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Original article

One-year follow-up of a dissonance-based intervention on quality of life, wellbeing, and physical activity after Roux-en-Y gastric bypass surgery: a randomized controlled trial

Fanny Sellberg, M.Sc., Ph.D.[a,*], Sofie Possmark, M.Sc.[a], Mikaela Willmer, Ph.D.[b], Per Tynelius, M.Sc.[a,c], Daniel Berglind, Ph.D.[a]

[a]*Karolinska Institutet, Department of Public Health Sciences, Stockholm, Sweden*
[b]*University of Gävle, Department of Health and Caring Sciences, Gävle, Sweden*
[c]*Centre for Epidemiology and Community Medicine, Stockholm County Council, Stockholm, Sweden*

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Abstract

Background: Health-related quality of life (HRQoL) peaks around 1 year after Roux-en-Y gastric bypass (RYGB) surgery, and thereafter, in many patients, slowly deteriorates.
Objectives: The aim of the present study was to test early effects (study endpoint 2 years) of a dissonance-based group intervention on HRQoL (primary outcome) and wellbeing among women who underwent RYGB: a 1-year follow-up of the WELL-GBP trial.
Setting: Women were recruited from 5 different hospitals in Sweden pre-RYGB surgery. Participants were randomized to intervention or a control group (regular care).
Methods: The intervention consisted of 4 group sessions, 2 to 3 months post-surgery, comprising the following 4 different topics: (1) physical activity, (2) eating behavior, (3) social relationships, and (4) intimate relationships. Participants answered questionnaires about HRQoL (SF-36, Short-Form Health Survey), social adjustment, body esteem, eating behavior, and wore an accelerometer for 7 days at pre- and 1 year post-RYGB.
Results: Two hundred fifty-nine women were recruited and 203 (78%) completed 1-year follow-up measurements. Mean body mass index pre-surgery was 40.8 (standard deviation = 4.5), mean age 44.7 (standard deviation = 10.3) years, and 61 of 120 women in the intervention group received the intervention according to protocol (≥3 group sessions). We observed no difference between the intervention and the control group at 1-year post-RYGB surgery. All scales improved in both groups from pre- to 1 year post-surgery.
Conclusions: We did not observe any 1-year early effects on HRQoL from a dissonance-based group intervention among female RYGB patients. Future studies may investigate long-term effects of the intervention. (Surg Obes Relat Dis 2019;15:1731–1737.) © 2019 American Society for Bariatric Surgery. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Key words: Bariatric surgery; RYGB; Gastric bypass; Health-related quality of life; Quality of life; Physical activity; Intervention; Randomized controlled trial; Body esteem; Eating behavior; Psychosocial adjustment

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*Correspondence: Fanny Sellberg, Karolinska Institutet, Department of Public Health Sciences (PHS), K9, Social Medicine, 171 77 Stockholm, Sweden.
E-mail address: fanny.sellberg@ki.se (F. Sellberg).

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Bariatric surgery has been shown to result in major weight loss and long-term weight maintenance, but many patients find it hard to adapt to the new lifestyle behaviors required after surgery. Before bariatric surgery, patients show a high prevalence of eating disorders, depression and anxiety, and low health-related quality of life (HRQoL), along with low levels of physical activity [1]. After surgery, most of these issues improve substantially. However, objectively measured physical activity shows mixed results, with possible small increases in moderate-to-vigorous physical activity (MVPA) [2]. However, the long-term outcomes of bariatric surgery (including weight maintenance) differ substantially between individuals. The reason for this is proposed to consist of several factors, for example, low self-efficacy [3], poor adherence to dietary and physical activity recommendations [4], lack of social support [5], and disordered eating behaviors [6]. HRQoL improves post-surgery with a peak improvement at approximately 1 year after surgery. Thereafter it decreases and, in many cases, remains below population norms [7]. HRQoL is commonly measured with the 36-item Short-Form Health Survey (SF-36), that is divided into 2 summary scores, physical component summary score and mental component summary score. The physical component summary score has shown peak improvements approximately 1 to 2 years after bariatric surgery followed by a decline; however, still better than pre-surgery. On the other hand, the mental component summary score showed smaller increases that are not maintained over time [8,9]. Thus, HRQoL after bariatric surgery still shows need for improvements.

