RESEARCH PARTICIPANT INFORMED CONSENT FORM
SUBJECT INFORMATION

Date: 03/14/2024
Protocol Number & Study Title: 20424 A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effects of a Dietary Supplement on Children's Health and Development Outcomes
NCT Number: NCT06704178
Name of Person In Charge of the Research Study (Investigator): Dr Swathi Varansi (Citruslabs)
Telephone Number(s), Daytime/ After hours: (805) 292-0714

CONCISE SUMMARY:

The purpose of this research study is to determine the efficacy of a dietary supplement in improving a range of health outcomes in children. Participation will be virtual, requiring participants to take one scoop of the test product every morning for six months. The children will complete cognitive assessments at Baseline and Month 6. The parents will need to complete surveys at Baseline and every month (Month 1-6), as well as provide weight and height measurements of the children at Baseline, Month 2, Month 4, and Month 6. You (the parent) will sign this form on behalf of your child.

This is a placebo-controlled study, so you/your child have an equal chance of being allocated to the test product or placebo group. The placebo products will taste and look the same without any active ingredients.

If you and your child are interested in learning more about this study, please continue to read below.

INTRODUCTION

Your child is invited to participate in a research study that examines a dietary supplement powder. The test product contains well-researched ingredients and is a commercially sold product.

Participation in this study is completely voluntary. Before you and your child decide to participate, please read this form carefully and ask the study staff for further information or clarification as necessary. Ask as many questions as required to fully understand what will occur during participation in the study. Please do not sign and date this form unless you are fully satisfied that your questions have been addressed. You may choose to stop participating in the study at any time, and you can do this without penalty or loss of benefits of participating in the study. Choosing not to participate or to stop participating at any time 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 you need to review the material and make an informed decision.

ABOUT THE STUDY

The primary objective of this clinical research study on a dietary supplement powder is to investigate the effect of this product on children's overall health, including height, weight, cognitive function, energy levels, digestion, and how often they get sick (immune function). This trial's data collection intervals were chosen to minimize participant burden while still gathering valuable information about the test product's efficacy.

This study is a randomized, double-blinded, placebo-controlled trial of 60 participants and their parents with a self-reported desire to improve overall health. Participants will be randomized into one of two arms. Arm 1 will take the product throughout the trial. Arm 2 will take a placebo product for the duration of the trial.

The results of the study will provide valuable information about the potential benefits of a dietary supplement on children's overall health. This data can then be used to inform stakeholders about the potential benefits of these supplements for children.

The test products contain the following ingredients:

NuBest Tall Growth Protein Powder: Protein, Vitamin A, Vitamin C, Vitamin D, Vitamin E, Thiamine, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Biotin, Pantothenic Acid, Choline, Calcium, Iron, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Chloride, Sodium, Potassium, Organic Flax Seed Powder, L-Taurine, Inositol Hexanicotinate, L-Arginine, Bacillus subtilis DE111® Complex (1 Billion CFU) (Probiotic), Eucommia Bark Extract, Vitamin K, Whey Protein Concentrate, Chocolate Bean Powder Processed with Alkali, Organic Evaporated Cane Sugar, Milk Protein Concentrate, Guar Gum Powder, Natural Flavor, Potassium Chloride, Silicon Dioxide, Rebaudioside A (from Stevia Leaf Extract), Sucralose.

Placebo Product: Maltodextrin, Guar gum powder, Silicon dioxide, Cocoa powder, Natural creamy vanilla flavor, Organic evaporated cane sugar, Stevia leaf extract, and Sucralose.

WHAT WILL WE ASK YOU TO DO?

Before the study begins, we will ask you to complete a Baseline questionnaire assessing your child’s overall health. You will also need to provide a weight and height measurement for your child. You will be provided with standardized devices to do this. Your child will also need to complete a cognitive assessment. This marks the Baseline assessment.

You and your child will be randomly allocated into the test products group or the placebo group. You will not know which group you are in, nor will you be able to distinguish the products by look, smell, or packaging.

Your child will take one scoop of the test product every morning, mixed with water, milk, or a smoothie. You will complete a follow-up questionnaire every month, and you will provide another weight and height measurement at the end of Months 2, 4, and 6. Your child will repeat the cognitive assessment at the end of Month 6. The measurements at the end of Month 6 mark the conclusion of the trial.

