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ORIGINAL CONTRIBUTIONS

Does Lifestyle Intervention After Gastric Bypass Surgery Prevent Weight Regain? A Randomized Clinical Trial

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Abstract

Background Weight regain after bariatric surgery often starts after 1–2 y, but studies evaluating strategies to prevent weight regain are lacking. The aim of this intervention was to evaluate the efficacy of a 2-y-group-based lifestyle intervention starting approximately 2 y after Roux-en-Y gastric bypass (RYGB) compared with usual care on weight regain and related metabolic risk factors.

Methods A total of 165 patients with a mean of 21 months (range 14–32) after RYGB were randomized to a lifestyle intervention group (LIG) or a usual care group (UCG). Of the 165 participants 86% completed the study. The LIG was offered 16 group meetings over 2 y with focus on healthy diet, physical activity, and behavioural strategies to prevent weight regain, in addition to usual care.

Results Mean (SD) total weight loss at study start was 30.1 ± 8.2%, while weight regain during the intervention was 4.9 ± 7.4 and 4.6 ± 9.2% in the LIG and UCG, respectively ($P = 0.84$). There were no differences in metabolic risk factors between the groups. The LIG participants attended 8 ± 4 group meetings, with no difference in weight regain between participants with high compared to lower participation. In all the participants, a positive association between weight increase from nadir to study start and weight regain during the intervention was found. Participants who reported physical activity ≥ 150 min/wk had smaller % weight regain compared with less active participants ($\beta = -5.2$ [SE 2.0, 95% CI −9.1 to −1.4]).

Conclusion We found no difference in weight regain between LIG and UCG.

Keywords RYGB · Weight regain · Randomized clinical trial · Lifestyle intervention

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Introduction

Bariatric surgery is an effective treatment for obesity [1], but long-term sustained weight loss is challenging, and weight regain is common [2, 3]. A review of randomized controlled trials (RCTs) that aimed at enhancing weight loss after bariatric surgery by offering follow-ups with focus on dietary habits, physical exercise, or behavioural therapy describes no or only modest effect on enhancing further weight loss compared with general standard care [4]. Factors associated with weight regain are poor dietary habits and a sedentary lifestyle [2, 5, 6], while social support, post-operative follow-up visits, and self-monitoring of weight have been associated with weight maintenance [2, 5, 6].

Several RCTs have investigated ways to optimize weight loss after bariatric surgery [7–11], and some non-randomized studies have described weight loss with remotely delivered, group-based, or individual follow-ups in patients with post-

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surgical weight regain [12–15]. A review by Bradley et al. [16] summarizes the results of interventions using remote assessments, such as telephone and internet, in order to enhance post-operative outcomes. Remote assessments may be a way to facilitate and increase rate of follow-up, and in addition be cost-effective and reduce patient burden [16].

To our knowledge, no other RCT has specifically focused on preventing weight regain, except for an ongoing study of an internet-based programme [17]. The objective of the present study was to test whether a 2-y-group-based lifestyle intervention programme after Roux-en-Y gastric bypass (RYGB) could prevent weight regain and related metabolic risk factors more efficiently than usual care. Factors at study start associated with weight regain during the intervention were also identified.

Methods

Study Design and Participants

The study was performed at Oslo University Hospital, Norway, during 2008–2012. The study was a single-centre, parallel group RCT designed to test the efficacy of a 2-y lifestyle intervention programme versus usual care on weight regain. Details about the study and the surgical procedure have been described earlier [18, 19]. A total of 630 patients underwent laparoscopic RYGB from January 2006 to July 2009 at this hospital. An invitation to attend an information meeting about the current study was sent to 614 of these patients. A total of 180 patients attended, whereof 165 were included in the study. Figure 1 shows the inclusion of participants to the study. Participants were included every autumn for a period of three years—August 2008, August 2009, and August 2010. Hence, time from surgery to study start varied (mean 21 months, range 14–32 months). The patients were randomly assigned to a control group that received usual care (UCG) or a lifestyle intervention group (LIG) that received additional lifestyle guidance in groups. A statistician prepared the list, which block randomized the participants according to sex and initial % total weight loss from time of surgery until study start in a 1:1 allocation ratio.

The Intervention

A PhD student (clinical dietitian) designed the project under the supervision of experienced investigators. Figure 2b shows the study design during the intervention, consisting of 3 and 4 in person assessments for retrieving data in the UCG and LIG, respectively. Figure 2a shows the usual care at Oslo University Hospital when the study was initiated in 2008 (consisting of three follow-up consultations with a clinical dietitian or a doctor on the first year followed by annual consultations on the next 4 years). In addition to usual care, the lifestyle intervention programme consisted of 16 group meetings (Fig. 2b, Table 1).

