Activation of the GLP-1 Hormone in a Randomized, Human Clinical Study Using the MindBody GLP-1 System™*Ω

Objective: To evaluate the effects of the MindBody GLP-1 System™ on GLP-1 concentration in blood and associated weight loss using biometric data in a 12-week clinical study.

Sponsor: LifeVantage Corp.

Principal Investigator: Lighthouse Research

Reference: LifeVantage Corp., Lehi, Utah 84043

Introduction

The prevalence of overweight individuals in the US has more than tripled since the 1970s and continues the rise. More than 2 out of 5 adults are classified as overweight by the Center for Disease Control (CDC). In the early 1990s, rates were around 12–15% and by the late 2000s this rate doubled to about 30%. The latest numbers showed that the prevalence of US adults over 20 years of age who are carrying too much weight was 41.9% (2017–2020). During the same time period, the prevalence of severely overweight adults was 9.2%. That means more than 100 million US adults were overweight, and more than 22 million US adults were severely overweight. The significant jump to over 40% reflects a broader lifestyle and environmental change in US adults.

Body Mass Index (BMI) is a measure used to assess body fat, with values over 30 considered overweight and those over 40 classified as severely overweight. We know excess weight is implicated with a range of health complications.

Approaching weight loss by significantly increasing the GLP-1 hormone or attaching to its receptors has become a popular means to lose weight fast. However, most products that increase GLP-1 or that function as GLP-1 agonists come with unwanted gastrointestinal side effects.

MindBody GLP-1 Study

This study set out to investigate if the LifeVantage MindBody GLP-1 System could holistically and sustainably increase GLP-1 hormone concentrations in overweight adults, without unwanted side effects. In a previous *in vitro* study, the MindBody GLP-1 System was seen to increase GLP-1 hormone production by 54% in specialized cells known to produce GLP-1 called L-cells.[§] These encouraging results warranted further investigation into the capabilities of the MB GLP-1 System to increase GLP-1 concentration in overweight subjects.*Ω

METHODS

A total of 60 participants were recruited to participate in a 12-week randomized trial and screened by phone for inclusion/exclusion criteria by a Clinical Research Organization (CRO). The screening consisted of a brief description of the study and its importance and risk factors. This was followed by a screening questionnaire, where eligibility criteria were reviewed and current medication, supplement, and allergy inventory was taken.

After participants were deemed eligible, they were asked to complete an enrollment form and sign a consent form. They were then randomized into one of the following groups:

1. Control (PG) group: no products or educational sessions provided. This was done to obtain a sense of the normalization curve in the population recruited regarding GLP-1 concentration, weight, and other biometrics.

[‡] Results may vary. Typical weight loss using this product in a 12-week weight management program is 1–2 pounds per week. This product should be used in conjunction with a healthy diet and regular exercise. Consult with a healthcare provider before starting any weight loss program.
[§] Results based on a cell culture study on active ingredient blends in the MindBody GLP-1 System.
[*] These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
[Ω] Results based on a randomized 12-week human clinical study.

2. Product Group 1 (CG): received MB Core, MB Enhance, and a commercial protein powder with instructions on how to consume them.
3. Product Group 2 (TG): received MB Core, MB Enhance, a commercial protein powder, and educational information on diet, exercise, and calorie recommendations.

At each study time point (Baseline, Week 4, Week 8, and Week 12), each group had to arrive at the CRO's facility in the morning at a predetermined time between 7–9 AM. All subjects arrived at the testing facility in an overnight fasted state. Blood samples for GLP-1 analysis and fasting glucose were taken, anthropometric/biometric measurements using a Renpho scale were taken, before/after picture were only obtained by both product groups, and subjective questionnaires of their food behavior and cravings were filled in. All subjects were compensated for their participation in the trial.

Anthropometric/biometric measurements
At each time point, each group was asked to step onto a Renpho scale (ES-30M or ES-CS20M model) that was connected to the Renpho Health app via Bluetooth. The scale uses impedance (resistance of electrical flow through the body) to measure biometric parameters. Muscle contains more water than fat and conducts electricity better, which allows the scale to estimate body fat % based on resistance.

