trial with the intention of improving her abdominal control in the hope of avoiding surgery:

"I'm told it will be a huge thing if I do have surgery, and the chances of the hernia coming back on the other side is phenomenally high, so, you know, all in all, I don't want that, I don't want to go down that route at all. So, the idea of tightening things up with a view to

making things better, really, or less chance of needing any more surgery was all to the good" (ID08)

Physical changes

Participants who received the exercise intervention perceived physical improvements such as, reducing the size of hernia, weight loss, core strengthening, core control, improved posture, and less need for support garments due to better core control:

"I feel like more stable when I'm running and that sort of thing, so, like, my core just feels stronger" (ID02)

"I found where I had the bulge from my stoma is definitely smaller now. And that, that feels like it… it's because I'm holding it in, I'm keeping it. It's not… if I do put the strapping on, it used to be you'd take the strapping off and you could physically see, you know, one side of you get bigger. I don't see that now, and that… that's given me the sort of feeling of I'm actually starting to strengthen this up a little bit……I really feel in control of me and my body and what I'm doing, which I didn't before." (ID03)

"There was one change about halfway through, overnight, like, it must be partly down to the weight loss, but partly down to the [exercise sessions] as well, the hernia almost vanished overnight…This morning, I pushed it in and it was gone, it didn't come out" (ID29)

"I wish I'd taken photographs before but I didn't, it is definitely smaller, the hernia… I could feel everything was tightening up, and for somebody of my age, that is quite amazing, really. The actual reduction in the hernia has probably been certainly more gradual. I mean, it wasn't, you know, one day it was there and the next day it wasn't sort of thing, it's not that dramatic" (ID07)

"I lost four inches around my hernia and my waist, which was really, really positive. And knowing now I have tummy control … the hernia is not smaller, but my area is. The hernia is actually more extended, because it looks… it's not sat within a round tummy, so to speak. But the fact that I now feel I have so much more control, I don't feel I have to rely on support underwear anymore" (ID05)

"... before I started doing the course with [name of exercise instructor], I would need to wear it [support garment] all the time, it became really uncomfortable because it was that bulbous and hanging and pushing that much. Now when I'm sat here it contains itself. So, if I'm not doing physical exercise, if I'm sat at my computer or watching telly or something like that, then no, I don't need to wear it anymore, and I try deliberately not, because by

not wearing it, I'm keeping my core a little bit more tense, I'm holding it together, and it's sort of self-perpetuating" (ID29)

Physical changes were also described by participants in the diary about any challenges and issues that they experienced relating to their stoma and parastomal bulge during the study. Five participants wrote in their diary about any changes to their hernia. Three did not perceive any change, one believed that the size of the bulge had reduced and one noticed a positive change although this was not specified. Four participants perceived that they were stronger, more toned and/or had better posture and five participants believed that they had greater abdominal control. Their written comments are presented in Table 7.

Table 7: Participant written comments about physical change

ID	Themes and written comments
Change to the hernia	
22	Hernia still same size
18	Have not noticed any change to hernia
05	No changes in my hernia or any pain
29	Hernia still feeling reduced
29	Not certain whether it is more down to weight loss (I've lost about a stone and a half - intentionally - since starting the program), or the physio, but overnight on Tues/Weds my hernia reduced considerably. On pushing the bulge in in the morning, usually against resistance, this time it moved quite easily and didn't immediately push back out, leaving the skin almost loose in its wake. It's like there's a threshold involving muscle tone and % fat body mass that dictates where the bowel, and therefore hernia sit when at rest… Since then normal movement does bring it back out, but only half the size it was before. It no longer looks red and stressed around the stoma. Impending bowel movements change its size and shape temporarily, but much more manageably… The reduced size is much more comfortable. Occurred overnight, but has persisted so far (3 days).
02	I am feeling really good and notice they are making a positive difference to my bulge the day after I do them. Also, now when sneezing I can feel a subconscious movement to "tighten the belt" which supports the area.
Strength, posture and tone	
14	Can feel a difference in my abdominal muscles, particularly around the hernia. Feels stronger, and my posture is much better
14	I feel the best I have for 10 years. My abdominal muscles feel stronger, my posture is much better, and my hernia feels tighter. I am enjoying it immensely, this will become a way of life.

