

A two-year clinical lifestyle intervention program for weight loss in obesity

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Abstract

Background: In recent randomised prospective studies, lifestyle intervention induced a weight loss of approximately 5%.

Objective: To describe and evaluate a 2-year on-going group intervention program in clinical practice in terms of weight loss and changes in metabolic risk factors, i.e. sagittal abdominal diameter (SAD), triglycerides, fasting blood glucose and blood pressure.

Design: The aim of the intervention program was to motivate lifestyle changes concerning food intake and physical activity. The emphasis was on lifestyle modification, followed up at regular visits during 2 years. Subjects evaluated were 100 women with mean BMI 37.6 kg/m² and 26 men with mean BMI 36.5 kg/m².

Results: One hundred of 151 enrolled women and 26 of 36 men completed the program. Mean weight decreased by 3.8 kg in women (from 103.5 to 99.7, $p < 0.001$) and 4.4 kg in men (from 116.5 to 112.1, $p < 0.05$), respectively. SAD decreased by 5% ($p = 0.001$ in women, $p = 0.01$ in men), and triglycerides by 16% in women ($p = 0.01$) and 24% in men ($p = 0.001$), however systolic and diastolic blood pressure increased slightly but significantly.

Conclusion: It is possible to perform a clinical lifestyle intervention program for outpatients on an ongoing basis with weight loss, lowered SAD and triglycerides, and a similar or lower dropout rate compared to clinical trials.

Keywords: *overweight; weight changes; triglycerides; sagittal abdominal diameter; food intake; physical activity*

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Obesity has been classified as an epidemic according to the WHO (1). In Sweden, the prevalence of obesity has increased over the last decades, and in 2004, according to the WHO definition (1), it was about 12% (2). Complications of obesity are increasing and there is strong evidence that obesity contributes to a number of metabolic disorders, such as insulin resistance, dyslipidemia, hypertension, hypercoagulability, microalbuminuria, type 2 diabetes mellitus and cardiovascular disease (3–7).

According to the WHO (8), subjects with insulin resistance or type 2 diabetes and two or more of the other risk factors are defined as having the metabolic syndrome. Insulin resistance is considered the key factor of these disorders (4, 5, 9, 10), and there is a need for a simple clinical marker of insulin resistance (11). Central obesity is associated with insulin resistance (7). It has been shown that the sagittal abdominal diameter (SAD) is

more strongly correlated to insulin sensitivity and the risk factors in the metabolic syndrome compared to BMI, waist girth and waist-hip-ratio (WHR) (12, 13). For several years, SAD has been measured at our clinic as a surrogate marker for insulin resistance.

Weight reduction is difficult to obtain and maintain, and the need for better performing treatment is vast (3, 14). Recent studies have shown that despite difficulties in reducing the overweight to normal weight, it is possible to markedly reduce the incidence of diabetes and obtain other beneficial health effects even at a moderate weight loss of approximately 5% (15–17). In the Diabetes Prevention Study (DPS) and the Diabetes Prevention Program (DPP), through lifestyle changing programs it was possible to reduce the incidence of diabetes by 58% in subjects with obesity and glucose intolerance (15, 16). The lifestyle change also reduced several other cardiovascular risk factors associated with insulin resistance (15).

Obesity treatment at the Outpatient Clinic for Obesity Care, Uppsala University Hospital, Uppsala, Sweden, addresses obese patients with a BMI >30 kg/m² or a BMI >28 kg/m² with concomitant metabolic disorders. Since the late 1970s, treatment for overweight has been carried out and developed at the clinic. Currently, about 700 patients are referred to the clinic each year. Among the different individualised treatments available is a 2-year group treatment with the emphasis on lifestyle changes.

The aim of the present work was to describe the 2-year clinical lifestyle intervention program in obesity and to evaluate the changes in body weight and metabolic risk factors, i.e. SAD, triglycerides and blood glucose, and to calculate the drop-out rate over the 2-year programme period.

