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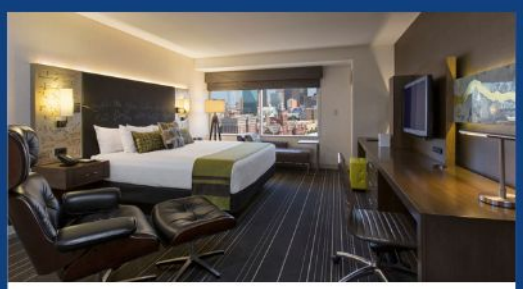

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ORIGINAL ARTICLE

Clinical Trials and Investigations

Impact of nutritional-behavioral and supervised exercise intervention following bariatric surgery: The BARI-LIFESTYLE randomized controlled trial

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Abstract

Objective: The study's aim was to investigate the impact of a 12-month adjunctive lifestyle intervention on weight loss and health outcomes after bariatric surgery.

Methods: A total of 153 participants (78.4% females; mean [SD], age 44.2 [10.6] years; BMI 42.4 [5.7] kg/m^2) were randomized to intervention ($n = 79$) and control ($n = 74$). The BARI-LIFESTYLE program combined 17 nutritional-behavioral tele-counseling sessions plus once-weekly supervised exercise for 12 weeks. The primary outcome was percentage weight loss at 6 months post surgery. Secondary outcomes included body composition, physical activity levels, physical function and strength, health-related quality of life, depressive symptomatology, and comorbidities.

Results: Longitudinal analysis of the entire cohort showed significant reductions in body weight, fat mass, fat-free mass, and bone mineral density at the total hip, femoral neck, and lumbar spine (all $p < 0.001$). The 6-minute walk test, sit-to-stand test, health-related quality of life, and depressive symptomatology improved significantly (all $p < 0.001$). The time spent in moderate-to-vigorous physical activity and sedentary behavior remained the same as before surgery (both $p > 0.05$). There was no significant difference in the primary outcome between the intervention versus control (20.4% vs. 21.2%; mean difference = −0.8%; 95% CI: −2.8 to 1.1; $p > 0.05$) and no between-group differences in secondary outcomes.

Conclusions: An adjunctive lifestyle program implemented immediately after surgery had no favorable impact upon weight loss and health outcomes.

INTRODUCTION

Bariatric surgery is the most effective treatment for people living with severe obesity, resulting in marked, sustained weight loss with improvement/resolution of obesity-linked comorbidities, improved health-related quality of life (HRQoL), and increased life expectancy [1]. At present, the prospective outcome data of bariatric surgery performed in the UK are lacking [2]. The National Bariatric Surgery Registry only collects data on outcomes such as weight loss, resolution of comorbidities, and HRQoL [3], whereas other important parameters such as the changes in body composition, including bone mineral density (BMD), physical activity levels, physical function, and strength are scarce [2]. These crucial data are needed to improve the post-bariatric care provided to patients.

Evidence has shown that weight loss and health benefits of bariatric surgery vary markedly between individuals, with approximately 20% to 30% of patients experiencing suboptimal weight loss [4]. It is also known that weight loss in the early postsurgery period is accompanied by a substantial loss of fat-free mass with a concomitant decline in BMD [5, 6]. To optimize weight loss and counteract the unfavorable outcomes, patients are required to follow post-bariatric lifestyle recommendations such as adequate protein intake, lifelong vitamin and mineral supplementation, and engagement in physical activity [7]. However, support from clinical teams in implementing these recommendations is often minimal, which may impact a person's ability to adapt after surgery [8]. In current clinical practice, most of the multidisciplinary input focuses on presurgery preparation [7]. This highlights the need to investigate the integration of effective follow-up care packages into post-bariatric care services to support patients after surgery [7].

To date, few studies have evaluated the efficacy of an adjunctive lifestyle program starting in the early postoperative period to support patients and maximize health outcomes [9–11]. Poor-quality studies, heterogeneity of the lifestyle program, and obsolete bariatric procedures reported in previous randomized controlled trials (RCTs) have meant that a definitive conclusion currently cannot be drawn as to whether a postsurgery lifestyle intervention can elicit further weight loss and health improvement [9–11]. Therefore, in the BARI-LIFESTYLE RCT study, we assessed the impact of a combined nutritional-behavioral and supervised exercise intervention, implemented immediately after surgery, on percentage weight loss (%WL) and health outcomes in the first postoperative year, compared with standard care.

Study Importance

What is already known?

- About 20% to 30% of patients experience suboptimal weight loss, defined as percentage weight loss less than 20% at 12 months post surgery.
- Prior to bariatric surgery, patients spend more time in sedentary behavior with low levels of physical activity. Postoperatively, despite weight loss, physical activity levels and sedentary behavior remain similar to preoperative levels.
- Fat-free mass is significantly reduced after surgery, which might contribute to weight regain in the long-term.

What does this study add?

- Provision of an early adjunctive program of nutritional-behavioral and supervised exercise intervention, implemented immediately after surgery, had no additional favorable impact on weight loss and non-weight-related health outcomes.

How might these results change the direction of research?

- Future studies should investigate whether shifting the start of an adjunctive lifestyle intervention program to a later time (i.e., during weight-loss maintenance phase) would improve weight loss and health benefits.
- Effective strategies are needed to improve physical activity levels, reduce sedentary behavior, and protect fat-free mass following bariatric surgery.

METHODS

Design, setting, and participants

BARI-LIFESTYLE was a two-arm, parallel-group, single-blind, multisite RCT study, embedded within an observational cohort study undertaken at three National Health Service bariatric centers in London, UK. A two-staged randomized consent design was employed [12]. The trial protocol and amendments (available in online Supporting Information) were approved by London-Dulwich Research Ethics Committee (17/LO/0950). This trial was carried out by the Centre for Obesity Research, University College London.