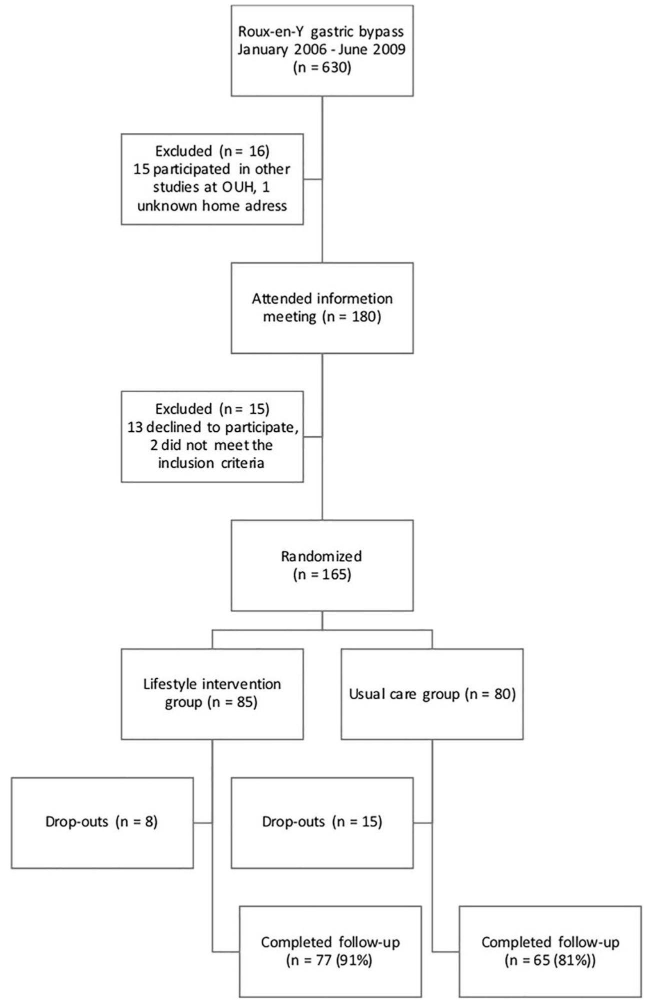

Fig. 1 Flowchart of patient inclusion. *OUH*, Oslo University Hospital

The design of the intervention was based on a Swedish behavioural treatment programme for weight reduction consisting of 25 meetings for a period of one year [20]. The aim of the present intervention was to prevent weight regain, and, thus, the participants were offered less frequent group meetings than the weight loss programme used as a guiding tool.

The 16 group meetings in the current intervention were offered over a 2-y period. Timeline for the scheduled group sessions is described in Table 1. The meetings lasted for 2 h and had 12–15 participants. Clinical dietitians or master students in clinical nutrition were responsible for leading the sessions, which included measurements of body weight, a lecture on a given topic, group work and/or an assignment, and 30 min with supervised physical activity.

The meetings were based on the Norwegian Directorate of Health's recommendations [21] regarding level of physical activity and diet. Dietary topics that were discussed were healthy food choices, meal frequency, portion size, and energy

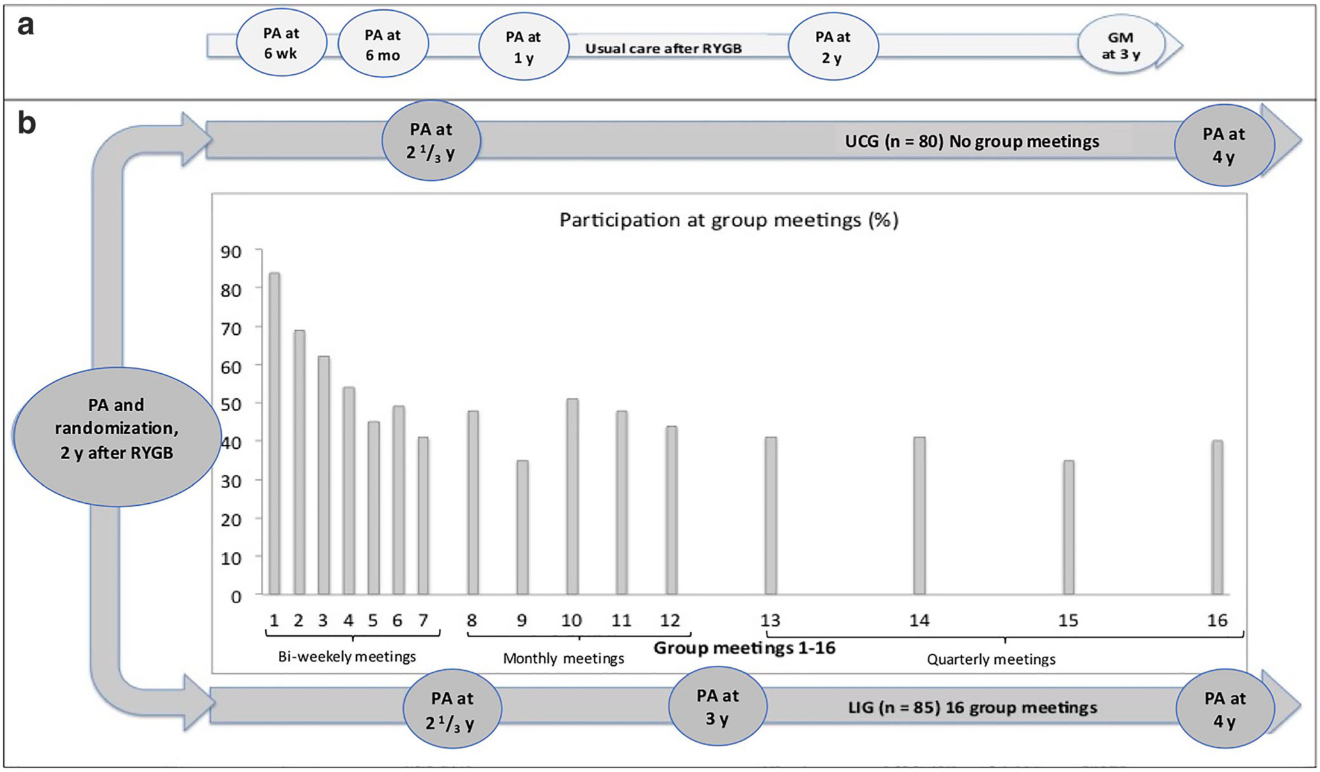

Fig. 2 **a** Usual care after Roux-en-y gastric bypass. *GM*, group meeting; *PA*, personal assessment; *RYGB*, Roux-en-Y gastric bypass. **b** Study design and participation at group meetings (%). *LIG*, lifestyle intervention group; *PA*, personal assessment; *RYGB*, Roux-en-Y gastric bypass; *UCG*, usual care group

density. The participants were advised to choose food items labelled with the Keyhole symbol, which is used in the Nordic countries to help consumers identify healthier options [22]. The participants were also advised to decrease time spent on sedentary activity, and they were recommended ≥ 150 min/wk with moderate activity or ≥ 75 min/wk with high activity, in accordance with Norwegian [21] and WHO [23] recommendations.

The physical activity session varied between Nordic walking, climbing stairs, and strength training, depending on the weather. A psychologist attended two meetings (talking about self-esteem, body image, and behavioural strategies), an activity coach attended two meetings (guiding the participants in the use of Nordic walking and use of pedometer), and an experienced user from the Patient Education Resource Centre attended one meeting (informing about self-help groups).

