A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effects of a Dietary Supplement on Children's Health and Development Outcomes

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Sponsor: NuBest

Clinical Research Organization: Citruslabs

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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 in 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

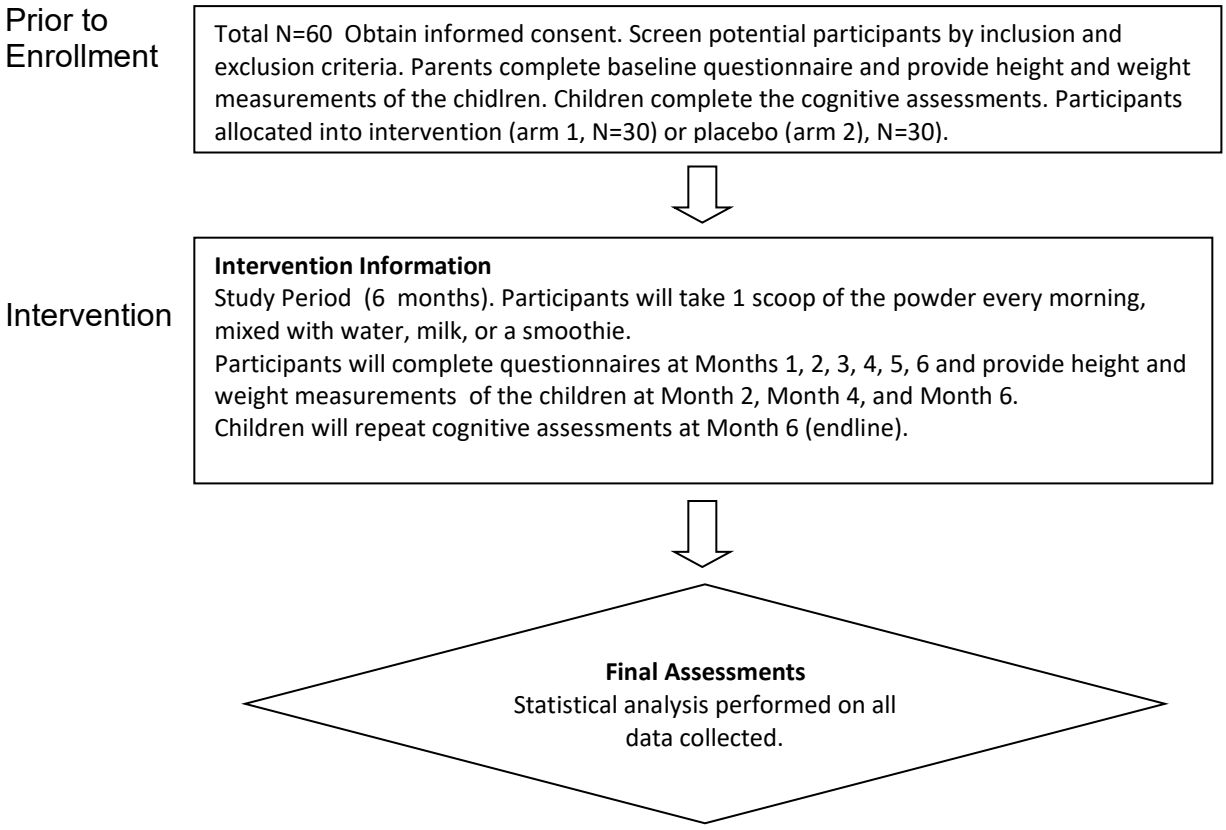
1.1 SYNOPSIS

Title:	A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effects of a Dietary Supplement on Children's Health Outcomes
Study Description:	This is a virtual, two-armed, randomized, double-blinded, placebo-controlled clinical trial that will last 6 months. Participants will take the NuBest Tall Growth Protein Powder or a placebo product daily. The children's parents will complete questionnaires at baseline and regularly during the study period (Month 1, Month 2, Month 3, Month 4, Month 5, and Month 6). The children will complete cognitive assessments at home at Baseline and Month 6 (Endline). Parents will also provide height and weight measurements of the children at Baseline, Month 2, Month 4, and Month 6.
Objectives:	***Primary Objective:*** To examine the effect of the NuBest Tall Growth Protein Powder on cognitive function. ***Secondary Objective:*** To investigate the impact of the NuBest Tall Growth Protein Powder on a range of health parameters, including height, weight, energy levels, immune function, and digestion.
Endpoints:	***Primary Endpoint*:** The primary endpoint of this study is an improvement in cognitive function. Cognitive battery testing scores will be compared across the trial measurement points. ***Secondary Endpoints:*** The secondary endpoint is an increase in a range of parameters associated with health, including height, weight, energy levels, immune function, and digestion. Parents will provide height and weight measurements for the children and will complete questionnaires evaluating other health outcomes.
Study Population:	This study will recruit 60 participants (60 pairs of parents + child). The parents may be of any age group, the children must be aged as follows: ● Boys: 12 to 16 years ● Girls: 10 to 14 years Arm 1: Intervention - 30 participants