Lifestyle interventions post-surgery could improve weight loss maintenance and have been shown to be quite effective [10], along with postoperative group sessions, psychotherapeutic interventions [11], and behavioral management [12]. But the effects of such interventions on mental health, HRQoL, and wellbeing have not been extensively studied, because weight loss is usually the studied primary outcome. Stolberg et al. [13] tried to improve HRQoL by increasing physical activity with some positive results. Exercise interventions involving bariatric surgery patients, in general, improve weight loss, fat mass loss, and physical fitness [14], supporting the importance of physical activity for this patient group. Usual care after bariatric surgery in Sweden differs between hospitals, but in most hospitals, there are no support groups, sessions with a psychologist, or anything else tailored to improve post-surgery HRQoL and wellbeing.

There is a need to find an intervention to prevent reductions in HRQoL and improve wellbeing and physical activity among postbariatric surgery patients, one that is easy to implement within the healthcare systems and not associated with high costs or effort for patients or caregivers. When recruitment for this randomized controlled trial started, Roux-en-Y gastric bypass (RYGB) surgery accounted for >80% of all 6608 bariatric procedures performed in 2014 in Sweden, and >80% of all patients undergoing RYGB were women [15]. Consequently, we developed a dissonance-based group intervention for women post-RYGB surgery aiming to prevent this reduction in general and specific parts of HRQoL, wellbeing, and physical activity 2 years after surgery.

The primary aim of this paper was to examine early intervention effects on HRQoL, 1 year after RYGB surgery. Secondary aims were to examine early intervention effects on physical activity, sedentary time, social adjustment, eating behavior, and body esteem 1 year after RYGB surgery.

Methods

The parallel group randomized controlled trial study presented in this paper started recruitment in January 2015 and finished in August 2018. The study covers recruitment from 5 hospitals in 3 counties in Sweden. The trial has been approved by the Ethical Review Board Stockholm (Dnr: 2013/1847-31/2) and registered (ISRCTN16417174). All procedures performed involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments. All participants gave written and oral consent before entering the trial. A detailed description of the current trial (the WELL-GBP) has been published earlier with the endpoint of 2 years [16]. This paper investigates early effects after 1 year; below follows a brief description of the procedures.

Participants

Women eligible for RYGB surgery and able to understand and speak Swedish signed an interest form at their first hospital visit. Questionnaires, informed consent forms, and an accelerometer were then sent out before surgery to the homes of those participants who agreed to take part. The participation flowchart is found in Fig. 1. Dropout rate at 1 year was 23% in the intervention group and 19% in the control group. Fig. 1 shows the participants who completed the baseline assessments (n = 259) and the 1-year follow-up assessments (n = 203). The intervention group is further divided by the number of group sessions they attended.

Intervention

The intervention consisted of 4 dissonance-based group sessions based on Stice's interventions [17] and is described in detail elsewhere [16]. In short, they consisted of 4 main topics known to be troublesome for patients after RYGB surgery, related to HRQoL or wellbeing as follows: (1) physical activity, (2) eating behavior, (3) social relationships, and (4) intimate relationships. This type of intervention has previously been shown to prevent eating disorders and unhealthy weight gain, but has never been tested in this population [18]. It is a brief intervention with a relatively high effect in preventing eating disorders and unhealthy weight gain. This makes it a preferred intervention type [17]. The group sessions were held in hospitals approximately 2 to 3 months post-surgery and lasted for