Material and methods

Subjects

The patients were referred to the outpatient Clinic for Obesity Care from general practitioners in Uppsala County and from clinics at the Uppsala University Hospital. A majority of the participants had previously undergone different weight reduction programs, e.g. weight-watchers or other diets, frequently with scant results and often with extra weight gain afterwards. Most patients suffer from complications due to their obesity, e.g. type 2 diabetes, hypertension, dyslipidemia cardiovascular disease or sleep apnoea disorder. Some patients were already taking pharmacological treatment for such diseases. Of the participants, 74% were women, which reflects the natural inflow of patients to our clinic where women are more prone to seek treatment for obesity.

The participants were referred to the program following a check-up at the outpatient clinic. The criteria

for inclusion into the program was: the patient should be >18 years of age and have a BMI >30 kg/m² or a BMI >28 with concomitant metabolic disorders. Exclusion criteria were inability to follow spoken or written instructions, refusing group treatment or not being able to participate in water gymnastics. Patients with severe heart failure (NYHA III–IV), chronic obstructive pulmonary disease or other conditions that preclude participation in exercise were not included. Such patients were offered other individualised treatment at the clinic. The present work was performed as part of a quality assurance evaluation at the clinic and the on-going lifestyle intervention program.

The patients included in this program evaluation started the lifestyle intervention program during the period between September 1998 and September 1999, and completed the program between 2000 and 2001.

Design

The design of the program was conventional dietary advice on food and physical activity combined, focusing on lifestyle changes, by means of group sessions, for 2 weeks of intensive education and follow-up visits during 2 years (for detailed information see Table 1).

The 2-year lifestyle intervention program

The current lifestyle intervention program started at the clinic in 1995. The program has been developed and improved throughout the years, but the basic design remains the same. The inflow of new participants included in the program is approximately 100 participants a year.

The aim of the program was to motivate the participants to perform lifestyle changes concerning food intake and physical activity. The aim was to achieve a decrease in weight and/or to improve metabolic status. According to the conclusion that beneficial health effects can be

Table 1. Clinical lifestyle intervention program protocol.

Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Week	1–2*	5	8	14	20	26	32**	38	44	50	56	68	80	92	104
Weight recording	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SAD recording	X						X								X
Biochemical control	X						X								X
Physician	X						X								
Dietician	X	X		X		X***	X		X		X***		X		X
Nurse	X		X				X	X				X		X	
Physiotherapist	X				X		X			X					
Almoner	X														

*Two weeks (80 h) introductory education at the outpatient clinic.

**Two days (16 h) rehearsal at the outpatient clinic.

***Two hours follow-up visit including dietician supervised cooking.

attained at a modest level of weight loss, the treatment goal for weight reduction was set to 5–10% (17). Follow-up was performed at regular follow-up visits during 2 years (Table 1).

On referral to the program, the patients were given oral and written information at the doctor's appointment. Two weeks before the start of the program, an appointment for repeated information was held for the group. The rules and aims of the program were given and the patients were asked to consider their motivation to participate throughout the entire 2-year program. Informed consent and a written contract were set up and the patients received a start date. Each group consisted of eight to ten members, women and men in separate groups. All data were registered decoded, deleting the individual civic number, thereby making it impossible to identify any given participants data in the dataset. This dataset was used for statistical analyses. The study was performed in accordance with the Helsinki Declaration of 1975, as revised in 1983 and applicable Swedish law.

Lessons – educational program

During the first 2 weeks of the program, the participants received an 80-h introductory lesson at the outpatient clinic. A team of a physician, dieticians, physiotherapists, nurses and almoners worked together according to a specified schedule in order to provide a holistic lifestyle message. The focus was advice on diet and physical activity combined with lifestyle changes. A detailed schedule may be obtained from the author.

The schedule consisted of group sessions given as theory lessons, discussions and practical tasks. Although held in a group, the discussions and tasks focussed on individual behaviour. The purpose was to make the participants aware of their own behaviour and to modify it to a more adequate lifestyle. The new regimen was to be maintained by setting up goals and practising the new habits on an everyday basis.