Eligible participants were adults aged 18 to 65 years who were planning to undergo either primary gastric bypass or sleeve gastrectomy (SG) surgery and who fulfilled the National Institute for Health and Care Excellence (NICE) eligibility criteria [7]; were medically safe to participate in an exercise program; were able to read and write in English; were able to comply with the trial protocol; were able to attend a supervised tailored exercise session weekly for 12 weeks; and were willing to wear a Fitbit and ActiGraph (wGT3X-BT, software V.6.13.3).

Patients were deemed ineligible if they had a body weight of 200 kg or more because of the limitation of the dual-energy x-ray absorptiometry (DXA) scan; if they were nonambulatory; if they had a functional limitation; or if they had a medical contraindication for exercise. All trial participants provided the first written informed consent to take part in the BARI-LIFESTYLE observational study that

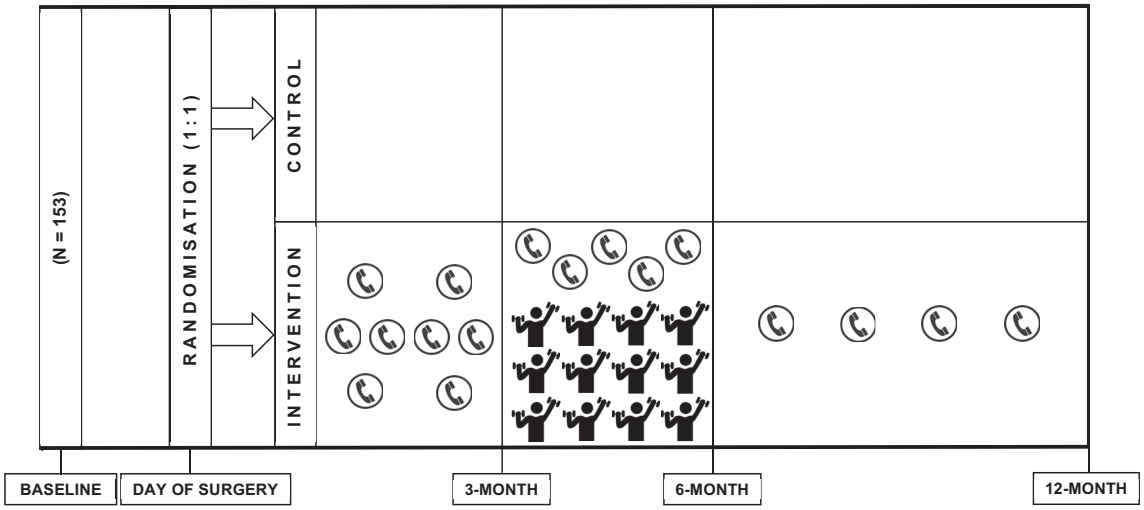

FIGURE 1 Schematic representation of BARI-LIFESTYLE trial

aimed to collect outcome data of bariatric surgery. During the consenting process, participants were told there might be the possibility they would be approached again for potential participation in a post-surgery lifestyle program. The study protocol of the observational cohort, including the study rationale, details of recruitment, procedures, outcome measures, and planned data analysis, has been published previously [2]. The details of each surgical technique (Roux-en-Y gastric bypass, one anastomosis gastric bypass, and SG) are outlined in online Supporting Information Methods.

Randomization

Immediately after surgery, all 153 participants in the observational cohort were randomized in a 1:1 ratio to receive either postsurgery standard care or standard care plus a lifestyle program. Randomization was carried out remotely by the investigators using an online randomization facility that generated a sequence with variable blocks of two, four, and six, stratified by the type of surgical procedure and trial site. All participants randomized to the intervention group were then invited to take part in the BARI-LIFESTYLE intervention study. Those who agreed to take part provided a second written informed consent prior to hospital discharge.

Participants allocated to the control group were not informed of the randomization and intervention study. This was to avoid contamination of the control group, which may have potentially diluted the treatment effects in the intention-to-treat (ITT) analysis. The outcome assessors and the trial statistician were blinded to the group allocation.

Interventions

Alongside the standard postoperative follow-up care, participants received a total of 17 nutritional-behavioral tele-counseling sessions in the first 12 months after surgery (Figure 1). The tele-counselors were all bariatric dietitians trained to deliver the sessions based on the tele-counseling manual, with each session lasting for up to 15 minutes. Participants were provided with a tele-counseling booklet containing dietary and exercise recommendations and diaries to self-report their food intake, step count, supplement intake, and body weight (see protocol in online Supporting Information). This information was used by the tele-counselor to guide and individualize the content of each session. The first eight sessions (weeks 1 to 12 post surgery) focused on ensuring participants achieved adequate nutrition and engaged in physical activity. Participants were given goals in relation to four key areas: (1) staged meal progression to meet a minimum of 60 g of daily protein intake; (2) self-monitoring of physical activity using Fitbit to achieve 10,000 steps daily; (3) intake of multivitamins and mineral supplements; and (4) self-monitoring of body weight. The following five sessions (weeks 13 to 24 post surgery) focused on maintaining adequate nutrition and protein intake, together with increased physical activity. In the last four sessions of the maintenance phase (weeks 25 to 46 post surgery), the tele-counselors continued to discuss the four key areas. In relation to exercise, participants were advised to achieve and maintain at least 150 minutes of moderate-to-vigorous physical activity (MVPA) per week. In all 17 sessions, participants were encouraged to raise their preferred topic for discussion and they received real-time feedback from the tele-counselor.

At 3 months post surgery, participants were enrolled in a supervised, once-weekly, individually tailored exercise program for 12 weeks. Each session lasted for up to 60 minutes, combining both aerobic and resistance exercises supervised by exercise therapists at the hospital gym (see protocol in online Supporting Information). Participants were provided with an exercise booklet containing a weekly exercise log for 12 weeks (protocol) and three types of exercise bands varying in resistance (PhysioRoom.com). The gym supervised exercise was converted to remote, live, supervised tele-exercise classes during the COVID-19 lockdown [13].