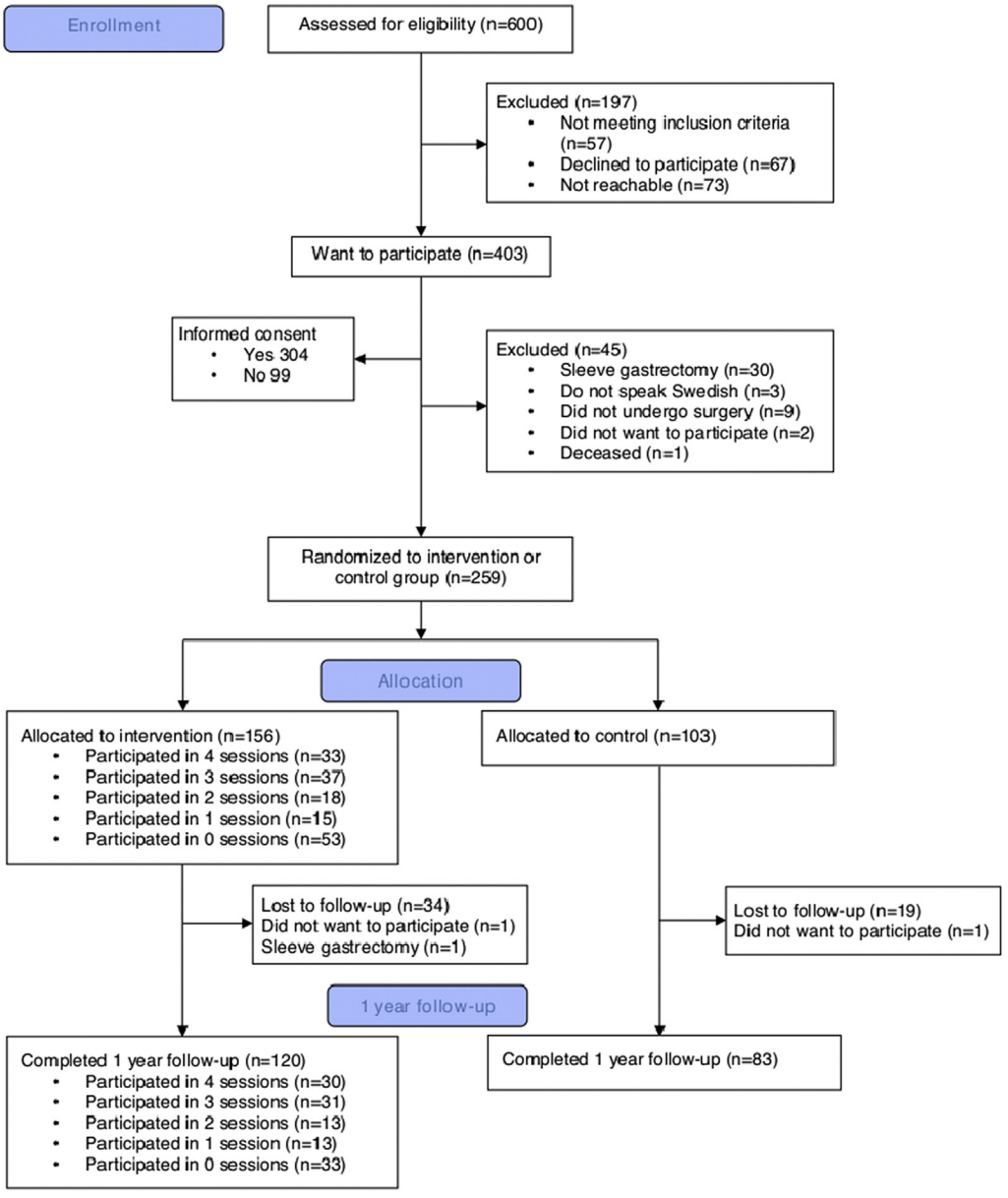

Fig. 1. Participation flowchart.

approximately 1.5 hours once a week for 4 weeks. The control group did not receive any additional intervention, only the regular follow-up care (also given to the intervention group). The regular follow-up differed between hospitals, but in general consisted of consultancy with a dietician, nurse, or surgeon usually about medical complications, weight loss, and proper post-surgery diet a few weeks, 6 months, and 1 and 2 years after surgery.

