

Original Article



Efficacy of Combined Lifestyle Interventions as a Complement to Bariatric Surgery (ECLIBS): Short Term Outcomes of a Pilot Study

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Received: Aug 13, 2024 Revised: Nov 16, 2024 Accepted: Nov 20, 2024 Published online: Mar 21, 2025

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Funding

No funding was obtained for this study.

Conflict of Interest

None of the authors have any conflict of interest.

Author Contributions

Conceptualization: Smeenk R, Janssen M; Data curation: de Jong P, Smeenk R, Janssen M; Formal analysis: de Jong P;

ABSTRACT

Purpose: Combined lifestyle interventions (CLI) is a program designed to treat (morbid) obesity and can possibly be an adjunct to bariatric surgery. Bariatric surgery can lead to 25–50% total weight loss (TWL) and up to 71% excess weight loss, yet the longevity of the weight reduction remains variable, primarily attributed to a lack of lifestyle change. This pilot study aims to assess the effect of a 3-year structured CLI program, additional to a 5-year bariatric surgery program in a regional hospital, on the short-term outcome following bariatric surgery.

Materials and Methods: A single-center prospective cohort study was performed on patients who underwent bariatric surgery between September 2021 and October 2022 (n=28). A structured CLI program was organized and offered by an official out-of-hospital CLI provider. CLI participants were matched with patients following regular follow-up. Primary outcome was quarterly measured excess weight loss (EWL). Secondary outcomes were TWL, fat measurements, sports participation and comorbidities.

Results: There were significant differences in sports participation after 1 year (92.9% vs. 62.5%; P=0.050), EWL at 21 months (18.3 kg; 95% confidence interval [CI], 0.14–36.4; P=0.049), fat mass at 18 months (-8.7 kg; 95% CI, -14.1, -3.3; P=0.008) and fat percentage at 18 months (-10.0%; 95% CI, -17.9, -2.0; P=0.017) in the CLI group compared to the control group. **Conclusion:** Preliminary short-term results show that a structured additional CLI program to bariatric surgery could benefit in terms of weight loss, perhaps due to better sports participation, but long-term results have to be awaited for.

Keywords: Obesity; Bariatric surgery; Healthy lifestyle; Weight loss; Longevity

INTRODUCTION

Lifestyle interventions and bariatric surgery are 2 important pillars in the treatment of (morbid) obesity. Current literature shows that lifestyle interventions and bariatric surgery can lead to up to 5–15% and 25–50% total weight loss (TWL) respectively, with excess weight loss of up to 71% following bariatric surgery [1-4]. However long-term results following bariatric surgery show a tendency to regaining weight after 1–2 years post-surgery in 20–30% of patients [5]. Combining lifestyle interventions and bariatric surgery leads to more

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Investigation: de Jong P; Methodology: de Jong P, Smeenk R; Project administration: de Jong P; Supervision: Smeenk R; Writing original draft: de Jong P; Writing - review & editing: Smeenk R, Janssen M. weight reduction than lifestyle interventions alone [6-8]. Furthermore, it leads to improved glycemic control and reduces use of anti-hypertensive, anti-diabetic medication and lipid-reducing medication [7]. The effects of bariatric surgery and lifestyle interventions appear to complement each other, though little medical research has been published supporting the combined use of a dedicated bariatric combined lifestyle interventions (CLI) program and bariatric surgery [8-10]. A study evaluating the effect of lifestyle interventions and bariatric procedures using an endoscopic gastric balloon, found a greater effect on short-term weight loss [10]. In this pilot study, we aim to assess the effect of CLI as a complement to bariatric surgery on (short-term) weight reduction in the treatment of obesity. We hope to gain a better insight in the positive effects of CLI to improve the treatment of obesity, hypertension, Obstructive Sleep Apnea Syndrome and type II diabetes.