An individual appointment with the physician in charge was made at the start and end of the initial 2 weeks of the program. Pharmacological treatment was discussed, introduced or altered and prescribed if necessary. The aim was to optimise the metabolic status according to current guidelines, but also to use the results that the patient achieved through changing lifestyle as a pedagogic tool for the maintenance of new lifestyle.

Dietary advice, food content and cooking practice

The nutritional education was based on the Swedish Dietary Recommendations (SNR) 1997 (18), communicated in theory and practice. The participants were encouraged to change their diet to achieve a balanced intake of fat, between 25 and 30% of the energy intake with a maximum of 10% from saturated fat, to increase the intake of fibre, to increase the intake of vegetables

and fruits, and to moderate the intake of sugar and alcohol. The balance between the other macronutrients followed the SNR, i.e. 55–60% of the total energy intake from carbohydrates and 10–15% from protein. According to SNR, three regular meals and two or three smaller meals, e.g. fruit or bread, were recommended. Without counting calories, the participants were taught to eat in a way that would give them between 1600 and 1800 calories. Theoretical discussions were followed up by dietician supervised practice; each day the participants made their own lunch and dinner to experience the methodology of cooking a balanced meal, to taste it and to feel the satiety after ingestion of a normal sized portion. For these meals, an energy-reduced version of the Swedish plate model (19) was used. The plate model is an easy, pedagogical tool to make a meal balanced, and is based on the principal that about one-third to a half of the plate consists of vegetables and the other part is shared equally between carbohydrate rich food and food rich in protein. This part of the program also included discussions on how to combine the new lifestyle into everyday life, such as planning meals, number of occasions allowing 'extravagance', shopping for food etc.

The participants were asked to perform a 2-day food record before the start of the program. The food record was calculated with a dietician and constituted the basis for individual food counselling.

Physical activity – theory and practice

The central message was to encourage the participants to increase their physical activity independent of their present level. An exercise test was performed at baseline and followed up at week 32. During the initial 2 weeks, each day water gymnastics was a morning activity, and other forms of training sessions took place in the afternoon, e.g. Nordic walking (walking with a walking-stick in each hand) and adapted workout or exercise bicycling. The aim was to enable the participants to discover different forms of activity that they might continue at home on an ongoing individual basis. Further topics discussed by the physiotherapists were injury prevention and the positive effects of physical activity on weight loss, metabolic status and wellbeing.

The follow-up visits

A 14-visit curriculum during 2 years, covering diet, exercise and lifestyle modification followed the introductory education. The aim was to help and support the participants to improve and maintain the new regimen. The pedagogic structure of the follow-up visits was based on different exercises designed as homework, that were individualised and flexible. The role of the supervisor at follow-up visits was altered between the staff members (Table 1). The relationship between the supervisor and the participants was based on collaboration, the super-

visor leading the motivating discussions and guiding the patients to increase their awareness of their habits and setting up adequate goals for homework. The individual experiences in the groups were brought up for discussion to create an interpatient-based support. The follow-up visits normally lasted 60 min, except two occasions involving cooking. At week 32, the structure of the initial 2 weeks was repeated for 2 days at the outpatient clinic. Weight was checked at every follow-up visit and baseline biochemical and anthropometric measurements at the 32-week rehearsal and at the end of 2 years (Table 1).

Measures

Anthropometrical and biochemical measurements

Biochemical and anthropometrical status were measured at baseline, at week 32 and at week 104. For patients with high values of blood glucose, lipids or blood pressure, blood samples were recollected during the initial 2 weeks and used as a basis for the discussion with the physician on adjustment of ongoing or possible new pharmacological treatment in addition to lifestyle intervention. Body weight was recorded at each follow-up visit, and was measured to the nearest 0.1 kg using an electronic scale with subjects wearing light clothing and no shoes. Height was measured to the nearest 0.1 cm without shoes and BMI (kg/m^2) was calculated. SAD (cm) was measured by standardised methods as previously described (12) to the nearest 0.1 cm after normal expiration while in supine position with legs bent, on a firm examination table. Systolic and diastolic blood pressure (SBP, DBP) was measured in the supine position using a Kifa Ercometer. SBP and DBP were defined as Korotkoff phases I and IV, respectively. Hypertension was defined as SBP >140 or DBP >90 mmHg on 3 visits.