Outcomes

The primary outcome was HRQoL measured with SF-36, a questionnaire divided into the following 8 dimensions: (1) physical functioning, (2) role limitations due to physical health problems, (3) bodily pain, (4) general health, (5) vitality, (6) social functioning, (7) role limitations due to emotional problems, and (8) mental health, where higher scores indicate better quality of life. Secondary outcomes included eating behavior measured with the Three-Factor Eating Questionnaire (lower scores indicate better eating behavior) divided into 3 different domains (cognitive restraint, emotional eating, and uncontrolled eating) and Disordered Eating after Bariatric Surgery (lower scores indicate healthier eating behavior). Body esteem was measured with the Body Esteem Scale (higher scores indicates healthier body-esteem) divided into 3 domains (weight

concerns, appearance, and attribution) and satisfaction with one's social life measured with the Social Adjustment Scale (lower scores indicates enhanced social adjustment) divided into 6 domains (work role, social and leisure activities, extended family, parent role, partner role, and family role), described in more detail elsewhere [16].

Physical activity was measured objectively using ActiGraph GT3X+ accelerometers (ActiGraph, Pensacola, USA), worn on the hip during all waking hours for 7 consecutive days. Valid measurements included at least 10 hours wear time per day for at least 3 days. Vector magnitude was analyzed and recorded in 10 second epochs converted to counts per minute (cpm). Wear time and classification of bouts were computed using ActiLife v.6.13.3 (ActiGraph, Pensacola, USA). For wear time we used an algorithm by Choi et al. [19] and nonwear time was classified as nonzero counts for at least 60 minutes, with a maximum break of 2 minutes. We classified sedentary time as <100 cpm, light physical activity as 100 to 3208 cpm, and MVPA as >3208 cpm [20].

Randomization

Participants with informed consent and baseline data were block randomized within their own county, approximately 2 months after surgery to either intervention or control group. The random allocation sequence was computer generated into 60%/40%, intervention/control using the SAS procedure Proc Plan. The assigning of participants to their allocation group was made by a researcher who was not working with the data collection.

Power calculations

Initial power calculations estimated that a total of 240 patients needed to be recruited with an expected drop-out rate of 20% [16]. Given the observed total number (n = 203) of participants with complete baseline and follow-up data (intervention group n = 120 and control group n = 83), and a significance level of 5%, the statistical power is still >90% to detect the preplanned moderate effect sizes (Cohen's d = .5).

Statistical analyses

For the primary analysis, intention-to-treat analysis was planned, and was conducted on individuals with complete follow-up data [21]. Differences in means between the 2 groups were calculated using *t*-statistics for normally distributed variables (all physical activity measures except MVPA) and with Wilcoxon signed rank test for nonnormally distributed measures, such as psychological outcomes and body mass index (BMI). BMI was calculated as weight (kg)/height $(m)^2$. For binary data, χ^2 tests were used. The effect size, based on differences between means, was calculated using Cohen's d for all psychological outcome measures at 1-year follow-up. Additional per-protocol analysis was performed only on the primary outcome (SF-36) comparing the control group to those who received the intervention according to the protocol (i.e., attended ≥3 group session), one of these participants did not complete the SF-36 and therefore the analysis is made in 60 participants (see Appendix 1). Individuals with missing data on specific questions were excluded when analyzing those questions only, but were retained in all other analyses. All statistical analyses were conducted using Stata/IC 15.1 (StataCorp, College Station, TX, USA).

Results

In total, 259 women were recruited to the WELL-GBP trial at baseline (see Fig. 1 for participant flow). Mean BMI pre-surgery was 40.8 (standard deviation = 4.5), mean age was 44.7 years (standard deviation = 10.3), and 52% of participants met the recommended >150 minutes of MVPA per week (in non-bouts) pre-surgery [22]. There were no differences between baseline measures in the control group versus intervention group. Table 1 shows participants' characteristics and baseline measures for the total group and for intervention and control group separately.

