Consent Form

Project title

Effect of dietary constituents on cognitive performance in healthy adults: A Randomized, Double-Blind, Placebo-Controlled, Crossover trial

Why are you being given this form?

You are being asked to be a participant in a 3 to 4-week randomized, double-blind, placebo-controlled, crossover trial to assess the effects of a Health Canada approved nutritional supplement called MindGain, on your cognitive performance.

The information in this form is intended to help you understand exactly what we are asking of you so that you can decide whether you want to participate. Please read this consent form carefully and ask all the questions you might have before deciding whether to participate in this study. Please take whatever time you want before reaching a decision and consult with others as you wish. Your participation in this study is entirely voluntary, and a decision not to participate will not in any way be used against you.

Project team and sponsors

This project is being supported by the National Research Council Industrial Research Assistance Program (NRC-IRAP).

The research team you will be interacting with in this study is the Principal Investigator is Dr. Delphie Dugal-Tessier, PhD, Chief Scientific Officer Alysen Clark, and research assistant, Giovana Amaro Link from Staterra Inc.

Why is the study being done?

In recent years, healthy adults are exposed to high demand cognitive activities such as workload stress, demanding schedules, and continuous multitasking on a frequent basis. These demanding cognitive activities can lead to decline in performance, as well as difficulties maintaining attention, motivation, and focus. There is increased interest in safe and effective methods to improving cognitive performance. The right natural health product supplementation, such as MindGain, can be a realistic and natural way to improve cognitive performance during demanding cognitive activities.

This is an online, double-blind, placebo-controlled, randomized, 2 period crossover trial. The study will include 42-60 men and 42-60 women, who will participate in 4 online testing sessions (week 0, 1, 2 and 3). The online session will take part at your own home or location of your choosing. You require a laptop, desktop, or tablet with a reliable internet connection.

The device and location should stay the same throughout the study

Each subject will be asked to take a single daily dose of the study product (MindGain or placebo) seven times. One week later, they will be asked to take the counterpart product. Subjects will be assigned which study product they will receive first in random order.

Who can participate in the study?

(1) a healthy men or women
(2) Aged 21-70 years
(3) Access to the internet and computer (laptop, desktop, or tablet)
(4) Willing to undergo a washout prior to enrollment if taking nootropic type supplements
(5) Participant must be capable and willing to provide consent, understand exclusion criteria, instructions, and protocols
(6) To speak and to read English fluently

Who cannot participant in the study?

