RESEARCH PARTICIPANT INFORMED CONSENT FORM
SUBJECT INFORMATION

Protocol Number & Study Title: 20349 A Single-Group Study to Examine the Efficacy of a Gut Health Supplement to Increase Metabolism, Improve Gut Health, and Support Weight Management
NCT Number: NCT06023082
Name of Person In Charge of the Research Study (Study Doctor/Investigator): Christopher Hill (Citruslabs), Ellen O'Gorman (Citruslabs)
Telephone Number(s), Daytime/ After hours: 424-248-9151
Date: 31st May 2023

CONCISE SUMMARY:

This research study aims to determine the efficacy of a gut health supplement to improve gut health, enhance metabolism, and support weight loss.

Participation will be virtual, requiring participants to take a gut health supplement at home. Questionnaires will be filled out and participants will conduct weigh-ins and take body measurements at Baseline, Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. Photos will be taken at Baseline and Week 12.

There are no expected potential risks other than some users might experience changes in their bowel movements or feel bloated as the body adjusts to the increased fiber intake.

Benefits may include reduced gut health issues (constipation, bowel movements, gas, and bloating), feeling healthier, reduced overeating, and potential weight loss. Furthermore, participants may experience feeling less tired and more energetic.

The study Sponsor and product name will remain anonymous to participants throughout the trial.

If you want to learn more about this study, please continue reading below.

INTRODUCTION

You are invited to participate in a research study that examines a gut health supplement product. The test product contains psyllium seed husk powder, L-carnitine tartrate, Capsimax® cayenne fruit extract, chromium, vitamin B6, vitamin B12, and iron. All participants will receive the test product as part of their participation.

We plan to enroll 120 people between 30-50 years old with a minimum BMI of 25 and have issues with gas, bloating, constipation, heartburn/acid reflux, and/or abdominal pain.

Participation in this study is entirely voluntary. It is your choice if you want to be in the study. No one can force you to be in the study. Before deciding to participate, please read this form

carefully and ask the study staff for further information or clarification. Ask as many questions as required to fully understand what your participation will involve. Please only sign and date this form if you are fully satisfied with the answers you have received. You may also stop participating at any time, and you can do this without penalty or loss of benefits to which you are otherwise entitled. Not participating does not affect your relationship with any stakeholder involved in this study.

This form is called an informed consent form, and it contains information regarding the purpose of the study, participation requirements, potential risks, potential benefits, and how your protected health information (PHI) will be managed.

Please take as much time as necessary to review the material and make an informed decision.