Data Collection

The data collection included anthropometric measurements, blood pressure measurements, fasting blood samples, oral glucose tolerance test, pre-coded food diaries, and questionnaires about smoking status and physical activity. Pre-surgery data were retrospectively retrieved from the patients' hospital records and a prospectively collected patient register at the Section of Morbid Obesity and Bariatric surgery at Oslo University Hospital. Before surgery, the patients were weighed on a scale (Seca Vogel & Halke), while body weight and body composition at study start and study end were assessed using the Tanita BC418MA Body Composition Analyzer (www.tanita.com). Height was measured to the nearest centimetre (cm), and body mass index (BMI) was calculated as body weight (kg) divided by squared height (m^2).

Food diaries [24] were used to assess energy intake and macronutrient distribution over a 4-day period before and after the intervention. The food diary has been validated among a group of Norwegian adults and found to be a useful tool [25]. A software system developed by the Department of Nutrition, University of Oslo, was used for dietary analyses [26]. A validated 7-day physical activity recall questionnaire was used to calculate physical activity level and time spent on low, moderate, or high activity [27]. The questionnaire included five main categories about work, transportation, daily activity at home, leisure time activity, and sedentary activity. Physical activity level was calculated by dividing energy expenditure by the resting metabolic rate [28]. Metabolic equivalent (MET) described the intensity of activities, which was divided into the following categories: < 3.0 MET (low) and > 3.0 MET (moderate or high) [27].

Table 1 Description of the group meetings in the lifestyle intervention group

Group meetings	Month of the intervention	Description of topics	Tasks and homework
1 Presentation and aims	2		Discuss individual goals, with time perspective.
2 Physical activity I	2	Reasons to exercise, positive experience of physical activity, and importance of activity concerning weight balance. Distribution of pedometers and guidance in use of walking sticks.	Physical activity: What do you want to change? Homework: Report activity on three active days and three non-active days
3 Fat and fat reduced products	3	How to read and how to understand food labelling and declarations. How to reduce the amount of fat.	
4 Fibre, fruit, and vegetables	3	How to increase the intake of fruits and vegetables, use more whole grain flour, and how to choose the most healthy food items? What is the Keyhole symbol?	How much fibre, fruits, and vegetables do you consume? Discuss strategies to increase the intake. Homework: Increase the daily intake of fruits and vegetables, use more whole grain products.
5 Food during holidays and celebrations	4	Serving sizes, healthy eating, and how to resist temptations.	
6 Low fat and low sugar	4	How to read and how to understand food labelling and declarations.	
7 New Year's resolutions and cravings	5	Food choices, portion sizes, meals and in between eating, healthy snacks, and fast food. Reduce the amounts of sugar and fat as well as using alternatives, such as whole grain flour instead of white flour.	What is your individual goal? How to achieve your goal?
8 Self-help groups	6	Encourage the group to meet on their own, between the group meetings.	
9 Physical activity II	7	How to integrate physical activity in daily routine.	Advantages and disadvantages with physical activity and physical inactivity.
10 Sweeteners	8	Reducing amounts of sugar and alternatives to sugar.	
11 Body image I	9	Moods and feelings. How to handle changes in body and mind after bariatric surgery.	
12 Summer food and challenges	10	Summer food and summer activities.	Strategies to make healthy choices in food and physical activity during the summer holidays.
13 Working groups/round table procedure	13	Small working groups discuss challenges of daily life, triggers for dysfunctional strategies, and strategies to deal with cravings.	
14 Body image II	16		
15 Food for the entire family (this group meeting was a regular meeting offered to all patients)	19	Regular mealtimes and planning. Recipes for healthy snacks.	
16 Cooking class	22	How to modify recipes, how to make healthy choices.	Healthy dishes prepared in small groups.

Blood samples were collected after an overnight fast, and the freshly collected samples (including diabetes markers and blood lipids) were measured using the hospital routine laboratory, whereas aliquots of plasma samples were stored at − 80 °C for later analyses of plasma total cysteine (tCys) (details given in [19]).

Body Weight Measurement and Weight Change Calculations

Total weight loss from pre-surgery to study start was calculated as kg weight loss and % weight loss. Body weight nadir was defined as the lowest weight until time of enrolment. This information was retrieved either from the patient's hospital journal or the measured body weight from the in-person assessment before enrolment, whichever was lowest. Weight regain was calculated as % weight regain from study start until the end of the intervention. A recent publication from 2018 aimed to assess weight regain by 5 continuous and 8 dichotomous measures [29]. The strongest association and best model was percent weight regain of maximum weight lost. However, most of the weight regain measures were associated with relapse of metabolic risk factors. No standard definition of weight regain after bariatric surgery existed at time of study start in 2008, and different definitions (from ≥ 2 kg to ≥ 15%) have been used in other studies [5, 13, 14, 30]. Based on a review by Stevens et al., weight maintenance during the intervention was defined as weight gain < 3% from time of inclusion, while clinically relevant weight regain was defined as a weight gain ≥ 5% [31].

Statistical Analyses

A sample size of 65 subjects in each of the two treatment groups provided 80% power to detect a 2.5 kg difference in mean weight change (primary endpoint). Due to lack of previous data to use as basis for the calculation, a SD of 5 kg and 5% type 1 error were used. The sample size provided a 20% allowance for dropouts. SPSS version 24.0 (Chicago, IL) was used for the statistical analyses. Between-group analyses are presented unadjusted, if not otherwise specified. Descriptive statistics are reported as frequencies, median, or mean. Two independent samples were examined using Mann–Whitney *U* for skewed variables, independent-sample *t* test for normally distributed variables, and chi-square or Fisher's exact for categorical variables. Paired samples were examined using Wilcoxon's signed-rank test for skewed variables, paired sample *t* test for normally distributed variables, and McNemar's test for categorical variables. $P < 0.05$ (two-tailed) was considered statistically significant. When multiple comparisons were performed, the significance level was adjusted using Bonferroni's correction.

Time since surgery at time of inclusion varied, but results of the statistical analyses were not affected when adjusting for time since surgery (data not shown). Intention to treat is the recommended model in randomized controlled trials [32]. Only participants who attended the first and last in person assessment were included in the analysis, except for the variable body weight which was analyzed with a linear mixed model to include all available information on weight at study start, 4 months after study start, and study end in completers and non-completers.