MATERIALS AND METHODS

1. Study design and setting

This study was conducted at the Albert Schweitzer Hospital in Dordrecht and Your Health Spot. Patients aged 18-66 who underwent a gastric bypass or gastric sleeve reduction between September 2021 and October 2022, and participated in the CLI program provided by Your Health Spot were included. They were individually matched to a control patient who underwent bariatric surgery without participating in the CLI program in the same period. Matching was based on age, gender, amount and type of comorbidities (i.e., suffering from arthrosis, but not diabetes), medical history and starting body mass index (BMI). When patients had no perfect match for type of comorbidities, they were matched on number of comorbidities. Exclusion criteria were a follow-up of less than nine months, insufficient understanding of the Dutch language and age lower than 18. We were only able to include a relatively small number of patients (14 out of 16 available in each arm), due to restrictions imposed by health insurance companies. Furthermore, due to local coronavirus disease restrictions a cohort of seven additional patients were unable to start the CLI program and were therefore excluded for participation. Two patients were excluded due to explicit nonconsent, one in each group. Usually, patients are only able to receive compensation from the health insurance company for one form of treatment at any given time, however for this study they were able to receive compensation for both treatments.

The CLI program was provided by Your Health Spot, a paramedical organization specializing in lifestyle coaching. The CLI program is a group-based coaching program, in which participants receive training regarding diet, exercise, sleep, stress- and time management. The CLI program additionally focuses on coaching participants in creating a physical and social environment that promotes and stimulates a healthy lifestyle and consists of 16–20 group sessions where participants can share their experiences and pitfalls, and bimonthly dietary- and lifestyle education sessions, where participants improve their health literacy. All sessions are guided by professional health coaches, and advice is in accordance with local dietary and physical activity guidelines. It is a 3-year program specifically designed to complement bariatric surgery, to enhance and prolong the weight reducing effect of bariatric surgery in the treatment of obesity. The 3-year duration was specifically chosen for the postbariatric surgery participants to encompass the 2-year pivotal point at which former bariatric patients have reported to experience a relapse into their unhealthy behaviors.



2. Variables and data collection

Demographical and clinical data was collected from Electronic Health Records (EHR's), and patients were matched using this data. Patients were classified as either CLI participants or non-CLI participants regardless of the type of surgery.

The primary outcome was quarterly measured effective weight loss (EWL) in percentage and kilograms. Secondary outcomes were sports participation after 1-year, TWL in percentage fat mass in kilograms, fat percentage, fat free mass (FFM) in kilograms and comorbidities. All data was collected during 3-monthly follow-up as part of the standard of care provided by our hospital.

3. Definitions

History of cardiovascular disease was defined as the presence of hypertension, congestive heart disease, heart failure or congenital heart disease prior to or at the time of presenting. History of pulmonary disease was defined as the presence of obstructive or restrictive pulmonary disease, chronic bronchitis, tuberculosis, or interstitial lung disease prior to or at the time of presenting. Sports participation was evaluated by the researchers of the CLI program and was defined as all regularly performed (at least once per week) physical activities including ball sports, endurance spots (i.e., track, swimming, cycling), dancing, extreme sports (i.e., skateboarding, mountainbiking, rock climbing) and/or weight lifting, excluding walking <10 km and activities of daily living, e.g., gardening, for a combined total of at least 120 minutes per week. Body composition measurements were made using DXA scans.

4. Statistical analysis

Descriptive statistics were presented as numbers and percentages, means and standard deviations. When variables were not normally divided, medians and Interquartile ranges were used. Comparisons between groups were done using the χ^2 test for categorial variables. For continuous variables independent t-tests were used. A 2-sided P value <0.05 was considered statistically significant. Binary logistic regression models were used to identify and adjust for confounders for statistically significant categorical outcomes, linear regression models were used to identify confounders for non-categorical outcomes.

5. Ethics

The Efficacy of Combined Lifestyle Interventions as a Complement to Bariatric Surgery (ECLIBS) study was approved by the Medical Ethics Committee Utrecht and the scientific committee for judging local feasibility (Wetenschappelijk Onderzoek Advies Commissie [WOAC]) of the Albert Schweitzer Hospital. Informed consent to use data was required and acquired via participation forms and/or verbal consent. When we received no acknowledgement of (non)consent after multiple attempts, EHR's were consulted to check for permission to use collected date for scientific research, as all patients undergoing treatment in the hospital are required to opt-in or -out for the use of data for medical research. Only patients who opted in were included. This study is exempt from Institutional Review Board oversight, as the CLI program is a public service program complementary to standard of care and uses no medical interventions on its participants. Approval of exemption was acquired by the WOAC.