All anthropometrical and biochemical measurements were performed by trained nurses. Blood samples were collected after an overnight fast and centrifuged. Plasma glucose, serum triglycerides (TG), total serum cholesterol and HDL-cholesterol were measured using standardised methods, analysed at the Department of Clinical Chemistry, University Hospital, Uppsala. Diabetes type 2 was defined as a fasting plasma glucose ≥ 7.1 mmol/l on two occasions.

Data collection and statistical analysis

Data was collected from patient files and made untraceable for identity. For statistical analysis, software SAS PC 8.0 was used. All statistics were calculated for women and men separately. Descriptive statistics include means and standard deviations. The mean (%) difference between the laboratory parameters at week 0, week 32 and week 104 were evaluated by Student's paired *t*-test. Differences were considered significant at $p < 0.05$. All tests were two-tailed.

Table 2. Baseline characteristics of patients completing the lifestyle intervention program.

Characteristics	Females	Males
Number	100	26
Age (years)	48 ± 12	50 ± 10
Body weight (kg)	103.5 ± 18.1	116.5 ± 22.5
Body mass index (kg/m^2)	37.6 ± 6.2	36.5 ± 5.3
Sagittal diameter (cm)	29.0 ± 2.9	31.5 ± 3.8
Total cholesterol (mmol/l)	5.6 ± 1.0	5.5 ± 1.2
HDL-cholesterol (mmol/l)	1.3 ± 0.3	1.2 ± 0.2
Triglycerides (mmol/l)	2.3 ± 1.2	3.7 ± 4.5
Blood glucose (mmol/l)	5.7 ± 1.7	7.0 ± 3.4
SBP (mmHg)	126 ± 16	131 ± 17
DBP (mmHg)	76 ± 9	82 ± 12
Diabetes type 2 (n (%))	20 (20)	9 (35)
Hypertension (n (%))	15 (15)	7 (27)

Data presented are arithmetic means ± standard deviations, number or percent.

Results

The baseline characteristics of the participants are given in Table 2. The evaluation include more women than men, reflecting the higher proportion of women that are referred to the outpatient clinic.

Dropouts

One hundred out of 151 women and 26 out of 36 men completed the program. Hence, the dropout rates were 34 and 28%, respectively, in total 33%. To be considered having completed the program, the participants had to attend at least one of the two last follow-up visits (week 90 or week 104). There were no significant differences in age, sex, weight or BMI between those who completed and dropouts.

Weight loss

During the first 32 weeks, the mean weight decreased among those who completed the course by 5.0 kg (6.5%) in women ($p < 0.001$) and 11.1 kg (8.2%) in men ($p < 0.001$). The initial weight loss was maintained during the first year, but during the second year some of the body weight was regained (1.2 kg among women and 6.5 kg men). However, at 2 years the mean weight was still significantly decreased by almost 4% in both sexes (Table 3). See Table 3 for changes in BMI. Fig. 1 presents the proportion of patients with a weight loss of 5–10% and more than 10% after 2 years.

Obesity-associated risk factors

After 32 weeks, there was a considerable decrease in triglycerides in both women and men, which was sustained also after 2 years. SAD was decreased by 5%

Table 3. Metabolic variables at 32 and 104 weeks in the lifestyle intervention program and percent changes from baseline in program completers.