14	The area around my hernia already feels more toned, probably because I haven't used those muscles for 44 years!
29	Feeling much stronger in myself
5	I have never had any issues with my hernia whilst doing these exercises, over the 12 weeks I have found that I now have developed muscle control of my tummy, and now have a much more toned body because of the exercises that I have been completing. Really enjoyed learning about Clinical Pilates and I will be continuing these exercises to help improve my core, and general wellbeing.
02	I am feeling stronger and more conditioned.
02	Felt good, feeling much stronger.
Abdominal control	
11	Feeling more in **control** as such and getting the connection
11	Learning about my body a lot more.
11	Feeling the benefit of all the exercises that I am doing, feeling more in **control** of the muscles in my abdomen, no issues with my Hernia at all.
11	I felt that I have really benefited from doing all the exercises, feeling that I now have a hold of my pelvic floor and improved greatly my core muscles.
02	Got a much better core connection without my ribs lifting due to the slight modifications
05	Beginning to understand the concept behind making use of the full body exercising as one, starting to do more complex levels, feeling the effects of work so far, now have more control on my muscles, x 3 new exercises to work on for the next two weeks.
22	More aware of core muscles
18	Can feel the muscles working during exercises

<u>Clinical exercise specialists</u>

The feedback given about the expertise and support from the two clinical exercise specialists who delivered the exercise intervention was unanimously positive. They provided a non-judgemental environment and participants felt that the positivity and attention given to them at each session was 'first class' and that despite sessions being via video call they felt very personal and there was close attention to detail:

"Having a rapport with [name of exercise instructor] the following week, she's very enthusiastic, positive, offering instruction, praise, when it… when it's deserved, but also kind of gentle criticism which I was able to work on." (ID01)

"it was actually nice to speak to her each week, just to… you know, for someone to understand what I… what we actually go through, and no judgements off her." (ID04)

"[name of exercise instructor] made it so easy to do, sort of face-to-face online, if that makes sense, that you felt she was in the room with you when you were doing stuff." (ID03)

"You can have in your mind, you think 'I think this is correct?' But then someone who is an expert in that field can look and go 'Actually, yeah, just tuck yourself in here a little bit, do that.' You know, or 'Don't do this.' And it really points you in the right direction. So, I definitely feel that was beneficial, having the coaching like that." (ID11)

"But, yeah, what struck me was the attention to detail that even remote video classes can have in terms of you've got the camera positioned correctly then it really enabled some pretty first-class feedback" (ID07)

Behaviour changes

Participants shared a number of ways they had changed their behaviour and way of thinking about exercise. The intervention encouraged them to think about their physical activity levels, and had gained confidence to things they may have previously avoided. Sub-conscious changes to breathing habits, and automatically engaging their core muscles before a daily activity indicate that the intervention has made some positive behaviour changes:

"I actually do much bigger walks……my son can benefit from me being able to do things with him like this now without it being a case of 'Oh, I'm so tired, no, no, this is going to hurt, I can't do this', it's like 'Well, give it a go' (ID03)

"On a daily basis it was things like I'd be thinking 'Oh, I can't lift that, I shouldn't do this, I shouldn't do that,' and actually when you actually started to use these muscles, what you're working on in the program, it was very helpful to understand when I should be recruiting certain muscles" (ID11)

"This has really brought home to me the importance of doing the behind the scenes things before you go off and do the thing that you perhaps enjoy doing most……having sort of recognised more what it is, it's easier to… to sort of consciously, almost subconsciously, engage now than it would have been before I started. (ID12)

Confidence

Many participants mentioned the improvement in their confidence to move more, and be in control of their health and health-related behaviours. They felt more equipped with the skills to breathe better, engage their muscles and be more body confident:

"The biggest thing has been my change in attitude towards my stoma. It's no longer a negative thing for me… I control it, it doesn't control me anymore" (ID03)

"It cheered me up, actually, and it made me feel quite proud of myself that I was able to discipline myself to doing these things" (ID06)

"The body confidence, I think, yeah, it's helped me with that, and it's the idea of getting into the best shape I can get into for me is a healthy one. So, I'm not punishing myself, but rather I'm actually going down a very healthy path of thinking actually this is really good for me now and I'm not being ill every day, I'm feeling pretty good" (ID11)