	Arm 2: Placebo - 30 participants
Description of Sites/Facilities Enrolling Participants:	Virtual
Description of Study Intervention:	● After eligibility is established, participants will complete a Baseline questionnaire, the Baseline cognitive assessment, and provide the Baseline height and weight measurements. ● Participants will be randomly allocated to either the intervention or placebo group. The participants and Citruslabs will not be informed who is in the test or the placebo group. ● Participants will begin taking their respective product for 6 months. The children will drink one scoop of the powder mixed with 6-8 oz of water, milk, or smoothies. ● Parents will complete questionnaires at the end of Month 1, Month 2, Month 3, Month 4, Month 5, and Month 6, and will provide further height and weight measurements at Month 2, Month 4, and Month 6. ● The children will repeat the cognitive assessments at Month 6 (endline).
Study Duration:	6 months
Participant Duration:	6 months
Product Instructions:	● The test products must be consumed in the morning. ● Combine one scoop of the powder with 6-8 oz of water, milk, or smoothies. ● Do not use NuBest Protein Powder for baking or cooking recipes.
Stadiometer Instructions:	● Step 1: Upon powering on the device, securely affix it to the wall, ensure that the height measuring instrument remains perpendicular to the ground and parallel to the wall at a 90-degree angle. ● Step 2: Once you've adjusted the height accordingly, press the measurement key only in the absence of any obstacles. ● Choose a flat ground without steps, and try to avoid testing on carpets or uneven areas with plush carpets or rugs. ● Ensure the device is perpendicular to the ground.
Compensation	● $150 Visa gift card ● FitBit Smart Scale

	• Ultrasonic Height Measuring Stadiometer

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	
Questionnaires	x	x	x
Height & Weight Measurements	x	x	x
Cognitive Battery Testing	x		x
Adverse event Review and Evaluation	x	x	x

2 INTRODUCTION

2.1 STUDY RATIONALE

Protein is fundamental to growth and the repair of body tissues; hence, its adequacy in children's diets is critical for optimal physical development. Studies have highlighted the role of dietary protein in increasing height and weight in children, suggesting a direct correlation between protein intake and growth metrics[1-3]. Similarly, essential vitamins such as Vitamin A, C, D, E, and B-complex and minerals like Calcium, Iron, and Zinc have well-documented contributions to other aspects of physical development, bone health, immune function, and cognitive development[4,5]. For instance, Vitamin D's role in bone mineralization is well-documented[6], while Iron and Zinc have been associated with cognitive function and immune defense[7] Furthermore, emerging research on the gut-brain axis underscores the significance of digestive health in cognitive and immune system functions, advocating for the inclusion of probiotics and prebiotic fibers in dietary regimens for children[8].

In the USA, many people are at risk of vitamin, mineral, and/or other micronutrient deficiencies[9-11]. Children and adults are consuming more low-nutrient foods with added sugar and excess fats as compared to healthy, high-quality calories and micronutrients. The risk of this is further exacerbated by socioeconomic and family income to poverty ratio[10]. However, research has suggested that dietary supplements can be helpful in meeting nutrient requirements for some micronutrients.

With this in mind, the test product has been developed and contains a proprietary blend of vitamins, minerals, and probiotics designed to enhance children's and teenager's health outcomes through the aforementioned mechanisms. This study will assess the effects of the test product on a range of health outcomes in children over the course of 6 months.

2.2 RISK/BENEFIT ASSESSMENT

Immediate *risks*:
There are no predicted risks associated with this product. However, some people may experience adverse reactions 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.
As dairy can interact with a number of medications, all medications should be separated by a minimum of 4 hours from taking the test product.

Long-term *risks*:
There are no predicted long-term risks related to using this product. Any short-term risk should dissipate after discontinuing the test product.

Immediate *benefits*:
Participants may experience positive changes in overall health. Also, participants might experience increased energy levels, immune function, and overall well-being.