Bivariate correlation was used to select prognostic factors for weight regain, based on univariate P values < 0.2. Analysis of covariance was performed to compare weight regain during the intervention by smoking status, physical activity, dietary habits, and metabolic risk factors, including hypertension (defined as systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg and/or use of antihypertensive drugs), type 2 diabetes mellitus (defined as $HbA_{1c} \geq 6.0\%$ and/or use of hypoglycaemic agents without type 1 diabetes), and metabolic syndrome (assessed using criterion from the National Cholesterol Education Program [33]), at study start. Plasma tCys was also included in the model based on earlier findings showing a positive correlation between high plasma tCys concentrations and weight regain post-surgery [19]. Based on these results, smoking status, physical activity, dietary habits, and plasma tCys were used in the final analysis.

Results

Baseline Characteristics and Follow-Up

A total of 165 patients (96% of Nordic ethnicity) were randomly allocated to treatment with LIG ($n = 85$) or to usual care ($n = 80$), of which 8 and 15 withdrew during the intervention, respectively. This corresponds to a completion rate of 91 and 81% in LIG and UCG, respectively. At study start, mean (SD) age was 45.7 ± 8.6 y, BMI was 30.9 ± 4.9 kg/m^2, body weight was 91.0 ± 18.0 kg, total weight loss was 30.1 ± 8.2%, 28.5% had hypertension, 9.7% had type 2 diabetes mellitus, and 26.1% had metabolic syndrome.

Baseline characteristics are described in Table 2. Between-group baseline characteristics were analyzed with Mann–Whitney *U*, Student's independent *t* test, or chi-square. There were no baseline differences between the groups (Table 2). Further, there were no differences between completers and non-completers. Data for completers at study start and study end are listed in Table 3, which

Table 2 Baseline characteristics at study start

	LIG $n = 85$	UCG $n = 80$	*P* value
Women [*n* (%)]	62 (73)	61 (76)	0.63
Age (y)	45.3 ± 8.8	46.1 ± 8.5	0.59
Smokers [*n* (%)]	13 (15.3)	21 (26.3)	0.082
Body weight (kg)	90.8 ± 17.9	91.1 ± 18.2	0.93
BMI (kg/m^2)	30.8 ± 4.9	31.0 ± 4.8	0.81
Height (cm)	171 ± 8.3	171 ± 9.7	0.84
Maximum weight loss from pre-surgery to nadir (kg)	41.2 ± 12.6	40.7 ± 11.6	0.80
Weight regain from nadir to 2 y post-surgery (kg)[a]	0.1 (0.0–2.9)	0.1 (0.0–2.7)	0.84
Total weight loss from 0 to 2 y post-surgery (kg)	39.6 ± 12.9	39.0 ± 12.3	0.77
Total weight loss from 0 to 2 y post-surgery (%)	30.3 ± 8.7	30.0 ± 7.7	0.79
Fat mass (%)	33.3 ± 8.6	33.6 ± 8.1	0.85
Energy expenditure (MJ/day)	10.9 ± 2.4	10.8 ± 2.2	0.78
Energy intake (MJ/day)	7.6 ± 2.5	7.1 ± 2.5	0.16
E% Carbohydrates	40.4 ± 6.0	40.8 ± 5.8	0.63
E% Protein	18.2 ± 3.4	18.7 ± 4.4	0.46
E% Fat	36.0 ± 6.5	34.7 ± 6.5	0.23
Fibre (g/day)	17.0 ± 6.2	18.1 ± 6.8	0.26
E% Sugar	8.9 ± 6.2	8.0 ± 4.8	0.31
Alcohol [*n* (%)]	39 (45.9)	32 (41.0)	0.53
Systolic blood pressure (mmHg)	125 ± 15	124 ± 17	0.85
Diastolic blood pressure (mmHg)	79 ± 10	79 ± 12	0.95
Antihypertensive drugs [*n* (%)]	14 (16.5)	15 (18.8)	0.70
Hypertension [*n* (%)][b]	20 (23.5)	27 (33.8)	0.15
Type 2 diabetes mellitus [*n* (%)][c]	7 (8.2)	9 (11.3)	0.51
Hypoglycaemic agents, including insulin [*n* (%)][d]	4 (4.8)	4 (5.0)	1.0[e]
Metabolic syndrome [*n* (%)][f]	22 (25.9)	21 (26.3)	0.96
Low activity or sleep (< 3 MET) (hour/day)	22.8 ± 1.1	22.7 ± 0.9	0.78
Moderate to high activity (> 3 MET) (hour/day)[a]	0.9 (0.5–1.7)	1.2 (0.5–1.7)	0.57
Reading, TV viewing and computer use (hour/day)	4.3 ± 2.3	4.3 ± 2.2	0.96
Physical activity level	1.6 ± 0.2	1.6 ± 0.2	0.97

Values are mean ± SD unless otherwise specified. Values are missing from 0 to 3 participants

LIG, lifestyle intervention group; *UCG*, usual care group

[a] Median (25–75 percentile)

[b] Systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg and/or use of antihypertensive drugs

[c] Type 2 diabetes mellitus is based on HbA_{1c} ≥ 6.0% and/or use of hypoglycaemic agents

[d] One with type 1 diabetes excluded

[e] Fisher's exact

[f] Assessed using criterion from the National Cholesterol Education Program

show some significant changes within the groups during the intervention. No significant differences in changes between the groups were found (Table 4).

Body Weight Regain During 2 Y Intervention

BMI changes in the two groups are presented in Fig. 3 which shows a significant loss from time of surgery to 1 y after surgery, a stable BMI from 1 to 2 y after surgery, followed by a small but significant regain during the intervention. Mean weight regain during the intervention was 4.9 ± 7.4 and 4.6 ± 9.2% in LIG and UCG, respectively ($P = 0.84$). Linear mixed model was used to analyze body weight at study start, 4 months, and study end for both completers and non-completers. The result showed no differences between groups (Table 5).

