THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**Milk Specialties Global / "A virtual, randomized, double-blind, placebo controlled, parallel study to investigate the safety and efficacy of milk fat globular membrane-enriched whey protein concentrate on stress and anxiety in adults with mild to moderate stress"**
Protocol Number:	**24MSCFP01**
Principal Investigator: (Study Doctor)	**David Crowley, MD**
Email:	**milkspecialties@kgkscience.com**
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Address:	**KGK Science Inc** **275 Dundas St, G02** **London, ON N6B 3L1**

You are being invited to participate in a clinical research study about how a natural health product may affect your stress and health. Your participation in this study is strictly voluntary. To decide whether you want to be part of this research you should understand the potential study risks and benefits to make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits, and risks of the study. This form will also describe how your medical information will be used. Please read this document carefully and do not hesitate to ask any questions you may have regarding the information given and the study. Study staff will answer all questions you may have.

You should not electronically sign this form until you understand all the information presented and until your questions about the research have been answered to your satisfaction.

Please note: whenever this document refers to emailing the study doctor or study staff, you should do so by emailing **milkspecialties@kgkscience.com** unless otherwise stated.

PURPOSE OF THE STUDY

Stress is an inevitable part of daily life, and while it's normal to experience it, prolonged or excessive stress can negatively impact our health. For many, consistently following lifestyle changes like regular exercise or meditation to manage stress can be difficult.

Phospholipids are crucial fats for our nervous system's health. Previous research has shown that phospholipid supplementation may help lower stress.

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The purpose of this study is to determine whether Milk Fat Globular Membrane (MFGM) – enriched whey protein concentrate, a product containing milk fat rich in phospholipids, is safe and effective in reducing stress and anxiety in adults who experience mild to moderate stress.

Milk Fat Globular Membrane (MFGM) is not approved by Health Canada. Its use in this study is considered investigational.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

- If you are eligible after the screening/baseline virtual assessment day, your participation in this study is approximately 56 days.
- You will have a total of 3 virtual assessments days (Screening/Baseline, Day 28 and Day 56). The first virtual assessment day is to screen and assess if you may be eligible to participate.
- 150 healthy individuals will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Before the study starts, you will need to sign this *Participant Information and Consent Form*. Please read all the information about this study and take the time to seek more information if needed. You have the access to this form and can review it at your leisure before making your decision. If agreeable and would like to participate in this study, please sign this consent form. Once you sign this consent form, an email will be sent to you from KGK Science so you can download this signed form. Please download a copy and keep it for your record. Once consent has been obtained, the virtual screening assessment will proceed.

If you have any questions about any aspect of the study, please ask your question(s) by emailing the study staff prior to signing this consent form. Study staff will address all your questions, and only then should you sign this consent form.

The table below lists the events, requirements, and procedures for the virtual assessments (Screening/Baseline Day, Day 0, Day 28 and Day 56 of the study).

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List of Abbreviations
▪ **SRI** = Stress Response Inventory ▪ **DASS-21** = Depression, Anxiety, and Stress Scale - 21 ▪ **BAI** = Beck Anxiety Inventory) ▪ **BDI-II** = Beck Depression Inventory-II
Screening/Baseline
• Informed Consent for participation in the study is obtained. • After providing consent, you will receive an email with a link to the screening assessment. You will be required to enter details about your medical history, medications, and current health status. • You will also complete the SRI and DASS-21 questionnaires. • Once the required assessments are complete, your eligibility will be assessed. Within 3 business days, you will receive an email from KGK Science informing you of your eligibility status. • If you are eligible, the email will include links to two additional questionnaires: the BAI and the BDI-II. • After completing the BAI and BDI-II, and if you continue to meet all necessary criteria, you will be randomized (like drawing numbers from a hat) to receive study product or placebo (inactive substance)and enrolled in the study. • The study product, instructions on use, and Clincard will be shipped to you. • You will receive an email from KGK Science notifying you when the study product has been shipped. This email will contain an orange button that you will need to click once you have received the study product.
Day 0
• After receiving the study product, please return to the email that notified you of its shipment, click the orange button, and complete the form to confirm receipt of the study product. • You should begin taking the study product the day after you confirm receipt. • Each week thereafter, you will receive an email from KGK Science prompting you to complete your weekly study diary and assessments.
Day 28 ± 3 **and** **End of Study – Day 56 ± 3**
• You will receive an email from KGK Science to complete your weekly diary, SRI and DASS-21 questionnaire. • You will then receive an email with links to complete the BAI and BDI-II questionnaires. • Any adverse events (side effects) and changes to medications you may report will be reviewed and a study staff will contact you if necessary.

Inclusion/Exclusion Criteria

To determine your eligibility to participate in this study, detailed information about your lifestyle and medical history will be collected. This information will help determine if you meet the necessary inclusion and exclusion criteria.

Please note that by signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.

Important Items to Note

A total of 150 participants aged 18 to 65 will participate in this study and will be randomized into 2 groups.