Long-term *benefits*:
Participants may experience an increase in height, maintenance of a healthy weight, and enhanced quality of life due to an increase in overall health.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	TIMEPOINTS	ASSESSED BY	JUSTIFICATION FOR ENDPOINTS
Primary				
To examine the effect of the NuBest Tall Growth Protein Powder cognitive function.	Improvement in score on assessments: ● Double Trouble ● Feature Match ● Grammatical Reasoning ● Digit Span ● Token Search	Baseline and Month 6	Cognitive Battery Testing	The combination of these cognitive assessments will provide objective data on the efficacy of the product in improving specific domains of cognitive function.
Secondary				
	Increase in height			

To investigate the impact of the NuBest Tall Growth Protein Powder on a range of health parameters, including height, weight, energy levels, immune function, and digestion.	Maintenance of a healthy weight	Baseline, Month 2, Month 4, Month 6 (height & weight measurements)	Height measured using an Ultrasonic Height Measuring Stadiometer	The combination of objective measurements and questionnaires will provide both independent and participant perception data on secondary health parameters.
	Increase energy levels			
	Improved signs of digestive health		Weight measured using a FitBit Smart Scale.	
	Increased immune function (assessed via the number of times the child has been ill in the past 6 months)	Baseline, Month 1, Month 2, Month 3, Month 4, Month 5, Month 6.	Study-specific questionnaires	

4 STUDY DESIGN

4.1 OVERALL DESIGN

This study is a randomized, double-blinded, placebo-controlled trial of 60 parent and child combinations i.e. 60 parents and 60 children.

Participants will be randomized into one of two arms. This study will be double-blinded; the study participants and study coordinators will be blinded to the intervention or product allocation. Arm 1 will take NuBest Tall Growth Protein Powder throughout the trial. Arm 2 will take a placebo product for the duration of the trial. Only the children will take the test product.

The parents will answer questionnaires at Baseline and on Month 1, Month 2, Month 3, Month 4, Month 5, and Month 6. Parents will provide height and weight measurements of the child at Baseline, Month 2, Month 4, and Month 6. The children will complete cognitive assessments at Baseline and Month 6. The trial will be a virtual study consisting of only virtual assessments, and the participants will follow the use instructions provided by the research team.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

To best understand the actual benefits of the test product without the influence of a potential placebo effect, a randomized, placebo-controlled, double-blinded study design is the gold-standard method. A 6-month study duration provides sufficient time for the test product to provide metabolic effects that may lead to enhanced health outcomes.

The data collection intervals for this trial were chosen to minimize the participant burden while still collecting valuable data about the efficacy of the test product. In addition to subjective data collected from questionnaires, height and weight measurements using a standardized tool will provide a non-biased, independent assessment of changes in height and weight across both groups. In addition, the cognitive assessments will provide an objective measurement of changes in cognitive function.

4.3 JUSTIFICATION FOR DOSE

The test product examined in this study will be taken in the exact dosage of the commercially available product. 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 they have completed all study phases, including the last scheduled assessments: Month 6 questionnaire, weight measurements, height measurement, and cognitive assessment.

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. A parent of a child within the following age ranges:
    - Boy: 12 to 16 years
    - Girl: 10 to 14 years
2. Interested in their child trialing a dietary supplement designed to improve overall health outcomes in children, including height, maintenance of a healthy weight, cognitive function, immune function, and energy levels.
3. Willing to refrain from giving their child any vitamins, minerals, or herbal supplements of any kind for the duration of the study
4. Parents willing to weigh and measure the height of their child throughout the study
5. Generally healthy - do not have 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 child with a history of endocrine disorder, heart disease, lung disease, kidney disease, digestive disease or skeletal dysplasia.
2. Any pre-existing chronic conditions that would prevent participants from adhering to the protocol, including oncological and psychiatric disorders.
3. Is undergoing or planning to undergo significant medical procedures in the next six months.
4. A history of severe allergic reactions, including but not limited to any of the product's ingredients.
5. Any child with a dairy allergy or lactose intolerance.
6. Has undergone any surgeries or invasive treatments in the last six months.
7. Has had any major illness in the last three months.
8. Having any planned invasive medical procedures during the study period
9. Currently participating in any other clinical study.
10. Unwilling to follow the study protocol.
11. Any child diagnosed with attention-deficit disorder (ADD) or attention-deficit hyperactivity disorder (ADHD).
12. Any child currently taking, or have they taken in the last 3 months, any prescription medication targeting ADD or ADHD (such as Adderall, Concerta, Focalin, Evekeo, or Ritalin).
13. Any child that is a ‘fussy’ eater or who the parent suspects may not tolerate consuming the test product daily for six months.

