Activation of Key Metabolism Hormones, including GLP-1, in a Placebo-Controlled, Double-Blind, and Randomized Human Clinical Study Using the MindBody GLP-1 System™

Objective: To evaluate the effects of MindBody GLP-1 System on GLP-1 concentration and other metabolism related hormones in the blood, and on associated weight loss and other biometric data in a 12-week clinical study.
Sponsor: LifeVantage Corp.

Principal Investigator: Lighthouse Research

Reference: LifeVantage Corp., Lehi, Utah 84043

Introduction

Emerging research shows the GLP-1 hormone has wide-ranging beneficial effects across multiple organ systems in the body, such as the central nervous system, cardiovascular system, kidney, liver, pancreas, and brain. And approaching weight loss by significantly increasing the GLP-1 hormone or attaching to its receptors has become a popular means to lose weight quickly.

However, several other metabolism hormones are also implicated, such as insulin, GIP (Glucose-dependent Insulinotropic Polypeptide), leptin, and PP (Pancreatic Polypeptide). These key hormones all contribute to energy metabolism as they help control appetite, satiety, digestion, and blood sugar.

Levels of these hormones can become imbalanced due to age, poor diet, lack of gut diversity, or other lifestyle factors. Imbalances in these metabolic hormones, especially GLP-1, can impact many aspects of your health, including healthy glucose regulation, bone health, cardiovascular and gastrointestinal function, and more.* Low GLP-1 levels can also lead to constant thoughts about eating or "food noise," intense cravings, more hunger, and, ultimately, weight gain. It can also lead to metabolic overcorrection, dysregulation of appetite pathways, mood changes, and gastrointestinal side effects.

An initial 12-week randomized, double-blind human clinical study was conducted using the MindBody GLP-1 System, which included lifestyle/nutritional guidance as well as a minimum daily protein intake, to evaluate its impact on blood GLP-1, biometric body data, and food behavior. Results showed an increase in GLP-1 concentrations in blood by an average of 140%, a decrease in weight of up to 25 lbs. (average 11 lbs.), up to 5.5% reduction in body fat percentage, up to 4.4% decrease in subcutaneous fat percentage, up to 27% reduction in visceral fat, and no loss in skeletal muscle. Subjects also experienced a decrease in food and sugar cravings, as well as a reduced urge to snack, which contributed to significant weight loss. They also reported positive changes in the way they thought and felt about food, with more consuming food for health instead of emotions. No side effects were observed.*ΩΩ ‡

A second study was performed to confirm the results from the first study. However, this study was designed as a randomized, double-blind, placebo-controlled study without lifestyle/nutrition guidance or minimum protein intakes to ensure they were not a potentially confounding factor. We also expanded the blood panel to include other metabolic hormones, such as GIP, as well as A1C concentrations.

METHODS

A total of 80 participants were recruited to participate in a 12-week randomized, placebo-controlled, double-blind study. Potential participants were 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 were taken.

After participants were deemed eligible, they were asked to complete an enrollment form and sign a consent form. They were then randomized into placebo or treatment group and asked to continue their normal lifestyle:

1. Placebo (P)
2. Treatment with US MindBody GLP-1 System (US)

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ΩΩ Results based on a randomized 12-week human clinical study (Study A, N=56).
‡ 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.

At each study timepoint (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 where taken for C-peptide, active Glucose-dependent Insulinotropic Polypeptide (GIP), active Glucagon-like Peptide 1 (GLP-1), glucagon, insulin, leptin and Pancreatic Polypeptide (PP) and fasting A1C analysis; anthropometric/biometric measurements using a Renpho scale were taken, and subjective questionnaires of food behavior and cravings were filled in. Before/after picture were taken at each timepoint. All subjects were compensated for their participation in the trial.

Anthropometric/biometric measurements

At each timepoint, 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 percentage based on resistance.

The following parameters were measured: weight (lbs. or kgs), BMI (kg/m^2), body fat (%), fat-free-mass (lbs.), subcutaneous fat (%), visceral fat score, 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 circumference was measured at each timepoint.

Before/after pictures

At each timepoint, 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 to each participant at each timepoint. This questionnaire asked about food behavior and cravings between the study timepoints.

Blood samples for metabolic hormones and fasting A1C levels

Fasting blood samples were obtained by a licensed phlebotomist at each timepoint 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 the metabolic hormones. These BD800 blood collection tubes (Becton Dickenson BD800 tubes contain spray-dried K_2EDTA—an anticoagulant that contains DPP-4 and other protease inhibitor cocktails) provide the means to analyze plasma metabolic markers such as GLP-1, glucagon, ghrelin, and GIP.

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 metabolic quantification kit (V-Plex Metabolic Panel 1 Human Kit K15235D; www.mesoscale.com) was used to analyze for C-peptide, active GIP, active GLP-1, glucagon, insulin, leptin, and PP concentrations.

Fasting A1C was measured by a licensed phlebotomist using a commercially available portable A1C test kit.

