A Single-Group Study to Examine the Efficacy of a Gut Health Supplement to Increase Metabolism, Improve Gut Health, and Support Weight Management

Protocol Number: 20349

National Clinical Trial (NCT) Identified Number: NCT06023082

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Sponsor: Gut Health, UAB

Clinical Research Organization: Citruslabs

Version Number: v.1.0

30 May 2023

Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale

STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP), and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. The protocol and consent form must be approved before enrolling any participant. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

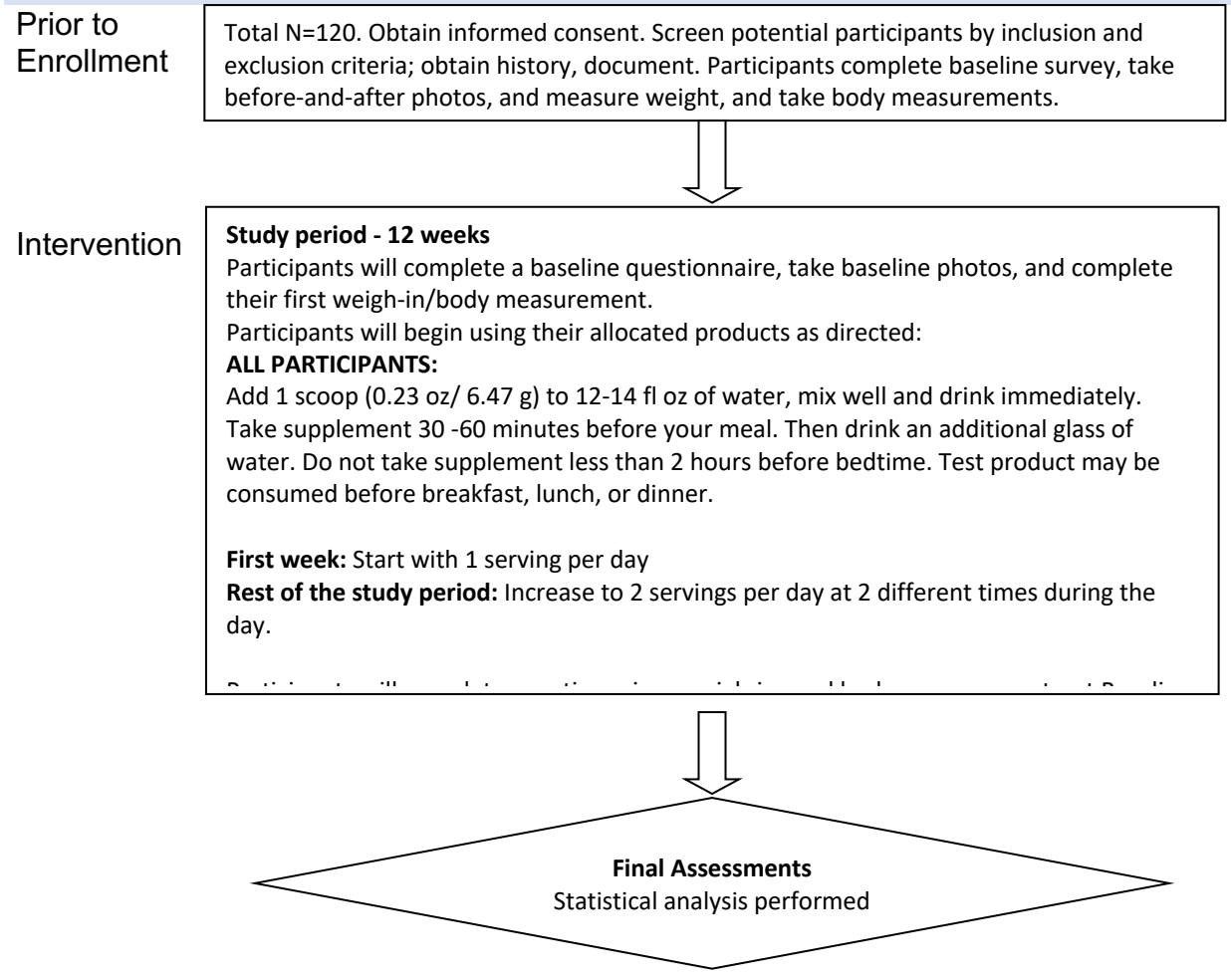
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	A Single-Group Study to Examine the Efficacy of a Gut Health Supplement to Increase Metabolism, Improve Gut Health, and Support Weight Management
Study Description:	This study will evaluate the efficacy of Colon Broom Premium on gut health, metabolism, weight management, and energy levels. The study will be conducted as a virtual single-group trial in which all 120 participants will use the test product. This study will last 12 weeks, and participants will take the product daily. Participants will complete study-specific questionnaires at Baseline, Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. Participants will also provide body weight measurements and body circumference measurements at Baseline, Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. Before & after photographs will be provided at Baseline and Week 12. The Colon Broom Premium supplement contains psyllium seed husk powder, L-carnitine tartrate, Capsimax® cayenne fruit extract, chromium (as chromium picolinate), vitamin B6 (as pyridoxine HCl), vitamin B12 (as cyanocobalamin), and Iron. The study Sponsor and product name will remain anonymous to participants throughout the trial. The Sponsor name or product name will not be included in any participant-facing documentation.
Objectives:	*Primary Objective:* To examine Colon Broom Premium's effect on improving gut health and metabolism. *Secondary Objective:* To determine the effects of Colon Broom Premium on weight management.
Endpoints:	*Primary Endpoint*: Improvement in gut health issues and metabolism. This will be measured through study-specific questionnaires, evaluating bowel movement regularity, satiety, energy levels, and gastrointestinal symptoms such as gas, bloating, constipation, heartburn/acid reflux, abdominal pain, and digestion. *Secondary Endpoints:* Weight management will be evaluated via weigh-ins, body measurements, questionnaires, and before-and-after photos.

