INFORMED CONSENT FORM

Sponsor / Study Title:	**Dr. Markus Besemann / "Effect of dietary constituents on cognitive performance in veterans: A Randomized, Double-Blind, Placebo-Controlled, Crossover trial."**
Protocol Number:	**Besemann_MindGain_001**
Principal Investigator: (Study Doctor)	**Markus Besemann, BSc, MD, FRCP(C)**
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Why are you being given this form?

You are being asked to be a participant in a 6-week randomized, double-blind, placebo-controlled, crossover research study 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.

The Principal Investigator for this study is Dr. Markus Besemann, MD and co-Investigators are Dr. Delphie Dugal-Tessier, PhD, and Dr. Ryan D'Arcy, PhD.

The co-investigators on this study have either developed the study natural health product or have an ownership interest in HealthTech Connex Inc., of which NeuroCatch Inc (manufacturers of the NeuroCatch Platform used as an outcome measure) is a subsidiary.. As a result, the investigators may benefit financially from a successful study. Additional steps have been taken to manage the potential conflict of interest that this financial arrangement may create. Please speak with your study doctor if you have questions about this.

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. In the military population in particular, veterans are likely to have been exposed to a unique constellation of stressors and cognitive demands. These demanding cognitive activities and stressors can lead to decline in performance, as well as difficulties maintaining attention, motivation, and focus.

There is increased interest in safe and effective methods for improving cognitive performance. The right natural health product supplementation, such as MindGain, could be a way to improve cognitive performance during demanding cognitive activities.

The purpose of this study is to evaluate the effect of MindGain on cognitive function and well-being in veterans. The findings of this study will inform the use of MindGain and guide the direction of future research.

Participants
The study will include approximately 30 veterans who will participate in 4 in-person testing sessions.

In-person testing sessions will take place at the study site listed on page one of this form.

Additional testing will be completed online, remotely.

Screening

You must qualify to participate in this study. If you choose to take part in this research study, first a Screening visit will be completed to determine your eligibility. The study doctor or study staff will assess your eligibility by asking you to answer questions about your health, medications, and medical history. The Screening visit will take approximately 30 minutes and may be conducted virtually.

What will you be asked to do?

Participants who meet all eligibility criteria will be entered into the study and assigned a unique study ID. Your name will not be linked to your study ID on any of the study questionnaires and cognitive testing.

Each participant will be asked to take a single daily dose of the study product (MindGain or placebo) for 14 days. Each participant will receive a box that contains 15 individual packets with study product (MindGain or placebo) inside. Each packet will be labeled with participant's study ID. One to two weeks later, they will be asked to take the counterpart product for 14 days.

Participants will be randomly assigned which study product they will receive first. Randomization is done by a computer and puts you into a group (either MindGain first, or placebo first) by chance, much like flipping a coin. You will have an equal chance of being

placed into either group. Both you and the research team will be blinded to the group you are assigned to. In other words, you will not know which study product you receive first or second. When the study is completed, you will be notified which group you belonged to and when.

Before the first testing session (Study Visit 1), participants will be asked to complete online baseline questionnaires pertaining to demographics, medical history, and mental health including history of traumatic events. Participants will also be asked to familiarize themselves with the web-based Creyos (https://www.creyos.com) cognitive testing used in this study. One round of Creyos testing is comprised of 3 different cognitive tests (approximately 15 minutes total). Participants will be asked to complete practice testing prior to the first study visit.

