

Pilot Studies on the Efficacy of a Diet Program on Body Weight in Overweight and Obese South Africans

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Background

Over the course of several years the Medical Nutritional Institute (MNI) based in Johannesburg South Africa developed a weight loss program to help combat obesity and weight related conditions. The program included a lifestyle change plan, meal plan and dietary supplement labeled as Antagolin.

Five studies were conducted in South Africa, in Cape Town and Johannesburg during 2009-2014 (Figure 1). The studies are referred to by the names SANLAM, ABSA, SAMANCOR, X-STRATA, and LIGHTHOUSE.

NaturPro Scientific LLC reviewed all study data provided and evaluated the apparent integrity and completeness of the data, and conducted statistical analysis, and wrote the reports. Data for each study was analyzed independently and then in a pooled analysis that combined study data of the same duration (12 or 25-27 weeks). All data from subjects completing the study were analyzed based on changes in endpoints from baseline using means, standard deviation and single-factor ANOVA (Microsoft Excel).

Methods

Participants for these studies were recruited through their employer as part of a wellness initiative. With the exception of ABSA which was 12 weeks only, all studies were designed as 12-weeks in duration, with the option given to subjects to continue the study for an additional 13 weeks.

The study subjects participated in one of two treatment groups: the Complete Program, or the Program without the dietary supplement, which was named the "Control Program".

South Africa Study Summary				
Study	Length	Subjects (N)	Treatment	Year
	Weeks			
SANLAM (12 wks)	12	17	Complete Program	2009
	12	4	Control-Program Only	
SANLAM (Ext 25 wks)	25	17	Complete Program	
	25	4	Control-Program Only	
SANLAM (Ext 61 wks)	61	(subset of 8 obese)	Complete Program	
SANLAM (Ext 102 wks)	102	(subset of 6 obese)	Complete Program	
ABSA	12	13	Complete Program	2010
	12	5	Control-Program Only	
SAMANCOR	12	14	Complete Program	2011
	12	6	Control-Program Only	
SAMANCOR (Ext 27 wks)	27	(subset of 10)	Complete Program	
X-STRATA	12	22	Control-Program Only	2012
	29	22	Control-Program Only	
LIGHTHOUSE	12	10	Complete Program	2014
	16	10	Complete Program	
Pooled 12 Week	12	54	Complete Program	
Results	12	37	Control-Program Only	
Pooled 25 Week	25-27	27	Complete Program	
Results	25-29	26	Control-Program Only	

Figure 1. Summary of Number of Subjects and Length of Studies.

Intervention

The Program portion of the system included tools for achieving a healthy lifestyle which included an eating plan based on portion control and caloric restriction, behavior modification guidance in the form of booklets that included a self-assessment and an exercise guide promoting strength and circuit training exercise to support cardiovascular and muscle maintenance and development.

The supplement contained a blend of plant-derived ingredients and minerals consisting of banaba leaf, barberry bark extract, inositol, and chromium. Recommended dosage was 2 capsules twice a day.

The Program including the supplement was termed the “Complete Program”, and the Program without the supplement was named the “Control Program”.

Inclusion and exclusion criteria

Adults older than 20 years old, with a body mass index $>25 \text{ kg/m}^2$ were included in all studies. Subjects were required to be healthy, pre-diabetic or diabetic people measured as overweight or obese. Excluded were pregnant or lactating subjects, and individuals with known allergies to the dietary supplement or any of its ingredients, determined by questionnaire. Subjects were instructed to continue to take all medications that they were prescribed before entering the study. Any subsequent changes in medication were made under supervision of the subjects’ personal physicians.

Study endpoints

In all studies, food and exercise logs were recorded by subjects daily, and clinical and anthropometric measurements such as vital signs and body weight were measured by full time staff members of the company conducting the trial. Each had a recognized medical qualification, including registered nurses, a dietician, a biokineticist and a pharmacist.

Compliance and Follow-up

Compliance was based on level of adherence to diet, supplementation and exercise recommendations as well as appearance for study visits. A minimum average compliance of 50% per subject was required for inclusion in the data analysis. After 26 weeks, obese subjects were invited to continue on the program for an additional 26 weeks.

Ethical Requirements

For all studies conducted, informed consent was given by all subjects. Study subjects were not compensated for participation.

Results

Overall, 54 subjects completed 12 weeks on the Complete Program, and 27 subjects continued for 25-27 weeks (See Figure 2). 37 subjects on the control program completed 12 weeks, and 26 subjects on the control program completed 25-29 weeks. Of eight dropouts, none were due to study- or treatment-related issues. Figure 13 below provides the reasons for all dropouts.