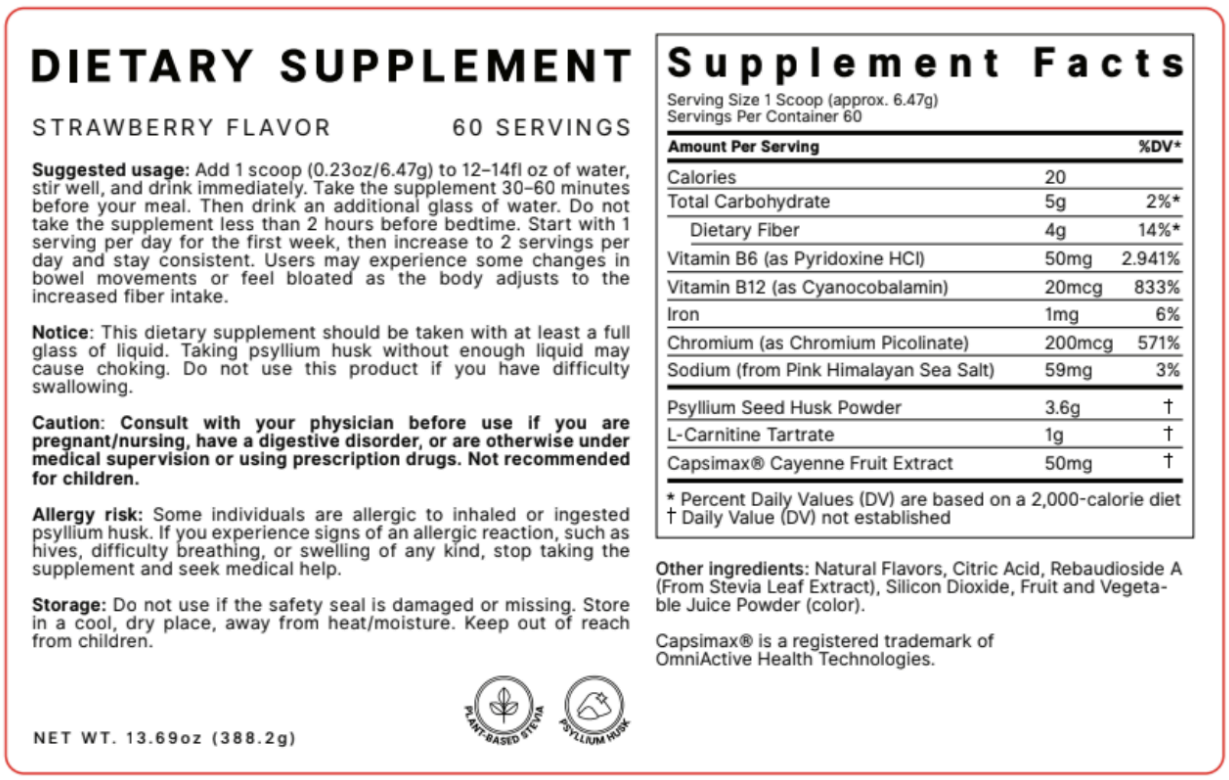
ABOUT THE STUDY

Many people worldwide experience gut health and weight problems, leading to lower quality of life. Maintaining the gut microbiome is essential for maintaining a healthy gut and weight. Dietary fiber supports a healthy gut microbiome and regulates appetite, inflammation, glucose metabolism, gut integrity, and the body's immune response.

The test product for this study was developed to improve gut health, assist in weight loss and improve energy levels.

The purpose of the study is to measure whether or not a gut health supplement, when used over 12 weeks, will lead to reduced gut health issues (constipation, bowel movements, gas, and bloating), as well as feeling healthier, reduced overeating, and potential weight loss. Furthermore, participants may experience feeling less tired and more energetic.

The study product contains:



DIETARY SUPPLEMENT

STRAWBERRY FLAVOR 60 SERVINGS

Suggested usage: Add 1 scoop (0.23oz/6.47g) to 12–14fl oz of water, stir well, and drink immediately. Take the supplement 30–60 minutes before your meal. Then drink an additional glass of water. Do not take the supplement less than 2 hours before bedtime. Start with 1 serving per day for the first week, then increase to 2 servings per day and stay consistent. Users may experience some changes in bowel movements or feel bloated as the body adjusts to the increased fiber intake.

Notice: This dietary supplement should be taken with at least a full glass of liquid. Taking psyllium husk without enough liquid may cause choking. Do not use this product if you have difficulty swallowing.

Caution: **Consult with your physician before use if you are pregnant/nursing, have a digestive disorder, or are otherwise under medical supervision or using prescription drugs. Not recommended for children.**

Allergy risk: Some individuals are allergic to inhaled or ingested psyllium husk. If you experience signs of an allergic reaction, such as hives, difficulty breathing, or swelling of any kind, stop taking the supplement and seek medical help.

Storage: Do not use if the safety seal is damaged or missing. Store in a cool, dry place, away from heat/moisture. Keep out of reach from children.