RESULTS

A total of 15 patients participated in the CLI program, 14 of whom consented to their data being used for this study. Two groups were created (CLI-participant [n=14] and non-CLI participant [n=14]) for a total number of 28 patients. The baseline characteristics are depicted in **Table 1**.

1. Primary outcomes

The baseline characteristics of both groups are shown in **Table 1**. There we no significant differences between both groups regarding in age, gender, starting weight, starting BMI, ideal weight, amount overweight, comorbidities and patient history. A full overview of comorbidities is shown in **Table 2**. Only 1 sleeve gastrectomy was performed in the CLI group, 3 were performed in the control group. The EWL in kg was higher in the CLI-group compared to the non-CLI group at 21 months (18.3; 95% confidence interval [CI], 0.14, 36.4; P=0.049), however there was no statistically significant percentual difference (**Figs. 1** and **2**). This effect was not consistent over all time points.

2. Secondary outcomes

There was a significant difference in sports participation in favor of the CLI group at 12 months (61.5% vs. 92.9%; P=0.05) (**Table 3**). There was a trend but no significant difference in sports participation at 6 months (71.4% vs. 92.9%; P=0.139). There were no significant differences between groups regarding comorbidities at 6 months, 12 months or number of comorbidities lost after 12 months (**Table 4**). The CLI group showed a significantly lower fat percentage (-9.9; 95% CI, -17.5, -2.5; P=0.017) and fat mass (-8.7; 95% CI, -14.1, -3.2; P=0.008) at 18 months compared to the non-CLI group. There were no significant differences between both groups in BMI, TWL and FFM (**Figs. 3-7**). A survey was conducted to assess the benefits experienced by participants of the CLI program (**Table 5**).

3. Regression models

There were no statistically significant confounders identified for sports participation at 6 and 12 months of follow-up. For EWL (kg) at 21 months and fat percentage at 18 months, no

Table 1. Baseline characteristics

Characteristics	CLI	Non-CLI	P value
Demographics			
Age at surgery (years)	49.8 (13.5)	48.6 (12.6)	0.943
Female gender	11 (78.6)	11 (78.6)	1.000
Physical			
Starting BMI (kg/m²)	41 (38.4-45.5)	40.5 (39.5-42.6)	0.752
Starting weight (kg)	123.7 (108.3-126.4)	121.2 (116.1-127.9)	0.506
Amount overweight (kg)	47.2 (35.9-57.8)	46.6 (42.6-53.5)	0.986
Ideal weight (kg)	70.6 (68.1-78.8)	72.7 (70.8-81.1)	0.308
Comorbidities	1.5 (1-3.3)	3 (1-3.3)	0.634
Patient history			
History of CVD	7 (50.0)	5 (35.7)	0.445
History of PD	1 (7.1)	3 (21.4)	0.280
History of diabetes	6 (42.9)	4 (28.6)	0.430
Type of surgery			
Gastric bypass	13 (92.9)	11 (78.6)	0.271

Values are presented as number (%) or median (interquartile range). No significant differences were found between the CLI and non-CLI group.

CLI = combined lifestyle interventions, BMI = body mass index, CVD = cardiovascular disease, PD = pulmonary disease.