South Africa Study Summary						
Study	Length Weeks	Subjects (N)	Treatment	Weight Loss (lb)	Weekly Loss (lb)	Waist Loss (inches)
SANLAM (12 wks)	12	17	Complete Program	32.1	2.7	*
	12	4	Control-Program Only	8.9	0.7	*
SANLAM (Ext 25 wks)	25	17	Complete Program	53.4	2.1	6.8
	25	4	Control-Program Only	9.5	0.4	6.3
SANLAM (Ext 61 wks)	61	(subset of 8 obese)	Complete Program	62.0	1.0	10.4
SANLAM (Ext 102 wks)	102	(subset of 6 obese)	Complete Program	83.8	0.8	12.1
ABSA	12	13	Complete Program	16.7	1.4	3.8
	12	5	Control-Program Only	7.7	0.6	0.7
SAMANCOR	12	14	Complete Program	20.5	1.7	2.2
	12	6	Control-Program Only	5.5	0.5	2.2
SAMANCOR (Ext 27 wks)	27	(subset of 10)	Complete Program	32.6	1.2	4.7
X-STRATA	12	22	Control-Program Only	6.7	0.6	*
	29	22	Control-Program Only	10.4	0.4	2.7
LIGHTHOUSE	12	10	Complete Program	9.0	0.8	*
	16	10	Complete Program	21.6	1.4	5.0
Pooled 12 Week Results	12	54	Complete Program	24.0	2.0	*
	12	37	Control-Program Only	8.1	0.7	*
Pooled 25 Week Results	25-27	27	Complete Program	44.9	1.7	6.8
	25-29	26	Control-Program Only	8.9	0.3	3.4
						* not measured

Figure 2. Average Study Results in Individual Studies and in Pooled Results.

SANLAM Study

In the SANLAM study, an average of 32.1 and 53.4 pounds were lost after 12 and 26 weeks, respectively, in those subjects using the Complete Program (Figure 3).

SANLAM (n=17)	Baseline	12 weeks	26 weeks
Weight (lb)	270.9	238.8	217.4
p-value		0.08	0.0041

Figure 3. Average body weight for subjects in the SANLAM study on the Complete Program.

A subset of 8 obese subjects in SANLAM who began the study weighing more than 240 pounds and who completed the initial 25 weeks continued the Complete Program for an additional 36 weeks (61 weeks total) experienced an average weight loss of 62 pounds (Figure 2). The difference from baseline trended to significance ($p < 0.059$). Six of these subjects continued for an additional 41 weeks (102 weeks total), and this group experienced an average weight loss of 83 pounds ($p = 0.03$).

Subject	Baseline	1 year	Change (lbs)
A	426	354	-72
B	252	209	-43
C	242	176	-65
D	315	252	-63
E	255	176	-79
F	321	255	-67
G	251	224	-27
H	267	184	-83
AVG	291	229	-62

Figure 4. SANLAM results in obese subjects using the Complete Program. A trend for significant reduction in body weight (lb) ($p=0.059$) was observed for 8 obese subjects in SANLAM (arbitrarily coded A-H) who continued on the trial for more than one year (61 weeks).

ABSA Study

Thirteen subjects on the Complete Program entered and completed the 12-week ABSA study. An average reduction in weight of 16.7 pounds was observed, although this result was not significant ($p=0.46$).

ABSA (n=13)	Baseline	12 weeks
Weight (lb)	229.0	212.3
p-value		0.46

Figure 5. Average body weight from ABSA in subjects on the Complete Program.

A subset of four subjects in the ABSA study on the Complete Program continued for 43 weeks. An average weight loss of 36.6 lb was observed in these subjects, and the result was significant despite the small sample size ($p=0.05$).

ABSA (n=4)	Baseline	43 weeks
Weight (lb)	186.1	149.5
p-value		0.05

Figure 6. Average body weight from ABSA for subjects continuing on the study for 43 weeks.

SAMANCOR Study

In the SAMANCOR study, 14 subjects using the Complete Program lost an average of 20.5 pounds, a result that was not significant due to the small sample size.

SAMANCOR (n=14)	Baseline	12 weeks
Weight (lb)	239.4	218.9
p-value		0.20

Figure 7. Average body weight from SAMANCOR in subjects on the Complete Program.

A subset of ten subjects using the Complete Program continued for 27 weeks in the SAMANCOR study, resulting in an average weight loss of 32.6 pounds, a significant result ($p=0.001$).