Variable	32 weeks				104 weeks			
	Female		Male		Female		Male	
	Mean \pm SD	n	Mean \pm SD	n	Mean \pm SD	n	Mean \pm SD	n
Body weight (kg)	98.5 \pm 17.9***	80	105.4 \pm 21.1***	24	99.7 \pm 18.3***	100	112.1 \pm 22.7*	26
Change (%)	-6.5 \pm 6.0***		-8.2 \pm 8.1***		-3.5 \pm 7.4***		-3.7 \pm 7.1*	
BMI (kg/m ²)	35.7 \pm 6.2***	80	33.6 \pm 4.9***	24	36.2 \pm 6.3***	100	34.7 \pm 4.5*	24
Change (%)	-6.5 \pm 6.0***		-8.2 \pm 8.1***		-3.5 \pm 7.4***		-3.7 \pm 7.1*	
SAD (cm)	-		-		27.6 \pm 3.5***	84	30.0 \pm 4.0**	18
Change (%)	-		-		-5.4 \pm 8.0***		-4.8 \pm 6.8**	
Total cholesterol (mmol/l)	5.5 \pm 1.1	92	5.2 \pm 1.2	21	5.5 \pm 1.1	94	5.6 \pm 1.0	21
Change (%)	-1.3 \pm 13.4		-0.6 \pm 16.5		-0.9 \pm 16.0		1.0 \pm 17.4	
Triglycerides (mmol/l)	1.9 \pm 1.2***	92	1.8 \pm 0.9	21	1.8 \pm 1.1***	93	2.2 \pm 1.0***	21
Change (%)	-15.8 \pm 31.3***		-22.8 \pm 22.4		-16.1 \pm 33.4***		-24.2 \pm 24.6***	
Blood glucose (mmol/l)	5.2 \pm 1.2***	92	5.1 \pm 1.4*	21	5.8 \pm 1.9	92	6.6 \pm 3.1	20
Change (%)	-6.2 \pm 18.0***		-16.1 \pm 18.0*		2.6 \pm 20.2		-5.9 \pm 20.3	
Systolic blood pressure	-		-		129 \pm 16	86	135 \pm 15	19
Change (%)	-		-		2.3 \pm 6.2**		3.0 \pm 8.2*	
Diastolic blood pressure	-		-		79 \pm 8	86	84 \pm 9	19
Change (%)	-		-		3.9 \pm 9.7**		2.4 \pm 6.5	

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, p -values were determined by Student's paired t -test for differences from baseline.

($p < 0.001$, $p < 0.01$) in both groups at 2 years. Fasting plasma glucose was lowered at 6 months for both women and men, but not after 2 years for women. For men, however, the decrease was not significant after 2 years (for details see Table 3). There were no statistically significant changes in blood cholesterol. Blood pressure was slightly but significantly increased in both men and women at 2 years (Table 3). Diabetes and hypertension

were treated if necessary according to guidelines. However, introduction or withdrawal of the pharmacological treatment of the patients was not registered in the database.

Discussion

This evaluation showed weight reduction of -3.8 kg in women and -4.4 kg in men (3.5 and 3.7%). Therefore, it was possible to obtain results in our continuously used clinical 2-year lifestyle program that are comparable to randomised controlled studies. For instance, in the DPS and DPP studies, the weight loss was -3.5 and -5.5 kg, respectively after 2 years of treatment (15, 16). Lifestyle intervention programs in obesity studies in Sweden have also shown weight reduction of a similar magnitude (20–22). Several studies confirm that lifestyle intervention treatment including diet and physical activity is capable of providing a remarkable improvement in risk factors even at a modest weight loss (17, 21, 22), and in the long term preventing more severe illness (15, 16, 23, 24)

Fasting blood glucose was significantly lowered at 6 months, but not significantly so after 2 years for both sexes. This suggests an acute effect on glucose by the initial weight loss and abolished blood glucose lowering at 2 years may indicate the progressive nature of the diabetic state. However, it should be considered that the average fasting blood glucose was higher in men, even

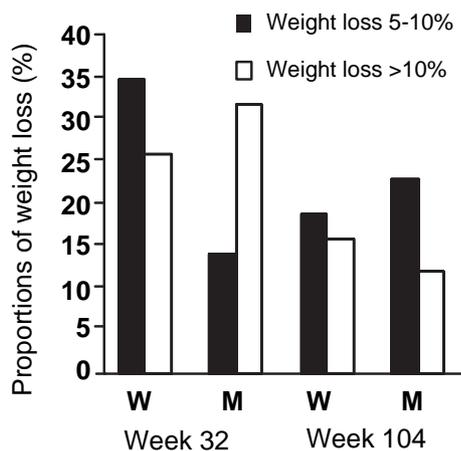


Fig. 1. Frequency of participants obtaining weight loss $\geq 5\%$. The black bars present percentage of participants losing ≥ 5 but $< 10\%$. The white bars present percentage of participants losing $> 10\%$.

above the present cut off limit for type 2 diabetes, but below in women.