"I helped my brother move flats, and we were lifting stuff around and I forgot my belt, and it was just like fine. I forgot my belt to the gym one day and just carried on, it was fine. As long as I breathe properly, not a problem." (ID02)

"Definitely more confident. I'm not scared of doing exercise" (ID08)

Mental health

Several participants referred to their mental health. The intervention gave one participant enough confidence and change in mindset to get back to work where previously they felt the workplace would not want them. And others reporting changes in their mental health and stating the intervention as a life changing experience:

"I'm genuinely starting now to get my CV together ready to go back to work, which before the trial, I would have been thinking twice about, because the discomfort and the pain and the tiredness were making me kind of go "Actually, what employer is going to really want me?' To now going 'You know what, yeah, there's issues, but I know how to manage them, and I will do…' (ID03)

"I'd go so far as to say it's a life changing experience, I'm absolutely chuffed, and it's… yeah, to think something so… so simple can be so effective" (ID07)

"it certainly increased my mental health, I think that that was not a requirement of the study, but it certainly made me feel a lot better about myself. It was good to have goals that I set and that I met." (ID01)

Barriers

Participants noted a few common barriers to successfully following the exercise prescription each week. Health issues were the main barrier because they had an effect on motivation. Other participants touched on time commitments, and their own preconceptions setting them back such as, anxieties about not being able to do what was asked, or fear of judgement. These barriers dissipated after meeting with the clinical exercise specialists.

"I suffer with reoccurring fissures, and I also suffer with constipation with slow transitional bowel. But I've also got a huge hernia which causes me a lot of pain around the belly button and pelvis. So, we had to ease off for a few weeks doing any of the exercises because I was in so much pain.… it was mainly my anxiety as well. I suffer from really bad depression and anxiety, and some days I had to push it, push the boundaries sometimes to get me doing it" (ID04)

"I work from home and, you know, I was at meetings a lot, they pop up whenever they want to. That was the only difficulty, was trying to find a time where… where, like, in the day you're guaranteed that you have half an hour, forty-five minutes no one would call you and you wouldn't have to suddenly run off" (ID02)

"I think the biggest barrier was I was a little bit worried about doing it… You know, sometimes you kind of think "they're going to think I can do things that I can't do." And that came very much from me because I was annoyed that I couldn't do what I wanted to do. And part of you was kind of thinking 'Oh, she's going to be really fit and I'm not, and she's going to judge the fact I can't manage" (ID03)

Intervention content

Technology

Participants reported that online video conferencing worked extremely well, and the exercise sessions were as good as being delivered in-person. It was also noted that the online experience gave more flexibility, saved travel time, allowed them to be anywhere, and kept them safe during the Covid-19 pandemic. There were issues with poor connections on occasion, and not feeling *tech savvy*, but these were navigated successfully.

"And I've got to say that a virtual class, I think, is as effective as physically being in someone's studio, which of course isn't possible at the moment" (ID03)

"In fact, personally, I found quite a lot of these things better than if you'd have to go somewhere to meet somebody to do it in person, because that usually involves quite a lot of wasting time, you know, you've got to travel to somewhere, find somewhere to park, then you might have to be sitting in a waiting room for goodness knows how long, and all that sort of thing. So, for me, doing it this way on Zoom is much, much better, I much prefer it" (ID10)

One participant would have preferred a telephone call rather than video conferencing:

"… I'm not, what they call it, tech savvy, or whatever the latest thing is. This is why we're talking on the phone and not Zoom and things. I couldn't get my head round that" (ID18)

Exercises

Feedback about the type, style and difficulty level of the exercises was positive. On the whole, participants found the exercises manageable but challenging to begin with then gained confidence and improved with time with the support of the clinical exercise specialist. Any challenges to performing the exercises were met with personalised feedback, and alternatives to the exercise offered where necessary. The importance of technique and visual feedback along with advice from the exercise specialist were highlighted:

"I'm quite fit generally and I'm quite determined, and I expected to work through these fairly quickly. I've done a bit of bodybuilding, I do a lot of cycling, I've done breakdancing. They [the exercises] look easy, but when you've held it for however long suddenly it's not so easy anymore. And it was just, I imagined they'd be much… I imagined they'd be much easier than they were at first. And in truth they were easy, it's just they weren't as easy as they looked (ID19).