Participants in the control group received the standardized post-operative bariatric care as stipulated by NICE [7]. A Fitbit wearable device, for self-monitoring purposes, was given to all participants to prevent unblinding of the study outcome assessors at recruitment to the initial observational study.

Primary and secondary outcome measures

The primary outcome was %WL at 6 months post surgery between the intervention versus the control groups. %WL was calculated using the following formula: %WL= ([weight on the day of surgery – weight at time point after surgery]/weight on the day of surgery) × 100. %WL was measured at each study time point (at 3, 6, and 12 months post surgery). Prespecified secondary outcomes included body composition and BMD measured by bioelectrical impedance analyzer (BIA) (Tanita DC-430MAS) and DXA scan (Discovery A DXA system, software version.13.4.2, Hologic). Habitual physical activity was assessed objectively by accelerometer-based activity monitor (ActiGraph). Functional capacity was assessed using 6-minute walk test (6MWT), lower body functional capacity was measured using sit-to-stand test, and static muscle strength of the upper extremities was assessed using handgrip test (Jamar Hydraulic Hand Dynamometer, Patterson Medical). HRQoL was assessed using European Quality of Life Five Dimension Three Level Scale and Impact of Weight on Quality of Life-Lite questionnaires [14, 15]. Attitude and symptoms of depression were assessed using Beck Depression Inventory-II [16]. Comorbidities resolution (hypertension, hyperlipidemia, and obstructive sleep apnea) was defined as the normalization of the corresponding characteristics without treatment. Complete remission of type 2 diabetes was defined according to the American Diabetes Association criteria of complete remission: no antidiabetic drug, fasting blood glucose <5.6 mmol/L, and glycated hemoglobin in the normal range of at least 1 year's duration. Partial remission was defined as the following: no antidiabetic drug and glycated hemoglobin < 6.5% of at least 1 year's duration [17].

Statistical analysis

The initial sample size was calculated based on the cohort data of patients who underwent bariatric surgery at one of the trial sites with the mean of %WL at 12 months post surgery of 27.8% (SD 8.4%) [4]. We calculated that a sample size of 198 participants (99 participants per study arm) would provide 95% power at a 0.05 significance level to detect a 5% difference in %WL between groups at 12 months, after allowing for up to 25% dropout. However, because of the high attrition rate at 12 months and the COVID-19 pandemic, the primary outcome time point was changed to 6 months post surgery following consultation with the trial steering committee. At this time point, 65 and 69 participants were available in the control and intervention groups. Continuing with the assumed mean difference of 5% and SD of 8.4%, the power to test a difference of 5% at 6 months was 93%.

The longitudinal analysis for the entire cohort has been described previously [2]. The analyses for the primary and secondary outcomes of the RCT were undertaken based on appropriate complete-case groupings for related measures on the ITT principle that no account was paid to the extent to which the treatments were followed. For the primary outcome analysis, the ITT principle was further strengthened by including participants whose weight at 6 months was based on self-measurement. Standard linear regression model for %WL at 6 months post surgery was undertaken, with explanatory variables to indicate treatment group, body mass index (BMI) on day of surgery, and trial site. The estimation of this coefficient was reported together with an associated 95% confidence interval (CI). A p value for a test of the null hypothesis that this mean difference is equal to zero against a two-sided alternative was reported using a significance level of 0.05. For weight at each time point (3, 6, and 12 months), additional models were fitted in which weight (in kilograms rather than percentage change) was modeled using linear regression with BMI at surgery, treatment group, and trial site as explanatory variables. Weight across time was modeled using a longitudinal mixed-effects model with weight on the day of surgery, time, treatment group, and trial site included as fixed effects and a random effect included at the participant level.

Other continuous secondary outcomes (fat mass, fat-free mass, BMD, physical activity levels, sedentary behavior, physical function and strength, HRQoL, and depressive symptomatology) were also analyzed using a longitudinal mixed-effects model. For obesity-related comorbidities, the proportion of participants with the conditions was reported in a table by treatment group at baseline and at 12-month follow-up. Tables were produced to report the number of participants who had new comorbidities and to report the status of comorbidities for participants who had comorbidities at baseline (complete/partial remission, improved, unchanged, worsened). For binary outcomes, we used Fisher exact test to compare between groups.

Analyses were performed using Stata 17 (StataCorp LLC). There is no data monitoring committee. The trial is registered at ClinicalTrials.gov, NCT03214471.

RESULTS

Between February 21, 2018, and November 13, 2019, 514 potential participants were assessed for eligibility. Of these, 153 participants (78.4% female) were enrolled and randomly assigned to intervention ($n = 79$) and control ($n = 74$) groups (Figure 2). The baseline demographic characteristics are shown in Table 1.

The mean number of tele-counseling sessions attended was 13 out of 17 sessions, by which 90.7% of participants completed more than half of the total sessions. However, for the supervised exercise session, 20 out of the 75 participants did not enroll in the program. The common reasons stated were time commitments associated with