Participants will be asked to attend 4 in-person testing sessions:

Study Visit 1: before starting first study product

Study Visit 2: after 2 weeks of taking the first study product

Study Visit 3: after approximately 2-week washout (no study product or other nootropics taken) and prior to starting second study product

Study Visit 4: after 2 weeks of taking counterpart study product

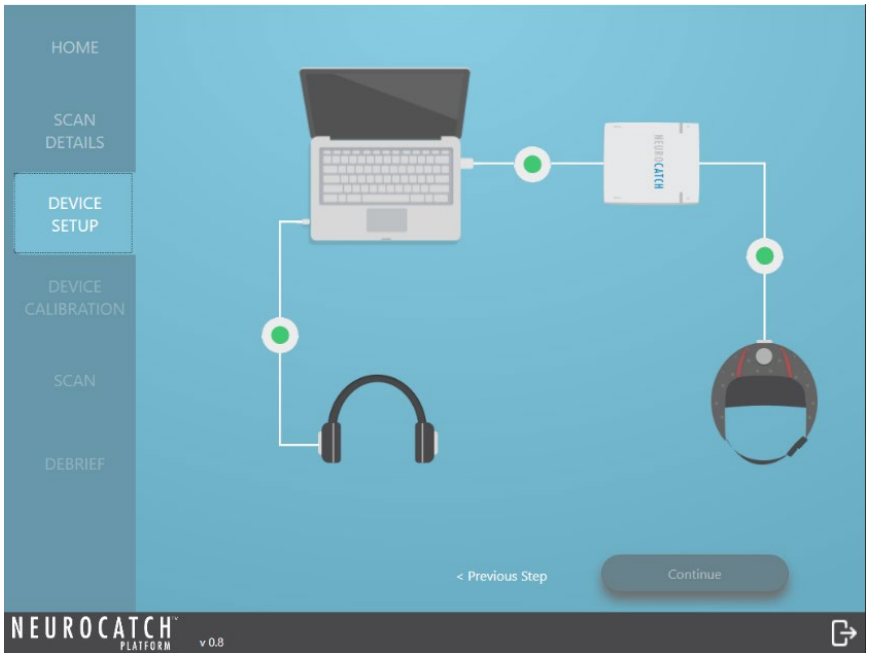
At these study visits, you will be asked to complete the Creyos cognitive tests, and a brain function assessment using the NeuroCatch® Platform 2.0 medical device described below. The brain function assessment will take at total time of approximately 20-30 minutes. The assessments visits will take about 1 hour each to complete.

In addition, participants will be asked to complete questionnaires regarding health and well being within 1 day of each in-person testing session, which may be completed online remotely.

NeuroCatch® Platform 2.0

The NeuroCatch® Platform 2.0, a Health Canada approved medical device system, consists of software and hardware that captures information about brain function. The platform intends to provide a quick and easy to use assessment of electroencephalograph (EEG) and event-related potential (ERP; brain response to a stimulus) information.

At each study visit, you will complete a NeuroCatch Platform 2.0 assessment, which involves an EEG recording session. Prior to each assessment, you will complete a pre-scan questionnaire, which will include questions about your total sleep (hours), caffeine intake, alcohol consumption, nicotine usage, and psychoactive substance usage, over the last 24 hours. Following the pre-scan questionnaire, we will place a cap with the EEG sensors on your scalp and make sure that we are getting good recordings of brain activity. We will use an alcohol pad to clean the skin of your forehead, and a plastic syringe tip or wooden dowel to move your hair out of the way of the electrodes. We will then apply a small amount of a conductive gel under each electrode. Once you are set up, we will ask you to listen to an auditory sequence, approximately 6 minutes long. You will listen to some tones and some words while we record your brain activity. The device set up will look like the following info graphic:



The NeuroCatch® Platform 2.0 will be used to create the sounds that you will hear and collect the ERP data indicating how your brain responds to those sounds. The specific ERPs that will be analyzed include:

- N100: Auditory sensation – measures how your brain acknowledges that there is a sound
- P300: Basic attention – measures the early processing activity of your brain
- N400: Cognitive processing – measures how your brain processes language

Prior to each in-clinic testing session, participants will be asked 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. Participants will also be asked to follow their regular daily routine for the 24 hours prior to the in-person study visits (for example, sleep time, alcohol consumption, etc.).