"I started off obviously doing the very basic ones, the pelvic tilt and the core and everything, and for me that was a revelation because I've never done anything like that before, and I can actually feel the difference quite quickly actually within a couple of weeks" (ID13)

"[Name of exercise instructor] gave me a specific exercise to do which involved laying on my side and lifting my legs, I started to get twinges, and she's always said from the start that if I felt uncomfortable doing anything, to stop. So, which is exactly what I did. She then addressed it by starting a simpler exercise, like a step back from the actual clam exercise itself, and that worked fine, that was no problem at all" (ID05)

"… because I suddenly realised, actually, it's much harder than it looks to do some of these things. And… and then when you can feel the benefit or the fact that you're doing… you've now started two lots of ten, for instance, or then three lots of twelve or three lots of fifteen, yeah, it's… you… you can see the incremental build up in terms of your fitness as well. So, no, it's fantastic (ID07)

Group sessions

Generally, participants felt that one-to-one sessions were the preferred option. This was primarily because participants felt inhibited and embarrassed in the presence of other people:

"I think for me it was the one for one I had with [name of exercise instructor]. I think I probably would have been a bit self-conscious if there had been a group session, if you know what I mean" (ID18)

"yeah, I would take place in the group session but I don't know if I'd be quite as open or revealing like in the same way as I've just shown you my colostomy bag, I don't know if I'd do the same if there was three other people who I didn't really know in the room" (ID29)

"I did like having a one-to-one. Partly you don't feel silly, you know, if you're not doing it properly or, you know, you're asking questions and you might think are silly questions, so if there are other people there, you might feel a bit inhibited. I don't know. I don't know, really. I certainly would prefer the one-to-one which I had. But if that wasn't available, then yes, three or four people would be better than nothing, I think" (ID08)

6.8 Results from advisory Steering group

A summary of the results against apriori criteria is presented in Table 8. The Steering group discussed all findings with the research team in a meeting. One recommendation relating to the exercise intervention was raised, which was to describe participants' improvements (if any) in the different exercises e.g. if they moved from level 1 to level 3 during the programme. The main concern however, was the low retention rate. Strategies to improve this were suggested including making it clear to all participants that their participation requires completing the same questionnaire 12 weeks apart. Building a good relationship was seen as key and therefore having regular communication about the study with all participants was also recommended such as, regular text messaging. Another issue raised was the need to describe participants in greater detail in order to assess if specific groups of patients who would benefit from the intervention were it to be implemented in practice were missing from the trial.

The meeting concluded that these issues were not insurmountable and could be addressed by the research team and that a full trial of the intervention should proceed but with clear strategies included for improving the retention rate.

Table 8: Summary of results against a priori criteria

PARAMETERS	RESULTS	
Number of sessions (maximum=12)	8	Green
Session duration in minutes	48	Green
SDT - Interpersonal Support	20.3	Green
SDT - Basic Psychological needs		
Competence	3.26	Amber
Autonomy	3.44	Amber
Completion rate of prescribed exercises	92%	Green
Adverse events	0	Green
Eligible patients' consent rate	74% single-arm 76% two-arm	Green
Retention rate	47% single-arm 42% two-arm	Red
Missing data rate		
EQ5D Descriptive Score	Single-arm 12.5%; two-arm 0%	Green
EQ5D VAS	Single-arm 0%; two-arm 0%	Green
Stoma-QOL Now	Single-arm 0%; two-arm 12.5%	Green
Stoma-QOL Past Month	Single-arm 0%; two-arm 25%	Amber
Stoma-QOL Work/Social Functioning	Single-arm 37.5%; two-arm 75%	Red
Stoma-QOL Sexuality/Body Image	Single-arm 37.5%; two-arm 62.5%	Red
Stoma-QOL Stoma Function	Single-arm 0%; two-arm 0%	Green
Stoma-QOL Financial Concerns	Single-arm 0%; two-arm 0%	Green
Stoma-QOL Skin Irritation	Single-arm 0%; two-arm 0%	Green
Self-Efficacy	Single-arm 0%; two-arm 12.5%	Green
Physical Activity	Single-arm 0%; two-arm 0%	Green
Do you have pain associated with your bulge/hernia?	Single-arm 0%; two-arm 0%	Green
What size do you consider your bulge/hernia to be?	Single-arm 0%; two-arm 0%	Green
Is your bulge/hernia larger than 5cm diameter?	Single-arm 0%; two-arm 0%	Green
How do you feel about managing your bulge/hernia?	Single-arm 0%; two-arm 12.5%	Green
How do you feel about your body image in relation to your bulge/hernia?	Single-arm 0%; two-arm 0%	Green