Table 3 Characteristics for completers at study start and at study end

	LIG ($n = 77$)[a]			UCG ($n = 65$)[a]		
	Study start	Study end	*P* value	Study start	Study end	*P* value
Women [*n* (%)]	57 (74)			50 (77)		
Body weight (kg)	91.2 ± 17.8	95.4 ± 19.2	< 0.001*	89.1 ± 17.0	93.0 ± 18.5	< 0.001*
BMI (kg/m^2)	31.0 ± 5.0	32.4 ± 5.3	< 0.001*	30.7 ± 4.7	32.0 ± 5.5	< 0.001*
Total weight loss (kg)	39.0 ± 13.0	34.8 ± 13.4	< 0.001*	38.4 ± 11.8	34.6 ± 14.2	< 0.001*
Total weight loss (%)	29.9 ± 8.8	26.6 ± 9.8	< 0.001*	30.1 ± 7.4	27.0 ± 9.8	< 0.001*
Fat mass (%)	33.7 ± 8.6	37.2 ± 7.8	< 0.001*	33.1 ± 8.2	36.6 ± 8.6	< 0.001*
Systolic blood pressure (mmHg)	124 ± 14	127 ± 16	0.007	125 ± 17	126 ± 16	0.39
Diastolic blood pressure (mmHg)	79 ± 10	80 ± 11	0.061	80 ± 12	79 ± 11	0.68
Hypertension [*n* (%)][b]	17 (22.1)	24 (31.2)	0.065	24 (36.9)	29 (44.6)	0.180
Type 2 diabetes [*n* (%)][c]	7 (9.1)	6 (7.8)	1.0	6 (9.2)	5 (7.7)	1.0
Metabolic syndrome [*n* (%)][d]	20 (26.0)	17 (22.1)	0.51	18 (27.7)	17 (26.2)	1.0
Fasting glucose (mmol/L)[e]	5.1 (4.8–5.5)	5.1 (4.9–5.5)	0.024	5.0 (4.8–5.4)	5.1 (4.8–5.5)	0.38
HbA_{1c} (%)	5.3 ± 0.6	5.5 ± 0.8	0.008	5.3 ± 0.7	5.4 ± 0.8	0.001*
Fasting insulin (pmol/L)[e]	30.0 (19.0–42.0)	34.0 (22.0–53.1)	0.007	29.0 (23.5–45.8)	32.3 (26.0–51.0)	0.19
Fasting C-peptide (pmol/L)	692 ± 269	719 ± 269	0.24	717 ± 245	681 ± 234	0.19
HOMA-Ir[e]	0.6 (0.4–0.9)	0.7 (0.5–1.3)*	0.001*	0.7 (0.5–1.1)	0.7 (0.5–1.1)	0.41
Insulinogenic index[e]	112.6 (62.2–287.5)	235.2 (60.9–460.9)	0.050	90.5 (51.8–237.7)	320.4 (73.6–937.7)	0.033
Total cholesterol (mmol/L)	4.4 ± 0.8	4.8 ± 0.8	< 0.001*	4.3 ± 0.8	4.6 ± 1.0	0.001*
Triglycerides (mmol/L)	1.1 ± 0.5	1.1 ± 0.6	0.56	1.0 ± 0.3	1.1 ± 0.5	0.065
Energy expenditure (MJ/day)	10.8 ± 2.3	11.0 ± 2.5	0.38	10.5 ± 2.0	10.8 ± 2.2	0.024
Low activity or sleep (< 3 MET) (hour/day)	22.8 ± 1.0	22.8 ± 1.2	0.75	22.8 ± 0.8	22.8 ± 0.9	0.75
Moderate to high activity (> 3 MET) (hour/day)[e]	0.9 (0.5–1.7)	0.9 (0.4–1.5)	0.90	1.2 (0.5–1.7)	1.0 (0.6–1.5)	0.93
Reading, TV viewing and computer use (hour/day)	4.2 ± 2.3	4.0 ± 2.2	0.45	4.3 ± 2.1	4.5 ± 2.0	0.38
Physical activity level	1.6 ± 0.2	1.6 ± 0.2	0.83	1.6 ± 0.2	1.6 ± 0.2	0.29
Energy intake (MJ/day)[f]	7.6 ± 2.3	7.9 ± 2.7	0.37	7.1 ± 2.5	7.4 ± 2.8	0.31
E% Carbohydrates[f]	40.8 ± 5.9	38.5 ± 8.7	0.034	40.5 ± 5.8	38.2 ± 7.7	0.038
E% Protein[f]	18.2 ± 3.4	18.1 ± 3.6	0.69	18.4 ± 4.4	18.4 ± 3.7	0.93
E% Fat[f]	36.2 ± 6.3	38.3 ± 8.1	0.025	34.9 ± 6.8	37.4 ± 6.6	0.019
Fibre (g/day)[f]	17.3 ± 6.1	18.7 ± 6.7	0.130	17.7 ± 6.3	18.6 ± 8.4	0.44
E% Sugar[f]	9.2 ± 5.9	7.1 ± 4.8	0.002	8.3 ± 4.7	6.6 ± 4.5	0.006
Artificially sweetened beverages (g/day)[e,f]	250 (0–801)	307 (19–1205)	0.001*	365 (0–840)	413 (0–1116)	0.010

Values are mean ± SD unless otherwise specified. Values are missing from 0 to 8 participants, except for fasting insulin and HOMA-IR (which are missing from 18 participants in the LIG and 17 participants in the UCG), C-peptide (which are missing from 16 and 15 participants in the LIG and the UCG, respectively). Insulinogenic index are collected from 12 participants in the LIG and 13 participants in the UCG

HOMA-IR, homeostatic model assessment of insulin resistance; *LIG*, lifestyle intervention group; *UCG*, usual care group

[a] Paired samples were examined using Wilcoxon signed-rank test (skewed variables), paired sample *t* test (normally distributed variables), or McNemar's test (categorical variables)

[b] Systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg and/or use of antihypertensive drugs

[c] Type 2 diabetes is based on HbA_{1c} ≥ 6.0% and/or use of antidiabetic drugs without type 1 diabetes

