

# Effectiveness of the LOVIDIA Way, a Combination of Lovidia Hunger Control Formula taken daily with Intermittent Calorie Restriction for Weight Management and Metabolic Health

Kim Chen, PhD, John Pullman, MD, FACP, Timothy Bailey, MD, CPI, Ken Fujioka, MD, Mark Tager, MD, Martin Brown, MBA  
Ambra BioScience LLC, 11975 El Camino Real, Suite 305, San Diego, CA 92130

## ABSTRACT

### BACKGROUND AND PURPOSE:

Previous clinical studies have shown that ingredients in Lovidia®Hunger Control Formula (Lovidia) delivered to the lower gut could augment the release of the satiety hormones PYY and GLP-1 following a meal. A subsequent randomized, double blind, placebo-controlled clinical study with 220-subjects established that Lovidia significantly reduced hunger.

### AIM

This study assessed the effectiveness of the LOVIDIA Way, a lifestyle approach to weight management and improved metabolic health, which involves Lovidia, taken daily, in combination with intermittent calorie restriction.

### SUBJECTS AND METHODS:

The 52 volunteers who enrolled in this study were randomly assigned to either 1 Lovidia tablet daily (QD) or 1 tablet twice daily (BID) and instructed to restrict daily caloric intake to 500 calories for 3 non-consecutive days each week for 13 weeks. Subjects visited their clinical trial site for enrollment, mid study (week 6) and end of study (week 13) visit assessments in addition to once-weekly telephone calls with a clinical trial research pharmacist (CTRP) to report self measured body weight, and adherence to Lovidia use and calorie restriction days (CRDs). Forty four subjects completed the mid study clinic visit and 38 completed all 13 weeks of study.

### RESULTS:

Compliance was high for both Lovidia use (> 98% overall), and for CRDs (>80% overall). CRD compliance was slightly higher in the BID group (85.1%) than in the QD group (80.6%). After 6 weeks, clinic measurements of body weight averaged 3.9% lower and waist circumference was 4.2% less than at baseline. After 13 weeks, body weight averaged 6.3% lower and waist circumference averaged 6.5% less. In addition, the following results were achieved after 13 weeks:

- Mean arterial pressure dropped 5.1% ( $p=0.01$ ) in subjects with elevated blood pressure ( $\geq 120/80$  mmHg) and 7.5% ( $p=0.02$ ) in subjects with hypertension ( $\geq 140/90$  mmHg) at enrollment.
- HbA1c was lowered from an average of 5.69% at baseline to 5.38% ( $p<0.0001$ )
- Total cholesterol, LDL cholesterol, non-HDL cholesterol and triglycerides were decreased by 9.1 mg/dL ( $p=0.08$ ), 7.0 mg/dL ( $p=0.01$ ), 10.6 mg/dL ( $p=0.02$ ), and 19.7 mg/dL ( $p=0.04$ ), respectively.
- HDL cholesterol increased in subjects with baseline values of 40-50 mg/dL by 1.9 mg/dL ( $p=0.04$ ) and in those with baseline values of <40mg/dL, HDL increased by 6.3 mg/dL ( $p=0.018$ ).

### CONCLUSIONS:

This study demonstrates that the LOVIDIA Way - daily use of Lovidia Hunger Control Formula in conjunction with calorie restriction 3 days per week - is an effective method to reduce body weight, reduce blood pressure, improve glucose control and improve blood lipids.



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## METHODS

This study was conducted at 2 IRB approved clinical sites. The 52 enrolled subjects were randomly assigned into 2 groups – a one tablet daily (QD) group, and a one tablet twice daily (BID) group. There were 3 clinical site visits: a baseline visit at enrollment, a mid-study visit after 6 weeks and an end of study visit after 13 weeks. Vital signs, waist measurement, and a blood draw for lipids, glucose, and HbA1c measurements were taken at the baseline and terminal visits and weight and waist circumference were measured during the mid-study visit. Subjects were instructed to take Lovidia every day (either QD or BID) and to restrict daily calorie intake to no more than 500 calories on 3 non-consecutive days each week. There were no calorie restrictions for the other 4 days of the week. Subjects were contacted weekly by a clinical trial research pharmacist to collect self-measured body weight, information on Lovidia use and calorie restriction compliance over the previous week and to answer any questions the subjects may have had.

## DEMOGRAPHICS

Of the 52 subjects randomized, 44 completed the 6 week clinic visit and 38 subjects completed the 13 week study visit per protocol. The participants were predominantly female and white; with an average weight and age of approximately 213lbs and 48yrs, respectively, at enrollment.

	Enrolled (n=52)	13 week Completers	
		QD (n=19)	BID (n=19)
<b>Male (%)</b>	23.1	31.6	15.8
<b>Female (%)</b>	76.9	68.4	84.2
<b>White (%)</b>	92.3	100	89.5
<b>Others (%)</b>	7.7	0	10.5
<b>Age (y)</b>	48.0	50.5	52.5
<b>Weight (lbs)</b>	213.1	193.5	228.2
<b>BMI</b>	35.2	31.5	38.0