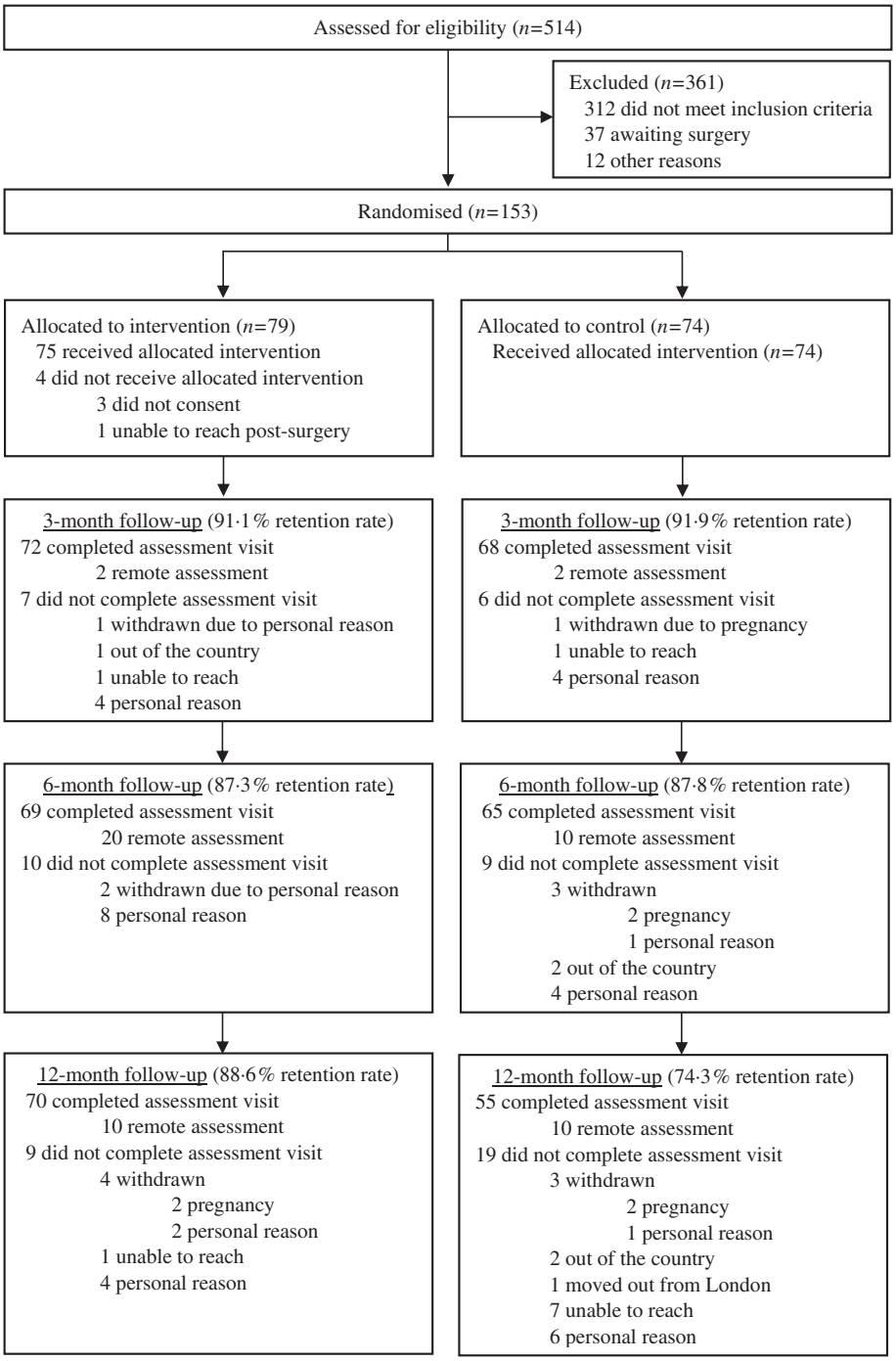

FIGURE 2 Flow of participant enrollment, group allocation and follow-up

family and work responsibilities, preferring to exercise on their own, and inconvenient gym locations and exercise class schedules. During the COVID-19 pandemic, 16 participants who had started the in-person gym exercise classes were invited to complete the remaining sessions virtually [13]. Overall, for the supervised exercise component, the mean number of attendances per participant was 8 out of 12 classes, with 76.4% of participants completing more than half of the exercise classes. The last participant follow-up was on December 17, 2020.

Weight-loss and health outcomes of the entire cohort

Overall, bariatric surgery significantly reduced body weight, fat mass, fat-free mass, and BMD at the total hip, femoral neck, and lumbar spine in the first 12 months following surgery (all $p < 0.001$). Furthermore, the 6-minute walk test, sit-to-stand test, HRQoL, and depressive symptomatology also significantly improved (all $p < 0.001$). No improvements were observed in the time spent on MVPA and sedentary behavior (both $p > 0.05$; Table 2). At 1 year post surgery, all

TABLE 1 Baseline demographic characteristics

	All	Intervention	Control
n	153	79	74
Age (y)	44.2 (10.6)	44.8 (10.8)	43.6 (10.5)
Gender, *n* (%)			
Male	33 (21.6)	20 (60.6)	13 (39.4)
Female	120 (78.4)	59 (49.2)	61 (50.8)
Menopause, *n* (%)	29 (24.2)	15 (51.7)	14 (48.3)
Weight (kg)	118.0 (19.1)	119.1 (18.2)	116.8 (20.1)
Height (m)	1.67 (0.09)	1.68 (0.08)	1.65 (0.09)
BMI (kg/m^2)	42.4 (5.7)	42.1 (5.8)	42.7 (5.7)
Type of surgery, *n* (%)			
RYGB	44 (28.8)	24 (54.5)	20 (45.5)
OAGB	25 (16.3)	13 (52)	12 (48)
SG	84 (54.9)	42 (50)	42 (50)
Surgery center, *n* (%)			
UCLH	70 (45.7)	37 (52.9)	33 (47.1)
Whittington	42 (27.5)	21 (50)	21 (50)
Homerton	41 (26.8)	21 (51.2)	20 (48.8)
Ethnicity, *n* (%)			
White/White British	89 (58.2)	43 (48.3)	46 (51.7)
Mixed race	7 (4.6)	4 (57.1)	3 (42.9)
Asian/Asian British	13 (8.5)	7 (53.8)	6 (46.2)
Black/Black British	35 (22.8)	19 (54.3)	16 (45.7)
Other ethnicity	9 (5.9)	6 (66.7)	3 (33.3)
Smoking status, *n* (%)			
Current smoker	1 (0.7)	0	1 (100)
Past smoker	71 (46.4)	38 (53.5)	33 (46.5)
Never	81 (52.9)	41 (50.6)	40 (49.4)
Comorbidities, *n* (%)			
T2D	36 (23.5)	19 (52.8)	17 (47.2)
Hypertension	52 (34.0)	31 (59.6)	21 (40.4)
Hyperlipidemia	28 (18.3)	12 (42.9)	16 (57.1)
OSA	43 (28.1)	27 (62.8)	16 (37.2)