RESULTS

A total of 80 participants were recruited (50% males and 50% females) in this 12-week study. At baseline, ages ranged from 30–75 years (average of 49.8 ± 12.5 years), weight ranged from 135–375 lbs., waist circumferences (in.) ranged from 31.7–66 inches, body fat (%) ranged between 21.6–64.8%, and subcutaneous (%) and visceral fat score ranged from 18.7–55.4% and 9–30, respectively. Skeletal muscle (%) and muscle mass (lbs.) ranged from 19.2–50.6 % and 84.2–170 lbs., respectively. There were no statistical differences between the groups at baseline. Biometric measurements are summarized in Table 1 below.

Table 1. Baseline measurements

Biometrics (Baseline)	US	Placebo	P-value
Weight	212.2 ± 48.3 lbs.	216.8 ± 35.6 lbs.	n.s.
Weight (range)	135–375 lbs.	135–327 lbs.	n.s.
Waist circumference (in.)	31.8–66.0 in	33.7–57.5 in	n.s.
Body fat %	22.3–64.6%	21.6–64.8%	n.s.
Subcutaneous fat (%)	19.4–54.8%	18.7–55.4%	n.s.
Visceral fat score	9–29	8–30	n.s.
Skeletal muscle (%)	25.7–50.1%	19.2–50.6%	n.s.
Muscle mass (%)	33.3–73.8%	31.2–74.5%	n.s.

n.s. no significant difference between the treatment groups

Objective Biometrics

By the end of the study, 4 people dropped out due to scheduling conflicts: 2 in each group, which left a total of 38 in each group. There were significant changes ($p<0.05$) in average weight loss of 10.5 lbs. in the treatment group as compared to placebo, with up to 24.2 lbs. lost at 12 weeks. This is consistent with the original study, which showed an average weight loss of 11 lbs. and up to 25 lbs. lost by the end of the 12-week period. Body fat %, subcutaneous fat %, and skeletal muscle % results improved in comparison to the original study. Visceral fat was less pronounced than in the original study but remained significantly greater than that of the placebo group at 12 weeks. Table 2 summarizes the results as compared to the original study (Study 1). ‡

Table 2. Biometric results at the end of week-12 as compared to placebo. ‡

Biometrics (Baseline)	US-Week 12 (%change), Study 1**	US-Week 12 (%change), Study 2**	Average of Both Studies
Weight (lbs.)	Up to 25 lbs. decrease, average 11 lbs.	Up to 24.2 lbs. lost, average 10.5 lbs.	10.75 lbs. decrease
Body fat %	Up to 5.5% decrease, average 2%	Up to 13.1% decrease, average 6.4%	Up to 9.3% decrease
Subcutaneous fat (%)	Up to 4.4% decrease, average 2%	Up to 12.7% decrease, average 4.6%	Up to 8.6% decrease
Visceral fat	Up to 27% decrease, average 15%	Up to 20% decrease, average 7%	Average up to 23.5% decrease
Skeletal muscle (%)	Up to 2.7% increase, average 1%	Up to 11.5% increase, average 3.6%	Up to 5.8% increase

** $p<0.05$; all measurements were significantly changed to placebo

Waist, hip, buttock, and primary biceps arm circumference were also measured in this study. The results had variability due to the person performing the measurements and are thus not included in the general analysis.

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 significant improvements in waist circumference, weight, fat % (body fat, subcutaneous fat%, and visceral fat change), and skeletal muscle %.‡

‡ 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.

A. Baseline photos of a 44-year-old female.

B. 12-week photos of a 44-year-old female.

Figure 1. Figure 1. Biometric results: Age: 44 years; starting weight 228.6 lbs., weight loss 14.4 lbs.; body fat % loss 7.6%; skeletal muscle % gain 6.9%; subcutaneous fat % loss 7.1%, and visceral fat change - 11.1%.‡

A. Baseline photos of a 48-year-old female

B. Baseline photos of a 48-year-old female

Figure 2. Biometric results: Age: 48 years; starting weight 140.6 lbs., weight loss 10.6 lbs.; Body fat % loss 9.6%; skeletal muscle % gain 4.9%; subcutaneous fat % loss 8.7%, and visceral fat change - 20.0%.‡

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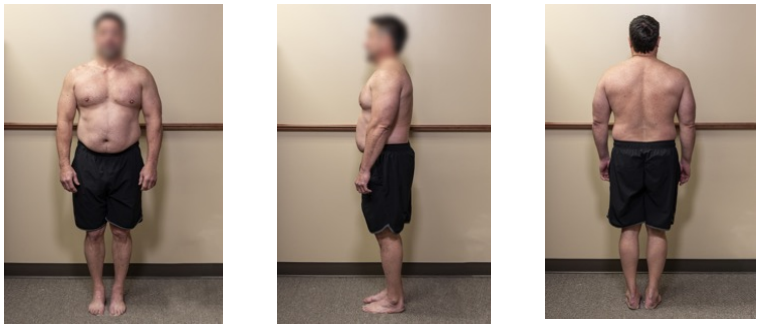
A. Baseline photos of a 34-year-old male