Table 2. Comorbidities at baseline, 6 months and 12 months

Comorbidity	CLI (n=14)	Non-CLI (n=14)
Baseline		
Arthrosis	3 (21.4)	10 (71.4)
Diabetes mellitus type II	7 (50.0)	4 (28.6)
Dyslipidemia	5 (35.7)	4 (28.6)
Hypertension	7 (50.0)	7 (50.0)
OSAS	5 (35.7)	3 (21.4)
Reflux	5 (35.7)	4 (28.6)
6 months		
Arthrosis	1 (7.1)	6 (42.9)
Diabetes mellitus type II	2 (14.3)	2 (14.3)
Dyslipidemia	4 (28.6)	4 (28.6)
Hypertension	3 (21.4)	4 (28.6)
OSAS	2 (14.3)	2 (14.3)
Reflux	3 (21.4)	3 (21.4)
12 months		
Arthrosis	1 (7.1)	4 (28.6)
Diabetes mellitus type II	1 (7.1)	1 (7.1)
Dyslipidemia	3 (21.4)	2 (14.3)
Hypertension	1 (7.1)	4 (28.6)
OSAS	0 (0.0)	0 (0.0)
Reflux	2 (14.3)	3 (21.4)

Values are presented as number (%).

CLI = combined lifestyle interventions, OSAS = Obstructive Sleep Apnea Syndrome.

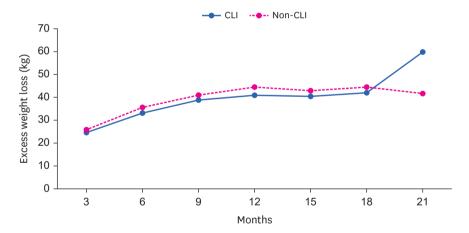


Fig. 1. Excess weight loss (kg) at 3–21 months. Excess weight loss was higher in the CLI group (P=0.049). CLI = combined lifestyle interventions.

confounders were identified in the full regression models. For fat mass (kg), starting weight and starting BMI were identified as confounders, however after adjusting for amount of excess weight at baseline, this effect was no longer statistically significant. The full models are shown in the supplements (**Supplementary Tables 1-5**).

DISCUSSION

In this study, we compared the sports participation and parameters commonly used to follow up weight-related diseases to assess the potential benefit of a CLI program as a complement to bariatric surgery. We found significant differences in sports participation after 1 year and EWL (in kg) after 21 months in favor of CLI-participation. The significant difference in

EWL (kg) between both groups was not replicated in the more widely used measurement for weight reduction, EWL (%), and was not consistent across all time points. Furthermore, we found fat percentage and fat mass were significantly lowered in the CLI-participation group

Table 3. Sports participation after 6 and 12 months

Sports participation	6 months		12 months	
	CLI	Non-CLI	CLI	Non-CLI
Yes	13 (92.9)	10 (71.4)	13 (92.9)	8 (61.5)
No	1 (7.1)	4 (28.6)	1 (7.1)	5 (38.5)
P value	0.3	139	0.0	05

Values are presented as number (%). A significant difference was found in sports participation after 12 months in favor of the CLI group. There was so statistically significant effect after 6 months.

CLI = combined lifestyle interventions.

Table 4. Comorbidities at 6 months and 12 months

Outcome	CLI	Non-CLI	P value
Comorbidities after 6 months	1.00±0.88	1.50±1.51	0.29
Comorbidities after 12 months	0.64±0.84	0.86±1.10	0.57
Comorbidities lost after 12 months	1.50±1.22	1.36±1.08	0.75

Values are presented as mean ± standard deviation.

CLI = combined lifestyle interventions.

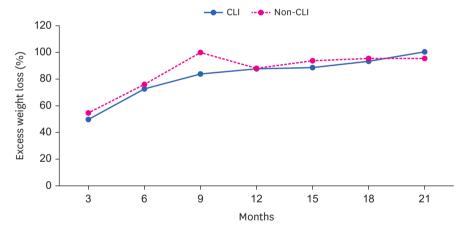


Fig. 2. Excess weight loss (%) at 3–21 months. No difference was found between groups (P=0.276). CLI = combined lifestyle interventions.

