

The effects of supervised exercise training 12-24 months after bariatric surgery on physical function and body composition: a randomised controlled trial

Running title: The Motion Study

Louisa Y Herring, Clare Stevenson, Patrice Carter, Stuart JH Biddle, David J Bowrey, Christopher D Sutton, Melanie J Davies.

Corresponding Author:

Dr Louisa Herring (PhD)
University Hospitals of Leicester NHS Trust
Leicester Diabetes Research Centre
Leicester,
LE5 4PW.

Contact telephone: 0116 258 8964

Contact email: louisa.herring@uhl-tr.nhs.uk

Affiliations:

School of Sport, Exercise and Health Sciences, Loughborough University, Loughborough, LE11 3TU
University Hospitals of Leicester NHS Trust, Leicester General Hospital, Leicester, LE5 4PW.

Co Authors and affiliations:

Dr Clare Stevenson (PhD), School of Sport, Exercise and Health Sciences, Loughborough University, Loughborough, LE11 3TU.

Dr Patrice Carter (PhD), Behaviour and Health Research Unit, University of Cambridge, Cambridge, CB2 0SR, UK; The University of Leicester, Diabetes Research Centre, Leicester, LE5 4PW.

Professor Stuart JH Biddle (PhD), Institute of Sport, Exercise and Active Living, Victoria University, PO Box 14428, Mebourne, VIC 8001, Australia.

Mr David Bowrey (MD) University Hospitals of Leicester NHS Trust, Leicester Royal Infirmary, Leicester, LE1 5WW.

Mr Christopher Sutton (MD) University Hospitals of Leicester NHS Trust, Leicester Royal Infirmary, Leicester, LE1 5WW.

Professor Melanie J Davies (MD) Professor of Diabetes Medicine, The University of Leicester, Diabetes Research Centre, Leicester, LE5 4PW.

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Abstract

Background

Bariatric surgery is effective for the treatment of stage II and III obesity and its related diseases although increasing evidence is showing weight regain approximately 12-24 months post-surgery. Weight regain increases the risk of physical function decline which negatively affects an individual's ability to undertake activities of daily living. The study assessed the effects of a 12-week supervised exercise intervention on physical function and body composition in patients between 12-24 months post bariatric surgery.

Methods

Twenty-four inactive adult bariatric surgery patients whose body mass index remained $\geq 30\text{kg.m}^2$ 12-24 months post-surgery, were randomised to an exercise intervention (n=12) or control group (n=12). Supervised exercise consisted of three 60-minute gym sessions per week of moderate intensity aerobic and resistance training for 12-weeks. Control participants received usual care. The incremental shuttle walk test (ISWT) was used to assess functional walking performance after the 12-week exercise intervention, and at 24-weeks follow-up. Measures of anthropometric, physical activity, cardiovascular, psychological, and biochemical outcomes were also examined. Using an intention-to-treat protocol, independent t-tests were used to compare outcome measures between groups.

Results

Significant improvements in the exercise group were observed for the ISWT, body composition, physical function, cardiovascular, and self-efficacy measures from baseline to 12-weeks. A large baseline to 12-week change was observed for the ISWT (exercise: $325.00 \pm 117.28\text{m}$; control: $355.00 \pm 80.62\text{m}$, $p<0.001$). The exercise group at 24-weeks recorded an overall mean improvement of 143.3 ± 86.6 metres and the control group recorded a reduction of -32.50 ± 75.93 metres. Findings show a 5.6kg difference between groups in body mass change from baseline to 24-weeks favouring the exercise group.

Conclusions

A 12-week supervised exercise intervention led to significant improvements in body mass and functional walking ability post-intervention, with further improvements at the 24-week follow-up.