Note: Data are mean (SD) unless otherwise indicated.
Abbreviations: OAGB, one anastomosis gastric bypass; OSA, obstructive sleep apnea; RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; T2D, type 2 diabetes; UCLH, University College London Hospitals.

bariatric procedures produced a comparable %WL as follows: Roux-en-Y gastric bypass (25.3%), one anastomosis gastric bypass (26.4%), and SG (24.3%), $p = 0.69$ (Supporting Information Figure S1 and Table S1). The mean percentage fat mass and fat-free mass loss was also comparable across all bariatric procedures, $p = 0.91$ and $p = 0.52$, respectively (Supporting Information Table S2). A detailed exploratory analysis of the primary and secondary outcomes of the observational cohort will be presented separately.

The impact of intervention on weight loss

A total of 49 participants in the intervention group and 55 participants in the control group with available BIA body weight were included for complete-case analysis (Table 2), regardless to the extent to which they complied with their randomization to conditions. No significant difference in %WL at 6 months post surgery was observed between the intervention versus control group [20.0% vs. 21.2%; mean difference (MD) = −1.2%; 95% CI: −3.5 to 1.1; $p = 0.29$]. In seeking to minimize bias by further following the ITT principle [18], a further 30 participants with self-reported body weight at 6 months, collected remotely, were included. This formed the primary outcome ITT analysis including 69 and 65 participants with %WL at 6 months post surgery between the intervention versus control group, 20.4% versus 21.2% (MD = −0.8%; 95% CI: −2.8 to 1.1; $p = 0.41$), respectively. This shows a very similar result to that from the complete-case analysis. A sensitivity analysis revealed that there was no significant correlation between the numbers of tele-counseling and exercise sessions completed with %WL at 6 months post surgery, $r = 0.172$ ($p = 0.16$) and $r = 0.129$ ($p = 0.30$), respectively (Supporting Information Table S3).

The impact of intervention on secondary outcomes

For the prespecified secondary outcomes analysis, no between-group differences were observed throughout the first postoperative year in fat mass, fat-free mass, BMD, habitual physical activity, physical function and strength, HRQoL, depressive symptomatology (Table 2), and comorbidities resolution (Supporting Information Table S4).

Adverse events

Twenty-two serious adverse events were reported in 13 participants from the intervention group and 5 participants from the control group who required hospitalization. Of all the serious adverse events, some were expected postsurgery events such as pregnancy, vomiting, cholecystectomy, and surgical-related complications (Table 3). None of the serious adverse events was related to either the tele-counseling or supervised exercise interventions. All serious adverse events were resolved with appropriate management. Most of the reported adverse events were mild (Supporting Information Table S5). The common adverse events reported in the intervention group were similar to those associated with post-bariatric surgery (e.g., constipation, vomiting, abdominal pain). The gastrointestinal and cardiovascular adverse events were more commonly reported by participants in the intervention group than in the control group. These differences were most probably associated with increased reporting by the intervention group compared with the control group, as there were more follow-up visits completed by the former group.