Study Population:	120 men and women ages 30 - 50 with a minimum BMI of 25.0.
Description of Sites/Facilities Enrolling Participants:	Virtual trial. Enrollment, questionnaires, photos, measurements, and weigh-ins will be completed virtually.
Description of Study Intervention:	A virtual single-group Colon Broom Premium supplement trial. Assessments will be conducted virtually through questionnaires completed at Baseline and then Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. Body measurements and weight measurements will also be taken at Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. Photos will be taken at Baseline and at Week 12.
Study Duration:	12 weeks
Participant Duration:	12 weeks

1.2 SCHEMA



1.3 SCHEDULE OF ACTIVITIES (SOA)

Procedures	Screening	Intervention	Conclusion
Informed Consent	x		
Demographics	x		
Inclusion/ Exclusion	x		
Administer Study Intervention		x	
Surveys	x	x	x
Photos	x		x
Weigh-Ins	x	x	x
Body Measurements	x	x	x
Adverse event Review and Evaluation	x	x	x

2 INTRODUCTION

2.1 STUDY RATIONALE

Digestive issues plague nearly 60 - 70 million people worldwide, and in the past ten years, diseases and disorders related to the gastrointestinal system have increased due to significant lifestyle changes[1]. Furthermore, several studies have documented a high prevalence of depression, stress, anxiety, and altered central nervous system processing among people with gastrointestinal issues[2].

The gut microbiome is a crucial factor in the pathogenesis of most gut issues, as well as having an important role to play in the development of obesity, energy maintenance, and immunoresponse[3].

Therefore, maintaining the gastrointestinal microbiome is vital to a healthy gut system and weight. Dietary fibers affect the gut microbiome and play essential roles in signaling pathways, regulating appetite, inflammation, glucose metabolism, gut integrity, and the body's immune response[4].

The Colon Broom Premium Supplement is a natural, plant-based dietary fiber complex that helps to promote digestive health, assist in weight loss, and relieve constipation. The supplement contains:

Psyllium husk: Commonly used fiber as a gentle, bulk-forming laxative. Psyllium husk can pass through the digestive system without being completely broken down or absorbed. Instead, it absorbs water and becomes a viscous compound that alleviates constipation and diarrhea, helps to control blood sugar and blood pressure, and benefits weight loss.

L-carnitine: L-carnitine can assist with physical performance and muscle recovery after exercise.