NET WT. 13.69oz (388.2g)

PLANT-BASED STEVIA PSYLLIUM HUSK

Supplement Facts

Serving Size 1 Scoop (approx. 6.47g)
Servings Per Container 60

Amount Per Serving		%DV*
Calories	20	
Total Carbohydrate	5g	2%*
Dietary Fiber	4g	14%*
Vitamin B6 (as Pyridoxine HCl)	50mg	2.941%
Vitamin B12 (as Cyanocobalamin)	20mcg	833%
Iron	1mg	6%
Chromium (as Chromium Picolinate)	200mcg	571%
Sodium (from Pink Himalayan Sea Salt)	59mg	3%
Psyllium Seed Husk Powder	3.6g	†
L-Carnitine Tartrate	1g	†
Capsimax® Cayenne Fruit Extract	50mg	†

* Percent Daily Values (DV) are based on a 2,000-calorie diet
† Daily Value (DV) not established

Other ingredients: Natural Flavors, Citric Acid, Rebaudioside A (From Stevia Leaf Extract), Silicon Dioxide, Fruit and Vegetable Juice Powder (color).

Capsimax® is a registered trademark of OmniActive Health Technologies.

Please review this product fact sheet carefully and consult with your doctor if you are unsure if you can take this product.

WHAT WILL WE ASK YOU TO DO?

Before the study begins, we will ask you to complete a baseline questionnaire, conduct an initial weigh-in, take body measurements, and take photos of your body.

After completing the baseline tasks mentioned above and you have received your gut health supplement, you will begin using the product as directed.

Every day, 30 - 60 minutes before a meal, add one scoop (0.23 oz / 6.47 g) to 12-14 fl oz of water. You will need to mix well and then drink immediately after preparing. Following the product, you should drink an additional glass of water. You should take the supplement at least 2 hours before bedtime. For the first week of the study, you will need to take one serving per day, and for the rest of the study period, you will need to take two servings per day. You must be consistent with the times of the day you consume the product.

You will complete questionnaires, weigh yourself, and take body measurements at the end of Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. You will also take a “before” photo at Baseline and an “after” photo at Week 12. The last photo in Week 12 marks the end of the study.

To collect accurate and reliable information, you must answer the questions honestly for this research study. All your responses will be anonymous and coded to your assigned case number in this study to protect your information.

The information will be collected via a separate secure online portal. The study staff will onboard you to this system via video chat or a phone call.

HOW LONG IS THE STUDY?

You will participate in the study for 12 weeks.

WHAT HAPPENS WHEN I DECIDE THAT I WANT TO PARTICIPATE?

If you decide to participate in this research, you will sign this Informed Consent Form (ICF) and be screened for eligibility. If eligible, you will be enrolled in the study, and a member of our research team will contact you to onboard you onto our software program and send you the product samples.

Following that, you will complete the baseline survey via the study portal. This will mark the start of your participation in this study. Next, you will take your baseline weight, body measurements, and photos. You will then use the products as directed, complete check-in questionnaires, weigh-ins/measurements, and take an “after” photo at specified intervals.

ARE THERE ANY POTENTIAL RISKS?

Minimal risk is foreseen for participants through their participation in the study. However, as with any study, there are some potential risks.

Some users might experience changes in bowel movements or feel bloated as the body adjusts to the increased fiber intake.

By signing this informed consent form, you acknowledge that you understand the potential risks and benefits of participating in this study. You acknowledge that the administration of the test

product may potentially result in unfavorable reactions and that neither the clinical research organization (CRO) nor the study sponsor shall be held accountable for such reactions. While precautionary measures are in place to limit the risks and safeguard your welfare, you acknowledge that no absolute assurances can be made regarding the occurrence of any untoward effects.

WHAT ARE THE POTENTIAL BENEFITS?

Benefits may include reduced gut health issues (constipation, bowel movements, gas, and bloating), as well as feeling healthier, reduced overeating, and potential weight loss. Furthermore, participants may experience feeling less tired and more energetic.

COMPENSATION AND COST

If you complete the study, which includes all of the questionnaires, weight measurements, body measurements, and photos, you will receive a $75 Visa gift card via email, at the end of your participation in the study. You will not receive any other compensation.