TABLE 2 Main outcomes of the trial at baseline and at 3, 6, and 12 months

	Intervention				Control				Change over time[a]	Intervention effect		
Group allocation	Baseline	3-month	6-month	12-month	Baseline	3-month	6-month	12-month	*p* value	Estimate (SE)	95% CI	*p* value
Bioelectrical impedance analyzer												
n	79	70	49	60	74	66	55	45				
Weight (kg)	119.1 (18.2)	101.9 (15.7)	97.0 (16.2)	88.4 (15.3)	116.8 (20.1)	100.9 (18.6)	92.3 (18.0)	88.6 (18.7)	<0.001	0.6 (0.8)	−1.0 to 2.1	0.46
BMI (kg/m^2)	42.1 (5.8)	36.0 (5.1)	34.6 (4.7)	31.3 (4.7)	42.7 (5.7)	36.9 (5.5)	33.8 (5.2)	32.1 (5.5)	<0.001	0.1 (0.3)	−0.4 to 0.7	0.64
Percentage weight loss (%)	-	14.4 (3.6)	20.0 (6.1)	24.9 (9.2)	-	14.3 (3.9)	21.2 (5.8)	25.0 (8.8)	<0.001	−0.4 (0.9)	−2.3 to 1.4	0.64
Fat mass (kg)	56.2 (15.0)	43.6 (12.5)	40.5 (11.9)	32.9 (10.9)	56.8 (14.3)	44.6 (13.8)	38.6 (12.1)	34.3 (13.2)	<0.001	0.4 (0.6)	−0.7 to 1.5	0.47
Body fat (%)	45.3 (7.3)	42.3 (7.9)	41.3 (7.4)	36.7 (8.1)	46.7 (6.6)	43.6 (7.9)	41.3 (6.8)	38.0 (8.5)	<0.001	0.4 (0.3)	−0.2 to 1.0	0.25
Fat-free mass (kg)	66.8 (10.7)	58.4 (9.5)	56.5 (9.3)	55.5 (9.5)	63.9 (11.6)	56.2 (10.0)	53.5 (9.5)	54.2 (10.3)	<0.001	0.1 (0.3)	−0.6 to 0.7	0.89
Dual-energy x-ray absorptiometry												
n	79			60	73			45				
Fat mass (kg)	53.2 (12.8)			32.2 (9.4)	53.2 (11.7)			33.8 (11.1)	<0.001	−0.3 (0.7)	−1.8 to 1.1	0.66
Body fat (%)	42.8 (6.0)			35.6 (6.9)	43.8 (5.6)			37.2 (7.8)	<0.001	−0.2 (0.4)	−1.0 to 0.6	0.59
Fat-free mass (kg)	70.3 (11.0)			57.2 (10.0)	68.1 (12.7)			56.2 (11.3)	<0.001	0.0 (0.4)	−0.7 to 0.8	0.93
Total hip BMD (g/cm^2)	1.173 (0.141)			1.085 (0.143)	1.133 (0.107)			1.032 (0.116)	<0.001	0.003 (0.004)	−0.005 to 0.011	0.48
Femoral neck BMD (g/cm^2)	0.950 (0.160)			0.895 (0.164)	0.907 (0.120)			0.839 (0.113)	<0.001	0.003 (0.005)	−0.007 to 0.014	0.51
Lumbar spine BMD (g/cm^2)	1.158 (0.159)			1.122 (0.172)	1.108 (0.148)			1.092 (0.172)	<0.001	−0.003 (0.004)	−0.011 to 0.004	0.40
Whole body BMD (g/cm^2)	1.196 (0.107)			1.207 (0.113)	1.185 (0.099)			1.189 (0.107)	0.03	0.003 (0.003)	−0.003 to 0.010	0.27
Habitual physical activity												
n	70	50	49	46	63	43	36	37				
Sedentary (min/d)	599.0 (98.5)	606.3 (80.6)	603.0 (118.1)	595.5 (102.0)	590.0 (74.4)	585.5 (98.0)	561.4 (114.2)	570.2 (106.2)	0.11	10.5 (7.7)	−4.6 to 25.7	0.17
Light physical activity (min/d)	291.7 (84.6)	302.3 (76.5)	289.9 (87.3)	298.2 (78.5)	312.6 (67.5)	308.6 (87.6)	320.4 (89.9)	327.0 (99.2)	0.44	−5.0 (6.5)	−17.7 to 7.8	0.44
MVPA (min/d)	41.2 (26.6)	43.8 (27.0)	41.3 (26.7)	43.6 (28.0)	44.1 (24.5)	41.3 (20.0)	40.7 (20.7)	40.0 (22.4)	0.34	1.6 (1.9)	−2.0 to 5.2	0.39
Steps/day	5414 (2502)	6555 (2859)	6069 (2966)	6339 (2985)	5768 (1773)	6070 (2105)	6412 (2503)	6033 (2633)	0.07	258 (194)	−122 to 637	0.18
Physical function and strength												
n	78	69	48	34	74	63	55	25				
6-minute walk test (m)	428.4 (64.7)	492.5 (71.0)	506.4 (70.1)	530.3 (85.5)	411.4 (56.9)	472.2 (60.0)	482.9 (71.8)	492.4 (52.7)	<0.001	6.2 (4.5)	−2.6 to 15.0	0.17
n	78	70	49	67	72	64	56	50				
Sit-to-stand test (s)	11.1 (5.6)	9.5 (4.5)	8.4 (2.9)	7.8 (3.2)	10.5 (3.4)	8.2 (2.0)	8.3 (3.0)	7.6 (2.4)	<0.001	0.3 (0.2)	−0.1 to 0.7	0.20
n	79	70	49	67	74	65	52	50				
HGS (kg)	34.6 (9.3)	34.4 (8.8)	34.6 (7.1)	34.4 (7.8)	32.4 (9.3)	32.7 (8.7)	31.3 (6.9)	31.7 (9.5)	0.05	0.4 (0.4)	−0.5 to 1.2	0.41
Health-related quality of life and depressive symptomatology												
n	79	72	71	71	74	68	66	54				
EQ-5D-index	0.73 (0.23)	0.83 (0.19)	0.83 (0.23)	0.83 (0.18)	0.68 (0.29)	0.87 (0.18)	0.88 (0.18)	0.85 (0.23)	<0.001	−0.01 (0.03)	−0.07 to 0.06	0.88

(Continues)

TABLE 2 (Continued)

	Intervention				Control				Change over time[a]	Intervention effect		
Group allocation	Baseline	3-month	6-month	12-month	Baseline	3-month	6-month	12-month	*p* value	Estimate (SE)	95% CI	*p* value
EQ-VAS (%)	62.9 (20.3)	74.8 (15.5)	79.0 (15.2)	83.5 (13.6)	58.4 (19.4)	79.3 (14.2)	80.8 (13.6)	86.0 (12.8)	<0.001	−0.5 (2.1)	−4.6 to 3.6	0.82
IWQOL-Lite total (%)	49.2 (19.4)	72.5 (20.2)	83.5 (17.6)	88.1 (15.6)	46.1 (20.7)	78.9 (17.1)	86.1 (15.4)	88.2 (15.6)	<0.001	−1.7 (2.5)	−6.7 to 3.3	0.15
Physical function	50.0 (21.7)	76.0 (18.9)	85.9 (15.7)	90.2 (12.5)	46.5 (20.7)	81.7 (16.1)	88.8 (13.8)	88.8 (13.7)	<0.001	−1.3 (2.4)	−5.9 to 3.3	0.11
Self-esteem	36.9 (27.1)	65.6 (28.4)	77.5 (24.0)	81.9 (21.3)	34.7 (26.7)	72.6 (20.8)	80.1 (21.8)	84.0 (22.3)	<0.001	−2.4 (3.4)	−9.0 to 4.3	0.32
Sexual life	52.0 (30.7)	66.3 (27.7)	78.1 (29.6)	86.5 (23.1)	48.7 (31.2)	76.2 (22.8)	82.2 (24.3)	86.5 (23.8)	<0.001	−3.1 (4.0)	−11.0 to 4.8	0.05
Public distress	49.9 (27.8)	73.5 (25.5)	85.4 (20.7)	90.6 (18.5)	48.6 (27.9)	78.8 (23.0)	87.6 (18.2)	91.7 (14.4)	<0.001	−2.2 (3.1)	−8.2 to 3.9	0.40
Work	64.8 (25.0)	80.9 (21.9)	90.6 (17.7)	92.9 (16.9)	60.4 (27.9)	84.8 (20.9)	90.4 (16.0)	91.7 (17.8)	<0.001	0.5 (2.8)	−5.0 to 6.1	0.46
BDI-II total (score)	16.1 (10.5)	9.8 (9.0)	8.0 (9.9)	7.2 (7.5)	16.7 (11.7)	7.2 (8.7)	6.0 (8.1)	7.3 (10.6)	<0.001	0.9 (1.4)	−1.9 to 3.6	0.55
Cognitive	5.8 (4.7)	3.0 (3.9)	2.5 (4.1)	2.0 (3.0)	5.8 (4.7)	2.0 (3.3)	1.6 (3.2)	2.2 (3.8)	<0.001	0.4 (0.6)	−0.7 to 1.6	0.47
Somatic	10.2 (6.7)	6.8 (5.6)	5.5 (6.2)	5.1 (5.0)	10.9 (7.7)	5.2 (5.8)	4.3 (5.4)	5.1 (7.1)	<0.001	0.4 (0.9)	−1.3 to 2.1	0.63