Key words

Obesity, exercise, bariatric surgery, physical activity, physical function

Introduction

Bariatric surgery is an effective weight-loss intervention for morbidly obese patients and is successful in the treatment of stage II and III obesity and its related diseases¹. However, there is increasing evidence of weight regain in patients after bariatric surgery^{2, 3}, generally occurring between 12 and 24 months post-operatively^{2, 4}. Weight regain increases the risk of physical function decline which negatively affects an individual's ability to undertake activities of daily living⁵. Weight regain also increases the likelihood of obesity related co-morbidities returning⁶, hence the importance of recommendations on diet and physical activity after bariatric surgery to prevent weight regain⁷.

Post-operative lifestyle interventions that adopt a combined diet, exercise, and behaviour modification approach have proven successful in aiding long-term weight maintainence and improving physical function⁸. NICE recommend that the two year follow-up care package after bariatric surgery should incorporate physical activity advice and support⁷.

At present, no quantifiable physical activity recommendations on post-operative exercise exist. There are a limited number of exercise interventions in bariatric surgery patients, however these mainly target the initial (first four) months after surgery. In a small non-randomised trial, Stegen *et al*⁹ observed that improvements in physical fitness were not induced by the weight loss from surgery alone (in the absence of exercise). Castello *et al*¹⁰, in a randomised controlled trial (RCT) that examined the effects of a 12-week aerobic exercise programme after gastric band surgery, found a significant improvement in the six minute walk test (6MWT) distance in the exercise group compared to those who received usual care¹⁰. More recently Coen *et al*¹¹ conducted a semi-supervised moderately-intense exercise intervention in 128 patients who had undergone gastric bypass. This RCT concluded that post-operative health education and exercise elicited similar improvements to weight and body composition, but those who received the exercise intervention had additional fitness benefits. These studies indicate the value of incorporating exercise into the early post-operative rehabilitation of patients after bariatric surgery. Whether exercise therapy at a later stage after surgery, specifically attempting to address late weight regain, is unknown.

The aim of this study was to examine the effects of a supervised 12-week exercise intervention on physical function and body composition maintenance in patients who were between 12 and 24 months after bariatric surgery.

Methods

Study design

A single-centre RCT with two parallel groups with balanced randomisation [1:1] was performed. Adult patients who were 12-24 months post-bariatric surgery were randomised to either supervised exercise training for 12 weeks or to usual follow up care. Assessments were performed pre-intervention, post-intervention at 12-weeks, and 24-weeks at Leicester Diabetes Centre, Leicester, UK. Ethical approval was received from the West Midlands NHS research ethics committee (Reference: 13/WM/0445; ISRCTN 17240262).

Participants

Eligible participants were adult patients (≥ 18 years) who had undergone any type of bariatric surgery 12 to 24 months earlier, remained obese (BMI of $\geq 30\text{kg}\cdot\text{m}^{-2}$ or $\geq 28\text{kg}\cdot\text{m}^{-2}$ for South Asians, and were classified as inactive (self-report ≤ 150 minutes MVPA per week). Participants completed a health assessment and treadmill exercise test (Balke protocol) before being deemed healthy enough to participate in moderate intensity exercise by a clinician. Volunteers with unstable diabetes, stage II hypertension, cardiovascular disease, pulmonary disease, renal disease, orthopaedic limitations, motor neurone disease, or who were chair-bound, were excluded.

Randomisation and masking

Patients were recruited from the post-operative bariatric surgery lists from the NHS University Hospitals of Leicester and Spire Leicester Private Hospital between January 2014 and February 2015. All patients who were within 12-24 months of their surgery date were sent invitation letters with reply slips signed by their surgeon, along with a participant information booklet. Upon the successful completion of consent, screening, and the

initial assessment, participants were randomly allocated into either the exercise or control group using random number sequencing in concealed brown envelopes. The algorithm for randomisation was designed by a statistician using the random permuted-block procedure (blocks of 4). The randomisation was performed by an independent researcher, who had no other involvement in the study to ensure allocation concealment. Both the participant and the researcher became aware of the study group allocation upon completion of the baseline assessment.

