Science Journal of Medicine and Clinical Trials
ISSN:2276-7487
http://www.sjpub.org/sjmct.html

Published By
Science Journal Publication
International Open Access Publisher

Research Article **Volume 2014, Article ID sjmct-206, 6 Pages, 2014. doi: 10.7237/sjmct/206**

MAINTENANCE OF WAIST CIRCUMFERENCE REDUCTION AFTER A NUTRITIONAL INTERVENTION: A 22-MONTH FOLLOW-UP

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Accepted 5th March, 2014

ABSTRACT

Aim: The objective of this study extension was to determine if the reduction in waist circumference previously achieved in 6 months, in order to normalise cardiometabolic risk, could be maintained beyond 12 additional months.
Method: Patients who had participated previously in a nutritional intervention including a medical nutrition product (Stablor®) were followed for at least 12 months after suspension of this nutritional care.
Result: The 29 participants maintained an average reduction of 4.2% in waist circumference 22 months on the average after the initial assessment.
Conclusion: A reduction in waist circumference achieved due to a nutritional intervention combining a medical nutrition product and calorie restriction is sustainable more than one year after the end of this intervention and remains below the threshold of cardiometabolic risk for the vast majority of patients.

KEYWORDS: waist circumference, nutritional intervention, diet, visceral fat, cardiometabolic risk, metabolic syndrome, weight maintenance, glycaemia

INTRODUCTION

According to the World Health Organisation (WHO), 1.4 billion adults worldwide are overweight, including over 500 million who are obese [1]. Excess weight exposes individuals to numerous co-morbidities, including type 2 diabetes and coronary disease; obese individuals, furthermore, have an increased mortality rate [2, 3].

Fat mass distribution plays a key role in the onset of co-morbidities and the accumulation of visceral fat, which can be routinely determined by a simple waist circumference measurement, and is an independent predictor of cardiometabolic risk [4-6].

Even a modest reduction in waist circumference contributes to a significant improvement in the risk profile of cardiovascular diseases and type 2 diabetes in patients presenting with the metabolic syndrome or obese individuals [7-14].
Therefore, it is essential that weight loss be focused on a clinically relevant loss of visceral fat, i.e. on bringing the waist circumference below the recommended threshold, or reducing it by approximately 10%.

However, it is common for patients to regain about 40% of their weight over the year following the diet, thus minimising the benefits of the initial weight loss [15-17].

Therefore, the success of the weight loss protocol can only be confirmed if the reduction in waist circumference is sustainable and weight remains stable, due particularly to the changes in lifestyle brought about by this treatment.

Research Aims

The purpose of this study extension is to verify that a reduction in waist circumference achieved by means of an appropriate nutritional intervention is sustainable for at least 12 months. A concomitant stabilisation of risk factors is expected.

MATERIALS AND METHODS

Patient selection criteria

Patients with the metabolic syndrome who have participated previously in a programme of nutritional intervention with Stablor®, and with an objective of a 10% reduction in waist circumference or a return to normal waist circumference, were followed at their discretion for at least 12 months after termination of initial nutritional care [18].
1
Stablor®: Nutritional composition: 15% carbohydrates, 15% lipids, 70% protein. Composition: whey protein concentrate, isolate and hydrolysate (emulsifier: soya lecithin); milk protein in calcium caseinate form; amino acids: L-glutamine, L-leucine, L-arginine, taurine, L-tryptophan; minerals: milk minerals and lactose, magnesium citrate, potassium phosphate, zinc gluconate, chromium chloride; fructooligosaccharides; maltodextrins; flavours; flax flour; wheat flour; thickeners: guar gum, carrageenans; acidity regulator: citric acid; salt; sweeteners:

How to Cite this Article: Dr. Bruno Ranson, M.d., "Maintenance of Waist Circumference Reduction after A Nutritional Intervention: A 22-month Follow-up", Science Journal of Medicine and Clinical Trials, Volume 2014, Article ID sjmct-206, 6 Pages, 2014. doi: 10.7237/sjmct/206

potassium acesulfame, sucralose; vitamins: D, B6, B9, E; colour: riboflavin; natural rosemary extract.