Note: Data are mean (SD) from each subsample at each time point.

Abbreviations: BDI-II, Beck Depression Inventory-II; BMD, bone mineral density; EQ-5D-index, European Quality of Life Five Dimension Index; EQ-VAS, European Quality of Life Five Dimension Visual Analogue Scale; HGS, handgrip strength test; IWQOL-Lite, Impact of Weight on Quality of Life-Lite; MVPA, moderate-to-vigorous physical activity.

[a]The change over time *p* value is testing the change for the pooled intervention and control groups.

DISCUSSION

Aligned with the existing literature [1, 3], longitudinal analysis of the BARI-LIFESTYLE cohort showed that bariatric surgery leads to a marked reduction in body weight and fat mass with improvement in physical function, HRQoL, and depressive symptomatology. However, physical activity levels and sedentary behavior did not change after surgery, with an undesirable impact observed on the changes in fat-free mass and BMD, similar to what has been previously reported [5, 6, 19, 20]. Of those participants enrolled in the BARI-LIFESTYLE intervention, their weight loss did not differ compared with those participants receiving post-bariatric standard care. Similarly, the BARI-LIFESTYLE intervention had no favorable impact on non-weight-related outcomes that include fat mass, fat-free mass, BMD, habitual physical activity, physical function and strength, HRQoL, depressive symptomatology, and comorbidities resolution.

The present trial is the first evidence, to our knowledge, to show that combining both nutritional-behavioral intervention and tailored supervised exercise in a single postoperative lifestyle program has no impact on weight loss in the first 12 months after surgery. Our finding further supports a few previous RCTs demonstrating that providing either postsurgery nutritional-behavioral intervention [21–25] or exercise programs [26, 27] within the first year after surgery did not lead to additional weight loss. The exact reasons are not fully understood, although these might be due to the predominant biological effects of weight loss in the early phase of bariatric surgery [28] that may have overridden the potential weight-loss impact of any adjunctive lifestyle interventions. This is consistent with the results of the STEP trials with the glucagon-like peptide-1 receptor agonist semaglutide. The STEP 3 trial that combined semaglutide with intensive behavioral therapy and a low-calorie diet led to no greater weight loss than semaglutide alone in the STEP 1 trial after 68 weeks of treatment [29, 30]. Our findings, therefore, highlight the need to identify preoperative predictors to maximize postsurgery weight loss.

No favorable impacts of the BARI-LIFESTYLE intervention on HRQoL and mental health outcomes were observed, which corroborates findings from previous RCTs [24, 31]. This could be explained by the fact that the peak improvement in HRQoL and mental health occurs in the 12 months following surgery [32, 33], and so, any adjunctive lifestyle interventions would not offer additional impacts. Furthermore, the similar marked weight loss observed between groups might have explained the comparable outcomes in HRQoL, mental health, and comorbidities improvement/resolution.

The lack of favorable impact of BARI-LIFESTYLE intervention on fat-free mass, BMD, and physical function and physical strength as compared with the previous post-bariatric exercise RCTs [34–38] could be explained by the heterogeneity in the content of the exercise program across studies. Although the present trial involved only a once-weekly exercise program for 12 weeks, the other RCTs involved three weekly exercise sessions with longer duration that ranged from 12 to 44 weeks [34–38]. These RCTs also consisted of predominantly resistance training, above and beyond the intensity of resistance training provided in the present trial. The reported adherence rates of the previous RCTs ranged from 39% to 83%, which are similar to our

TABLE 3 Serious adverse events

	All ($n = 153$)	Intervention ($n = 79$)	Control ($n = 74$)
All serious adverse events			
Number of serious adverse events	22	17	5
Number of participants with any serious adverse events	18	13	5
Unanticipated serious adverse events			
Cardiovascular			
Arrhythmia	2	2	0
Chest pain	2	2	0
Faint	1	1	0
Mild heart attack	1	1	0
Dermatological			
Back abscess	1	1	0
Musculoskeletal			
Elbow operation	1	1	0
Anticipated serious adverse events			
Gastrointestinal			
Abdominal pain	3	2	1
Bowel obstruction	1	1	0
Cholecystectomy	1	1	0
Ulcer	1	0	1
Vomiting	3	3	0
Infectious			
Sepsis	1	0	1
Reproductive			
Pregnancy	4	2	2

study (76.4%). Taken together, the frequency, duration, and intensity of resistance training are key when designing an effective exercise program for patients after bariatric surgery. The lack of favorable outcome on these parameters could also be due to no additional impacts of the BARI-LIFESTYLE intervention on the time spent in MVPA and sedentary behavior. Indeed, previous findings from bariatric cohorts have suggested that improved time spent in MVPA and reduced time spent in sedentary behavior were associated with higher fat mass loss and better preservation of fat-free mass after surgery [20, 39]. Preventing loss of fat-free mass and BMD after bariatric surgery is crucial, as an excessive loss might negatively impact the ability to carry out activities of daily living and increase fracture risk over the long term [5]. This is important as the majority of people undergoing bariatric surgery are above the age of 30 [1, 3], a point when muscle mass and strength start to decline involuntarily, with the rate of decline accelerating after the age of 60 [40]. Women especially have an even higher fracture risk once they enter menopause, which represents more than 75% of patients undergoing bariatric surgery [1, 3]. Given that the new antiobesity medications that engender weight loss in the bariatric surgery range are likely to be used in a similar group of patients [41, 42], studies are needed to examine the impact of these on habitual physical activity and body composition changes.