Study Intervention

MindGain (or placebo) will be taken after completing the Study Visit 1 in-clinic testing. Participant will be asked to take the supplement each following day at around the same time until Day 14. Participants will be asked to record when they take the study product each day in a log. On Day 14, each participant will repeat the same testing protocol as Day 1.

Participant will be asked to take an approximately 2-week washout period, where no nootropic or cognitively enhancing supplements can be taken. Participant will repeat the testing protocol with counterpart test product (Mind Gain or placebo).

Day	Testing	Duration	Location
Baseline	Baseline questionnaires	~ 20 minutes	Remote (online)
	Creyos cognitive testing-practice	~ 15 minutes	
	TOTAL TIME FOR Baseline = ~30-45 minutes		
Intervention 1			
Study Visit 1	Questionnaires *within 1 day of in-person visit*	~ 15 minutes	Remote (online)
	Creyos cognitive testing	~ 15 minutes	Clinic
	NeuroCatch Platform 2.0 Scan	~ 30 minutes	Clinic
	Receive study product, log, and instructions for intervention	~15 minutes	Clinic
	TOTAL TIME FOR Visit 1 = ~1-1.5 hours		
Intervention 1 14 Days	Daily ingestion of study product (1 packet in 250ml [about 8 fl oz] of water) Recording in log	~ 1-5 minutes	Remote
Study Visit 2 *~2 hours post-final study product ingestion*	Questionnaires *within 1 day of in-person visit*	~ 15 minutes	Remote (online)
	Creyos cognitive testing	~ 15 minutes	Clinic
	NeuroCatch Platform 2.0 Scan	~ 30 minutes	Clinic
	Review compliance log	~15 minutes	Clinic
	TOTAL TIME FOR Visit 2 = ~1-1.5 hours		
Washout: 2 weeks			
Intervention 2			
Study Visit 3	Questionnaires *within 1 day of in-person visit*	~ 15 minutes	Remote (online)
	Creyos cognitive testing	~ 15 minutes	Clinic

	NeuroCatch Platform 2.0 Scan	~ 30 minutes	Clinic
	Receive counterpart study product, log, and instructions	~15 minutes	Clinic
	TOTAL TIME FOR Visit 3 = ~1-1.5 hours		
Intervention 2 14 Days	Daily ingestion of study product (1 packet in 250ml [about 8 fl oz] of water) Recording in log	~ 1-5 minutes	Remote
Study Visit 4: *~2 hours post-final study product ingestion*	Questionnaires *within 1 day of in-person visit*	~ 15 minutes	Remote (online)
	Creyos cognitive testing	~ 15 minutes	Clinic
	NeuroCatch Platform 2.0 Scan	~ 30 minutes	Clinic
	Review compliance log	~15 minutes	Clinic
	TOTAL TIME FOR Visit 4 = ~1-1.5 hours		

Ingredients used in the study product include:

MindGain		**Placebo**	
Ingredients	**Dosage (mg)**	**Ingredients**	**Dosage (mg)**
Vitamin C (Ascorbic acid)	500	Maltodextrin	4250
Vitamin B6 (pyridoxal-5-phosphate)	25	microcrystalline cellulose	4250
Taurine	1000		
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 are no known drug interactions with MindGain. 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. You should not breast-feed a baby during this study.

Please speak to your study doctor if you become pregnant during your participation in the study.

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

Allergic Reaction:
As with taking any supplement, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

Risks related to study questionnaires:

Some of the questions asked in this study examine topics of a personal nature (for example, mental health). You do not have to answer all the questions if you do not want to. If you do not wish to answer a question, you may skip it and go to the next question. If feelings of discomfort or sensitivity arise for you during the study, remember that you may stop at any time without explanation or penalty.