Study Groups

Exercise group

The exercise intervention incorporated three 60 minute gym sessions per week for 12 weeks. Sessions were hospital based and supervised by a qualified gym instructor with the appropriate immediate life support training. All sessions consisted of a warm-up period, moderate intensity aerobic and resistance training ending with a cool-down period. The aerobic exercise training element typically lasted 45 minutes; the first exercise programme for participants consisted of 35 minutes with a longer warm-up period and was progressed to 45 minutes by the end of week two. Warm-ups were longer at the beginning of the 12 weeks, and reduced to 5 minutes as individuals' fitness improved. The exercise session was personalised for each individual and re-assessed every two weeks within the 12 week programme. For the few participants who did not progress to 45 minutes within the first two weeks they were re-assessed weekly to reach this duration. Moderate intensity aerobic exercise was expressed as a percentage of maximum heart rate; in the main exercise session this equated to between 64 and 77% (RPE 12-14). Typically the resistance training element consisted of four core and lower body resistance exercises (e.g. leg press, abdominal twists, leg extensions) per week. Moderate intensity for resistance exercises was expressed as 60% of the participants' estimated one-repetition maximum (1-RM). At the first session the 1-RM was identified which was equated by performing a weight where 17 repetitions were possible¹². Two resistance exercises were performed per participant per gym session; these varied but only included core and lower body exercises. Participants would perform three sets of 12 repetitions with 30-60 seconds rest between sets. The whole exercise session amounted to a total of 60 minutes per participant.

Programmes were personalised, specifying durations, resistances, inclines, sets and repetitions. Any limiting comorbidities were taken into consideration when designing the programmes. Due to the large variation in patients' abilities, programmes were designed to meet the individuals' needs, and progression expectation varied but all patients had the same target training element duration and all met this before the end of the 12 week training programme. Programme progression was based on heart rate; ensuring patients were consistently working at moderate intensity. The exercise programme was reviewed on fortnightly basis and the intensity was progressed accordingly. Gym session attendance was monitored throughout the intervention.

Upon completion of the 12-week structured exercise training programme, the participants received a standard lifestyle advice session lasting 30 to 60 minutes. This individualised advice session represented a typical discharge advice session given to patients in follow-up care. Relevant topics such as physical activity maintenance, overcoming barriers, and goal setting were discussed. In addition, a maintenance exercise programme was provided (e.g. gym continuation or home-based alternatives). Finally, a diet information sheet was provided based on standard post-operative advice given to patients after surgery.

Control group

During the 12-week exercise intervention period, participants in the control group continued with usual follow-up care. After their 12-week assessment the control group also received the discharge advice session discussing the same topics. All participants were given an example exercise programme and progression (e.g. home-based exercise, walking, swimming), along with the diet information sheet.

Outcomes

All measurements were taken at the pre-intervention assessment (baseline), post-intervention assessment (12-weeks) and at the follow-up assessment (24 weeks).

Physical function measurements

The primary measure of physical function was the ISWT. The ISWT reflects walking ability, an important measure of daily living in these patients. This involved patients walking consecutive 10-metre shuttles in time

with an audible beep that became progressively faster, until they were no longer able to maintain that pace. Patients performed a practice ISWT beforehand to minimise the influence of learning effects. Participants were asked to walk for as long as possible until reaching test termination criteria while the assessor recorded the total number of shuttles performed¹³. The ISWT has been validated against VO₂ max and VO₂ peak in clinical populations¹⁴.

Grip strength was measured using the Takei A5001 Analogue Hand Grip Dynamometer (Takei Scientific Instruments, Japan). The protocol was repeated three times on right and left sides. The five times sit to stand (STS) test was used to measure functional lower limb muscle strength. Participants started seated with their groups folded across their chest, they were then instructed to stand up and sit down five times as quickly as possible.

Anthropometric measurements

Body composition outcomes (fat mass, fat-free mass, body fat percentage, body mass) were measured using validated bioelectrical impedance (Tanita Scales BC-418-MA [Tanita Corporation, Japan])¹⁵. Body mass and stretch stature were measured to calculate BMI. Waist (1cm above the iliac crest) and hip (widest area around the gluteus maximus) circumferences were recorded.