Capsimax® Cayenne Fruit Extract: Capsimax is a concentrated natural capsicum extract from red hot chili peppers. Capsaicinoids found in chili peppers and pepper extracts have been found to enhance metabolism and assist in weight loss[5].

Chromium (as Chromium Picolinate): Chromium is an essential human micronutrient. Some take it as a supplement for a complementary and alternative therapy to help control blood sugar levels, lower cholesterol, or lose weight[6].

The product also contains vitamins B6, B12, and iron to assist in maintaining a healthy body and improving mental health.

This trial examines the efficacy of the Colon Broom Premium supplement in improving gut health, metabolism, weight loss, and mental health outcomes. This study will include 120 participants using the test product for 12 weeks. The trial will last 12 weeks, and the participants will record self-perceived outcomes, weight, and body measurements at Baseline and then at Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. In addition, participants will take photos at Baseline and Week 12.

2.2 Risk/Benefit Assessment

Immediate *risks*: There are no expected immediate risks for participants using this supplement; however, some users may experience some changes in bowel movement or feel bloated as the body adjusts to the increased fiber intake.

Long-term *risks*: There are no expected long-term risks for participants using this supplement.

Immediate *benefits*: Participants may see benefits to overall health and gut health (reduced constipation, regular bowel movements, feeling lighter, less gas, decreased bloating). Furthermore, participants may feel more energetic with improved mood, focus, energy, and weight reduction.

Long-term *benefits*: Participants may see benefits to overall health and gut health (reduced constipation, regular bowel movements, feeling lighter, less gas, decreased bloating). Over time, the immediate benefits can improve the overall quality of life and ability to complete activities of daily living.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	TIMEPOINTS	ASSESSED BY	JUSTIFICATION FOR ENDPOINTS
Primary				
To examine the effect of Colon Broom Premium Supplement on gut health and metabolism.	Questionnaires	Baseline, Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12.	Self-reported questionnaire	To evaluate the perceived effects of the treatments on gut health and metabolism
Secondary				
To examine changes in weight and body measurements, and overall health	Photos	Baseline and Week 12	Virtual grading of body size	To identify visual changes in weight
	Questionnaires	Baseline, Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12.	Self-reported questionnaire	To evaluate the perceived effects of the treatments on weight and overall health
	Body weight measurements	Baseline, Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12.	Self-reported weight and tape measurements	To evaluate the effects of the treatments on weight and body size.
	Tape measurements of the body			

4 STUDY DESIGN

4.1 OVERALL DESIGN

This study is a single-group trial with 120 participants with gut health issues and who are overweight. Participants will take a Colon Broom Premium supplement daily for 12 weeks. Participants will provide questionnaires, weight measurements, body measurements, and photos at baseline before the study starts. Follow-up questionnaires, weight measurements and body measurements will be completed at the end of Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12. At the end of Week 12, participants will also take final photos, marking the end of the study. The trial will be a virtual study, and the participants will follow the product use instructions provided by the research team.

4.2 Scientific Rationale for Study Design

A single-group study is an appropriate design best to understand the efficacy and safety of the test product. A design that encompasses 12 weeks is also long enough to determine if the supplement is effective at improving gut health and measuring changes to weight and size beyond short-term fluctuations that may occur. The data collection intervals for this trial were chosen to minimize the burden on the patients (i.e., not having to travel to a clinic) while still collecting valuable data about the efficacy of the test product over time.

4.3 Justification for Dose

The test product examined in this study will be taken in the exact dosages of the commercially available products. This will be done to help establish marketing claims that can be used with the test product and to understand the current formulation of the test product.

4.4 End of Study Definition

A participant is considered to have completed the trial if he or she has completed all study phases, including the last scheduled procedure (Week 12 questionnaire, weigh-in, body measurements, and photos).