5.3 PARTICIPANT COMPENSATION

All participants will be compensated $150 for their time and effort in the form of a Visa gift card. Participants will also be permitted to keep the FitBit Smart Scale and the Ultrasonic Height Measuring Stadiometer.

5.4 JUSTIFICATION OF SAMPLE SIZE

60 participants, 30 each in the intervention and placebo arms, is sufficient to establish differences between the two study conditions. This will allow for meaningful between-group comparisons to adequately assess the efficacy of the test product versus placebo control.

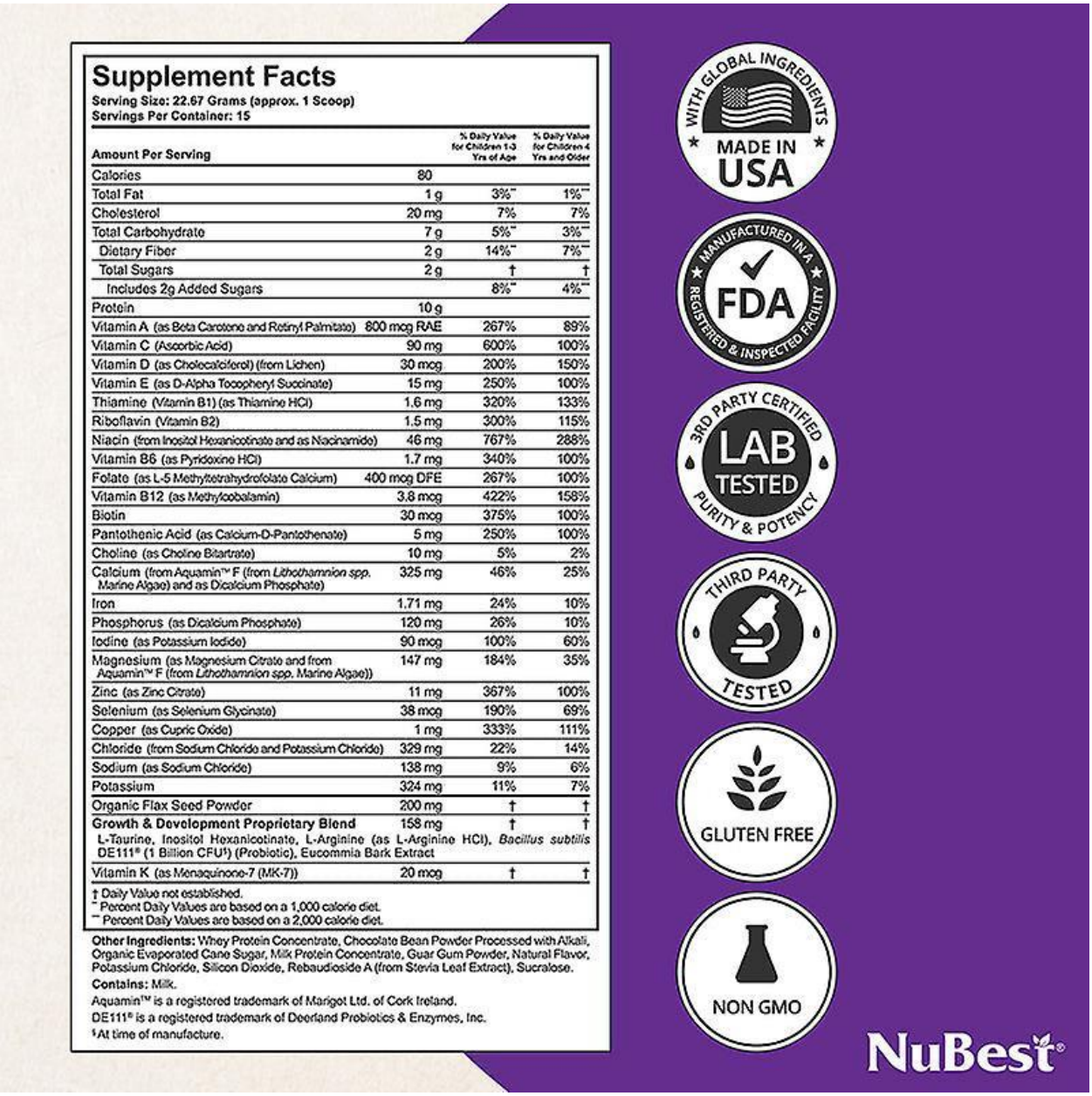
6 STUDY INTERVENTION

6.1 STUDY INTERVENTION

- Potential participants (parents + child) who meet the initial inclusion and exclusion criteria can participate in this trial
- If participants meet the inclusion and exclusion criteria after the parents have signed the informed consent, participants will begin the trial.
- The parents will complete the Baseline questionnaire and provide the Baseline height and weight measurements of the children. The children will complete the Baseline cognitive assessments.
- After the baseline data collection, participants will be randomly allocated into the intervention or placebo study group. The participants and Citruslabs will not be informed who is in the intervention or the placebo group.
- The children will take 1 one scoop of the powder mixed with 6-8 oz of water, milk, or smoothies every morning.
- Parents will complete questionnaires at the end of Month 1, Month 2, Month 3, Month 4, Month 5, and Month 6.
- Parents will provide height and weight measurements of the children at Month 2, Month 4 and Month 6.
- The children will repeat the cognitive assessments at the end of Month 6.
- Completion of the Month 6 measurements marks the end of the study.

6.2 INTERVENTION FORMULATION

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

6.3 Randomization and Blinding

Participants will be randomized into the intervention group (NuBest Tall Growth Protein Powder) or into a placebo product control group. Randomization occurs via a randomization tool that will equally place participants into a group that will use product A or B. The research coordinator who will conduct the randomization will not know which product is the test product and which is the control.

This study will be double-blinded; the study participants and study coordinators will be blinded to the intervention or product allocation. Only the sponsor will know which product, A or B, contains the active ingredients. After the study is complete, the allocation will be unblinded prior to the analysis. Both groups will receive products that look identical.

6.4 Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in 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 the 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 In-person diagnostic testing

N/A

6.6 COGNITIVE BATTERY TESTING

All children will complete cognitive assessments at the following time points:

- Baseline
- Month 6

The tests included are as follows:

Double Trouble - 1:30 timed test

- Based off of a classic Stroop test, Double Trouble measures selective attention, processing speed, and the brain's ability to focus on specific information when presented with conflicting and layered stimuli

Feature Match - 1:30 timed test

- Feature Match is a focus and processing task that requires surveying an increasingly difficult array of information and rapidly assessing the correct response while holding previously processed and detailed information in attention