Study programme

Patients were monitored during outpatient nutrition consultations. All patients had followed the first part of the study that consisted of intensive nutritional care, including a balanced diet (50% carbohydrates, 35% lipids, 15% proteins; carbohydrates with glycaemic load less than 10), low-calorie (700 kcal restriction on base metabolism, accompanied by a whey-based medical nutrition product taken twice daily (Stablor®) and contributing 360 kcal to the daily ration. Patients were called in for a new assessment about 16 months after this weight loss phase, which had an average duration of 6 months. In the interval, patients were not following any particular treatment, but were encouraged to maintain a balanced diet without calorie restriction, and moderate physical activity equivalent to 5,000 steps per week. (Table 1).

RESULTS

Description of the Population

In total, 29 (45%) of the 64 patients who had participated in the initial study consisting of intensive nutritional care were included in the study extension. The characteristics of the population included for intensive nutritional care are described in Table 2. It should be noted that patients who participated in the study extension differed from those who completed the intensive phase by their smaller waist circumference (92.6 cm versus 94.2 cm) and a lower BMI in men, with a difference of over one point.

Effects on waist circumference

Amongst the 29 patients who took part in this follow-up, the vast majority (27/29) maintained their waist circumference below the initial level. The average decrease of waist circumference over the entire 22-month follow-up period was 4 cm (4.2%); one-third of patients (9/29) maintained a 5% decrease in waist circumference. (Figure 1).

Secondary outcome measures

Weight loss (Table 3): weight loss was on the same order of magnitude as waist circumference reduction, i.e. 4.9 kg. This loss was mainly due to a reduction of fat mass (4.2 kg).

Blood pressure: this parameter remained within normal standards in one-half of 14 hypertensive subjects at inclusion, more than one year after the weight loss phase, in spite of a slight increase in systolic blood pressure.

Biological parameters: all evolved favourably.

Blood glucose profile: The fasting blood glucose levels of 9 out of 11 hyperglycaemic and non-diabetic patients remained within normal standards at the end of the study extension. None of the 16 normoglycaemic patients developed impaired fasting glucose (IFG).

Inflammation markers: the 5 patients with non-standard CRPus levels at inclusion that had returned to normal values at the end of the weight loss phase remained within normal standards after the follow-up months.

Lipid profile: no patient developed lipid abnormalities

Tolerance

No adverse events were spontaneously reported. During follow-up visits, patients were questioned about the onset of adverse event since their last visit.

DISCUSSION

A balanced low-calorie diet, supplemented twice daily with Stablor® resulted in a reduction in waist circumference of nearly 10% after 6 weeks on average. This reduction in waist circumference was associated with a weight loss due mainly to a loss of fat mass and a favourable evolution of the cardiometabolic risk profile [18].

Sixteen (16) months later, the vast majority of patients maintained a sharply diminished waist circumference and weight compared to initial values; most of the weight loss was due to a loss of fat mass. No worsening of, and even improvement, in their biological parameters was noted.

Over nearly 2 years of follow-up, weight loss was almost exclusively due to loss of fat mass, which may explain the concomitant results for biological parameters and particularly for blood glucose, inflammatory markers, and high blood pressure.

Stablor® appears, in fact, to have had a particularly notable effect on the blood glucose profile, CRPus and blood pressure. The long-term maintenance phase also showed that no patient developed IFG and that two-thirds of hyperglycaemic or diabetic patients at inclusion were standardised at the end of follow-up. In spite of a slight increase in systolic blood pressure after stopping Stablor®, one-half of hypertensive patients at inclusion remained within normal standards at the end of the extension phase.

Fourteen (14) additional patients received comparable nutritional care including Stablor® for 6 months and follow-up for at least 12 months. An analysis grouping initial patients (29) and additional patients (14) showed the same evolution as the first patient group, i.e. a sustainable decrease in waist circumference (Figure 2) and loss of weight, due mainly to a loss of fat mass at 20 months on average. A similar evolution of biological parameters with an effect on the blood glucose and inflammatory profiles more than one year after stopping the weight loss phase was observed: once again, no worsening was noted and the majority of patients returned to normoglycaemia.