[d] Assessed using criterion from the National Cholesterol Education Program

[e] Median (25–75 percentile)

[f] Two male participants were excluded from the dietary analyses at 4 y after surgery due to extreme values of alcohol intake and energy intake

*Statistically significant change during the intervention with post-hoc Bonferroni correction

Table 4 Changes during the intervention and between-group difference in change[1]

	LIG ($n=77$)	UCG ($n=65$)	Between-group difference in change	
	Changes during the intervention		Mean (95% CI)	P value[a]
Weight (kg)	4.2 ± 6.4	3.9 ± 8.1	0.3 (− 2.1–2.7)	0.82
BMI (kg/m^2)	1.5 ± 2.2	1.4 ± 2.9	0.1 (− 0.8–0.9)	0.84
Weight (%)	4.9 ± 7.4	4.6 ± 9.2	0.3 (− 2.5–3.0)	0.84
Fat mass (%)	3.5 ± 3.6	3.4 ± 4.4	0.0 (− 1.3–1.4)	0.96
Systolic blood pressure (mmHg)	2.9 ± 9.3	1.1 ± 10.8	1.8 (− 1.5–5.1)	0.29
Diastolic blood pressure (mmHg)	1.6 ± 7.2	− 0.4 ± 8.2	2.0 (− 0.6–4.5)	0.13
Fasting glucose (mmol/L)	0.3 ± 1.0	0.0 ± 0.6	0.3 (0.0–0.5)	0.08
HbA_{1c} (%)	0.1 ± 0.5	0.2 ± 0.4	0.0 (− 0.2–0.1)	0.85
Fasting insulin (pmol/L)	5.7 ± 15.5	2.6 ± 17.7	3.1 (− 3.3–9.5)	0.34
Fasting C-peptide (pmol/L)	27 ± 176	− 37 ± 195	64 (− 6–133)	0.07
HOMA-IR	0.1 ± 0.3	0.0 ± 0.4	0.1 (0.0–0.2)	0.12
Total cholesterol (mmol/L)	0.4 ± 0.6	0.3 ± 0.6	0.1 (− 0.1–0.3)	0.54
Triglycerides (mmol/L)	0.0 ± 0.4	0.1 ± 0.5	− 0.1 (− 0.2–0.1)	0.26
Energy expenditure (MJ/day)	0.2 ± 1.9	0.4 ± 1.2	− 0.2 (− 0.7–0.4)	0.60
Low activity or sleep (< 3 MET) (hour/day)	− 0.1 ± 1.3	0.0 ± 0.8	0.0 (− 0.4–0.3)	0.86
Moderate to high activity (> 3 MET) (hour/day)	0.1 ± 1.3	0.0 ± 0.8	0.0 (− 0.3–0.4)	0.86
Reading, TV viewing and computer use (hour/day)	− 0.2 ± 2.2	0.2 ± 1.7	− 0.4 (− 1.1–0.3)	0.26
Physical activity level	0.0 ± 0.3	0.0 ± 0.2	0.0 (− 0.1–0.1)	0.67
Energy intake (MJ/day)[b]	0.3 ± 2.5	0.2 ± 1.9	0.0 (− 0.7–0.8)	0.95
E% Carbohydrates[b]	− 2.2 ± 8.5	− 2.3 ± 8.4	0.0 (− 2.9–3.0)	0.97
E% Protein[b]	− 0.2 ± 3.6	0.1 ± 4.6	− 0.2 (− 1.6–1.2)	0.75
E% Fat[b]	2.1 ± 7.7	2.5 ± 8.1	− 0.4 (− 3.1–2.4)	0.79
Fibre (g/day)[b]	1.4 ± 7.4	0.8 ± 8.2	0.6 (− 2.1–3.3)	0.68
E% Sugar[b]	− 2.1 ± 5.3	− 1.7 ± 4.8	− 0.4 (− 2.1–1.4)	0.69
Artificially sweetened beverages (g/day)[b]	154 ± 411	248 ± 737	− 94 (− 304–116)	0.38

Values are mean ± SD unless otherwise specified. Values are missing from 0 to 8 participants, except for fasting insulin and HOMA-IR (which are missing from 18 participants in the LIG and 17 participants in the UCG), and C-peptide (which are missing from 16 and 15 participants in the LIG and the UCG, respectively). Insulinogenic index are collected from 12 participants in the LIG and 13 participants in the UCG

HOMA-IR, homeostatic model assessment of insulin resistance; *LIG*, lifestyle intervention group; *UCG*, usual care group

[a] Student's independent-sample *t* test with post-hoc Bonferroni's correction

[b] Two male participants were excluded from the dietary analyses at study end due to extreme values of alcohol intake and energy intake

Group Meeting Attendance in the LIG

Participant attendance at each meeting varied from 35% at the group meeting with the lowest attendance to 84% at the group meeting with the highest attendance (Fig. 2). One participant did not attend any meeting, while two participants attended all of the meetings. The average attendance was 8 ± 4 group meetings. Analysis of covariance revealed no association between % participation at group meetings and % weight regain ($\beta = -0.03$ [standard error (SE) 0.03, 95% confidence interval (CI) − 0.1 to 0.04)]. Further, no difference in % weight regain between participants in the highest compared with the lowest attendance quartile was found: % weight regain of 4.5% (CI 1.2–7.8) among the participants with the 25% highest participation compared with 6.3% (CI 2.2–10.4) among the participants with the 25% lowest participation ($P = 0.41$). Neither did we find any difference in weight regain between participants with ≥ 75% attendance compared with < 75% (4.6% (CI 1.2–7.9) and 5.0% (CI 3.0–6.9) weight regain, respectively ($P = 0.84$)).

Diet and Physical Activity

No changes within the groups in intake of macronutrients or in physical activity level during the intervention were revealed (Table 3). Further, there were no differences between the groups in changes in physical activity level, time spent on different activities, energy intake, and macronutrient distribution during the intervention (Table 4).

