Real-world Investigation of JBA Collagen GlucoTrojan® - Effect on Metabolic Health Biomarkers.

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About Us

Tastermonial Platform serves as a valuable resource for food and supplement brands, facilitating cost-effective, data-driven insights from the public. Comprising passionate scientists and engineers, Tastermonial specializes in real-world clinical studies, aiding companies in assessing product efficacy and health impacts. Our studies contribute to building consumer trust, guiding product development, and mitigating clinical trial risks.

Disclaimer

While Tastermonial's studies provide reliable real-world data, they are conducted outside controlled laboratory settings and are not suitable for FDA approval purposes.

Background

Affordable Quality Pharmaceuticals, Inc. (“Company”) developed a powdered supplement sachet, JBA Collagen GlucoTrojan®, targeting individuals on carbohydrate-heavy diets. This blend features proprietary ingredients, including Reducose®, proven to reduce sugar and carbohydrate absorption by up to 40%.Besides mulberry extract, GlucoTrojan® formulation also contains *Mangifera indica* (mango) leaf extract and banana stem juice extract, which benefit consumers’ health as well. This product is combined with collagen, which also claims to help strengthen hair, nails, skin, and joints.

Our earlier study has shown that JBA GlucoTrojan® effectively decreased postprandial glucose levels and glycemic index of white rice in healthy individuals.

Our study aims to assess the real-world efficacy of JBA Collagen GlucoTrojan®, incorporating Reducose®, on metabolic health biomarkers.

Rationale

Overconsumption of dietary carbohydrates and sugar intake can lead to blood glucose level fluctuations, with negative physiological outcomes. Mulberry leaf extract, a key active ingredient in Glucotrojan® as well as Reducose®,, has shown promise in moderating postprandial blood glucose level fluctuations. Multiple clinical trials have demonstrated significant reductions in postprandial glucose level elevations by a reduction of up to 40% (see Appendix).

In the previous phase of our trial, we assessed the immediate glycemic response of Glucotrojan® by measuring postprandial glucose peak amplitude and the Incremental Area Under the Curve (iAUC). We compared these parameters between a standardized meal with and without Glucotrojan®.

Study Objectives

This study aims to investigate the impact of JBA Collagen GlucoTrojan® on metabolic health indicators in non-diabetic individuals at risk of metabolic disorders over a four-week period, from Week 0 to Week 4.

Aim: Evaluate the improvement of parameters of overall sugars physiology status by measuring baseline (Day 0) and final (Day 28) values of physiological parameters reflecting long term responses: fasting glucose levels, Hemoglobin A1c (HbA1c), fasting insulin levels, lipid profile, and body composition.

Our observation methods of the above parameters include utilizing blood tests, wellness questionnaires and product surveys.

Rationale

We hypothesize that daily consumption of JBA Collagen GlucoTrojan® in non-diabetic individuals at risk of metabolic disorders for four weeks will improve physiological responses to dietary sugars as reflected in metabolic health biomarkers. Positive outcomes of the trial parameters would indicate that the product might have beneficial effects in weight management

Participants Enrollment, Inclusion & Exclusion

A sample size of 19 participants will berecruited for the purposes of this study by following the inclusion/exclusion criteria. We expect that up to 12 participants will follow the study to completion. Drop outs and incomplete data will be recorded and removed from the final analysis.. All participants will submit digital written informed consent forms (ICFs) prior to inclusion in the study. Below is a complete list of the eligibility criteria for participants selection.