Cardiovascular measurements

Blood pressure was obtained using the Omron M7 Digital Intellisense Upper Arm Cuff Blood Pressure Monitor (Omron Corporation, Kyoto, Japan). Blood pressure was taken three times; the first measurement was discarded and a mean of the following two measurements was reported. Resting heart rate was measured using the Contec Full-Colour OLED USB Finger Pulse Oximeter & Heart Rate Monitor (CONTEC DTxInc, Melbourne, FL, USA).

Physical activity measurements

Objective measures of physical activity were collected using an accelerometer (GT3X+, ActiGraph, Pensacola, FL, USA). Participants wore the device on an elastic waist belt and positioned it in line with the axillary line of the right iliac crest. Participants were instructed to wear the accelerometer for seven days from the moment they woke up until they went to bed at night, only removing it for water-based activities such as showering and swimming. Participants were asked to complete seven days following all three assessment visits. This is a validated method of measuring physical activity with high inter-instrument reliability (0.97 ICC; $p < 0.001$)¹⁶. The Freedson adult 1998 cut points were used to determine physical activity intensity¹⁷. The accelerometer measured sedentary time (standing and sitting; <100 counts), light activity (100 to 1951), MVPA (>1951) and step count. Data were included if it showed four valid days; a valid day was wear time of 10 waking hours.

Self-reported physical activity was measured using the short form international physical activity questionnaire (IPAQ); a seven day recall measure assessing weekly physical activity and daily sitting time. The IPAQ-short form is validated and has demonstrated moderate associations with accelerometer measurements¹⁸.

Self-efficacy for physical activity was assessed with the self-efficacy for regulating physical activity (SERPA) scale. This 18-item questionnaire asks individuals to rate their degree of confidence to perform their exercise routine regularly on a scale from 0 to 100. The results are reported as an average out of 100 to reflect the individual's confidence¹⁹.

Dietary measurement

The 24-hour food recall was used to assess dietary behaviour. This is a validated method of assessing calorie intake delivered via a structured interview²⁰. The investigator asked participants to recall all foods and drinks they consumed the previous day whilst prompting for food quantities and portion sizes. All 24 hour food recalls were analysed using NetWispVersion 4.0 (Tinuviel Software, Warrington, UK) software to estimate total daily calorific intake in kilocalories (Kcal).

Statistical analysis

A sample size calculation indicated that a total of 28 participants were required to detect a difference of 50 metres in the ISWT (primary outcome) between the two groups at the 12-week assessment point, with 80% power, and a two-sided 0.05 significance level, and a standard deviation of 45 metres. A difference of 50 metres

has been identified as clinically meaningful for another clinical population²¹. In order to allow for a 20% drop out rate, 34 participants was the recruitment target.

Data analysis used an intention to treat (ITT) protocol to include all participants who were randomised, using the last-observation-carried-forward method for missing data. The baseline to 12 week change and baseline to 24 week change were compared between groups using an independent t-test. Change differences for objectively measured physical activity between each group were determined using ANCOVA controlling for accelerometer wear time. The magnitude of an effect has been reported using the Cohen's d statistic.

Results

Participant characteristics

Of 115 patients initially invited, 57 responded, and 47 expressed interest, and were screened for trial eligibility. A total of 24 patients met study criteria and consented to randomisation. Three discontinued before the end of the trial. Figure 1 details the flow of participants throughout the trial.

Mean time since surgery was 19.3 ± 5.4 months. Participants had a mean age of 48.4 ± 8.9 years, and mean pre-operative body mass of 136.3 ± 18.7 kg. At baseline assessment, mean body mass was 106.8 ± 16.7 kg (BMI of 39.0 ± 5.2 kg·m²). Of a possible 36 gym sessions, those randomised to the intervention group of the study attended a mean of 34.2 ± 2.5 sessions (95% adherence). No adverse events or injuries were recorded throughout the exercise intervention. Table 1 presents baseline characteristics.