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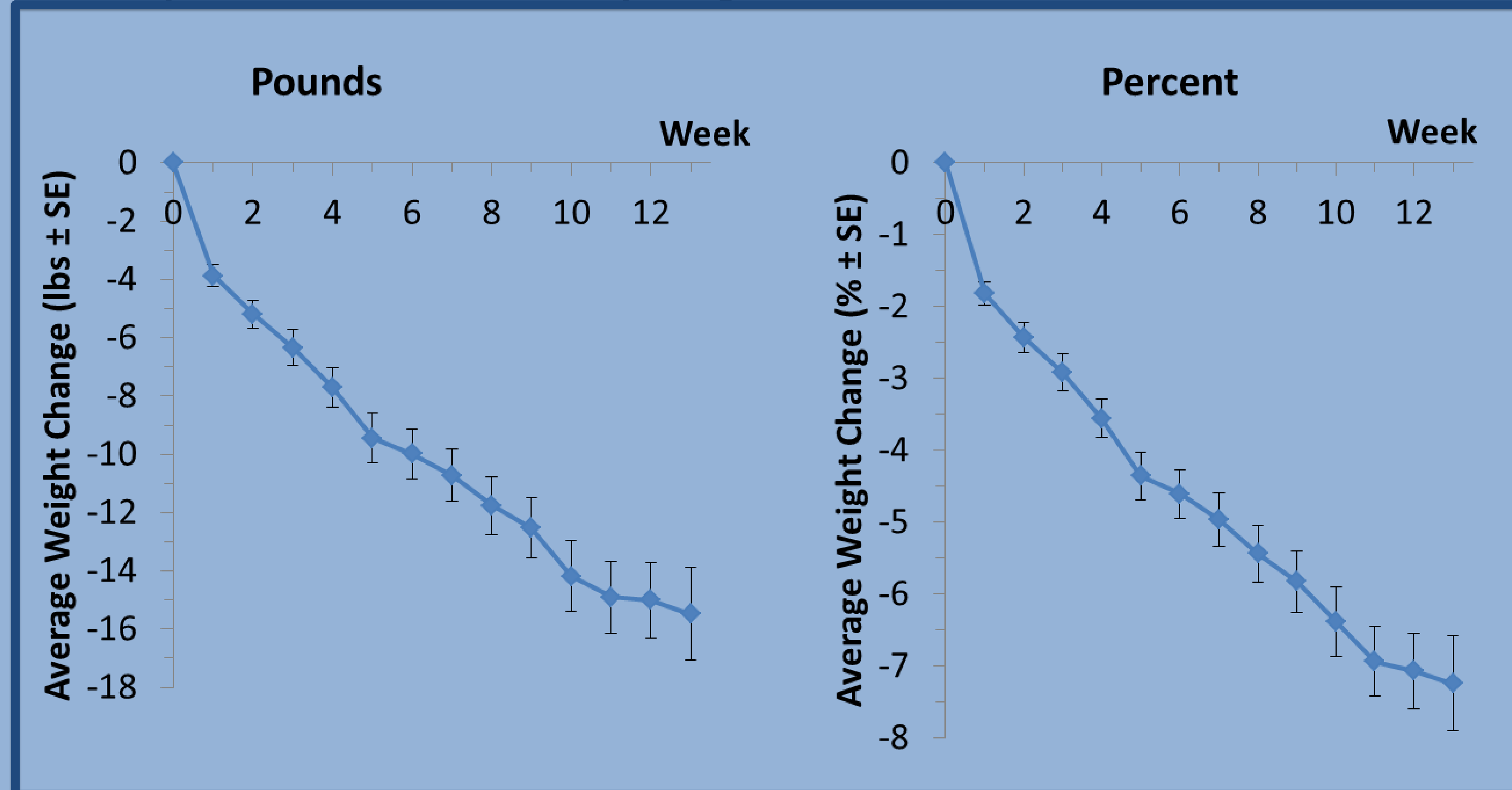
## RESULTS

### BODY WEIGHT AND WAIST REDUCTION

#### Clinic Measured Results

			Average (lbs/inches)	(%)	P value
Body Weight	6 Week Completers n=44	Baseline	213.5		
		Change	-8.5	-3.9	< 0.0001
	13 Week Completers n=38	Baseline	210.8		
		Change	-13.6	-6.3	< 0.0001
Waist Circumference	6 Week Completers n=44	Baseline	41.0		
		Change	-1.8	-4.2	< 0.0001
	13 Week Completers n=38	Baseline	40.9		
		Change	-2.7	-6.5	< 0.0001

#### Participant's Self-Measured Body Weights





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## BLOOD PRESSURE LOWERING

Systolic/Diastolic blood pressure	All	Normal < 120/80 mmHg	Elevated ≥ 120/80 mmHg	High ≥ 140/90 mmHg
Average MAP(mmHg)	113.75	106.87	116.21	125.31
Average Change in MAP (mmHg)	-3.87	1.77	-5.88	-9.42
P value	0.05	0.66	0.01	0.02
N	38	10	28	12

## IMPROVED GLUCOSE CONTROL

Baseline HbA1c Category	N	Average HbA1c (%)			P value
		Baseline	Week 13	Difference	
All	38	5.69	5.38	-0.31	< 0.0001
Normal	20	5.395	5.14	-0.26	< 0.0001
Prediabetes	17	5.92	5.64	-0.28	0.003
Diabetes	1	7.6	5.8	-1.8	-

## IMPROVED LIPID PROFILE

### Total/HDL Cholesterol Ratio

Baseline Total/HDL Cholesterol	N	Average Total/HDL Cholesterol		P value
		Baseline	Change at Week 13	
All	38	4.13	-0.357	0.0012
<3.5	14	2.95	-0.129	0.0823
≥ 3.5	24	4.82	-0.492	0.0035

### Triglycerides

Triglycerides (mg/dL)	N	Average Triglycerides (mg/dL)		P value
		Baseline	Change at Week 13	
All	38	143.5	-19.68	0.0418
<150	24	100.1	2.33	0.7481
150 - 199	6	175.3	-27.83	0.2662
>200	8	250.0	-79.63	0.0188
≥ 150	14	218.0	-57.43	0.0084

## CONCLUSION

Daily use of Lovidia Hunger Control Formula in combination with intermittent calorie restriction resulted in significant weight loss and significant improvements in blood pressure, lipids and glucose control.