Inclusion criteria:

1. BMI: 21 to 29.9 kg/m2
2. Age: 18 to 75 years old
3. Sex : 6 males 6 females

Exclusion criteria:

1. Any known food allergy or intolerance to the test product
2. Medical condition(s) or medication(s) known to affect glucose regulation or appetite and/or which influence digestion and absorption of nutrients
3. Participants with restricted or abnormal eating behavior
4. Major medical or surgical event requiring hospitalization within the preceding 3 months
5. Volunteers self-reporting as currently dieting or having lost >5% body weight in the previous year
6. Volunteers who have significantly changed their physical activity in the past 2-4 weeks or who intend to change during the study
7. Participation in another experimental study or receipt of an investigational drug/product within 30 days of the screening visit
8. Physician-diagnosed T1D or insulin - dependent T2D
9. An underlying health condition that warrants non-participation
10. Individuals who are pregnant
11. Unable to follow remote guidance via the Internet or smartphone
12. Unable to follow experimental procedures or testing guidelines
13. Are currently taking supplements supposed to affect blood glucose levels.

Compensation/Incentives:

Each of the participants who successfully completed the study will be/has been provided with a reward of $50 or more worth of free product.

Data Collection

Before the beginning (Week 0) and at the end of the study (Week 4), participants will be required to make a visit to a nearby Labcorp location to take a venous blood sample to be used for the evaluation of : test HbA1c, lipid profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides), fasting glucose levels, and fasting insulin. Before each of the tests, the participants will be instructed to fast overnight (for 10-12 hours), excluding water in moderation. They were also asked to refrain from alcohol, caffeine, and intense physical activity.

Data management

Study documents, including completed ICFs, are hosted on a secure online portal. The ICFs are completed using a secured data transfer system on the HIPAA-compliant online portal. The Company has access to the de-identified data set. The data is saved to a secured internal network. All data is anonymized during the analysis. HIPAA-relevant PHI data privacy of participants is ensured on a secured online portal that uses the HIPAA-compliant Cloud servers. All participants are de-identified and labeled using a coding system.

Preliminary data

Nineteen individuals were enrolled as participants, with an age range of 53 ± 5 years and a BMI of 25 ± 1.5. Of these, twelve participants completed the study, attending laboratory visits at weeks 0 and 4, submitting a wellness questionnaire, and confirming daily supplement intake over four weeks. Three participants were unable to attend the initial laboratory visit and were excluded prior to the commencement of the supplement intervention, resulting in a total of sixteen enrolled participants.

During the four-week observation and testing phase, participants were provided with a supply of the test product and instructed to consume two daily doses, one in the morning and one in the evening, by incorporating it into their meals or beverages. Compliance was ensured through weekly check-ins conducted via text messages or telephone calls. Additionally, participants utilized Tastermonial's mobile application to log their meals and record any variables that could potentially impact the study results, such as medications or physical activities.

Age Range	Female	Male	Total
Age: 30-39	3	2	5
Age: 40-49	1	0	1
Age: 50-59	5	2	7
Age: 60-69	2	1	3
	11	5	16

Table 1: Participant age and gender information at baseline lab visit

During the course of this study, valuable feedback was gathered from participants concerning the supplement's effects during the weekly check ins. Of the participants, five reported mild side effects, with stomach bloating being the most common. This may be due to the prebiotic nature of the supplement. This feedback is instrumental in guiding future improvements to the supplement's formulation.

Notably, although two participants chose to discontinue due to discomfort, their input provides critical insights that enhance our understanding of the supplement's interaction with different body chemistries.

One case of a urinary tract infection and one case of allergic reaction (rash) was reported, which may not be related to the supplement. This participant prudently paused their supplementation and later resumed with a reduced dose of once per day contributing further to our robust safety protocols by confirming the ability to rejoin the trial comfortably.

The experiences reported are invaluable to our ongoing efforts to improve supplement safety and efficacy, ensuring that participant well-being remains our top priority. Future studies will incorporate these findings to enhance participant experience and study outcomes.

Participants also completed an online wellness questionnaire to track overall well-being and feelings throughout the study. Two blood tests were conducted to assess fasting glucose, fasting insulin, HbA1c, and lipid profile. Primary outcomes focused on documenting changes in these factors, while secondary outcomes included wellness questionnaire results and product surveys. Participant demographics, such as age, sex, BMI, weight, and height, were incorporated into their profiles.