No differences in any outcome between intervention and control group were observed at 1-year follow-up (Table 2). The effect sizes were mostly small or none (.01–.37) and not statistically significant. A great improvement from baseline to 1-year follow-up was seen in all domains of SF-36, body esteem, eating behavior, and social adjustment in both groups (Table 2). There was also a small increase in physical activity measures and a good increase in step counts, mean increase 1405 steps/d (standard deviation = 2554).

Additionally, per protocol analyses showed no differences in SF-36 scores between participants receiving the intervention (attending ≥3 group session) and the control group (Appendix 1). The participants receiving the intervention did not differ in any baseline characteristics or SF-36 values from the ones not receiving the intervention, data not shown.

No harmful or unintended effects of the intervention were reported.

Discussion

We found no early effects at 1-year follow-up of a post-RYGB dissonance-based group intervention on HRQoL, physical activity, body esteem, eating behavior, or social adjustment. However, we observed great improvements in HRQoL, body esteem, eating behavior, and social adjustment from pre- to post-surgery in both the intervention and control group. This is in line with earlier studies investigating HRQoL and body esteem after bariatric surgery [7,23]. Eating behavior has shown inconsistent results [24], but another study using the Three-Factor Eating Questionnaire showed similar results to our study 4-years postRYGB surgery [25].

As mentioned in the introduction, postoperative psychosocial interventions and support groups might improve

Table 1
Baseline characteristics for the total sample, the intervention group and the control group of women undergoing Roux-en-Y gastric bypass surgery

Variables	Total sample, n = 203/259 recruited	Intervention group, n = 120/156	Control group, n = 83/103
BMI, kg/m^2	40.8 (4.5)	40.8 (4.5)	40.7 (4.6)
BMI change at 1 yr post-surgery	−13.1 (3.6)	−13.3 (3.7)	−12.7 (3.5)
% total weight loss	31.8 (7.2)	32.3 (7.1)	31.3 (7.3)
% excess BMI loss (excess BMI >25 kg/m^2)	85.0 (20.7)	85.7 (19.5)	84.1 (22.6)
Age, yr	44.7 (10.3)	44.2 (10.5)	45.3 (10.1)
Education, university level (%)	31.0 (63)	30.0 (36)	32.5 (27)
Smokers (%)	5.4 (11)	4.2 (5)	7.2 (6)

BMI = body mass index.
Presented as mean (standard deviation) or percentage (numbers). There were no statistically significant differences (all $P > .05$), in any presented variables, between the 2 groups.

weight loss after surgery [10], but few studies have investigated the impact of such interventions on psychosocial outcomes. However, a study quite similar to ours, which included a more extensive intervention (8 face-to-face group sessions and 6 video conference group sessions), also did not find any early effects (1 yr post-surgery) on SF-36, eating disorders, or self-efficacy [26]. However, when using a longer follow-up time, they found a positive effect from the intervention, expressed as a smaller decline in self-efficacy and depression scores [27]. Therefore, it will be of interest to continue following the present study, with the planned 2-year follow-up, because it was also originally designed to prevent the decline in psychological measures starting from approximately 1 to 2 years post-RYGB.

An additional thought regarding the results include the delivery format of the presented intervention. Only 73% of women included in this study and randomized to the intervention group attended at least 1 session and 51% attended 3 or 4 sessions, which was considered as having received the intervention. Perhaps an alternative delivery, such as Internet- or smartphone-based group sessions, would fit this patient group better. We have unpublished (under revision) qualitative data from this trial showing that the large drop-out can partially be explained by the women not finding the time to attend the group-based sessions held at the hospitals, although they found the discussed topics to be of importance.

The results from this study have high generalizability to other women undergoing RYGB surgery in Sweden, because we included participants with similar demographic characteristics as the general female population undergoing RYGB in Sweden [28] from several different hospitals in diverse areas of Sweden. Results may also be somewhat generalizable to the rest of the world, although our patients were slightly younger and had lower BMI compared with other countries [29]. Another strength of the study is that physical activity was measured objectively [30].