SAMANCOR (n=10)	Baseline	27 weeks
Weight (lb)	229.7	197.1
p-value		0.001

Figure 8. Average body weight from SAMANCOR for subjects using the Complete Program.

Lighthouse Study

In the LIGHTHOUSE study, an average of 19.9 pounds were lost over 12 weeks, a result which was not significant ($p=0.38$).

LIGHTHOUSE (n=10)	Baseline	12 weeks
Weight (lb)	223.8	203.9
p-value		0.38

Figure 9. Average body weight from LIGHTHOUSE for subjects using the Complete Program.

Pooled Results

A pooled analysis was conducted on studies with the same durations and study design in order to understand overall population effects. Pooled subjects completing 12 weeks on the Complete Program lost an average of 24.0 pounds, an effect which was significant from baseline (p=0.02). Subjects completing 25weeks on the Complete Program lost an average of 44.9 pounds, which was also significant (p=0.0004).

Study	Subjects (N)	Treatment	Length Weeks	Weight Loss (lb)	Weekly Loss (lb)	Waist Loss (inches)
Pooled	54	Complete GOLO Program	12	24.0	2.0	*
Pooled	37	Control-Program Only	12	8.1	0.7	*
Pooled	27	Complete GOLO Program	25-27	44.9	1.7	6.8
Pooled	26	Control-Program Only	25-29	8.9	0.3	3.4

Figure 10. Pooled results of average body weight for subjects completing 12- and 25-week studies. (*not measured).

The changes in body weight for control subjects pooled across the 12- and 25-week studies were similar to those previously published on other widely available diet programs. Although subjects in the control group lost an average of 8.1 and 8.9 pounds over 12 and 25 weeks, respectively, the effect was not significant (p>0.05).

Below, individual pooled 12-week data is shown.

Complete Program	
Pooled 12-weeks	
Weight (lb)	
Baseline	12 weeks
255.3	211.2
245.6	195.8
267.2	224.2
252.0	218.5
321.2	280.2
201.1	173.9
425.9	369.3
270.3	243.2
241.6	218.9
245.1	219.8
240.5	222.2
360.9	282.4
251.3	232.8
315.3	284.8
239.9	221.3
208.3	176.4

263.0	239.4
203.0	186.5
240.1	210.5
214.1	197.2
242.5	220.3
253.1	218.7
199.5	191.8
255.3	237.9
254.9	229.7
227.7	204.4
207.0	181.0
197.1	179.7
249.1	227.5
368.2	339.5
240.3	238.3
249.1	228.6
205.8	184.3
295.9	263.0
219.6	203.5
175.0	154.2
228.0	208.6
303.8	294.3
165.8	147.3
233.7	210.1
160.2	145.1
212.1	189.2
173.1	150.4
177.0	158.3
257.3	244.5
200.6	189.8
297.6	282.2
197.1	183.0
140.4	130.3
297.4	292.3
280.9	245.8
181.9	153.4
249.8	230.6
311.3	309.5
243.9	219.9
	Average

Figure 11. Individual results for average body weight for subjects on the Complete GOLO Program, pooled for subjects completing 12 weeks.

Below, individual pooled 25-week data is shown.

Complete Program	
Pooled 25-weeks	
Weight (lb)	
Baseline	25 weeks
203.0	188.3
227.7	197.1
240.1	196.1
214.1	186.3
253.1	207.2
242.5	202.8
199.5	184.1
255.3	228.0
254.9	222.7
207.0	179.7
360.9	229.5
255.3	178.8
245.6	172.6
267.2	189.8
252.0	200.2
321.2	255.5
201.1	160.3
425.9	341.9
270.3	224.9
239.9	201.1
241.6	205.9
251.3	216.0
208.3	181.7
315.3	275.1
245.1	216.0
240.5	212.5
263.0	235.0
255.6	210.7
	Average

Figure 12. Individual results for average body weight for subjects on the Complete Program, pooled for subjects completing 25 weeks.

Study	Duration (weeks)	Weight (lb)		Reason cited
		Baseline	End	
SANLAM	14	259.9	257.5	became pregnant
ABSA	4	151.5	149.5	work stress; failed to attend visits
ABSA	8	179.7	172.4	work stress; failed to attend visits
SAMANCOR	8	210.1	203.3	alcoholism
SAMANCOR	4	419.8	399.3	Work stress
X-STRATA	0	305.1	NA	failed to attend visits
X-STRATA	4	219.1	207.5	lost interest
X-STRATA	8	331.8	289.0	employment change

Figure 13. Weights for subjects withdrawing from the studies, and reason for withdrawal.