How you ever considered surgical repair?	Single-arm 12.5%; two-arm 25%	Amber
Are you currently considering surgical repair?	Single-arm 0%; two-arm 12.5%	Green

7. DISCUSSION AND CONCLUSIONS

The eligible consent rate was similar recruiting participants via social media and hospital. The eligible consent rate was higher in the hospital site where patients were screened for eligibility by their clinical care team compared to by research nurses. It was feasible to recruit participants across a range of age groups, gender, bowel disease and type of stoma. The retention rate was slightly higher in participants recruited via social media than hospital. It is not clear why participants did not complete measures at follow up which makes it difficult to know which strategies could be used in a future RCT to improve the retention rate. A recent systematic review and meta-analyses of strategies to improve retention in randomised trials concluded that there is no high-certainty evidence pointing to an effective strategy but did find moderate-certainty evidence for monetary reward.[56] The distribution of responses for outcome measures were within a typical range,[54 55] suggesting that the intervention and trial procedures did not have a negative impact on participants. Missing data from the majority of the outcome measures was small to none suggesting that participants did not have any trouble with the questions that we asked them. However, missing data for two subscales of the Stoma-QOL scale (Work/Social Functioning and Sexuality/Body Image) was substantial; this could suggest that these measures are not fit for the sample we are recruiting. On the other hand, the items on the work/social functioning subscale may not have been applicable due to participants completing these during national lockdowns in the UK and if participants were furloughed. Both of these subscales should be reviewed by a patient advisory group, with alternative scales considered before proceeding with a future RCT.

The exercise intervention that we developed was delivered as intended and in accordance with SDT principles. The study shows that it is feasible to deliver online exercise sessions. All three intervention components but in particular, the one-to-one online sessions with a clinical exercise instructor were acceptable to participants. Group exercise sessions were tested with a small number of participants but participants preferred one-to-one sessions with the instructor. There was variation in the number and duration of sessions delivered which can be attributed to different need for support from an exercise instructor. Some participants required support from the exercise instructor about the use of video conferencing technology. Adherence to the prescribed exercise was high. Participants perceived physical and mental health benefits of the exercise intervention. Physical benefits aligned with the hypothesised benefits of the exercise programme i.e., improved breathing

technique, core control and strength. The exercise programme was safe; there were no adverse events. Participants experienced challenges and issues during the exercise programme including pain and discomfort around the stoma but these were within acceptable limits and not all were attributed to the exercise programme.

Conclusions

The exercise intervention is feasible to deliver and acceptable to participants. In a future study, more information about participants' characteristics is required in order to assess if the study and the intervention if implemented in practice, would attract a range of patients who it is designed to benefit. Additional information on for example, ethnicity, level of education, lifestyle behaviours, and internet use may be relevant. Strategies to improve retention need to be included in a future study. Retention strategies could be tested in an embedded pilot RCT of a future effectiveness RCT with clear progression criteria.

8. OTHER INFORMATION

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Ethical approval

The protocol and all study documents were approved by the North of Scotland Ethics Committee on 06 February 2020 (REC reference 20/NS/0007).

Registration

The feasibility study was registered with the International Standard Registered Clinical Study Number (ISRCTN15207595).

AVAILABILITY OF DATA AND MATERIALS

The intervention materials, Questionnaires, PIS, Consent Form and an anonymized dataset is available from the Principal Investigator on reasonable request.

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APPENDICES

Appendix 1: Change to protocol

Changes made to the published protocol[35] due to the Covid-19 pandemic.

Recruitment

All recruitment in hospitals was ceased and we reverted to recruitment by social media only in the single-arm trial during the first waves of the pandemic. Recruitment in hospital was allowed by the NHS director in research in the feasibility RCT.