Grammatical Reasoning - 1:30 timed test

- Grammatical Reasoning is a deductive reasoning task that requires quickly interpreting phrases and making logical conclusions from understanding. Variation between text and shapes on screen require holding key information in short-term memory in order to properly complete the task, leveraging the same parts of the brain that enable an individual to remain focused between varied stimuli.

Digit Span - performance-based test (3-4 min)

- Increasing in length after each successful attempt, Digit Span requires users to focus on displayed numbers, hold them in short-term memory, and repeat them back correctly, thereby showing cognitive flexibility and the brain's ability to perform memory and attention related tasks without error

Token Search - performance-based test (3-4 min)

- Leveraging the brain's executive functioning skills, Token Search requires participants to hold information in working memory and remain focused on completing sequential steps without making mistakes. The tasks become increasingly difficult, requiring more active utilization of brain regions associated with processing, attention, and memory as the task continues.

6.7 REQUIRED DEVICES

Participants require access to a computer, laptop, or tablet to complete the cognitive assessments.

All participants will be provided with the FitBit Smart Scale and the Ultrasonic Height Measuring Stadiometer required for the height and weight measurements.

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 versus the placebo. Between-arm and participant repeated measures between time point statistical tests will be used to examine differences in health outcomes during the study and compared to the placebo. Percentages of people who experienced improvements will also be examined. The analysis will adopt an intent-to-treat (ITT) approach, reflecting the primary objective of assessing the effectiveness of the test product as it would be used in the general population, inclusive of all randomized participants, irrespective of adherence or protocol deviations.

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 prior to starting intervention/administering study intervention. The following consent materials are submitted with this protocol: an informed consent form and a patient bill of rights.

8.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved, 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 have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to 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. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form will be 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 continue to be kept 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 is responsible for ensuring 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 Citruslabs. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. 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. Any employees of, or people with any connection to, the sponsor or Citruslabs will not be eligible for participation in this study.

The sponsor has a conflict of interest in that they may benefit financially from the success of the study. To manage the conflict of interest, an independent third party (Citrusabs) will be handling

all design and administration of participant-focused materials, all participant recruitment and data gathering, and data analysis.

9 REFERENCES

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