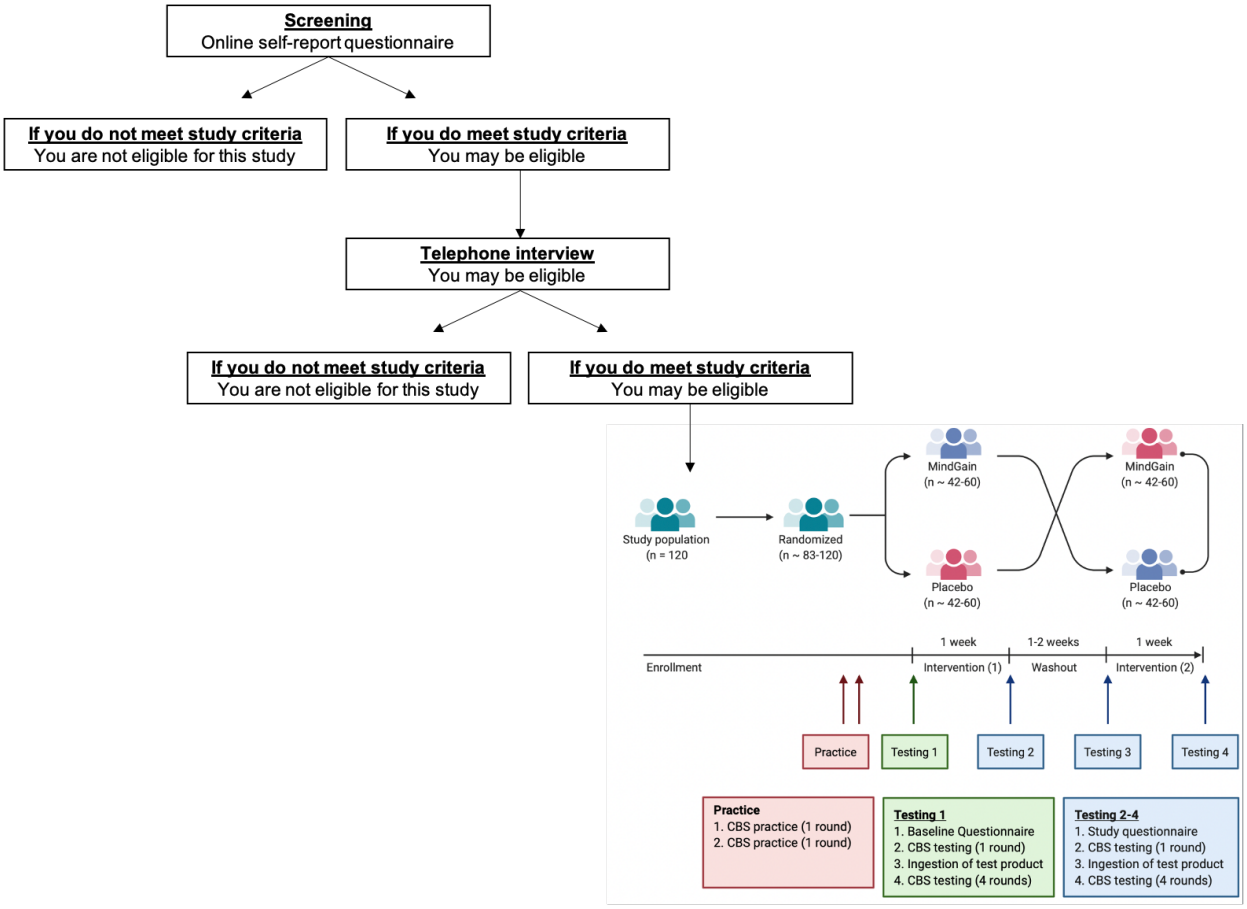
(1) Pregnant, planning to become pregnant during the study period, or breastfeeding
(2) Allergy/intolerance to any ingredient of the nutritional supplements
(3) Colour Blind
(4) Currently have or at risk of liver disease, kidney diseases and/ or a seizure disorder, or any serious medical conditions with major medical intervention anticipated during the trial
(5) Any non-controlled medical condition which could influence results or could be worsened by the participation in the study
(6) Metabolic diseases such as diabetes
(7) Major medical or neurological illnesses
(8) Requiring treatment with a drug which might obscure the action of the study treatment

Screening data will be reviewed to determine subject eligibility. There are no known drug interactions with MindGain. However, in the rare circumstance where a deeper evaluation of the medications and health may need to be addressed, you will be notified during the phone interview, and you may choose to decline or continue. If you choose to continue, a physician, Dr. Pierre Tessier, will be contacted. No personal information such as your name will be shared and no record will be kept. You will simply be advised whether or not you can participate in the study.

Subjects who meet all inclusion criteria and none of the exclusion criteria will be entered into the study, and given a study ID. All testing will require you to enter your study ID. Your name will not be linked to your study ID on any of the study questionnaires and cognitive testing.

What will you be asked to do?

The diagram below outlines the research study (the details follow the diagram). Start reading at the top left and read down the list following the lines.



Randomization:

If you are eligible to participate in the study, you will be "randomized" into one of the study groups described below. Randomization is done by a computer and puts you into a group by chance, much like flipping a coin. You will have an equal chance of being placed into either group. You will not be able to choose which group you are assigned. Neither you, nor the principal investigators or research team will know your group. When the study is completed, you will be notified which group you belonged to and when.