Annual visits providing a follow-up for a total of 5 years are planned. This follow-up will show the evolution of waist circumference and risk factors, even if only complete epidemiological studies are able to estimate the effect of nutritional care with Stablor® and the resulting changes in lifestyle, for the improvement of risk factors or for the onset of diseases such as diabetes.

CONCLUSION

This open study shows that a reduction in waist circumference achieved due to a nutritional intervention

combining a medical nutrition product and calorie restriction is sustainable more than one year after the end of the intervention. The residual effect of this reduction in waist circumference 16 months on average after stopping nutritional care can be observed in all cardiometabolic risk factors.

As no normoglycaemic patient at inclusion developed fasting hyperglycaemia almost two years after the start of the study, and as the majority of patients who were initially hyperglycaemic remain standardised, this study warrants further exploration of preventive care of pre-diabetic patients with Stablor®.

This study also shows the sensitivity of high blood pressure with reduction in waist circumference under Stablor® and also with the recovery of this waist circumference.

Additional randomised and controlled studies on large numbers of subjects should specify the specific role of Stablor® in the control of inflammation factors and the blood glucose profile, and even its impact on the prevention of diabetes or glucose intolerance. Furthermore, current investigation of the effects of whey bioactive peptides could be used to better characterise the action of Stablor®.

Abbreviations

BMI	Body Mass Index
BMR	Basal Metabolic rate
CRPus	Ultra-sensitive C-reactive Protein
HDL	High-Density Lipoprotein
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
LDL	Low-Density Lipoprotein
SD	Standard deviation

Acknowledgment

This study was entirely funded by Laboratoires Nutrition et Cardiométabolisme (Bordeaux, France), a Research and Development company, owner of Stablor® patent.

Statement of Competing Interests

The author has no competing interests.

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FIGURES AND TABLES

Fig 1. Changes to waist circumference during the study (N=29)