5 STUDY POPULATION

5.1 Inclusion Criteria

To be eligible to participate in this study, an individual must meet all of the following criteria:

1. Male or female between ages 30-50
2. Have a BMI of 25 or more
3. Have self-reported issues with gas, bloating, constipation, heartburn/acid reflux, abdominal pain, or digestion at least three times per week
4. Be willing to maintain their standard dietary pattern, activity level, and body weight for the duration of the study
5. Be generally healthy - do not live with any uncontrolled chronic disease

5.2 Exclusion Criteria

An individual who meets the following criteria will be excluded from participation in this study:

1. Any pre-existing chronic conditions that would prevent participants from adhering to the protocol, including oncological and psychiatric disorders
2. Anyone who is currently undergoing, or planning to to undergo any gut or weight-related procedures in the next 12 week.
3. Anyone with a history of severe allergic reactions including but not limited to psyllium seed husk powder and strawberries
4. Anyone taking any prescription medications targeting the gut

5. Anyone taking any supplements targeting the gut in the past month
6. Use of antibiotics in the past 3 months
7. Women who are pregnant, breastfeeding, or attempting to become pregnant
8. Anyone unwilling to follow the study protocol
9. Anyone following any particular dietary regime, such as a ketogenic diet or intermittent fasting.
10. Anyone who has had bariatric surgery in the past 6 months
11. Anyone who has chronic constipation
12. Anyone who has Irritable Bowel Disease (IBD)
13. Anyone diagnosed with severe digestive issues

5.3 PARTICIPANT COMPENSATION

All participants will be compensated $75 for their time and effort in the form of a prepaid VISA card.

5.4 JUSTIFICATION OF SAMPLE SIZE

120 participants is sufficient to establish differences between baseline and endline while accounting for the natural variance in different people. This will allow for meaningful comparisons between baseline and endline to test the efficacy of the Colon Broom supplement adequately.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION

Potential participants who meet the initial inclusion and exclusion criteria will have the option of participating in this trial. After signing the informed consent, participants will begin the trial by taking the initial baseline survey, taking baseline photos, conducting the initial weigh-in, and taking baseline body measurements.

After the baseline data collection, participants will begin using their allocated products.

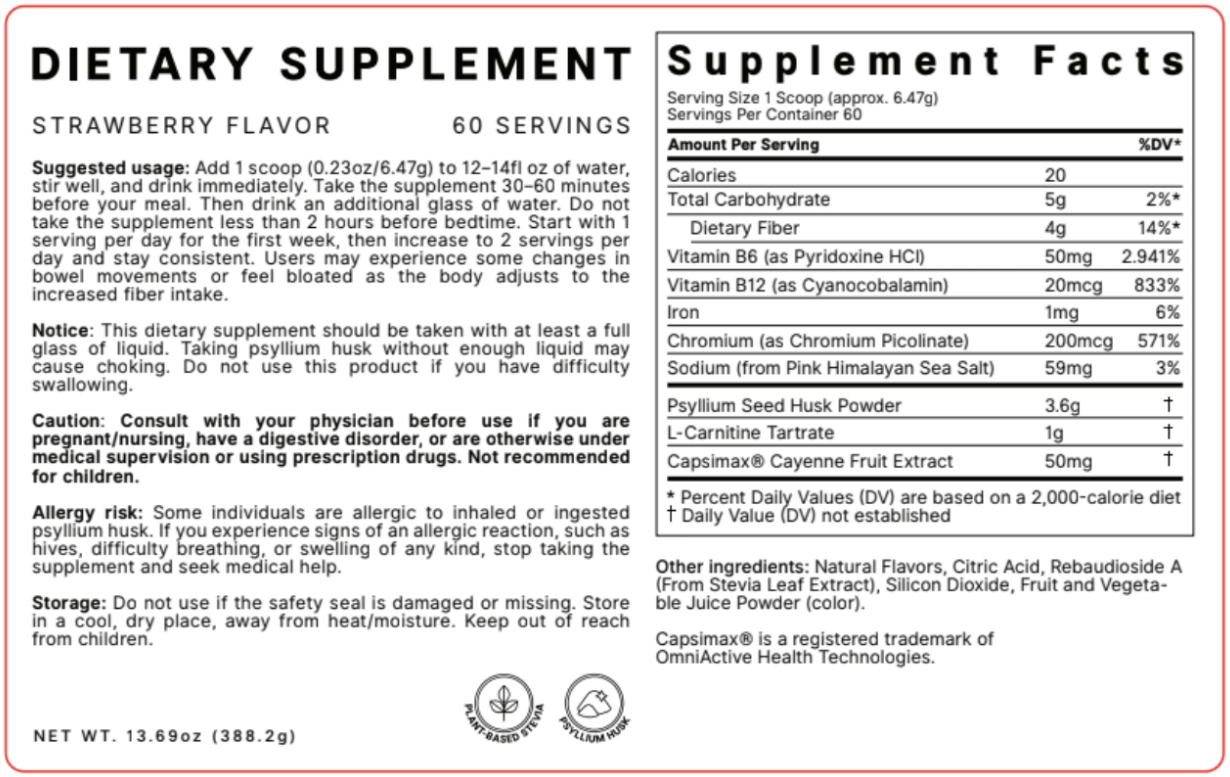
- Participants will be sent 3 containers of Colon Broom Premium containing 60 scoops per container, amounting to a minimum of 180 scoops over the 12-week period
- The product should be taken as follows:
    - Participants will add 1 scoop (0.23 oz / 6.47 g) to 12-14 fl oz of water, mix well and drink 30 - 60 minutes before eating.
    - The supplements should be consumed immediately after preparation and followed by an additional glass of water.
    - Participants should not take the supplement less than 2 hours before bedtime.
    - Participants should start with 1 serving per day for the first week, then increase to 2 servings per day after that.