B. 12-week photos of a 34-year-old male

Figure 3. Biometric results: Age: 34 years; starting weight 259 lbs., weight loss 20.6 lbs.; body fat % loss 13.1%; skeletal muscle % gain 6.1%; subcutaneous fat % loss 12.7%, and visceral fat change - 13.3%.‡

A. Baseline photos of a 55-year-old male



B. 12-Week photos of a 55-year-old male

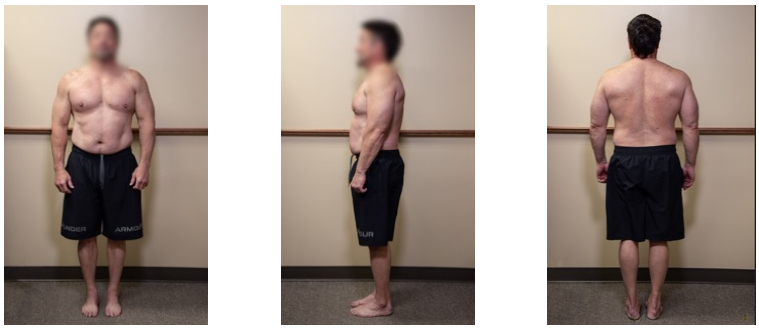


Figure 4. Biometric results: Age: 55; starting weight 205.2 lbs., weight loss 8.6 lbs.; Body fat % loss 6.3%; skeletal muscle % gain 2.95%; subcutaneous fat % loss 6.2%, and visceral fat change - 13.3%.‡

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Subjective Questionnaire

The results were normalized to reflect percentage changes in responses as compared to placebo. The results are summarized in Table 3 below.

Table 3. Summary of subjective questionnare at the end of 12 weeks.

Question	Study 1	Study 2
% Agreed that their food cravings decreased*	85%	86%
% Agreed that their sugar cravings decreased*	95%	86%
% Agreed that their portion sizes decreased	96%	86%
% Agreed that their urge to resist snacking throughout the day decreased*	64%	81%
% Agreed that their appetite decreased*	85%	86%
% Agreed that they eat for health instead of emotional eating	85%	81%
% Agreed that their satisfaction between meals increased*	73%	76%

Table 4 shows additional subjective questions that were not included in the first study and were added to expand on the participants' experience with food noise.

Table 4. Additional results from subjective questions in Study 2.‡

Question	Study 2
% Agreed that their salt cravings decreased*	86%
% Agreed that their alcohol cravings decreased*	95%
% Agreed that their soda cravings decreased*	86%
% Agreed that their fast-food cravings decreased*	89%

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‡‡ Results based on the averaged data of two 12-week randomized human clinical studies.

GLP-1, GIP, and A1C Parameters

In the treatment group, fasting GLP-1 levels increased by 358% on average. Study 1 showed an average increase in GLP-1 levels of 140%.ΩΩ When data from both studies were combined, the result was a 249% average increase in GLP-1 hormone levels.‡‡

Other parameters such as GIP increased by an average of 140% as compared to baseline.§§ (Figure 5) Glucagon, leptin, insulin, C-peptide, and PP concentrations did not significantly change throughout the 12-week study, and no significant changes were seen in the placebo group in any of the metabolic blood parameters.

A total of 78% of participants in the treatment group also experienced positive changes to their A1C levels. *

% Changes in average Blood GLP-1 and GIP Concentration

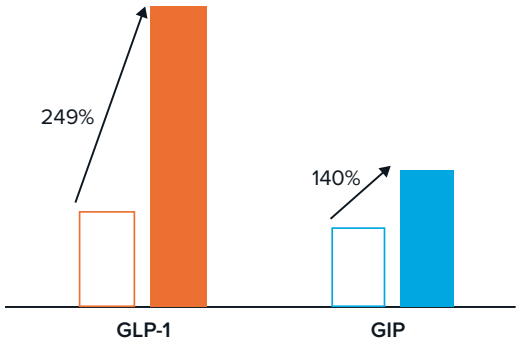

Figure 5. % Changes in average blood GLP-1 and GIP concentration.

Conclusion

The second study using the MindBody GLP-1 System was shown to increase GLP-1 concentrations in blood by an average of 359%. Taking both study results into account, this gives us an average increase in GLP-1 by 249%.‡‡ GIP also increased by an average of 140%.* §§

Similar results were seen in the subjective food questionnaires in which subjects using the MindBody GLP-1 System experienced a significant decrease in food, soda, salty, alcohol, and sugar cravings. Their urge to snack also decreased, leading to measured weight loss. 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 emotions. ‡*‡‡

This study further confirmed that 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 and GIP and by acting through the microbiome to create the ideal environment for gut bacteria to make short-chain fatty acids that fuel the L-cells to further produce GLP-1 and GIP. ‡*‡‡

The MindBody GLP-1 System is an important tool to help people more easily make lifestyle changes needed to support their weight loss goals and general health. All of these benefits are achieved without requiring shots or prescriptions. ‡‡◊ ‡

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

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‡‡ Results based on the averaged data of two 12-week randomized human clinical studies.
◊ MindBody is a dietary supplement and not a replacement for any prescription therapy for a disease.
§§ Results based on a randomized 12-week human clinical study (Study B, N=107).