In comparison with previous controlled randomised trials (15, 16), the limitations in clinical routine care made it impossible to perform an oral glucose-tolerance test every 6 months and comment on type 2 diabetes. However, despite the modest weight loss, the treatment resulted in significant improvements in some important factors. SAD was decreased by 5% in both women and men, and triglycerides were decreased by as much as 16% in women and 24% in men at 2 years. Both measurements are associated with insulin resistance, which is suggested to precede the development of diabetes 2 and cardiovascular disease (4, 5, 11, 25, 28). SAD has been shown to correlate to insulin resistance and other signs of disturbed glucose metabolism (12) more strongly than other anthropometric measurements (13). SAD has also shown a strong correlation to mortality in men (29, 30). Change in SAD was also related to a change in the metabolic syndrome in the SOS study (22). This highlights that measurement and decrease in SAD is of clinical importance.

Triglycerides were lowered by 20%, whereas total serum cholesterol was not decreased, which indicates that the lowering of TG was induced by weight loss and lowered central obesity and not by the introduction of lipid lowering medication, such as statins. However, the overall aim was to optimise metabolic control. Further, we cannot exclude that a few patients used anti-obesity drugs for a short period of time at the end of the program evaluation period. Orlistat, which was the only anti-obesity drug available for prescription at that time, was not subsidised and thus very expensive for the individual patient. Hence, it was most probably not used often by patients included in this evaluation.

Obesity is a chronic condition and calls for life-long treatment (1), which is a demanding task. Although public health care has to deal with the consequences of obesity, the possibilities for obesity treatment are few. The pedagogical structure of our out-patient lifestyle program was to motivate the participants to make stepwise improvements in eating patterns and physical activity, which are unlikely to be maintained (31). The participants were encouraged to keep their new habits in a long term, and learning maintenance strategies was a part of the program. The initial weight loss was maintained during the first year, as long as the follow-up visits were held every 6 weeks, but during the second year a slight body weight regain was observed. This effect has been shown in other obesity treatments (16, 20, 21, 32). An optimal structure and pedagogic model for long term weight stability is not yet defined and further development in this area is needed.

The group plays an important role as social support, which is correlated to weight maintenance (31). Our

experience is that group treatment is not only cost cutting and time-saving compared with individual counselling, but often creates a base for recognition and support. Here, the group discussion was used as a pedagogical tool. For instance, it may be good for a participant to get feedback from group members, in addition to feedback from health care professionals. When a group is well functional, friendship and security are created. Our clinical experience is that a well-functioning and intact group throughout the whole program improves results. This, however, has not been formally evaluated. Further, such groups tend to continue to work after the 2-year program without support from the clinic, according to reports from individual patients.

The dropout frequency in our 2-year lifestyle intervention program was 33%, which is comparable to other long-term obesity treatment (20, 21, 33). For instance, the Gustaf-study had a dropout of 34% (21), the XENDOS-study 37% (20), and the study by Melin et al. of 53% (33) after 2 years. Dropout rates also differ between studies due to differences in study designs, but are obviously possible to keep at the same level in a clinical setting used in the present study.

In summary, our 2-year lifestyle obesity program for out-patient clinic patients could be considered well performing and the treatment effect was as good as in other lifestyle intervention programs and in randomised controlled studies. Weight loss and reduced central obesity improved metabolic risk factors after 2 years of treatment, making it probable that the conclusions drawn in randomised controlled studies, that type 2 diabetes and related complications may be prevented or postponed (15, 16, 23, 24), also apply to a 2-year lifestyle intervention program such as the program presented here. It would be realistic to implement such a lifestyle intervention program in primary health care. However, further research is needed on the long-term effects.

SAD has been suggested to be the most useful and simple tool to identify insulin resistance and is easily implemented in the clinic. Studies to compare waist circumference measurements and SAD for measuring central obesity in a clinical setting are warranted.

Conflict of interest and funding

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