Functional outcomes

Table 2 displays the physical function change data between baseline and 12 and 24 weeks by trial group. For the primary outcome (ISWT), significant differences favouring the exercise group were recorded for the changes recorded at both 12-weeks ($t_{(22)}= 5.820$, $p<0.001$, $d=2.38$), and 24-weeks ($t_{(22)}= 5.289$, $p<0.001$, $d=2.16$). The overall mean improvement in distance walked at 24-weeks was 143.3 ± 86.6 metres for the exercise group, while there was a reduction of 32.50 ± 75.93 metres for the control group (Figure 2). Similarly for the STS test, performance had improved by 4.2 ± 4.0 seconds in the exercise group at 6 months, and slowed by 0.2 ± 2.1 seconds in the control group ($t_{(22)}=-3.411$, $p=0.003$, $d=1.39$).

Anthropometric outcomes

Table 3 presents the anthropometric outcome change data between baseline and 12 and 24 weeks by trial group. The exercise groups body mass change data was significantly different to the control group at both 12-weeks ($t_{(22)}=-3.278$, $p=0.003$, $d=1.34$) and 24-weeks ($t_{(22)}=-3.179$, $p=0.004$, $d=1.30$), amounting to a 5.6 kg difference between groups by 24-weeks. Fat mass change was also significantly different between groups at both 12-weeks ($t_{(22)}=-3.573$, $p=0.002$, $d=1.46$) and 24-weeks ($t_{(22)}=-2.843$, $p=0.009$, $d=1.16$). By 24-weeks, total fat mass was 4.0kg lower among the exercise group compared with the control group.

Physical activity outcomes

Table 4 displays the physical activity and self-efficacy change data between baseline and 12 and 24 weeks by trial group. Objectively measured MVPA change from baseline to 12-weeks showed a significant difference between groups ($f_{(2,19)}=4.788$, $p=0.043$, $d=0.98$), with the exercise group increasing by a mean 10.5 minutes per day. No other significant group differences were observed in objective or self-reported outcomes. By 24-weeks, mean daily MVPA in the exercise group was 7.5 minutes greater than baseline, and not significantly different from the change in the control group. From 12 to 24 weeks, there were declines in all physical activity measures in both the exercise and control groups. The exercise group's self-efficacy was highest at 12-weeks showing a mean increase of 20.44 ± 18.90 points whereas the control group remained the same -0.42 ± 7.91 points, showing a statistically significant difference between groups ($t_{(22)}=3.527$, $p=0.002$, $d=1.44$). When focusing on baseline to 24-week mean change, the exercise group sustained an increase from baseline, however this was lower than the 12-week change (6.05 ± 23.32 points). The control group also displayed a mean improvement of 9.04 ± 17.06 points at 24-weeks. There was no significant difference between the groups in the self-efficacy change at 24-weeks.

Cardiovascular and dietary outcomes

Table 5 presents the cardiovascular and dietary measurements change data between baseline and 12 and 24 weeks by trial group. Systolic blood pressure was significantly lower in the exercise group at 12 ($t_{(22)}=-2.738$, $p=0.012$, $d=1.12$) and 24-weeks ($t_{(22)}=-2.738$, $p=0.012$, $d=1.12$).

Resting heart rate decreased to a greater extent in the exercise group (11.25 ± 9.04 bpm) compared with the control group (2.83 ± 7.52 bpm) between baseline and 12-weeks ($t_{(22)}=-2.480$, $p=0.021$, $d=1.01$). The mean change at 24-weeks remained lower in both groups but was not significantly different. No significant differences in dietary intake were noted between groups at 12 or 24 weeks.

