



Hernia Active Living Trial (HALT): a feasibility study of a physical activity intervention for people with a bowel stoma who have a parastomal hernia/bulge

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#### **INTRODUCTION**

Parastomal bulging/hernia is a common complication associated with a stoma. Strengthening of the abdominal muscles via exercise may be a useful selfmanagement strategy.

Trial registration: ISRCTN1520 7595

# AIM

The aim of this feasibility work was to address uncertainties around testing a Pilates-based exercise intervention for people with parastomal bulging.

#### **METHOD**

An exercise intervention was developed and tested in a singlearm trial (n = 17 recruited via social media) followed by a feasibility randomised controlled trial RCT (n = 19 recruited from hospitals). Adults with an ileostomy or colostomy with a bulge or diagnosed hernia around their stoma were eligible. The intervention involved a booklet, videos, and up to 12 online sessions with an exercise specialist. Feasibility outcomes included intervention acceptability, fidelity, adherence, and retention. Acceptability of self-report measures for quality of life, self-efficacy, and physical activity were assessed based on missing data within surveys pre- and post-intervention. Interviews (n = 12) explored participants' qualitative experiences of the intervention.

## RESULTS

The results of the study using the *a priori* 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 Autonomy	3.26 3.44	Amber Amber
Completion rate of prescribed exercises	92%	Green
Adverse events	0	Green
Eligible patients' consent rate	74% single-arm 76% two-arm	Green
Retentionrate	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	Single-arm 12.5%; two-arm 25%	Amber
repair?	Single-arm 0%; two-arm 12.5%	Green

#### Key findings from qualitative interviews include:

- 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.
- The intervention encouraged participants to think about their physical activity levels and had gained confidence to engage in activities that they may have previously avoided.

"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"

### CONCLUSIONS

The exercise intervention was feasible to deliver, acceptable to participants, and potentially helpful. Qualitative data suggests physical and psychosocial benefits. Strategies to improve retention need to be included in a future study.

## INFORMATION

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