Before starting the study protocol, subjects will be invited to familiarize themselves with the cognitive testing used in this study. One round is comprised of 12 different cognitive tests developed by Cambridge Brain Science (CBS: https://www.cambridgebrainsciences.com). Each subject will be asked to complete 2 rounds (30 minutes each) prior to the start of the study.

For the study protocol, each subject will receive a box that contains 8 individual packets with study product (MindGain or placebo) inside. Each packet will be labeled with subject's study ID. Cognitive testing and questionnaire will be done on day 0 and 7. Following a 1-week washout (where no nootropic or study product will be taken), subject will repeat the study protocol with the counterpart product (MindGain or placebo).

Day	**Testing**	**Time requirements**	**Intervention**

Practice sessions	CBS practice 1 (learning the tasks) CBS practice 2 (learning the tasks)	~ 30 minutes ~ 30 minutes	
Intervention 1 Begins **NO FOOD, OR BEVERAGES WITH THE EXCEPTION OF WATER and TEST PRODUCT SHOULD BE CONSUME DURING THE TESTING SESSION (approximately 4 hours)**			
DAY 0	Baseline questionnaire	~ 15 minutes	
	CBS testing (complete 1 round)	~ 30 minutes	
	Ingestion of test product	~ 1-5 min	Take 1 packet in 250ml of water
	Wait 60 minutes	60 minutes	
	CBS testing (complete 4 rounds)	~ 2 hours	
	TOTAL TIME FOR DAY 1 = ~ 4 hours		
DAY 1	Ingestion of test product	~ 1-5 min	Take 1 packet in 250ml of water
DAY 2	Ingestion of test product	~ 1-5 min	Take 1 packet in 250ml of water
DAY 3	Ingestion of test product	~ 1-5 min	Take 1 packet in 250ml of water
DAY 4	Ingestion of test product	~ 1-5 min	Take 1 packet in 250ml of water
DAY 5	Ingestion of test product	~ 1-5 min	Take 1 packet in 250ml of water
DAY 6	Ingestion of test product Compliance questionnaire	~ 1-5 min ~ 3 min	Take 1 packet in 250ml of water
DAY 7	Study questionnaire	~ 15 minutes	
	CBS testing (complete 1 round)	~ 30 minutes	
	Ingestion of test product	~ 1-5 min	Take 1 packet in 250ml of water
	Wait 60 minutes	60 minutes	
	CBS testing (complete 4 rounds)	~ 2 hours	
	TOTAL TIME FOR DAY 7 = ~ 4 hours		
WASHOUT (1 week)			
Intervention 2 **NO FOOD, OR BEVERAGES WITH THE EXCEPTION OF WATER and TEST PRODUCT SHOULD BE CONSUME DURING THE TESTING SESSION (approximately 4 hours)**			
Same as Intervention 1 • With counterpart product			

During the testing sessions (Day 0, and Day 7), you will have to refrain from consuming caffeine (tea, coffee, soft drinks, energy drinks etc.) for a minimum of 2 hours prior to testing. Testing should be done at least 2 hours before or after taking other medications or drugs.

Study Intervention

MindGain (or placebo) will be taken on Day 0 following completion of study questionnaire and 1 round of cognitive testing (12 tasks). Supplement will be taken in 250ml (1 cup) of water, and subject will wait 30 minutes. After the wait time, each subject will be asked to complete 4 consecutive rounds of cognitive testing. Subject will be asked to take the supplement each following day at around the same time until Day 7. On Day 7, each subject will repeat the same testing protocol as DAY 0 using the same computer (laptop, desktop, tablet) at around the same time and location.

Subject will be asked to take a minimum of 1 week and a maximum of 2-week washout period, where no nootropic or cognitively enhancing supplements can be taken. Subject will repeat study protocol with counterpart test product (Mind Gain or placebo).