- Participants will complete questionnaires at Baseline, Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12.
- Participants will complete weigh-ins and body measurements at baseline and at Week 1, Week 2, Week 3, Week 4, Week 6, Week 8, Week 10, and Week 12.
- Participants will complete “before” photos at baseline and “after” photos at endline (Week 12). This will mark the conclusion of the trial.

6.2 Intervention Formulation

The product contains the following ingredients:

- Psyllium Seed Husk Powder
- L-Carnitine Tartrate
- Capsimax® Cayenne Fruit Extract
- Chromium (as Chromium Picolinate)
- Vitamin B6 (as Pyridoxine HCl)
- Vitamin B12 (as Cyanocobalamin)
- Iron



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.

6.3 Randomization and Blinding

The study Sponsor and product name will remain anonymous to participants throughout the trial. The Sponsor name or product name will not be included in any participant-facing documentation. There is no randomization for this study.

6.4 Participant Discontinuation/Withdrawal from the Study

Participants can withdraw from the study at any time upon request.
An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Pregnancy
- Significant study intervention non-compliance
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- Disease progression which requires discontinuation of the study intervention
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- Participant should be withdrawn from study if they start on a new drug or receive antibiotics

The reason for participant discontinuation or withdrawal from the study will be recorded on a Case Report Form (CRF). Participants who sign the informed consent form but do not receive the study intervention may be replaced. Participants who sign the informed consent form, receive the study intervention, and subsequently withdraw or are withdrawn or discontinued from the study, will not be replaced.

6.5 Photo Instructions

The photos taken during this study will be used to track weight loss.

Participants will provide photos at the following time points during the study:

- Baseline (Week 0)
- Endline (Week 12)

At baseline and endline, participants will take three photos from their chin down to their knees at the following angles: front-facing, side profile, and facing backward.

Photo guidelines:

- Have someone take the photos for you if possible
- Flash OFF
- Wearing underwear if comfortable (tight clothing if not comfortable wearing underwear)
- The photo should include the entire area between the chin and the knees of the participants
- Take three photos (front-facing, side profile, back-facing)
- Take photos in a well-lit room without shadows
- Take photos in the same location at the same time

6.6 Body Measurements

The body measurements taken during this study will be used to track weight loss. Participants will receive a tape measure to gather their measurements.

Participants will provide measurements at the following time points during the study:

- Baseline (Week 0)
- Week 1
- Week 2
- Week 3
- Week 4
- Week 6
- Week 8
- Week 10
- Endline (Week 12)

Participants will measure the following areas:

- Waist
- Hips
- Legs (thighs)

Participants must adhere to the following instructions when taking measurements:

- To ensure accurate measurements, wear tight-fitting or form-fitting clothing or wear your undergarments while measuring. This will help you get precise measurements without any bulky layers of clothing distorting the measurements.
- Stand up straight with your feet shoulder-width apart. Relax your body and keep your arms at your sides. It may be useful to do this in front of a mirror.