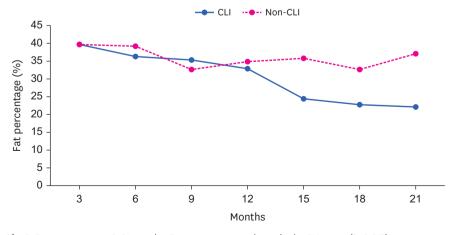


Fig. 3. Fat percentage at 3-21 months. Fat percentage was lower in the CLI group (P=0.017). CLI = combined lifestyle interventions.

compared to non-CLI participants after 18 months. We hypothesize the greater reduction in fat percentage and fat mass can be contributed to the education in healthy diet-choices

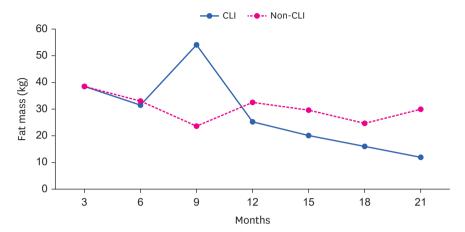


Fig. 4. Fat mass (kg) at 3-21 months. Fat mass was lower in the CLI group (P=0.008). CLI = combined lifestyle interventions.

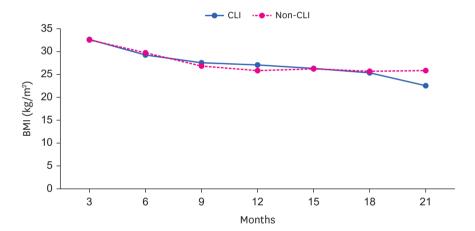


Fig. 5. BMI (kg/m^2) at 3-21 months. No differences were found between groups (P=0.404). BMI = body mass index, CLI = combined lifestyle interventions.

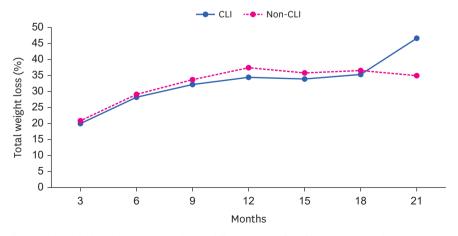


Fig. 6. Total weight loss (%) at 3–21 months. No differences were found between groups (P=0.106). CLI = combined lifestyle interventions.

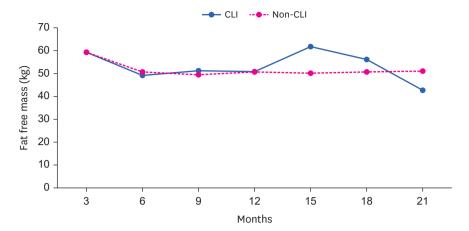


Fig. 7. Fat free mass (kg) at 3–21 months. No differences were found between groups (P=0.194). CLI = combined lifestyle interventions.

Table 5. Survey data amongst participants

Subject	Obstructive (%)	Equal (%)	Beneficial (%)
Weight reduction	0	40	60
Healthy weight loss	0	27	73
Healthy dietary pattern	0	20	80
Dietary health literacy	0	27	73
Healthy exercise pattern	7	40	53
Exercise literacy	0	47	53
Stress handling	7	40	53
Time management	0	40	60
Self-image	7	20	73
Goals & tracking improvement	0	13	87
Motivation	13	20	67
Help with pitfalls	0	20	80
Dealing with social environment	13	53	34

Subject, questionnaire subject; Obstructive, participants found the CLI program to be obstructive regarding this subject (%); Equal, participants found the CLI program to be equal to standard of care regarding this subject (%); Beneficial, participants found the CLI program to be beneficial regarding this subject (%).

CLI = combined lifestyle interventions.

provided by the CLI program, resulting in a diet more prone to reducing fat mass and building muscle mass. The lack of significance in the other variables used to assess weight reduction gives context to the effect seen in EWL (kg), and suggests similarity of short-term weight reduction, rather than superiority of the CLI program. However, as the CLI program was designed for better maintenance of weight reduction on the long-term, this can be expected but is to be awaited for after longer follow up (5 years).

Though these results imply CLI-participation can be beneficial on some points, these results are only the preliminary findings (short term). The programs last for a total of 5 years (3 years for the CLI program, after which participants will have another 2 years of regular follow-up), and therefore these findings are to be interpreted in that context. Our data shows a trend in favor of the CLI group with regards to weight loss starting from 18 months, and we believe this trend might remain or increase into significance in the long-term results, even with this small number of patients It is important to note that long-term results remain to be evaluated.