There are some limitations to consider in this study. First of all, there is a possibility that the intervention had other unexpected effects that we did not detect. Another possible limitation is the sample size, especially in the per-protocol analyses, which may have been too small to detect the smaller effect sizes seen in Disordered Eating after Bariatric Surgery score and Three-Factor Eating Questionnaire. However, other variables did not show any meaningful differences; thus, this should not be a substantial concern. Additionally, the 61 participants that received the intervention and attended the 1-year follow-up might differ from the 156 recruited and randomized to the intervention group and results from the per-protocol analysis might therefore be biased. However, they did not significantly differ from each other on any baseline characteristics or SF-36 values, data not shown.

Conclusions

There were no early effects at 1-year follow-up on HRQoL and wellbeing from a dissonance-based intervention targeting women who have undergone RYGB surgery. However, a longer follow-up might be needed to evaluate the intervention effect. Judging by the relatively poor group attendance rates and unpublished qualitative data from interviews of non-attendance participants, the intervention delivery format of the present study may not be optimally suited to this patient group. Further interventions may wish to explore alternative means of delivery.

Ethics and consent

This study was approved by the Ethical Review Board Stockholm (Dnr: 2013/1847-31/2) and registered with ISRCTN: 16417174. All procedures performed involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments. All individual participants gave written and oral informed consent before entering the trial.

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Table 2
All outcomes pre and one year post-Roux-en-Y gastric bypass surgery in the intervention versus the control group