Data analysis was conducted by Tastermonial’s in-house data scientist, with oversight from the Principal Investigator and Tastermonial team using the supporting platform.

The figure below illustrates participant enrollment and dropout rates.

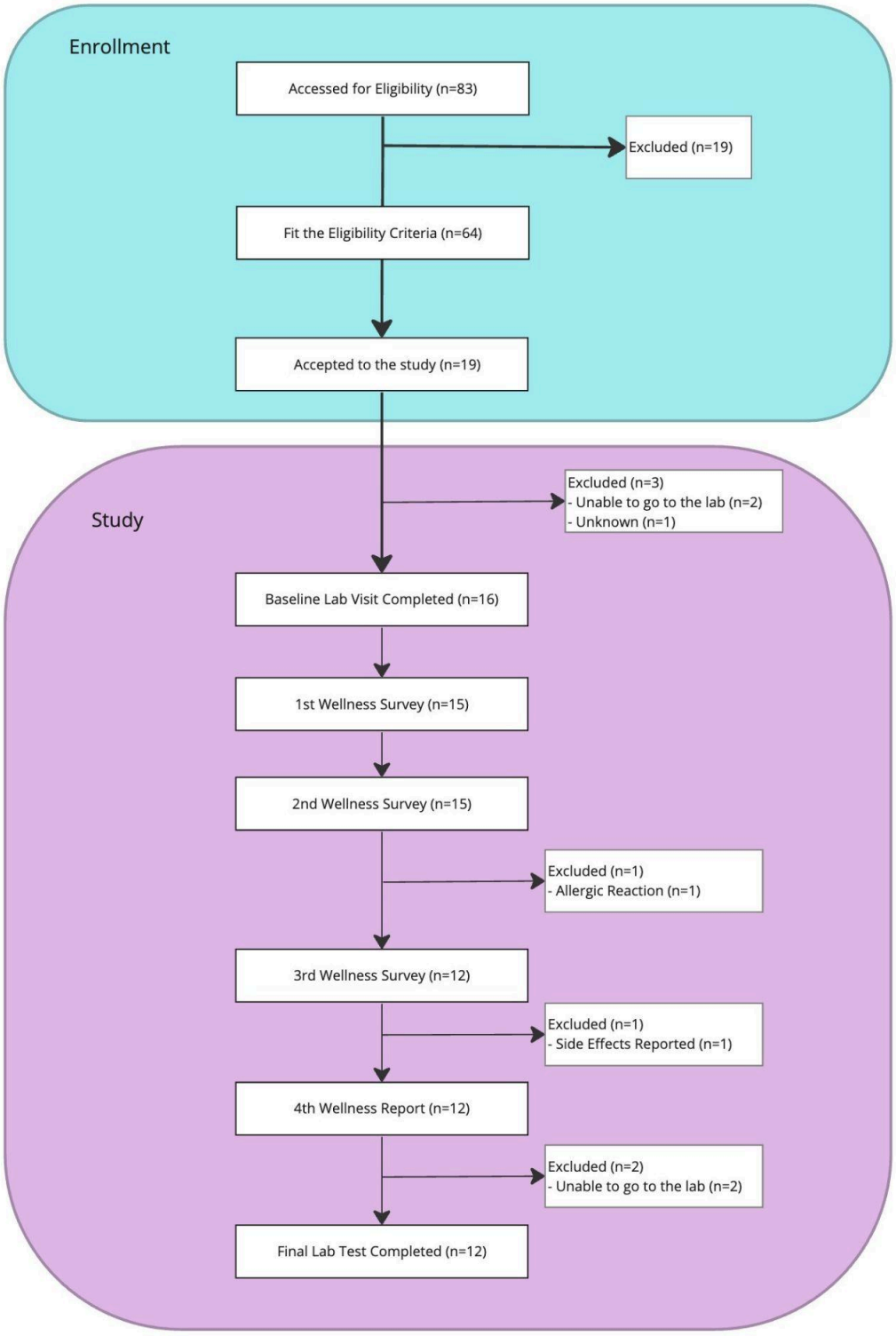

Figure 1: Participant flow diagram

Health Biomarker Observation and Discussion

While the mean values of metabolic health biomarkers did not show significant differences before and after four weeks of JBA Collagen GlucoTrojan® consumption, our analysis uncovered promising trends in specific indicators.