Our study shows comparable weight loss expressed as BMI, TWL and EWL (kg) as previously reported in other studies [1-3,11-14]. Both our CLI and control groups performed better than

can be expected according to previous studies in EWL (%), however no significant difference was found between both groups [1,11-13]. This can be contributed to selection bias, resulting from the relatively heathy and motivated participants who opted for the CLI program and their matched controls. The change in body composition following bariatric surgery was comparable in our cohort compared to other studies [15,16]. Sjöström [17] previously reported 80–90% of subjects being physically active 1 year after surgery, which was similar to the CLI group in our study, however a significantly lower percentage was physically active in the control group, similar to a study by Ruiz-Tovar et al. [18].

We hypothesize that a group-based program causes a stronger support system and increases the likelihood of maintaining diet and exercise following bariatric surgery. The CLI program enhances health literacy and prepares participants for the physical and social changes following bariatric surgery. In our hospital the aftercare lacks on these points. The group-based nature of the program also allows for a mutual experience leading up to and following the procedure, allowing patients to share their problems with each other. These factors together allow for an increased likelihood of maintaining lifestyle changes following bariatric surgery. A survey was conducted amongst participants of the CLI program to assess the benefits of the group-format of the program. The CLI participants reported they experienced the group-format in the follow-up of post-surgery as beneficial in weight reduction (60%), health literacy with regards to healthy diet (73%) and healthy eating patterns (80%), self-image (73%), motivation (67%) and pitfalls (80%) (**Table 3**). Though we believe the CLI program is beneficial for mental support in this type of treatment compared to standard follow-up, there remained at least one person who indicated mental health should have a bigger role in the program.

Although we believe the findings of this study show a potential benefit of a group-based program as a complement to bariatric surgery, our study has limitations. Firstly, the CLI program has not yet reached its full-length follow-up, and therefore our data is incomplete. Secondly, due to the recent implementation of this program, only 14 participants have been included in this pilot study, and only one center is participating. Furthermore, this study is susceptible to selection bias, as the more motivated patients are more likely to participate in the program and could therefore more likely to maintain the weight reduction after surgery. Two patients from the CLI group who underwent a gastric bypass were matched with controls who underwent sleeve gastrectomy. Although studies (just to name a few here) show that on the long-term weight loss seems higher after a gastric bypass then a sleeve gastrectomy, the type of surgery does not affect the short term primary endpoints [9,12], and we therefore believe these matches are accurate. For long-term analysis an analysis with correction for type of surgery might be relevant, although patient numbers remain very low for such analysis.

We have identified several confounders in our linear regression models, however after adjusting for the amount of excess weight, this effect was no longer statistically significant. Patients were matched based on several variables which had a non-significant trend towards confounding, therefore we expect any confounding effect to be minimal when comparing our groups. Lastly, the significant differences in the parameters were only present at 18 and 21 months respectively, as insufficient data was available to accurately compare both groups beyond those points in time.

In this study we have shown that the short-term weight loss following bariatric surgery while participating in the CLI program has similar efficacy as the regular follow-up. Our results

show that the CLI program could be beneficial for retained weight loss, demonstrated by the early significant differences in fat percentage and fat mass. Most importantly, these preliminary results show a significant difference in sports participation after 12 months in favor of the CLI group. This supports our hypothesis that CLI-participation could result in better compliance of post-surgery instructions to maximize and maintain long-term weight loss following bariatric surgery in the treatment of obesity.

CONCLUSION

This pilot study shows a potential benefit of CLI participation on longevity of weight reduction following bariatric surgery in the treatment of obesity, but long-term results have to be awaited for.

SUPPLEMENTARY MATERIALS

Supplementary Table 1

Binary logistic regression model for sports participation after 6 months

Supplementary Table 2

Binary logistic regression model for sports participation after 12 months

Supplementary Table 3

Linear regression model for excess weight loss (kg) after 21 months

Supplementary Table 4

Linear regression model for fat percentage after 18 months

Supplementary Table 5

Linear regression model for fat mass (kg) after 18 months

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