RANDOMIZATION TO STUDY GROUP: If eligible, you will be enrolled into the study and will be randomized into 1 of 2 groups:

- Nutripro MFGM-Enriched Whey Protein Concentrate group
- Placebo group

Randomized means that you will be assigned by chance (like drawing numbers from a hat) to a study group. This is a double-blind study, so neither you nor the study doctor will know which group you have been randomized to. We will dispense study products based on randomization. You have an equal (1 in 2) chance of being in any of the study groups. Neither you nor the study doctor will be able to pick which group you are in, but the study doctor can find out if it is necessary to know for your health.

For further information on the study product's ingredients and directions, see the "Study Product Information" section in this document.

STUDY ASSESSMENTS:

You will be required to complete the following study assessments:

- **DASS-21 (Depression, Anxiety, and Stress Scale – 21):** This test is a self-reported tool that measures depression, anxiety and stress over the past week. You will complete this test on Screening/Baseline, Day 28 and Day 56.

- **SRI (Stress Response Inventory):** This test will assess somatic (physical), cognitive (mental), and behavioral stress responses. You will complete this test on Screening/Baseline, Day 28 and Day 56.

- **Beck Anxiety Inventory (BAI):** This is a self-report questionnaire that assesses symptoms of anxiety. You will complete this test at Screening/Baseline, Day 28 and Day 56.

- **Beck Depression Inventory- II (BAI- II):** This test will assess the severity of depression symptoms. You will complete this test on Screening/Baseline, Day 28 and Day 56.

- **Study Diary:** You will complete a weekly study diary that will collect information regarding changes in health, adverse events and the study product you consumed.

If you are taking any prescribed medications, you must agree to maintain your dosing regimen during the study, unless otherwise recommended by your doctor. If your doctor recommends any medication changes, you are required to report this in the study diary.

You are expected to maintain your current lifestyle. Do not change your diet, exercise, or sleep. Continue taking your current supplement and natural health product and do not start any new supplement or natural health product during this study.

Please be prepared to answer questions during the screening assessment regarding your prescription and over-the-counter medications (including vitamins, nutritional supplements, "natural" remedies, homeopathic medicine and herbal preparations) and functional foods (that is, probiotic containing foods, high fibre foods) you are consuming.

Birth control, pregnancy, and breastfeeding
The effect of the study product on pregnancy and breast milk is not known. You must not participate if you are pregnant, breastfeeding or planning to become pregnant during the study. Individuals able to become pregnant (not post-menopausal, have had a menstrual period in the past 1 year, or has not had any of the following surgeries: hysterectomy [removal of the uterus], bilateral oophorectomy [removal of ovaries], complete endometrial ablation [removal of the lining of the uterus], or bilateral tubal ligation [surgical procedure that blocks the fallopian tubes]) must be using an approved method of birth control during the study. If using hormonal birth control, you must have been using it for at least 3 months. Some examples of approved methods of birth control include:

- Hormonal contraceptives including oral contraceptives, hormone birth control patch, vaginal contraceptive ring, injectable contraceptives, or hormone implant
- Double-barrier method
- Intrauterine devices
- Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner at least 6 months prior to screening
- Abstinence and agrees to use contraception if planning on becoming sexually active

If you become pregnant during the study, you must stop taking the study products immediately and contact the study doctor by emailing milkspecialties@kgkscience.com.

Since the study product is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

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STUDY PRODUCT INFORMATION:

Study Product Ingredients:

Dietary Ingredient	Quantity per capsule
Nutripro MFGM-Enriched Whey Protein Concentrate	20 grams

Non-medicinal ingredients: Vanilla Flavor, Stevia, Erythritol, Xanthan Gum, Silicon Dioxide, Sodium Chloride

Placebo Ingredients: Maltodextrin, Vanilla Flavor, Sodium Chloride, Xanthan Gum, Stevia

DIRECTIONS

You are to take the study product by thoroughly mixing one sachet (packet) of the study product with water once per day for 55 days. If you forgot to take the study product, please take it as soon as you remember on the same day. Please do NOT exceed one sachet daily.

ADDITIONAL SAFEGUARDS

If you need regular medical care for current medical conditions, you should continue with this medical care unless otherwise instructed by your regular physician or other health care professional. For your safety, you must report your current medical care as well as any changes in medical conditions during the study in your study diary. In addition, all new medications that are taken during the study should be recorded in your study diary. Some medications may affect how well the study product works or how safe it is. If you are taking one of these medications, you won't be allowed to participate in the study. These include medications and natural health products for sleep, stress, anxiety, or depression.

The study product is intended for your use only as the study participant. It should not be given to anyone else or left in a place where a small child or a pet could accidentally swallow it.

ALTERNATIVE TREATMENTS

This study is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the study.

RISKS TO YOU

It is possible that you could have problems or side effects from the study product that nobody knows about yet. There may be unknown risks with taking the study product.

Potential side-effects of taking the study product may include:

- Gastrointestinal discomfort/disturbance

If you think you are experiencing a side effect, please report it in your study diary and inform the study doctor/staff via email.