The following parameters were measured: weight (lbs. or kgs), BMI (kg/m2), body fat (%), fat-free-mass (lbs.), subcutaneous fat (%), visceral fat, body water (%), skeletal muscle (%), muscle mass (lbs., %), bone mass (lbs., %), protein (%), basal metabolic rate (BMR, kcal), metabolic age (yrs.).
A Renpho tape measure (ES Tape) was also connected via Bluetooth to the Renpho Health app and waist circumferences were measured at each time point.

Before/after pictures
At each time point, subjects in each product group had a picture taken from the side and from the front, in the same location and under the same conditions. Subjects were asked to wear same or similar clothing.

Questionnaires
A questionnaire was given at each time point to each participant. This questionnaire asked about food behavior and cravings between the study time points.*

Blood samples for GLP-1 and fasting glucose levels
Fasting blood samples were obtained by a licensed phlebotomist at each time point for each subject. Specialized tubes were used to collect at least 2 mL of venous blood and transported to a certified lab to analyze for GLP-1 concentration. These BD800 blood collection tubes (Becton Dickenson BD800 tubes contain spray-dried K2EDTA—an anticoagulant that contains DPP-4 and other protease inhibitor cocktails) provide the means to analyze plasma metabolic markers such as glucagon-like peptide-1 (GLP-1).

Blood sample preparation: Samples were centrifuged at 1,000–1,300 rpm using a swing out rotor centrifuge for 10–20 minutes and separated into plasma and red blood cells. Aliquots of plasma were then frozen and stored at ≤70° Celsius until further analyzed. At the end of the study, all samples were thawed and prepared according to manufacturer recommendations. A GLP-1 Active Kit (Mesoscale, K1503OD-2; www.mesoscale.com) was used to analyze for GLP-1 concentrations.

Fasting glucose was measured by a licensed phlebotomist using a commercially available portable blood glucose meter and test strips.

RESULTS

A total of 60 participants were recruited (50% males and 50% females) in this 12-week study. At baseline, ages ranged from 31–78 years (average of 50.2 ± 10.6 years), weight ranged from 154–467 lbs., waist circumferences (in.) ranged from 33.2–67 inches, body fat (%) ranged between 20.7–63.4%, and subcutaneous (%) and visceral fat (lbs.) ranged from 15.4–54.2 % and 7–27 lbs., respectively. Skeletal muscle (%) ranged from 21.2–53.2 %. There were no statistical differences between the groups at baseline, and biometric measurements are summarized in Table 1 below.

Table 1. Baseline Measurements.

Biometrics (Baseline)	Ranges
Weight (lbs.)	154-467 lbs.
Waist circumference (in.)	33.2-67 in.
Body fat %	20.7-63.4%
Subcutaneous fat (%)	15.4-54.2%
Visceral fat (lbs.)	7-27 lbs.
Skeletal muscle (%)	21.2-53.2%

Week 12 data saw no significant differences between the two groups (CG and TG) in any biometric parameters, so they were analyzed as 1 group.

Objective Biometrics
At the end of the study, there was an average of 11 lbs. lost (9 lbs. in 8 weeks), with up to 25 lbs. lost at 12 weeks. There was no difference in weight loss changes between the 2 product groups (CG and TG). Both groups showed that 92% of participants lost weight and body fat % at 12 weeks, with an average of 11 lbs. of weight lost and 1 in 4 participants losing more than 15 lbs. One subject lost up to 11% of total body weight over the study period, with a 5.5% decrease of body fat, a 4.4% decrease in subcutaneous fat, and a 27% decrease in visceral fat. All subjects who lost weight, maintained or increased their skeletal muscle % over 12 weeks. Results are summarized in Table 2 below. ‡

Table 2. Biometric responder rates at week 12. ‡

Biometrics (Baseline)	% Responders[1]
Weight (lbs.)	92% (up to 25 lbs. decreased, average 11 lbs. decrease)
Body fat %	92% (up to 5.5% decrease, average 2% decrease)
Subcutaneous fat (%)	91% (up to 4.4% decrease, average 2% decrease)
Visceral fat (lbs.)	71% (up to 27% decrease, average 15% decrease)
Skeletal muscle (%)	91% (up to 2.7% increase, average 1% increase)

[1]Percentage of participants who responded to an improvement in biometric parameters over the 12-week study period. 8% of participants did not improve or saw no changes in their biometric parameters.