Risks related to EEG preparation and recording using the NeuroCatch® Platform 2.0 include:

- Auditory Stimulation: You may experience discomfort arising from auditory stimulation, but the sound has been selected to be played at a safe level.
- EEG Preparation: The elastic cap and electrodes are disinfected after every use using a low-level disinfectant. Skin abrasion and cleansing that is required to measure EEG might result in minor skin irritation and/or discomfort. For example, your hair can get tangled and pulled when scratching skin with a plastic syringe. We will ask about your comfort level regularly, and we encourage you to let the study staff know if you experience any discomfort.
- Study staff are trained in proper application of the NeuroCatch Platform 2.0.
- EEG Recording: The risks of being connected to the EEG recording device are negligible. The electrodes that we will place on your scalp will be used to record your brain electricity only; the electrodes will NOT provide any electrical stimulation to you during the recording sessions. The EEG recording devices are battery powered, and properly grounded. All equipment has been tested for electrical safety.

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 participant will receive a cognitive report based on their own cognitive testing scores. Each participant 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. Information learned from the study may help other people in the future.

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 marketing the already commercialized MindGain based on the results of this study.

New findings

Any new important information that is discovered during the study which may influence your willingness to continue participation in the study will be provided to you in a timely manner.

Alternatives to participating in the study

This study does not involve medical treatment, you will not benefit from this research from a medical point of view. This research study is for research purposes only. The only alternative is to not participate in this study.

Privacy and confidentiality

All participants will be assigned a participant ID. This participant ID will be used to identify all your data. Your identity will be kept confidential at all times, except where disclosure is required by law. All personal information collected will be kept in a secure location. Only study staff members directly involved in this study will have access to any data collected. The research study staff 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 study doctor and study staff, and will be obliged to protect your privacy and not disclose your personal information.

On-site records will be kept in a secure, locked location on site and only accessible to study staff. Electronic data other than NeuroCatch and Creyos data will be housed by a secure website, hosted by Transit Network. Staterra employs multiple layers of security to make sure that user data remains private and secure. These layers include an advanced firewall, SSL encryption, password strength requirements, and automated server resource monitoring/allotment.

De-identified NeuroCatch scan data will be stored on the investigational device local storage and in secure, region-controlled cloud storage. The de-identified Creyos data will be stored in secure cloud storage (managed by Amazon Web Services, servers located in Oregon, USA).

De-identified data from the Creyos tests may be shared with an authorized representative from Creyos.

Data collected during the study will be stored in Canada for up to fifteen (15) years. De-identified digital data may be stored indefinitely.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from NeuroCatch Inc., such as monitors and auditors (for support with data analysis)
- The research ethics review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants)
- Regulatory authorities, such as Health Canada

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.

Compensation for injury, legal rights

In case of an injury or illness suffered by participating in this study, you will receive appropriate medical care. The sponsor will cover necessary medical costs not covered by the public health plan or your private medical insurance (if any). By signing this consent form, you are not waiving your legal rights or releasing anyone involved in the research from responsibility for mistakes.

Reimbursement of expenses/payments for participating

You will not receive monetary compensation for participating in this study. Participants who meet study criteria and perform the assessments will receive a cognitive report based on their test scores, and NeuroCatch scan report. These reports are not for diagnostic purposes.

Cost for participating

There is no cost to you, the public health plan, or your private medical insurance (if any) for your participation in this study.

You have the right to change your mind

Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time, without giving a reason, even if you have signed and dated this consent form. If you do not take part or withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled. Participants that withdraw before the end of the study will still receive a cognitive report based on the tests they have completed.

The study doctor may also withdraw you from the study if circumstances arise which warrant doing so; for example, if you become pregnant, if you do not follow the study doctor's instructions, to protect your safety, if the study doctor feels it is in your best interests to be withdrawn, if you develop a condition that falls within the exclusion criteria of the study, or if the study is discontinued. You can be withdrawn without your consent, but the study doctor will tell you why.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00071711.

Primary Health Care Provider Notification Option

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒YES
❒NO

Statement of consent – print and sign name

Participant:

I have read and understand the information given in all pages of 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.

Name: _____

Signature: _____Date: _____

Study staff member who explained consent to the participant:

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

Name: _____

Signature: _____Date: _____