Discussion

This is the first RCT to introduce supervised structured exercise for post-bariatric surgery patients when weight regain is most likely. Significant improvements in physical function, anthropometric, cardiovascular, self-efficacy and physical activity outcomes were observed directly after 12 weeks of exercise training compared with routine care. After a further 12-week follow up period, the exercise group had maintained an advantage over the control participants in physical function, anthropometric, and cardiovascular outcomes.

Physical functioning relates to the ability to perform basic activities of daily living such as walking, stair climbing, and transitioning from sitting to standing. These functional abilities are often limited in obese individuals, hence exercise training that improves physical function is important⁵. The ISWT is a valid field based test of functional capacity and aerobic fitness as it strongly relates to VO₂ max²². Improvements displayed in blood pressure and resting heart rate in the exercise group alongside an increased walking distance could also indicate enhanced fitness. The increased mean ISWD in the exercise group after 24-weeks was 143 metres, representing a very large effect size ($d=2.2$). Although, minimum clinically important differences (MCID) for the ISWT in bariatric surgery patients have not been established, this is considerably higher than the 47.5 metres identified as a MCID in performance for patients with chronic obstructive pulmonary disease²¹, hence is likely to translate into meaningful improvements in functional ability.

The largest functional improvements in the exercise group occurred from baseline to 12-weeks (during the supervised training). Nonetheless, although the changes were smaller, walking performance, sit-to-stand speed, and grip strength all continued to improve in the 12 weeks after completing the supervised training programme (follow up phase). The degree to which the sustained levels of physical function are directly attributable to the maintenance of physical activity after the intervention is difficult to determine. Objectively recorded MVPA was 7.5 minutes higher per day than at baseline in the exercise group, and step counts and self-reported activity also remained higher than at baseline. However, increases in some of these outcomes were also observed in the control group after the advice session received at the end of the intervention period where an example exercise programme and diet sheet were provided, although no significant differences existed between groups. The increases seen in moderate intensity physical activity are noteworthy since general adult activity guidelines are based on moderate intensity (≥ 150 minutes weekly²³) and moderately intense exercise is currently recommended for interventions in obese populations for retention and motivation purposes²⁴. The exercise group recorded positive changes from baseline to 6-months in MVPA, this equated to 52.4 minutes more MVPA weekly whereas MVPA in the control group decreased. Previous research has suggested that 89% of bariatric surgery patients were not meeting the minimum MVPA guideline of ≥ 150 minutes weekly 12 months after surgery²⁵. Despite the encouraging changes in physical activity, conclusions are nonetheless limited by discrepancies between self-reported and objectively measured behaviour at baseline.

Despite physical activity being an important method for optimising surgical outcomes, it can sometimes lead to a compensatory response of increased calorific intake²⁶. The American Society for Metabolic and Bariatric Surgery (ASMBS) has reported that exercise changes body composition, with increased fat-free mass resulting in slower loss of overall body mass. The frequency and intensity of exercise may also affect metabolic rate contributing to weight loss plateaus²⁶. Based on this and the results of previous trials of post-operative exercise interventions^{9-11, 27, 28}, total body mass change was not expected in this trial. However body mass in the exercise group decreased progressively at every assessment with a loss of 2.7kg by 24-weeks. In contrast, the control group had gained 2.9 kg over the study period. A similar change in body mass was achieved in a 10-month running intervention initiated between one and three years after bariatric surgery for seven patients, with a mean BMI loss of $2.2\text{kg}\cdot\text{m}^{-2}$ reported compared with control participants, and a 1% reduction in body fat²⁹.

Typically, when patients undergo bariatric surgery, rapid weight loss occurs losing both fat mass and fat-free mass which negatively impacts basal metabolic rate³⁰. Fat-free mass loss typically accounts for between 33% and 50% of total body mass loss³¹. Exercise interventions implemented during this period of rapid weight loss have not found any significant differences in body composition through the addition of exercise^{9-11, 27, 28}. However in the current trial with exercise training introduced later, a reduction of 2.1kg of fat mass was observed after 12 weeks of training, which was largely maintained 12 weeks later.