You must answer the questions honestly for this research study to collect accurate and reliable information. 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 to which you will be onboarded through the study staff as well, either via video chat or a phone call.

HOW LONG IS THE STUDY?

You and your child will participate in the study for 6 months.

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, your child will be enrolled in the study, and a member of our research team will contact you (the parent) to onboard you (the parent) onto our software program and send you the product samples.

Following that, you will complete the Baseline questionnaire and provide the Baseline measurements of your child. Your child will also complete the cognitive assessment battery via an online program. This will mark the start of your participation in this study.

ARE THERE ANY POTENTIAL RISKS?

Minimal risk is foreseen for participants through their participation in the study. However, with any study, there is the risk of an unexpected reaction when trying a new product. NuBest Tall Protein contains milk-based ingredients, so it is not suggested for those with a dairy allergy. It does not contain soy, grain, wheat, GMO, or gluten.

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 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?

Participants may experience improvements in their overall health.

COMPENSATION AND COST

If you complete the study, which includes appropriate consumption of the product in line with the inclusion and exclusion criteria and completion of the check-in documentation throughout the duration of the study, you will receive a Visa gift card of $150 sent to your 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. This means that to receive compensation, you must complete all visits, surveys, cognitive assessments, and procedures as outlined here. If you do not complete all study actions for any reason, 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 each participant without any cost. Any leftover test product will not need to be returned.

Participant's Responsibilities:

- The Participant agrees to fully comply with all study-related activities and requirements outlined here which is in compliance with the study design.
- The Participant agrees to attend all scheduled study visits, at-home testing, and/or surveys and complete any required actions within the specified timeframes.

Compensation:

- In consideration for the Participant's time and commitment to the Study, the Participant will be eligible to receive compensation as outlined here.

- The Participant acknowledges and agrees that timely completion of all study actions is a prerequisite for eligibility to receive compensation.
- The Participant acknowledges that partial compensation is not provided.

Timely Completion Requirement:

- The Participant understands and agrees that failure to complete study actions within the specified timeframes may result in the Participant becoming ineligible for compensation.
- The Participant acknowledges that the Sponsor may, at its sole discretion, determine whether a delay in completing study actions is acceptable and whether compensation will be provided.

DEVICE PROVISION AND RETURN AGREEMENT

As a participant in this study, you will be provided with the device(s) necessary for the successful completion of the study activities. The device(s) are provided to you for the primary purpose of facilitating your participation in the study.

By agreeing to participate in this study and accepting the device(s), you hereby acknowledge and agree to the following terms:

- Purpose of Device(s): The device(s) provided to you are for the primary use of participating in and completing the study activities as directed.
- Return of Device(s): If you decide to withdraw from the study, fail to complete the study, or do not follow the instructions provided for the study activities, you are required to return the provided device(s) to the study coordinators within one (1) week of receiving a request to do so. You are responsible for the associated shipping charges.
- Condition of Return: The device(s) must be returned in the same condition as when provided, which is brand new and in the provided manufacturer packaging.
- Failure to Return Device(s): In the event that you fail to return the device(s) within the specified one (1) week period, or return the device(s) in a damaged condition, you will be invoiced for the full retail price of the device(s). Payment of this invoice will be due within seven (7) days of issuance.
- Option to Keep Device(s): At the completion of the study, your device will be unlocked and available to you for your own personal use.
- Acknowledgment of Agreement: By accepting the device(s) and participating in the study, you acknowledge that you have read, understood, and agreed to these terms. You understand that your participation in the study is voluntary and that you are free to withdraw at any time without penalty, except as noted in this agreement regarding the return of the device(s).

This agreement serves to protect the interests of both the study participants and the research institution conducting the study. Your cooperation and compliance with these terms are greatly appreciated and essential for the smooth operation and success of the study.

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 log in to a secured 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. In order 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 be collecting personal health information related to the study.

The information we collect will be kept confidential and will be used only for the purpose of this study. Only the study staff involved in this study and the people 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 overall results of the study 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?

During the study if you have any questions, concerns, or complaints about the study, please contact Dr Swathi Varanasi and the team at (805) 292-0714.

An Independent 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 Citruslabs and Argus IRB will keep your data confidential and that your name and other identifying information (such as email address) 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.

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

Participant/Child Name	Signature	Age	Date

Parent Name (Printed)	Relationship to Child	Signature

Date

citruslabs

Person Obtaining Consent Signature Date

Keep a copy of this consent form for your records.

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.