To thoroughly assess the impact of the supplement on health biomarkers, we computed the following essential metrics:

Biomarker	**Biomarker details**	**Effect after four weeks of JBA Collagen GlucoTrojan® consumption**
HOMA-IR	This metric illustrates the level of insulin sensitivity where lower numbers are better. Calculated by multiplying Glucose (mg/dl) by Insulin mIU/L and dividing the result by 405.	reduced in 42% participants (5/12)
LDL/HDL Ratio	Low-Density Lipoprotein ("bad" cholesterol) to High-Density Lipoprotein ratio ("good" cholesterol) - we want to see it reduced	Reduced in 67%(8/12)
TC/HDL Ratio	Total Cholesterol to High-Density Lipoprotein ratio ("good" cholesterol) - we want to see it reduced	Reduced in 67%(8/12)

Table 2: Biomarkers of insulin sensitivity and lipid metabolism showing promising trends

In the prior study of JBA Glucotrojan® Supplement we have shown that GlucoTrojan® effectively decreased postprandial glucose levels and glycemic index of white rice in healthy individuals. The table below combines the data from both studies:

Study	**Sample**	**Intervention and measurements**	**Main outcomes**
Evaluation of JBA Glucotrojan® Supplementation in Regulating Postprandial Glycemic Response	25 participants ages 24-59 years; 36% females, mean BMI 26.4	Consuming white rice (82 g of net carbohydrates) with and without JBA GlucoTrojan® Measurements: CGM data for 14 days	Postprandial blood glucose levels were reduced by 14 ± 6 mg/dl (P < .0005) over 2 hours compared to white rice consumption alone (26.1% reduction) in 84% of the participants
JBA Collagen GlucoTrojan® supplement efficacy	12 participants ages 30-69, 66% females, mean BMI 25	JBA Collagen GlucoTrojan® supplement taken daily for 4 weeks Measurements: fasting glucose levels, hemoglobin A1c (HbA1c), fasting insulin levels, lipid profile measured in a blood sample before and after the study	In addition to the promising health metrics changes shown in the table above (HOMA-IR reduced in 42% participants, LDL/HDL Ratio Reduced in 67% and TC/HDL Ratio Reduced in 67%) 2/12 showed clinically meaningful reductions in fasting insulin (>=1uIU/mL reduction). Clinically meaningful improvements were observed for LDL cholesterol (7/12, -10 to -41mg/dL), total cholesterol (4/12, -23 to -42mg/dL), HDL cholesterol (4/12, +3 to +9 mg/dL), and triglycerides (2/12, -22 to -31mg/dL).

Table 3: JBA Collagen GlucoTrojan® and JBA Collagen GlucoTrojan® studies overview

HbA1c typically reflects glycemic control for the past 3 months, therefore a 4 week intervention is likely too short to see changes in this metric. Notably 5/12 participants demonstrated lower HbA1c levels after 4 weeks, however reductions were too small to be clinically meaningful (<0.5%).

It is notable that there were also participants who demonstrated detrimental changes in cardiometabolic parameters reaching a clinically meaningful threshold, including insulin sensitivity (2/12), fasting blood glucose (2/12), fasting insulin (5/12), LDL cholesterol (3/12), total cholesterol (2/12), and HDL cholesterol (7/12).