Intervention

Two changes were made to the intervention:

1. In the interests of safety, all exercise sessions delivered by the clinical exercise instructor were delivered online. That is, participants were not given the option of having the session conducted in-person as originally intended.
2. In the first wave of the UK pandemic there were concerns about transmission of the coronavirus on parcels delivered to the home. Hence, in the interests of safety and as a precaution, we did not post out to participants a biofeedback stabilizer to help them monitor intraabdominal pressure during exercise.

Measuring intervention adherence and safety

Instead of providing a paper version of an exercise diary this was moved to online software as it was considered high risk during the first waves of the pandemic to post items out to participants.

Patient-reported outcomes

It was necessary to remove some outcome measures to avoid the use of NHS staff during the pandemic and to avoid the risk of viral infection from parcels. Hence, in the interests of safety and as a precaution, Hernia Classification, muscle activation, body composition, and accelerometer measured physical activity were not measured.

Eligibility

Following initial ethical approval and after discussion with clinical teams on both sites, it was decided that the exclusion of patients who had undergone a previous hernia repair was not required. This patient group have a high risk of hernia recurrence, and would benefit from the intervention in the same way as those with an existing parastomal bulge. The approval for this amendment was delayed due to the Covid-19 pandemic. The approval to include patients with a previous hernia repair came with only 2 weeks remaining of recruitment.

Appendix 2: Semi-structured interview schedule

Preamble and welcome. Re-confirm that the participant knows they will be recorded and they are happy to continue.

1. Why did you decide to participate in this particular study?

2. Talk me through what happened during the 12 weeks of the physical activity programme
Referral and initial meeting
Consultations with exercise instructor
Type of exercises?

Discuss each in turn

3. What do you think you gained from being involved in the physical activity programme?

Discuss each benefit in turn

4. Did you face any barriers to being physically active?

Discuss each in turn and any strategies for addressing the barriers

5. Have you noticed any changes in your abdominal area?
Hernia changes?
Abdomen area?

6. Have you changed any of your behaviours as a result of this intervention?
Physical Activity?
Diet?
General activities?
Considerations for surgery for your hernia?

7. Did you use any support garments during your exercise?

8. How did you find being part of a trial generally?

9. Were the questions appropriate?
Did you feel well informed about what was involved for you?
Is there anything you would change about the trial part of your experience?

Appendix 3: Results of outcomes

Results of the paired t-tests showing mean difference between baseline and follow-up in the single arm trial are presented below:

Scales (range)	N	Baseline Mean (SD)	Follow-up Mean (SD)	Mean difference (SD)	95%CI
EQ5D Descriptive Score (-1 – 1)	7	0.55 (0.40)	0.62 (0.33)	0.07 (.23)	-0.13; 0.28
EQ5D VAS (0-100)	8	60.00 (27.26)	71.00 (24.69)	11.00 (11.81)	1.13; 20.87
Stoma-QOL Now (0-100)	8	65.63 (32.12)	65.00 (30.36)	-0.63 (11.16)	-9.96; 8.71
Stoma-QOL Past month (0-100)	8	61.88 (32.84)	63.75 (29.97)	1.88 (11.00)	-7.32; 11.07
Stoma-QOL Work/Social Function (0-100)	5	59.17 (28.78)	67.50 (23.46)	8.33 (13.50)	-8.43; 25.10
Stoma-QOL Sexuality/Body Image (0-100)	5	70.00 (23.72)	65.00 (21.51)	-5.00 (7.07)	-13.78; 3.78
Stoma-QOL Stoma Function (0-100)	8	68.23 (26.06)	65.63 (17.64)	-2.60 (13.90)	-14.22; 9.02
Stoma-QOL Financial Concerns (0-100)	8	84.38 (35.20)	100.00 (0)	15.63 (35.20)	-13.80; 45.05
Stoma-QOL Skin Irritation (0-100)	8	65.63 (18.60)	59.38 (29.69)	-6.25 (17.68)	-21.03; 8.53
Body Image Scale (0-30)	8	12.63 (10.56)	13.88 (9.00)	1.25 (3.28)	-1.50; 4.00
Self-Efficacy (1-10)	8	6.41 (3.32)	7.63 (2.57)	1.22 (1.47)	-0.01; 2.45
Patient Specific Functional Scale (0-10)	7	2.53 (1.87)	3.88 (2.61)	1.35 (1.31)	0.14; 2.56
Physical activity	8	244.38 (233.72)	179.00 (165.27)	-65.38 (173.90)	-210.76; 80.01
Ability to manage hernia	8	5.25 (2.87)	6.13 (3.72)	0.88 (1.55)	-0.42; 2.17
Body image in relation to bulge/hernia	8	2.75 (3.45)	3.00 (3.34)	0.25 (1.49)	-0.99; 1.49