Compensation in this study is contingent upon the completion of all study actions. To receive compensation, you must complete all visits, surveys, photos, and procedures as outlined here. If you do not complete all study actions, you are not eligible for compensation.

There will be no charge to you for your participation in this study. The test product will be sent to you without any cost. Any leftover test product will not need to be returned.

HOW WILL MY INFORMATION BE PROTECTED?

The Health Insurance Portability and Accountability Act (HIPAA) describes how your Protected Health Information (PHI) may be used, disclosed, and made accessible. You will be asked to login to a secure software (patient portal), accessed via the internet, using a login code and a password. The patient portal used for the data collection is HIPAA compliant, meaning your private information is protected by law. To confirm your identity, communicate with you, determine your eligibility, and send you the product, we will collect your name, address, phone number, email address, and date of birth. Through the surveys, we will collect personal health information related to the study.

The information we collect will be kept confidential and will be used only for this study. Only the study staff involved in this study and those overseeing the study, including Argus IRB, will have access to your study records and PHI. All reports and communications released from this study will identify participants by an identification number only and will not contain identifying information. The study's overall results may be published; however, the identity of participants will not be included. Your right to access your PHI in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions, concerns, or complaints about the study during the study, please contact Christopher Hill and the team at 424-248-9151.

An Institutional Review Board (IRB) is an independent committee (group of people) established to help protect the rights and well-being of research subjects participating in research studies. The IRB reviews those studies. If you have any questions about your rights as a research subject and/or concerns or complaints regarding this research study, or if you do not want to talk to the investigator or study staff, contact Argus IRB at argusirb@cox.net or call 520-298-7494.

Argus IRB has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean Argus IRB has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

You will not lose any of your legal rights by agreeing to participate in this study.

You also understand that the sponsor, Citruslabs, and Argus IRB will keep your data confidential and that your name and other identifying information (such as date of birth) will never be used in any presentations, reports, or public documents related to this research study. You understand that your data and information will be analyzed as part of a group and that all study results will be presented in aggregate format.

My return of this form implies my consent to participate in this research and I have been given a second copy of this form to keep for my records.

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.
- I take all responsibility for using this supplement, I have checked the supplements fact table and know what ingredients the product contains.
- If necessary, I have consulted with a doctor and confirmed that I can use this product.

Your signature will be electronically captured if you agree to participate.

Participant Name	**Signature**	**Date**

Person Obtaining Consent	**Signature**	**Date**

Keep a copy of this consent form for your records.

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Image Publication Release & Photographic Consent Form

As part of the consumer perception study, you will need to take photographic images of your face at certain times during the study. This form is called an “Image Publication Release & Photographic Consent Form”, and once signed, it means that you grant the sponsor permission to use your photographic images that were produced for this study for their publications (for example as “before and after pictures”). You will make no monetary or other claims against the sponsor for the use of the photograph(s) that were taken of your face for this study. Your name will not be used in any of the publications. You’ll receive photo guidelines about how you’re supposed to take the images. Your smartphone camera or any other digital camera will be sufficient for this and you will not need to purchase any equipment. If any of the images are published, your eyes will be blacked out to ensure that you remain anonymous.

If you have any questions or concerns about this form, please contact Christopher Hill at 424-248-9151.

PARTICIPANT CONSENT

By signing below, you acknowledge that:

1) You are 18 years of age or older.
2) Hereby grant the sponsor permission to use the photographic images that were taken of you in this study for publication.
3) Hereby release the sponsor from any liability for any adverse events that might occur during the study.
4) Any questions you have about the use of your image have been answered satisfactorily.
5) There will be no further compensation for any photographs.
6) Your name will not be used in any publication.

I understand and agree to the conditions outlined in this Image Publication Release & Photographic Consent Form. I hereby allow the sponsor to use these photographs/images, and I give up any and all of my own future claims and rights to use these photographs/images.

Print Name: _____ Date: _____

Signature: _____

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Bill of Rights for Human Subjects in Medical Research

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.