Although participants with a BMI over 25 showed mixed outcomes, it's crucial to note that the analysis was affected by a dropout rate of three out of four individuals with a BMI over 25, potentially impacting the overall interpretation.

Additionally, participants who withdrew from the study cited various reasons ranging from experiencing side effects like bloating, to the inconvenience of frequent lab visits. This feedback indicates that integrating a health coach into the trial could improve participant adherence and overall compliance with the study protocol.

These study data are observational due to a small number of participants (12). Even though many parameters are normally distributed, the data set is too small to allow us to see statistically significant differences between pre and post treatment values observed. However, even this small set study showed very promising results that need to be corroborated by further studies. Although only RCTs can determine cause-and-effect relationships, real-world observational studies like this one provide value in collecting data outside of the strict laboratory conditions.

Collagen GlucoTrojan® as a Potential Alternative to GLP-1 Medications

Collagen GlucoTrojan®, which contains 250mg of Reducose® (white mulberry leaf extract), may offer an alternative solution to GLP-1 (Glucagon-like Peptide-1) medications without the undesirable effect of muscle loss. While GLP-1 is known for enhancing insulin secretion, reducing hunger, and promoting satiety, white mulberry leaf extract supports blood glucose management through a different mechanism.

Research suggests that white mulberry leaf extract helps regulate blood glucose levels after meals by inhibiting enzymes that break down carbohydrates into glucose, leading to reduced postprandial blood glucose spikes. This contributes to better glucose control and may aid in weight management.

Studies on Collagen GlucoTrojan® also suggest that it may delay gastric emptying, which can further help in managing postprandial blood glucose levels. This delay in gastric emptying can

be measured using the blue dye method, which involves ingesting a blue dye and measuring the transit time through the digestive system.

Although the exact mechanisms are still under investigation, the role of white mulberry leaf extract in modulating glucose metabolism and enzyme inhibition is considered significant.

An observed 40% increase in HOMA-IR and self-reported data on delayed gastric emptying, though not statistically significant due to study limitations, may be linked to the effects of white mulberry leaf extract.

Structured Approach for Evaluating Collagen GlucoTrojan® as an Alternative to GLP-1 Medications

To explore these trends further, we propose a within-subject single-group study measuring post-meal glucose levels, satiety, and delayed gastric emptying to assess the potential of Collagen GlucoTrojan® as an alternative to GLP-1 medications.

Study Design

- **Duration**: 8 weeks
- **Participants**: Individuals using a CGM device to measure post-meal glucose patterns before and after using the supplement.
- **Measurements**: Changes in HbA1c, HOMA-IR, triglycerides, cholesterol, body composition (via DEXA scans), and muscle mass preservation.

Study Phases

1. **Baseline Phase (7 Days)**
    - Collect CGM data to establish baseline glucose levels.
    - Participants eat a reference meal, log satiety, and test gut transit time using the Blue Dye Transit Test.
2. **First Intervention Phase (Day 7 to 14)**
    - Coaching support.
    - Monitor blood sugar trends with CGM and log satiety after meals.
    - Participants eat a reference meal with Collagen GlucoTrojan® and test gut transit time.
3. **Second Intervention Phase (Day 14 to 30)**
    - Continue coaching support without CGM.
4. **Third Intervention Phase (Day 30 to 60)**
    - Continue supplement without coaching.

Lab and DEXA Scan Visits

- Conducted at baseline, during the second phase, and during the third phase for comprehensive data collection and analysis.

This approach will robustly evaluate Collagen GlucoTrojan® as a potential alternative to GLP-1 medications, focusing on metabolic, satiety and body composition parameters.