Results of the independent t-tests of mean change scores from baseline to follow-up of the control and intervention groups:

Scales (range)	Group	N	Baseline Mean (SD)	Follow-up Mean (SD)	Mean Change (SD)	Mean difference (SD)	95%CI
EQ5D Descriptive Score (-1 – 1)	Control	4	0.68 (0.09)	0.78 (0.19)	0.10 (0.17)	0.13 (0.10)	-0.13; 0.38
	Intervention	4	0.80 (0.06)	0.77 (0.80)	-0.03 (0.12)		
EQ5D VAS (0-100)	Control	4	65.00 (17.80)	83.13 (12.81)	18.13 (13.44)	18.13 (16.74)	-22.75; 59.10
	Intervention	4	85.00 (12.68)	85.00 (23.45)	0 (30.67)		
Stoma-QOL Now (0-100)	Control	3	66.67 (23.09)	65.83 (27.42)	-0.83 (25.54)	-5.58 (12.57)	-37.90; 26.74
	Intervention	4	89.00 (8.60)	93.75 (6.29)	4.75 (4.11)		
Stoma-QOL Past month (0-100)	Control	3	71.67 (20.21)	65.83 (27.42)	-5.83 (17.01)	-18.83 (10.43)	-47.80; 10.14
	Intervention	3	82.00 (10.82)	95.00 (5.00)	13.00 (6.08)		
Stoma-QOL Work/Social Function (0-100)	Control	0	-	-	-	-	-
	Intervention	2	87.50 (5.89)	75.00 (5.89)	-12.50 (0)		
Stoma-QOL Sexuality/Body Image (0-100)	Control	1	30.00	35.00	5.00	12.50 (4.33)	-42.52; 67.52
	Intervention	2	82.50 (10.60)	75.00 (14.14)	-7.50 (3.54)		
Stoma-QOL Stoma Function (0-100)	Control	4	46.88 (19.06)	42.71 (22.41)	-4.17 (5.89)	-22.92 (7.12)	-40.33; -5.51
	Intervention	4	55.21 (17.47)	73.96 (18.44)	18.75 (12.96)		
Stoma-QOL Financial Concerns (0-100)	Control	4	87.50 (25.00)	87.50 (25.00)	0 (0)	-	-
	Intervention	4	100.00	100.00	0 (0)		
Stoma-QOL Skin Irritation (0-100)	Control	4	50.00 (20.41)	25.00 (20.41)	-25.00 (35.36)	-43.75 (21.35)	-95.99; 10.28
	Intervention	4	43.75 (31.46)	62.50 (25.00)	18.75 (23.94)		
Body Image Scale (0-30)	Control	4	10.75 (6.65)	11.25 (5.32)	0.50 (1.73)	2.75 (2.85)	-4.23; 9.73
	Intervention	4	7.00 (4.16)	4.75 (2.22)	-2.25 (5.44)		
Self-Efficacy (1-10)	Control	3	3.33 (1.33)	4.50 (1.80)	1.17 (1.92)	-0.02 (1.05)	-2.72; 2.68
	Intervention	4	8.38 (0.63)	9.56 (0.55)	1.19 (0.83)		