Strengths and limitations

The main strength of BARI-LIFESTYLE is the use of a high-quality trial design. The adherence rate of the tele-counseling sessions in the present study was also high (90.7%). Both BIA and DXA, the latter being a reference gold standard [43], were used to assess the changes in body composition. The habitual physical activity was measured objectively using an accelerometer, as patients who have undergone bariatric surgery tend to overreport their physical activity levels when assessed using the conventional questionnaires [44]. In addition, the present trial used an obesity-specific HRQoL questionnaire [15] and a validated instrument to assess depressive symptomatology [16], both of which are sensitive to detecting small changes.

We acknowledge several limitations in our study. The prespecified secondary outcomes were not powered to detect a significant difference between groups. During the nationwide COVID-19 lockdown, all in-person follow-up assessments were carried out remotely; hence throughout this period, outcome data that required a face-to-face assessment such as body composition and physical function were missing. In addition, the last 16 participants who had started the in-person exercise classes had to complete the remaining sessions remotely because of the lockdown. Nevertheless, through a

qualitative substudy that we undertook, the participants reported that the intensity of the remote exercise was similar to the gym exercise they attended before the lockdown. The virtual exercise classes also helped with adherence by removing the barriers when attending the in-person exercise classes before COVID such as traveling time, parking issues, and poor weather conditions [13]. Last, as previously mentioned, approximately one-quarter of participants randomized to the intervention group did not enroll in the exercise program, with reasons similar to a previous RCT study [27].

Implications for practice and considerations for future studies

The high adherence toward the remote dietary tele-counseling suggests that this method of service delivery could be implemented as an alternative to the usual in-person dietetics follow-up. Indeed, a recent survey reported that 81.7% of patients were satisfied with the virtual bariatric follow-up clinics provided during the COVID-19 pandemic mainly because of the time and cost efficiency to attend, with 76% of patients expressing their preference to continue with virtual care [45].

Our trial provides a low-dose exercise program and has no favorable impact compared with previous positive studies [34–38], suggesting that higher frequency, duration, and intensity of resistance training are needed to achieve the beneficial impact on non-weight-related outcomes.

For future studies, the following recommendations should be considered:

1. We previously showed that patients who lose less than 1 lb a week during the 3- to 6-month postoperative period will not achieve a maximal %WL of more than 20% [4]. Therefore, future studies should target patients who exhibited early poor weight-loss response as a main inclusion criteria.
2. The optimal timing to deliver a postsurgery lifestyle intervention program remains unclear, although our data suggest no impact when delivered within the first 12 months after surgery. Therefore, future studies should consider randomizing patients to either receive the lifestyle intervention during the substantial weight-loss phase or during weight-loss maintenance.
3. Studies with longer term follow-up are needed to provide further evidence of whether an early adjunctive lifestyle intervention would have favorable impacts on long-term weight-loss maintenance or the rates of weight regain.
4. Our study highlights that marked weight loss alone, despite support to increase habitual physical activity, does not lead to increased MVPA or reduced sedentary behavior. Given that the use of antiobesity medications that engender weight loss in the bariatric surgery range is likely to become widespread [41, 42], future studies should focus on strategies to improve these non-weight-related outcomes in patients who lose significant weight with lifestyle programs, pharmacotherapy, or bariatric surgery.

CONCLUSION

Our findings add to the existing evidence [21–27] that the provision of a lifestyle intervention in the first 12 months following bariatric surgery does not improve weight loss or health outcomes.

AUTHOR CONTRIBUTIONS

Friedrich C. Jassil: conceptualization; literature search; participant recruitment; data collection; data interpretation; writing – original draft; figures. Alisia Carnemolla: conceptualization; project administration; supervision; writing – review and editing. Helen Kingett, Jacqueline Doyle, Amy Kirk, Neville Lewis, Adrian Brown: delivering intervention; writing – review and editing. David Boniface: data analysis; data interpretation; writing – review and editing. Gemma Montagut, Kusuma Chaiyasoot, Roxanna Zakeri, Jessica Mok: participant recruitment; data collection; writing – review and editing. Parastou Marvasti: data management; writing – review and editing. Kalpana Devalia and Chetan Parmar: principal investigator; writing – review and editing. Rachel L. Batterham: chief investigator; conceptualization; methodology; data curation; funding acquisition; resources; supervision; writing – review and editing. All authors approved the final version.

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CONFLICT OF INTEREST STATEMENT

Outside of the submitted work, Rachel L. Batterham reports personal fees from Novo Nordisk A/S, ViiV Healthcare Ltd., Pfizer, Gila Therapeutics Inc., Eli Lilly & Co., and International Medical Press. Rachel L. Batterham also reports unpaid roles with Royal College of Physicians, the Association for the Study of Obesity, British Obesity and Metabolic Surgery Society, National Bariatric Surgery Registry, International Federation for the Surgery of Obesity and Metabolic Disorders, European Society of Endocrinology, Obesity Empowerment Network UK, and National Institute for Health and Care Excellence. Outside of the submitted work, Adrian Brown reports support from Novo Nordisk; honoraria from Novo Nordisk, Public Health England, and Obesity UK; and serving on the Medical Advisory Board and as a shareholder of Reset Health Clinics Ltd. Outside of the submitted work, Roxanna Zakeri reports funding from National Institute for Health Research and Royal College of Surgeons of England. The other authors declared no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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