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Before and After Pictures
Pictures taken at baseline and at week 12 show significant changes in body profiles (Figures 1– 4). All participants pictured showed an improvement in waist circumference, weight, and visceral fat %. ‡

Figure 1.

Baseline   Week 12

Figure 2.

Baseline   Week 12

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Figure 3.

Baseline

Week 12

Figure 4.

Baseline

Week 12

Subjective Questionnaire

The results were normalized to reflect % changes in responses. The results are summarized in Table 3 below.

Table 3. Summmary of subjective questionnaire at the end of 12 weeks. ‡*

| Question	CG	TG	Average
% Agreed that their food cravings decreased	77%	93%	85%
% Agreed that their sugar cravings decreased	98%	91%	95%
% Agreed that the amount they eat at each meal decreased	80%	100%	90%
% Agreed that the portion size at each meal decreased	91%	100%	96%
% Agreed that their willpower to resist snacking increased throughout the day	87%	42%	65%
% Agreed that their energy levels increased throughout the day	50%	88%	69%
% Agreed that their appetite decreased	85%	85%	85%
% Agreed that their satisfaction between meals increased	60%	85%	73%
% Agreed that their urge to snack decreased throughout the day	65%	63%	64%
% Agreed that they eat for health instead of emotional eating	82%	88%	85%
% Agreed that they have more control of their relationship with food	71%	93%	82%
% Agreed that they eat just the right amount for overall health	43%	77%	60%

Diet and exercise recommendations played no significant role in the results of the study.

GLP -1 in Blood and Fasting Blood Sugar

Fasting blood glucose levels showed no change throughout the 12-week study period.

Fasting GLP-1 levels increased on average in both the CG and TG group by 205% and 77% respectively, with and average increase in blood GLP-1 hormone of 140% on average at the end of the 12-week study.[Ω] (Figure 5)

Figure 5. % Change in blood GLP-1 concentration
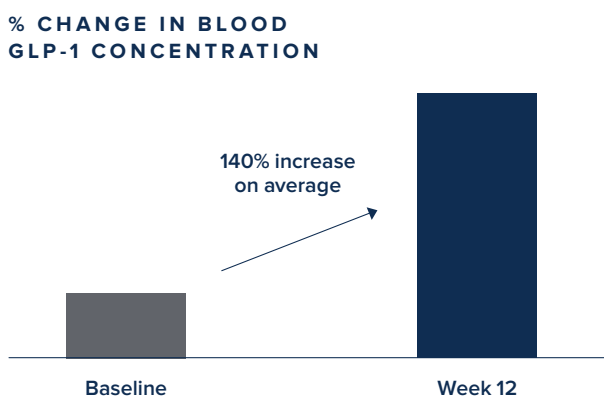
% CHANGE IN BLOOD GLP-1 CONCENTRATION

140% increase on average

Baseline | Week 12

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Ω Results based on a randomized 12-week human clinical study.

Conclusion

The MindBody GLP-1 System was shown to increase GLP-1 concentrations in blood by an average of 140%. ‡*

Subjects in the clinical trial also saw a decrease in food and sugar cravings, as well as their urge to snack decreased, leading to the weight loss seen. Subjects also had positive changes in the way they thought and felt about food, with more reporting they now consumed food for their health instead of for their emotions. ‡*

The MindBody GLP-1 System is a natural, more holistic approach to weight loss. It works with the body by activating L-cells to produce GLP-1 as well as work through the microbiome to create the ideal environment for your bacteria to create short chain fatty acids that fuel the L-cells to further produce GLP-1. And you get all these benefits without requiring shots or prescriptions. ‡◊

No side effects were seen, including gastrointestinal side effects.*