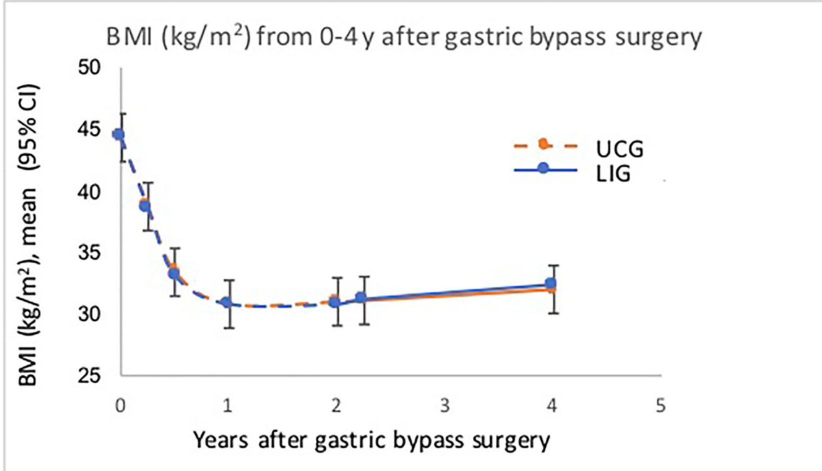

Fig. 3 Body mass index from pre-surgery until end of the intervention. The dotted lines show changes from time of surgery until study inclusion. The solid lines show changes during the study period. *LIG*, lifestyle intervention group; *UCG*, usual care group

Metabolic Risk Factors and Biochemical Markers

Both groups had an increase in HbA_{1c} and total cholesterol, but the proportion of participants with type 2 diabetes mellitus, hypertension, and metabolic syndrome remained unchanged in both groups during the intervention (Table 3). Further, no differences were found between groups in changes in biochemical markers, including blood lipids and diabetes markers (Table 4), or in the presence of metabolic risk factors.

Factors Associated with Weight Regain

Independent of group allocation, mean weight regain was 4.7 ± 8.2% (4.0 ± 7.2 kg). During the study period, 43% ($n = 61$) maintained or lost weight, 9% ($n = 13$) experienced a weight regain between 3 and 5%, and 48% ($n = 68$) experienced a weight regain ≥ 5%. Analysis of covariance showed a significant positive association between % weight increase from nadir to study start with % weight regain during the intervention ($\beta = 0.5$ [SE 0.2, 95% CI 0.1–0.9)]. Smokers had a significantly lower % weight regain during the intervention ($\beta = -4.8$ [SE 1.7, 95% CI −8.3 to −1.4]) than non-smokers. A total of 86% of the participants reported being in moderate or high physical activity ≥ 150 min/wk at study start, and a significant inverse association between physical activity ≥ 150 min/wk at study start and % weight regain during the intervention ($\beta = -5.2$ [SE 2.0, 95% CI −9.1 to −1.4] was found. No bivariate correlations were found between energy intake, intake of macronutrients, and food groups or food items at study start with % weight regain during the intervention (data not shown). Analyses of covariance with prognostic factors for % weight regain during the intervention revealed that smoking, higher age, and higher intake of artificially sweetened beverages at study start were all associated with a significantly lower % weight regain during the intervention, while high concentration of plasma tCys and time spent on reading, TV viewing, and computer use at study start were associated with more % weight regain during the intervention (Table 6).

Discussion

This 2-y group-based lifestyle intervention, focusing on behavioural change in diet and physical activity, did not prevent weight regain compared with a control group that received usual care. Despite some weight regain, the proportion of participants with metabolic risk factors remained unchanged in both groups.

Several RCTs have aimed at improving weight loss post-surgery [7–11, 34–36]. The majority of these RCTs have described no differences in weight loss between intervention groups (that received counselling in dietary habits, physical activity, and/or cognitive therapy) and control groups [9, 11, 34, 35]. One study found a short-time moderately greater total weight loss in the dietary counselling group that was not maintained beyond the intervention [8]. Some studies show beneficial effect of lifestyle intervention on weight loss start prior to or shortly after surgery [7, 10, 36] and include only Hispanic Americans [10] or only females [7, 36]. Kaviani et al. found better weight loss with a closely supervised 20-wk exercise programme compared with a minimally supervised exercise programme [36]. Improved weight loss is also observed in non-randomized lifestyle intervention studies that selectively target patients with weight regain post-surgery [12–15]. In contrast to the present intervention, the non-randomized studies and most of the RCTs are characterized by frequent follow-ups (weekly or every second week), weekly self-monitoring of weight, and/or daily record of food intake [8–10, 12–15, 34–36]. Further, the non-randomized studies [12–15] and some of the RCTs [10, 35] were of short duration (≤ 6 months), with small sample size ($n \leq 30$)

Table 5 Linear mixed model of body weight during the intervention. Estimates of fixed effects

Parameter	Estimate[a]	Std. error	Sig.	95% Confidence interval	
				Lower bound	Upper bound
Intercept	90.8	2.0	< 0.001	86.9	94.8
Group, UCG	0.25	2.9	0.93	− 5.4	5.9
Group, LIG	0[b]	0	.	.	.
Time study start–4 months	0.23	0.08	0.007	0.1	0.4
Time 4 months–study end	0.16	0.04	< 0.001	0.1	0.2
UCG * time study start–4 months	− 0.15	0.12	0.22	−0.4	0.1
LIG * time study start–4 months	0[b]	0	.	.	.
UCG * time 4 months–study end	0.02	0.06	0.75	−0.1	0.1
LIG * time 4 months–study end	0[b]	0	.	.	.

LIG, lifestyle intervention group; *UCG*, usual care group

[a] Dependent variable: body weight, kg

[b] This parameter is set to zero because it is redundant

[12–15] or included only a selected group [7, 9, 10, 12–15, 35, 36]. The frequency of 16 group meetings in the present study was based on hospital resources and feasibility, and a more intensive intervention could possibly have resulted in better long-term weight outcomes.

No dietary differences between the groups and no association between energy intake at study start with weight regain during the intervention were found. The lack of association may reflect the limitations of using self-reported methods. The food diary used in the study has been validated among a group of Norwegian adults and was found to be a useful tool [25]. However, food diaries are found less suitable for women and elderly men with overweight and obesity [37, 38]. Different methods can be used to calculate misreporting of energy, but it requires a body weight in balance, which was not the case in the present study [39, 40].