Variables	Pre-surgery intervention group	Pre-surgery control group	*P* value	1-yr post-surgery intervention group	1-yr post-surgery control group	*P* value	Cohen's *d* (95%CI)
SF-36							
Mental summary score	46.9 (10.8)	46.4 (10.6)	.742	53.0 (9.8)	52.3 (9.8)	.450	.07 (−.21 to .35)
Physical summary score	41.8 (9.5)	43.4 (9.5)	.178	53.5 (8.7)	54.1 (7.3)	.661	−.09 (−.37 to .19)
Physical functioning	58.5 (21.9)	60.1 (24.4)	.342	88.5 (16.9)	90.5 (14.2)	.590	−.13 (−.41 to .15)
Role limitations due to physical health problems	68.4 (27.9)	73.5 (30.2)	.082	86.8 (24.0)	90.4 (17.8)	.523	−.17 (−.45 to .12)
Bodily pain	48.9 (27.6)	50.6 (28.4)	.612	74.9 (26.6)	74.4 (27.5)	.987	.02 (−.27 to .30)
General health	51.5 (23.3)	53.1 (23.0)	.582	79.2 (20.3)	79.0 (20.0)	.873	.01 (−.27 to .29)
Vitality	39.1 (23.8)	41.2 (21.5)	.464	65.8 (23.9)	63.2 (22.1)	.321	.11 (−.17 to .39)
Social functioning	66.6 (27.0)	67.1 (27.3)	.861	87.8 (23.3)	89.2 (19.7)	.854	−.06 (−.34 to .22)
Role limitations due to emotional problems	78.9 (27.6)	77.4 (28.0)	.645	89.8 (21.5)	89.1 (22.1)	.829	.03 (−.25 to .31)
Mental health	66.5 (19.5)	66.2 (20.1)	.974	80.5 (16.9)	80.2 (17.0)	.981	.02 (−.26 to .30)
Secondary outcomes							
TFEQ-total	48.7 (9.4)	49.4 (9.0)	.589	38.5 (8.6)	40.5 (8.2)	.092	−.24 (−.52 to .04)
TFEQ-cognitive restraint	13.4 (2.9)	15.0 (3.2)	.003	14.8 (3.9)	15.8 (3.5)	.056	−.28 (−.56 to .01)
TFEQ-emotional eating	14.3 (5.0)	15.0 (4.4)	.283	10.0 (3.8)	10.7 (4.3)	.342	−.17 (−.45 to .11)
TFEQ-uncontrolled eating	21.0 (6.3)	19.6 (5.7)	.106	13.7 (4.0)	14.0 (4.1)	.668	−.06 (−.34 to .22)
BES-total	25.3 (12.7)	26.3 (11.4)	.558	55.2 (18.5)	57.5 (15.8)	.370	−.13 (−.42 to .16)
BES-weight concerns	2.5 (2.9)	2.5 (2.5)	.881	14.3 (6.0)	15.0 (5.7)	.465	−.11 (−.39 to .17)
BES-appearance	14.1 (8.4)	15.5 (7.5)	.254	29.1 (10.9)	30.8 (9.4)	.265	−.16 (−.45 to .12)
BES-attribution	5.8 (2.0)	5.9 (1.8)	.689	8.0 (2.1)	7.8 (1.9)	.607	.07 (−.21 to .36)
DEBS	-	-	-	10.9 (18.9)	16.5 (27.0)	.255	−.25 (−.53 to .04)
SAS-total	1.6 (.5)	1.6 (.5)	.835	1.3 (.4)	1.3 (.5)	.897	−.02 (−.30 to .26)
SAS-work role	1.4 (.7)	1.4 (.6)	.667	1.1 (.6)	1.1 (.6)	.456	.05 (−.23 to .33)
SAS-social and leisure activities	1.8 (.6)	1.9 (.6)	.590	1.5 (.6)	1.5 (.6)	.469	−.10 (−.38 to .18)
SAS-extended family	1.4 (.6)	1.3 (.6)	.689	1.1 (.5)	1.1 (.5)	.697	−.06 (−.34 to .23)
SAS-parent role	1.4 (.6)	1.5 (.5)	.609	1.4 (.6)	1.4 (.6)	.873	.02 (−.32 to .37)
SAS-partner role	2.0 (.7)	2.0 (.8)	.690	1.8 (.7)	1.8 (.6)	.614	.10 (−.22 to .43)
SAS-family role	.7 (.9)	.7 (.8)	.696	.5 (.6)	.5 (.6)	.840	−.02 (−.33 to .29)
Accelerometer outcomes							
Mean wear, time hours/d	14.3 (1.2)	14.1 (1.1)	.434	15.0 (1.8)	14.8 (1.4)	.416	.24 (−.13 to .62)
Mean counts, per min/d	557.1 (203.2)	595.8 (191.0)	.264	573.7 (177.8)	601.0 (179.3)	.344	−.24 (−.61 to .14)
MVPA, min/d	26.4 (17.8)	27.4 (20.9)	.933	27.4 (17.5)	29.7 (22.2)	.830	−.05 (−.43 to .32)
LPA, min/d	356.3 (92.2)	372.4 (71.4)	.277	392.7 (86.8)	401.8 (77.9)	.500	−.16 (−.54 to .21)
Sedentary time, min/d	474.4 (102.5)	447.6 (90.8)	.119	480.5 (113.0)	456.3 (100.0)	.169	0.37 (−.00 to .75)
Mean steps, counts/d	6054.9 (2353.0)	6314.1 (2629.7)	.544	7388.6 (2677.6)	7547.2 (2888.3)	.723	−.07 (−.45 to .30)

CI = confidence interval; SF-36 = 36-item short-form health survey; TFEQ = three factor eating questionnaire; BES = body-esteem scale; DEBS = disordered eating after bariatric surgery; SAS = social adjustment scale; MVPA = moderate-to-vigorous physical activity; LPA = light physical activity.

Presented as mean scores (standard deviation) for each group and subscale, *P* value for the difference between the 2 groups both at baseline and at 1-year follow-up and effect sizes measured with cohen's d (95% CI). From the intervention group, 120/156 were included and 83/103 from the control group. Participants with valid accelerometer data pre-surgery were 89 in the intervention group and 53 in the control group, post-surgery there were 98 in the intervention group and 63 in the control group.

participants and to the study participants who participated in the data collection.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.1016/j.soard.2019.07.001.

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