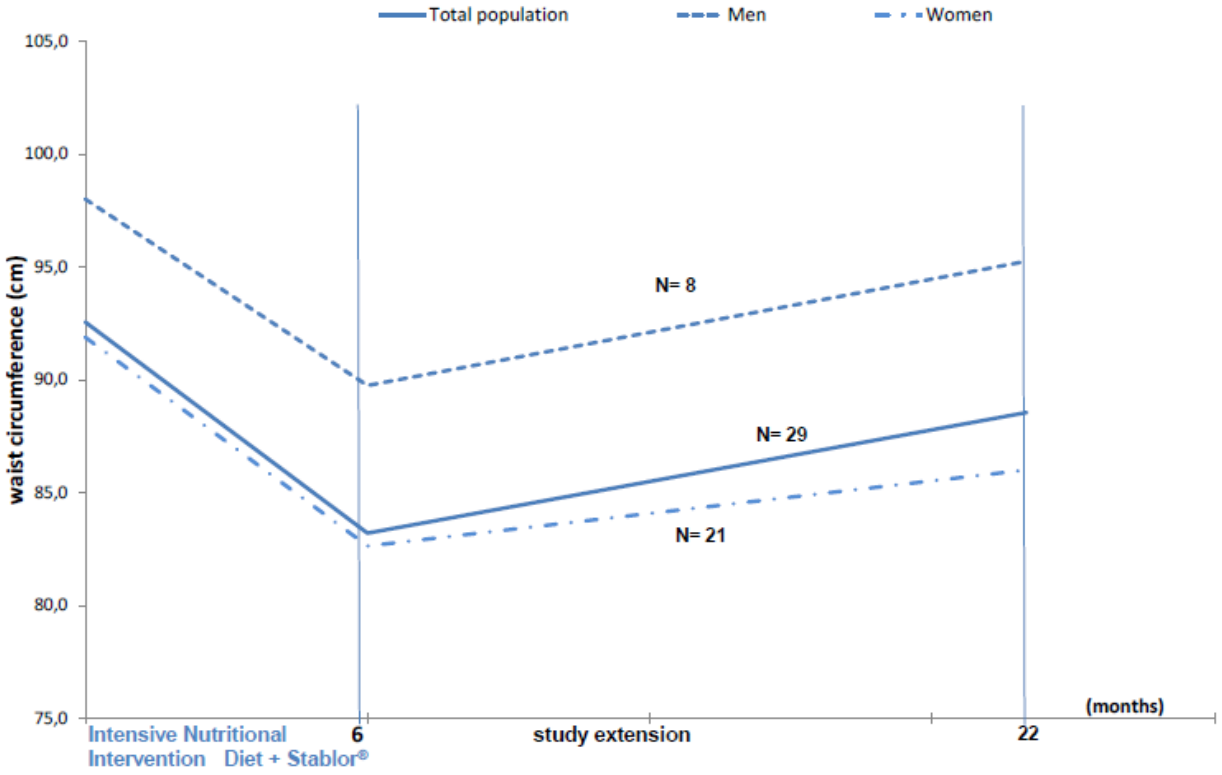

Figure 2. Changes to waist circumference (pooled analysis grouping initial (29) and additional patients (14) - N=43)