Survey results

Product Satisfaction

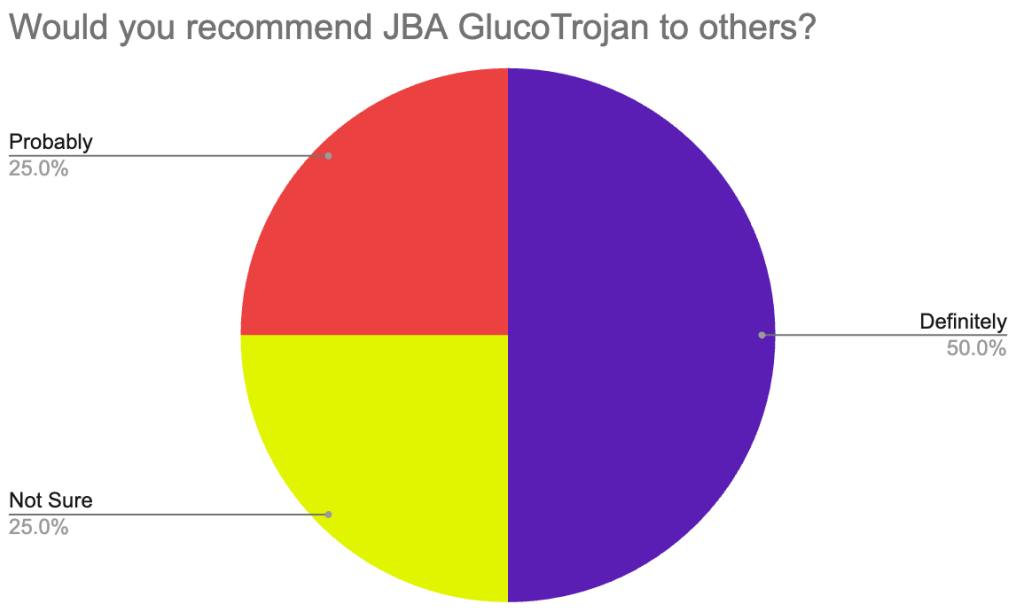

Figure 2: Net Promoter Score Survey

It is worth noting that certain respondents who answered may not have clinically significant alterations in their biomarkers. This is because we think that the intent to buy the supplement could also be motivated by subjective perceptions and other features mentioned in the feedback on product qualities.

Participant Feedback on Product Qualities

- Participants generally found the daily use of Collagen GlucoTrojan® powder to be an easy and convenient way to improve their health. They expressed a willingness to continue using GT if they saw improvements in their blood measurements.

- Collagen GlucoTrojan® was reported to mix well with yogurt, which was perceived as the best way to consume it by some participants. However, it was noted that Collagen GlucoTrojan® does not work well when sprinkled on savory food, as it imparts a sweet taste that may not be desirable.
- Some participants did not prefer consuming Collagen GlucoTrojan® with water due to difficulties in dissolving it properly, leading to clumps. However, others found that the product dissolved well in water and expressed a preference for it, especially considering its reasonable price and comparable collagen content to other products like Costco collagen.
- Despite some challenges with dissolution, participants found it easy to take Collagen GlucoTrojan® twice a day and generally found the taste to be acceptable. They appreciated the convenience of being able to take the supplement with meals or before meals.

Participant Feedback on Product Effects

44% of respondents noted that they have noticed slight improvement to the condition of skin. 25% of the respondents noticed slight improvement to the energy level, however when asked what can cause the improvement none of the participants tied it to the supplement intake.

Limitations of the Study

The study's limitations include a small sample size, absence of a washout period, and short duration, necessitating cautious interpretation of results.

Disclaimer

The findings of this study are presented with the understanding that they are subject to the aforementioned limitations. Therefore, they should be interpreted as preliminary and indicative rather than conclusive. Future research involving a larger cohort over an extended period, with appropriate washout phases, is recommended to validate and expand upon these findings. The study's results are not intended to serve as a basis for clinical practice or health-related recommendations without further corroborative evidence.

Conclusion

While preliminary findings gave some clues, further research with larger cohorts and longer durations is recommended to validate and expand upon these observations.

References

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Appendix

Reducose® white-paper
Glucotrojan® white-paper