Patient Specific Functional Scale (0-10)	Control	3	3.21 (0.66)	2.94 (0.42)	-0.27 (0.69)	1.57 (0.80)	-1.86; 4.99
	Intervention	1	5.33	3.50	-1.83		
Physical activity	Control	4	286.00 (452.79)	297.50 (259.28)	11.50 (406.87)	322.75 (439.25)	-752.04; 1397.54
	Intervention	4	731.25 (598.67)	420.00 (519.47)	-311.25 (778.59)		
Ability to manage bulge/hernia	Control	4	5.75 (3.20)	4.25 (1.71)	-1.50 (1.73)	-4.17 (1.80)	-8.79; 0.45
	Intervention	3	5.33 (1.16)	8.00 (2.00)	2.67 (3.06)		
Body image in relation to bulge/hernia	Control	4	2.75 (2.50)	1.00 (1.41)	-1.75 (1.89)	-2.50 (2.94)	-9.69; 4.67
	Intervention	4	4.75 (4.27)	5.50 (1.73)	0.75 (5.56)		

Descriptive statistics for questions related to bulge/hernia are presented below:

Outcome measure		Single arm trial		Feasibility RCT			
		Baseline n (%)	Follow-up n (%)	Control		Intervention	
				Baseline n (%)	Follow-up n (%)	Baseline n (%)	Follow-up n (%)
Do you have pain associated with your bulge/hernia?	Yes	7 (87.5)	8 (100)	2 (50.0)	1 (25.0)	3 (75.0)	1 (25.0)
	No	1 (12.5)	0	2 (50.0)	3 (75.0)	1 (25.0)	3 (75.0)
If yes, what is your pain score (Mean (SD))		4.71 (2.87)	4.88 (3.09)	2.00 (1.41)	7.00	1.33 (0.58)	1.00
Does your pain affect any of the following:	Being active or participating in your hobbies	6 (75.0)	6 (75.0)	0	1 (25.0)	0	0
	Completing your day-to-day activities	6 (75.0)	6 (75.0)	0	1 (25.0)	0	0
	Lifting items you find heavy	6 (75.0)	7 (87.5)	1 (25.0)	1 (25.0)	2 (50.0)	0
	Doing your job	2 (25.0)	1 (12.5)	0	0	0	0
	Other	0	0	1 (25.0)	0	0	0
What size do you consider your bulge/hernia to be?	Small	2 (25.0)	1 (12.5)	0	0	1 (25.0)	2 (50.0)
	Medium	3 (37.5)	3 (37.5)	3 (75.0)	0	2 (50.0)	2 (50.0)
	Large	2 (25.0)	3 (37.5)	1 (25.0)	3 (75.0)	0	0
	Very large	1 (12.5)	1 (12.5)	0	1 (25.0)	1 (25.0)	0

Is your bulge/hernia larger than 5cm diameter?	Yes	7 (87.5)	6 (75.0)	3 (75.0)	4 (100.0)	2 (50.0)	2 (50.0)
	No	1 (12.5)	2 (25.0)	1 (25.0)	0	2 (50.0)	2 (50.0)
Do you use any of the following to help manage your bulge/hernia:	Support garments	8 (100)	8 (100)	3 (75.0)	3 (75.0)	4 (100.0)	4 (100.0)
	Exercises	5 (62.5)	6 (75.0)	0	1 (25.0)	0	4 (100.0)
	Dietary management or restriction	3 (37.5)	4 (50.0)	0	0	0	0
	Other	0	0	0	0	0	0
Does your bulge/hernia affect any of the following:	Your stoma output	2 (25.0)	3 (37.5)	0	1 (25.0)	2 (50.0)	0
	Your bag adherence	1 (12.5)	2 (25.0)	3 (75.0)	3 (75.0)	1 (25.0)	2 (50.0)
	Other bag issues	0	1 (12.5)	2 (50.0)	0	1 (25.0)	1 (25.0)
	The food you eat	3 (37.5)	3 (37.5)	1 (25.0)	0	0	0
	Other	0	1 (12.5)	0	0	1 (25.0)	0
How you ever considered surgical repair?	Yes	3 (37.5)	3 (37.5)	2 (50.0)	1 (25.0)	2 (50.0)	3 (75.0)
	No	5 (62.5)	4 (50.0)	2 (50.0)	1 (25.0)	2 (50.0)	1 (25.0)
Are you currently considering surgical repair?	Yes	2 (25.0)	3 (37.5)	1 (25.0)	1 (25.0)	1 (25.0)	2 (50.0)
	No	6 (75.0)	5 (62.5)	3 (75.0)	2 (50.0)	3 (75.0)	2 (50.0)