Conversely, fat-free mass decreased in the intervention group and increased in the control group; this is not surprising because of the control group's overall increase in body mass. Loss of fat-free mass at the end of the 12 week exercise intervention amounted to 13% (0.32kg) of the total body mass reduction. This is lower than observed in the trials initiated earlier (23-39%)^{9, 10, 27}, and did not negatively impact strength outcomes (grip strength and STS performance), which continued to improve during the trial.

Previous research has found that in stage II and III obesity, exercise education alone is insufficient for preventing declines in health related fitness³². The supervised exercise approach in the current trial provided regular professional support, on-going counselling and an increased knowledge and understanding of exercise. The benefits of this are reflected in the self-efficacy levels of the exercise group, with low baseline scores increasing markedly after the completion of the exercise intervention. Notably self-efficacy was increased among control participants following the advice session. Due to the variation of abilities in this patient population it is not possible to develop a standardised universal exercise prescription, therefore individualised exercise prescription is necessary. However, the development of guidelines is possible and is needed for optimising post-operative physical function and body composition outcomes. Despite the exercise intervention having a substantial effect on physical function, little effect on objectively measured physical activity and sedentary time was observed. This supports previous research in this clinical population which indicates that physical function improvements do not directly translate into increased physical activity and ultimately undermines the argument that limited exercise capacity is a result of inactivity in this patient population^{8, 33}. This therefore indicates the need for a combined approach of supervised exercise with a behavioural component to promote exercise uptake and long term physical activity maintenance to fit into patients' lifestyles. The control participants in the current study demonstrated that an example home based programme was insufficient to improve physical function or MVPA as they declined further highlighting the importance of the need for further support.

The strengths of the trial include its rigorous design. This is the first RCT initiated at the point of weight regain, delivered at 12 to 24 months post-bariatric surgery. It is also the first intervention to report follow-up outcomes 12 weeks after completion of the exercise intervention, and to include objective measurement of physical activity. The study obtained dietary information to allow potential confounding by dietary changes to be detected. Finally in comparison with previous research, there were low drop-out rates and high session attendance indicating a good level of adherence with the intervention. Of the 115 patients invited by postal invitation, 41% were assessed for eligibility. Previous exercise and behavioural interventions have predominantly recruited directly in clinics via clinicians or via telephone and report higher percentages of patients interested. A good example is the recent Bari-Active trial, a behavioural intervention to increase home-based walking exercise, which screened 85% of patients referred for eligibility³⁴, previous exercise training studies to our knowledge do not report response rates; therefore we cannot make a direct comparison with other exercise trials. However, as with all trials this raises the possibility of a selection bias.

Despite a thorough recruitment and screening process, the recruited sample was slightly smaller than intended, contributing to some minor differences between intervention and control groups at baseline. However, none of these were statistically significant, and analysis of change data indicated large and significant inter-group differences in the primary outcome measure (ISWT), and many other outcomes. Nonetheless it is difficult to know if baseline differences in physical activity have influenced some of the outcomes. In addition, not all participants had undertaken the same bariatric procedure and no formal record of post-operative weight loss patterns was available; however patients typically self-reported weight plateau or gain. The recruited sample was predominantly female, with only four men randomised, reflecting the general gender bias in the characteristics of bariatric surgery patients [at a ratio of 3:1].

Exercise intervention research after bariatric surgery is still in its infancy. This RCT has provided a foundation for future research for the use of physical activity to optimise long term post bariatric surgery outcomes. In particular, larger scale RCTs and longer follow-up periods to determine maintenance of outcomes from such a programme are needed. The combination of pre and post-operative counselling targeting physical activity behaviour change before initiating supervised exercise requires investigation, along with cost effectiveness and feasibility of implementation in routine care.

Conclusion

These findings suggest that the implementation of a supervised exercise intervention at the typical point of weight regain is effective for improving physical function and body composition in this population. However, since physical activity declined after the end of the supervised intervention, patients may need on-going support to develop independence in order to sustain these improvements long-term.

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