Required questionnaire

Day	Questionnaire
Intervention 1	
DAY 0	• Demographic questionnaire • Cognitive flexibility Scale • Perceived stress scale
DAY 6	• Compliance questionnaire
Day 7	• Perceived stress scale • Adverse effects scale
Intervention. 2	
DAY 0	• Cognitive flexibility Scale • Perceived stress scale
DAY 6	• Compliance questionnaire
Day 7	• Perceived stress scale • Adverse effects scale

Ingredients used in this study includes:

MindGain		**Placebo**	
Ingredients	**Dosage (mg)**	**Ingredients**	**Dosage (mg)**
Vitamin C (Ascorbic acid)	500	Maltodextrin	4250 mg
Vitamin B6 (pyridoxal-5-phosphate)	25		

Taurine	1000	microcrystalline cellulose	4250 mg
Magnesium (glycinate)	30		
Acetylcarnitine	3000		
Organic Black Maca Powder (Lepidium meyenii- root)	500		
Choline (Bitartrate)	500		
L-Theanine	250		
L-Tyrosine	2500		
Maritime pine (Pinus pinaster-75% procyanidines)	200		
Flavour (Natural Flavours)	Will not exceed 20% of final formulation by weight	Flavour (same as MindGain)	Will not exceed 20% of final formulation by weight

Potential harms / inconveniences / benefits

There are minimum harms associated with your participation in this research. There may be side effects from the nutraceutical ingredients from this study. The side effects **we know about now** are described below.

It is important to note that MindGain used in this study is Health Canada approved. The facility that will be manufacturing MindGain and placebo for this study is Health Canada site licensed.

Risks related to placebo:

Ingredient	**Possible side effects**
Maltodextrin/microcrystalline cellulose	Mild and rare • Gas • Diarrhea • Cramping • Bloating

Risks related to MindGain:

Ingredient	**Possible side effects**
MindGain	Mild and rare • Headache • Vomiting • Diarrhea • Stomach cramps • Nausea • Heartburn

There also may be other side effects or discomforts that we cannot predict, especially to a fetus or embryo. Because the ingredients in this study may affect an unborn baby, you should not become pregnant while on this study. Acceptable methods of birth control, according to the Health Canada Guidelines, include oral contraceptives ("the pill"), an intrauterine device ("IUD"), or conscientious use of condoms and spermicidal foam. Your doctor can discuss this with you. There is a slight risk that a pregnancy test could be inaccurate, thus exposing a woman to the potential loss of pregnancy as well as other unknown effects on a developing fetus. You should not breast-feed a baby while on this study.

Products are manufactured in a facility that also processes ingredients derived from or containing: tree nuts, dairy, fish, shellfish, and soy.

Risks related to study questionnaires:
There is the risk that you may find some of the questions to be sensitive and may cause emotional discomfort. If you do not wish to answer a question, you may skip it and go to the next question.

Benefits:
Being in this study may or may not lead to any direct benefit. The major benefit from participating in this study is that each subject will receive a cognitive report based on their own cognitive testing scores. Since CBS has a database with 75,000+ participants complied from their larger database of 8 million tests, each subject will get an extensive report of their cognitive health compared to others of the same age group and gender. These types of assessments are extremely expensive outside a health and research setting. These reports will give each subject a richer understanding on their cognition, how repetitive tasks affects their cognitive performance and whether nutritional supplement can support their cognitive performance during repetitive cognitive testing, like what they would expressing during periods of high cognitive stress.

Commercialization

The researchers from Staterra Inc. will benefit from your participation in this study. The results of this study will be used to promote the nutritional supplement, MindGain. You will not receive monetary profit or compensation from the commercialization of this research-based supplement. The data collected in this study would set Staterra Inc apart in the marketplace and help show the efficacy of MindGain on cognitive performance.

Staterra Inc. plans on publishing as well as market the already commercializing MindGain based on the results of this study.

Alternatives to participating in the project

This project does not involve medical treatment, you will not benefit from this research from a medical point of view.