Measure your waist:

- First, locate your natural waist which is the narrowest part of your torso. This is usually located just above your belly button.
- Start by wrapping the measuring tape around your waist. Hold one end of the tape against your body at your natural waist and bring the other end around your waist, keeping it parallel to the floor. Ensure that the tape is snug against your body without digging into your skin or compressing it. Make sure the tape is level and not twisted.
- Exhale and take the measurement: Once the tape is in position, take a normal breath and then exhale. Read the measurement at the point where the end of the tape meets the rest of the tape around your waist. Take note of the measurement in inches.

Measure your hips:

- First, locate the widest part of your hips. The hip measurement should be taken at the fullest part of your buttocks and hips.
- Start by wrapping the measuring tape around your hips. Hold one end of the tape against your body at the fullest part of your hips and buttocks. Bring the other end of the tape around your hips, making sure it remains parallel to the floor. The tape should go over the largest part of your buttocks.

- Take the measurement by reading the point where the end of the tape meets the rest of the tape. Note down the measurement in inches. Ensure that the tape is snug against your body without being too tight.

Measure your thighs:

- First, locate the widest part of your upper thigh on both legs. This is where you will take your measurement.
- Wrap the measuring tape around your thigh: Hold one end of the tape against your thigh at the chosen point and wrap the tape around your thigh, keeping it parallel to the floor. Make sure the tape is snug against your skin without digging in or compressing your thigh.
- Take the measurement by reading the point where the end of the tape meets the rest of the tape. Note down the measurement in inches.

6.7 DEVICES

Participants must have access to a body weight scale and a smartphone or digital camera for the duration of the study. Participants will be provided with a measuring tape.

7 STATISTICAL CONSIDERATIONS

Following data collection and the completion of the trial, the data will be analyzed by Citruslabs to determine the effect of the intervention. Participant repeated measures between time point statistical tests will be used to examine differences in gut health, weight, metabolism, and mental health. Percentages of people who experienced improvements will also be examined.

8 CONSENT, PRIVACY AND OTHER POLICIES

8.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant, and written documentation of informed consent is required before starting intervention/administering study intervention. The following consent materials are submitted with this protocol: informed consent form and patient bill of rights.

8.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated before the individual agrees to participate in the study and continues throughout the individual's study participation. Consent forms will be approved by Institutional Review Board (IRB), and the participant will be asked to read and review the document. These documents will explain the research study to the participant and answer any questions that may arise. A verbal or written explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will be able to carefully review the written consent form and ask questions before signing. The participants should have the

opportunity to discuss the study with their family or surrogates or think about it before agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. The participants will be given a copy of the informed consent document for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

8.3 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants (not applicable to this study). Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any third party without prior written approval of the sponsor.

The study participant's contact information and records will be securely stored on an AWS server. At the end of the study, all records will remain in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

8.4 Data Collection and Management Responsibilities

Data collection is the responsibility of Citruslabs, which ensures the accuracy, completeness, legibility, and timeliness of the data reported.

Trial data will be entered into a 21 CFR Part 11-compliant data capture system provided by Citrus Labs. The data system includes password protection and internal quality checks, such as automatic range checks, to identify inconsistent, incomplete, or inaccurate data. Clinical data will be entered directly from the source documents.

8.5 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the CRO staff. As a result of deviations, corrective actions are to be developed by the trial administrator (Citruslabs) and implemented promptly.

It is the responsibility of Citruslabs to use continuous vigilance to identify and report deviations within 7 working days of identification of the protocol deviation, or within 7 working days of the scheduled protocol-required activity. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. Citruslabs is responsible for knowing and adhering to the reviewing IRB requirements.

8.6 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies: the study may be published in an open-access preprint server. The study administrators (Citruslabs) will be acknowledged in any publications relating to this study. This trial may be registered with clinicaltrials.gov and results may be submitted to clinicaltrials.gov following publication. No part of this study, including protocol and results, may be published in any form without explicit prior approval in writing by the study sponsor.

8.7 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

The sponsor has a conflict of interest because they may benefit financially from the study's success. To manage the conflict of interest, an independent third party (Citrusabs) will handle all design and administration of participant-focused materials, all participant recruitment and data gathering, and data analysis.

9 REFERENCES

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