Large differences between objective and subjective measures of physical activity have been described [41, 42], and a study reported that 18 and 80% met the recommended level according to objective and self-reported measures, respectively [41]. In contrast, a Norwegian study using objective measures to investigate physical activity after gastric bypass registered 245–567 min/wk of moderate or high physical activity [43]. This is in line with the current intervention, where reported physical activity was higher than the national recommendations of at least 150 min/wk [21].

The Scandinavian Obesity Surgery registry described a weight regain of ~ 5 kg from 2 to 5 y post-surgery [1], which is comparable with the weight regain in the present study population. Considering the initial large total weight loss of nearly 40 kg achieved after surgery, the 4 kg weight regain is relatively small. An earlier publication from the present hospital reported a mean weight regain of 8 kg from 2 to 5 y post-surgery [44]. The more modest weight regain in the present study may be related to recruitment bias, with participants being more motivated for lifestyle changes regardless of being in the LIG or the UCG.

No difference in weight regain between high compared to lower participation at group meetings was found in the present intervention. These observations strengthen the suggestion that this group-based lifestyle intervention programme had no effect on weight regain. More focus on cognitive therapy, targeting the underlying causes of obesity, such as binge eating and emotionally motivated eating, may have improved the weight results in the intervention group. Frequent follow-up individually or in groups may also have been beneficial, but it was difficult to implement due to limited hospital resources. Participants in the present intervention were encouraged to attend self-help groups in between the scheduled group meetings, but there was no interest for such groups among the participants. The reason for this might be long travel distance, a busy life with work and family, or the participants were satisfied with the frequency of the scheduled group meetings.

The participants evaluated the group meetings at the end of the study. This information was not collected for scientific purposes, but it was meant to help improve the treatment offered to bariatric patients. The general impression was that the participants were satisfied with the group meetings and the topics. However, for some of the participants, travel distance to the hospital and a busy time schedule with work and family made it difficult to prioritize the group meetings.

As no differences in changes between the groups were found, data from all the participants were analyzed regardless of group allocation in order to identify baseline factors associated with weight regain. The positive association between plasma tCys concentration and weight regain during the intervention in the total study sample is in line with several epidemiological studies showing that plasma tCys is associated

Table 6 Analyses of covariance with prognostic factors at study start for % weight regain during the intervention

Parameter estimates

Dependent variable: % weight regain during 2 y intervention.

Parameter	B	Std. error	Sig.	95% Confidence interval	
				Lower bound	Upper bound
Intercept	5.0	5.6	0.37	− 6.0	16.0
Men	0.28	1.6	0.86	− 2.9	3.4
Women	0a	.	.	.	.
Smoking	− 3.5	1.7	0.043	− 6.9	− 0.1
Non-smoking	0a	.	.	.	.
Lifestyle intervention group	0.43	1.3	0.74	− 2.1	3.0
Conventional treatment group	0a	.	.	.	.
Age (y)	− 0.20	0.08	0.015	− 0.4	− 0.04
Total cysteine (pmol/L) at study start	0.03	0.01	0.034	0.0	0.1
Artificially sweetened beverage (g/day) at study start	− 0.003	0.001	0.015	− 0.01	− 0.001
Reading, TV viewing, and computer use (hour/day) at study start	0.73	0.31	0.021	0.1	1.3
Meat (g/day) at study start	− 0.02	0.01	0.078	− 0.1	0.003

a This parameter is set to zero because it is redundant.

with obesity [45–47]. As plasma tCys concentrations do not significantly decline after bariatric surgery, it is suggested that plasma tCys is a cause of obesity rather than a consequence [46, 48]. The association between physical activity and less weight regain is endorsed by other studies [2, 49, 50]. It has also previously been shown that consumption of artificially sweetened beverages can improve weight loss and weight maintenance within the context of a weight management programme [51]. Less weight regain was found among smokers in the present study, and it is previously observed that smoking cessation results in weight regain post-surgery [52]. Smokers planning cessation may thus benefit from additional follow-ups.

The strength of this study includes its randomized design, large sample size, and low attrition rate. To our knowledge, the present study is the first RCT specifically targeting weight regain during a 2-y intervention from mean of 21 months after surgery, which is a time most patients experience weight regain. Several of the previously published studies are pilot studies [8, 9, 12, 15] of limited duration (≤ 3 months) [12–15, 35]. As body weight nadir is usually reached between 1 and 2 y post-surgery [1, 3, 53], time of inclusion in the present study appears to be optimal to investigate the risk of weight regain. The baseline characteristics and the weight loss were similar to what is described in a review and meta-analysis from 2014 [54]. Dietary intake and physical activity are based on self-reported data with known limitations [37, 38, 41, 42, 55]. Another limitation was the low attendance rate at the group meetings. The 2 h duration of the group meetings was based on the Swedish treatment programme that was used as a guiding tool [20] and allowed time for a physical activity session in addition to the lecture and interactive participation at the meeting. However, the long duration of the sessions may limit the generalizability of the findings to other lifestyle interventions that have shorter sessions but rely more on modern technology to promote behavioural changes.

In summary, the present lifestyle intervention programme did not prevent weight regain. Still, several factors, including rapid weight regain after nadir, sedentary lifestyle, younger age, smoking cessation, and higher concentration of plasma tCys 2 y after surgery may identify subjects of increased vulnerability for weight regain. Based on these results, a better strategy to prevent long-term weight regain may be to selectively target patients at risk of future weight regain and offer earlier and more frequent follow-ups instead of providing a group-based intervention to all patients.

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Author Contribution SEH, HR, and AMA designed the research; SEH conducted the research; SEH, KJV, EBL, OK, HLG, HR, and AMA analyzed data; SEH, KJV, HR, and AMA wrote the paper; and all co-authors reviewed and commented on the manuscript; SEH had the primary responsibility for the final content.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval The study was approved by the Regional Committee for Medical and Health Research Ethics. The research was conducted according to the Declaration of Helsinki.

Informed Consent All subjects signed informed consent before participation in the trial. The study is registered in ClinicalTrials.gov (NCT01270451).

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