Privacy and confidentiality

Your privacy will be respected at all times. All your personal information (information about you and your health that identifies you as an individual) collected or obtained, whether you choose to participate or not, will be kept confidential and protected to the fullest extent of the law. All personal information collected will be kept in a secure location. The research study staff at Staterra Inc. may look at your personal information for purposes associated with the study but will only be allowed to see your records under the supervision of the Principal Investigator, Dr. Dugal-Tessier, and will be obliged to protect your privacy and not disclose your personal information. None of your personal information will be given to anyone without your permission unless required by law. You will be notified of the study end date (approximately 1 year), and consent

forms, the master list and questionnaires will be destroyed.

The final results will be reported as part of a large group as numbers and percentages. Your name will never appear in any reports related to this study. Furthermore, if the results of this research are also published or presented at scientific meetings, your identity will not be disclosed.

Confidentiality will be respected. Unless required by law, no information that might directly or indirectly reveal your identity will be released or published without your specific consent to the disclosure.

National Research Council Research Ethics Board (NRC REB) will have access to the individual data, for monitoring purposes.

Compensation for injury, legal rights

By signing this consent form, you are not waiving your legal rights.

Reimbursement of expenses/payments for participating

You will not receive monetary compensation for participating in this study. Participants who meet study criteria and perform cognitive testing will receive a cognitive report based on their test scores.

You have the right to change your mind

Your participation is entirely voluntary. You can refuse to take part in this project at this point or withdraw from it at any time during the study, without incurring any penalty. Participants that withdraw before the end of the study will still receive a cognitive report based on the tests they have completed.

No scores or data will be collected for the two practice rounds prior to start of the study, this is simply to familiarize yourself with the 12 cognitive tests.

You also have the right to choose which arm of the study to complete if you decide not to complete the study in its entirety. Either the parallel arm at week 0 and week 1 (you may not choose which study product you will receive), or crossover portion, week 0 and week 3. You can contact Dr. Dugal-Tessier, by email delphie@staterra.ca or by phone 1-883-545-2643 to inquire about this option.

Following the study, you can contact Dr. Dugal-Tessier, at any time to revoke your consent. Research results will be destroyed, and Staterra Inc. will notify you of the destruction and the date of destruction. Participants will be notified of the study end date (approximately 3-12 months from the end of your participation). Following this date, results will be finalized, personal information will be destroyed (consent form, master list, and questionnaires) and only de-identified data will be kept. After this point, withdrawal will no longer be possible since there will be no way to identify your information. Following the end of the study, data will be de-identified for retention and future use. De-identified data will be kept by Staterra Inc.

Dr. Dugal-Tessier during the study may withdraw you from this research if circumstances arise which warrant doing so.

Who to contact if you have any further concerns or questions?

Should you have concerns or questions regarding the study, please contact Dr. Delphie Dugal-Tessier, Principal Investigator, Staterra (by phone: 1-833-545-2643 or by email: delphie@staterra.ca)

Should you have any ethical concerns about this study, please contact the NRC REB Secretariat, NRC-REB@nrc-cnrc.gc.ca , (613) 949-8681.

Ethics review

This study has been approved by the NRC Research Ethics Board (NRC-REB) under protocol number 2021-113. REB review seeks to ensure that research projects involving humans as participants meet Canadian standards of ethics. Any questions or concerns about the ethics of this study may be directed to the NRC-REB Secretariat, NRC-REB@nrc-cnrc.gc.ca , (613) 949-8681.

Statement of consent – print and sign name

I, _____have read and understand the information given in this informed consent and all my questions have been answered to my satisfaction. I have had sufficient time to consider whether to participate in this study. I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time without penalty.

I voluntarily consent to participate in this study.

Signature: _____Date: _____

Team member who interacted with the participant

To the best of my knowledge, the information in this consent form, and the information that I, Dr. Delphie Dugal-Tessier have provided in the response to any questions, fairly represents the project. I am committed to conducting this study in compliance with all the ethical standards that apply to projects that involve human participants. I will ensure that the participant receives a copy of this consent form.

Name of Principal Investigator (print): Delphie Dugal-Tessier
(1-833-545-2643 or delphie@staterra.ca)

Signature: _____Date: _____