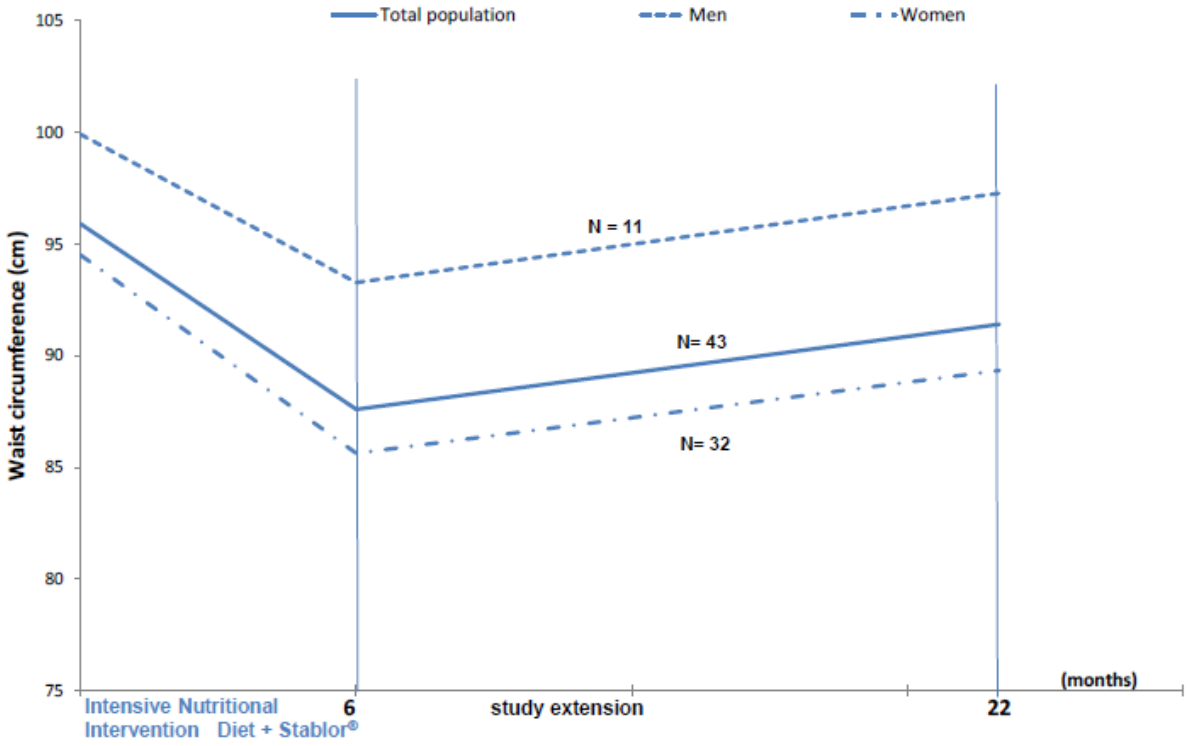

Table 1. Study assessments

	Initial visit	**Start of study extension / End of the intensive nutritional intervention phase**	**End of the Study extension**
Informed consent signed	x	x	
Motivations, weight loss history, smoking, current medication, family history of cardiovascular events, height	x		
Clinical examination, weight, waist circumference, BMI	x	x	x
Lean mass, fat mass (impedance measurement)	x	x	x
Diastolic and systolic blood pressure	x	x	x
Biological profile: - Inflammation and coagulation markers: CRPus; fibrinogen - Lipid profile: triglycerides, total cholesterol, HDL cholesterol and calculated LDL cholesterol -Glycaemic profile: fasting blood glucose	x	x	x
Adverse events collection	x	x	

Table 2. Baseline characteristics of patients who participated in the study extension (N=29) and patients who completed the initial intensive nutritional phase

	Patients who participated in the study extension (mean ± SD, or number of patients) N=29		**Patients who completed the initial intensive nutritional phase (mean ± SD, or number of patients) N=64**	
	Men	**Women**	**Men**	**Women**
	8	21	15	49
Mean age (years)	58.6±8.2	55.5 ± 8.4	53.7±11.1	53.0 ±11.0
Waist circumference (cm)	98.0±5.4	90.5±10.8	101.9±7.3	91.9±10.2
Height (cm)	177.3±4.3	163.1± 6.6	177.8±4.9	163.6±6.1
Weight (kg)	87.4±4.0	73.0±13.2	92.3±8.6	74.3±11.5
BMI (kg/m^2)	27.8±1.4	27.6±6.1	29.2±2.6	27.8±4.9
with BMI<25 with BMI>25 *including obese subjects ((BMI> 30)*	0 8 1	7 14 3	0 15 4	13 36 11
BMR, basal metabolism rate (kcal)	1719±163	1349±102	1745±272	1367±110
Co-morbidities *Diabetes* *Sleep apnoea*	 1 0	 1 0	 1 0	 2 1
Concomitant treatment: *Central antihypertensive* *Diuretic* *Oral antidiabetic*	 1 0 1	 3 0 1	 2 1 1	 4 0 2
Smokers	0	1	1	2
Family history	4	7	8	18
Previous diet	1	16	1	39

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Table 3. Results for the 29 patients who participated to study extension

	Initial value (mean ± SD	Final value	Change (mean ± SD)	% change
Waist circumference (cm)	92.6±10.1	88.6±9.8	-4.0±4.7	-4.2
Weight (kg)	77.0±13.1	72.1±13.1	-4.9±4.3	-6.4
BMI (kg/m^2)	27.7±5.2	25.9±5.0	-1.8±1.6	-6.4
Fat mass (kg)	26.4±8.0	22.3±7.5	-4.2±3.6	-16.1
Lean mass (kg)	50.6± 9.8	49.8 ±9.8	-0.8 ±2.5	-1.4
Fat mass (%)	34.3± 6.5	30.7± 6.9	-3.6±3.3	-10.5
Systolic blood pressure (mmHg)	128.3±15.5	130.7±9.4	2.4±16.2	3·0
Diastolic BP (mmHg)	80.0±10.0	70.1±6.2	-9.9±11.1	-11.2
T. Cholesterol (mmol/l)	5.80±0.87	5.58±0.77	-0.22±0.29	-3.5
HDL (mmol/l)	1.54±0.45	1.52±0.44	-0.02±0.11	-0.3
LDL (mmol/l)	3.71±0.76	3.61±0.75	-0.10±0.35	-2.3
Triglycerides (mmol/l)	1.28±1.35	1.11±0.52	-0.18±0.88	-1.4
Blood glucose (mmol/l)	6.10±3.84	5.37±0.61	-0.73±3.72	-1.6
CRPus (mg/l)	1.85±2.06	1.16±0.80	-0.69±1.58	-5.4
Fibrinogen (g/l)	3.53±0.78	3.11±0.53	-0.42±0.58	-10

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