Could I have an allergic reaction? It is possible for people to have allergic reactions to the study product. If you have a serious allergic reaction, you could die. Please read the study ingredients carefully to make sure you are not allergic to any of them. Some effects of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

- Rash
- Difficulty of breathing
- Wheezing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

You should get medical help or go to the emergency room immediately, and contact the study doctor or study staff, if you have any of the above-listed effects or any other side effects during the study. Please also refer to section "Whom To Contact About This Study" for instructions on what to do in case of an emergency.

Email the study doctor or study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form.

Please report in your diary and email the study doctor or study staff right away if you experience any side-effect, problems with your health or the way you feel during the study, whether you think these problems are related to the study products or not.

If I stop taking my regular medication, what are the risks? You should not stop your regular medication unless your doctor has informed you to do so. If you stop your regular medication to be in the study, your health might worsen. Please tell the study doctor or study staff right away if you have stopped taking your regular medication.

Potential risks from eConsent You will be emailed a PDF copy of this signed consent form or provided with a link via email/text message to download a copy of this consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

WITHDRAWAL FROM THE STUDY

- You are free to choose to stop participating in the study at any time however, you will not be compensated for the virtual assessment days you've completed.
- If the study doctor or study staff finds out any non-study related information that may greatly affect your well-being (for example, information related to your health and mental health), they will share it with you immediately.
- If the study doctor determines that you need to be withdrawn from the study for safety reasons related to mental health, a call to your primary care practitioner will be offered and a list of community mental health resources will be provided to you.

If you wish to withdraw from the study at any point, please inform the study doctor or study staff immediately.

NEW FINDINGS

- Any significant findings that become available during the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

BENEFITS

- While there may be no immediate benefit to you, the results of this study will provide some of the required scientific evidence for the study products in this clinical research study.
- Your participation in this study supports the research that is required to ensure the science behind the study products.

COSTS TO YOU

- There is no cost to you, the public health plan, or your private medical insurance (if any) to participate in this study. For study participation, study product will be provided and mailed to you at no cost.
- You, the public health plan, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions. These expenses will not be paid as part of your participation in this study.
- The Sponsor of this study is paying your study doctor for the time, effort, and expenses to conduct this study.

COMPENSATION FOR PARTICIPATION

For your time and participation in the study, you will be compensated a total of $100 if you complete the entire study and all associated requirements.

You will receive your compensation after completion of the study on a Clincard, which can be used like a prepaid Mastercard. It can be used anywhere that accepts Mastercard, or the funds can be withdrawn from an ATM (ATM fees apply). Processing times may apply before funds become available on Clincard. The Clincard will be shipped to you together with the study product. You will receive detailed instructions on how to activate the card upon completing the study.

Once enrolled, for any case in which you or the study doctor determine you cannot complete all of the virtual study assessment days, you will not be receiving compensation for the days you have completed. You will be paid at the end of your participation in the research study if you complete all the virtual assessment days. You may be removed from the study as a result of non-compliance with study procedures.

COMPENSATION AND TREATMENT FOR INJURY

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 provincial health plan or your

private medical insurance (if any). By signing and dating this form, you are not giving up your legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations.

Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

VOLUNTARY PARTICIPATION

Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave at any time, for any reason, without affecting your relationship with the study doctor or study staff and without penalty or loss of benefits to which you are otherwise entitled.

The Sponsor has the right to stop the study at any time.

The study doctor may also stop your participation in this study at any time without your consent, but the study doctor will tell you why. Reasons for this may include, but are not limited to:

- Missing scheduled study assessments
- Not taking study product as directed
- Not completing required study diaries and questionnaires
- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes

CONFIDENTIALITY OF RECORDS

- KGK Science contract research staff (the organization managing this study) will keep all your medical information confidential to the extent permitted by law
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States
- You will not be identified in any publication that might result from the study
- Unless required by law, only the following may have access to confidential study data at the study site to check the accuracy of study data and to ensure that the study is being conducted properly:
    - The study doctor and study staff
    - The Sponsor (including its monitors and auditors)
    - Members of the Institutional Review Board - Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
    - Government regulatory authorities including Health Canada and other foreign regulatory agencies
- Study records will be kept by the Sponsor for a minimum of 15 years after study completion, as required by Canadian clinical trial regulations
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name

- You have the right to check your study records and request changes if the information is incorrect
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy
- As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor
- While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the study doctor, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant

By signing the consent form, you give your consent to collect, use and disclose your health information as described above.

FUTURE USE OF DATA

Your personal information during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information cannot be linked back to you. As a result, we will no longer be able to identify them or identify you.

Investigators, including investigators from collaborating institutions, can request this data for new research. This data may also be shared with outside non-profit academic investigators as well as with for-profit investigators or commercial entities, with whom we collaborate.

You will not be asked to provide additional informed consent for the use of your de-identified information in future research.

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

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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: Pro00081310.

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VOLUNTARY CONSENT TO PARTICIPATE

By signing and dating this document I agree that I have been provided enough time to read and consider whether to participate. I have read and understand all pages of the consent form and information it contains regarding the study in a language I understand. I have been given the opportunity to ask all my questions regarding the study with answers to my satisfaction. I understand that I may consult with the study doctor or the study staff, should anything become unclear or if I have further questions.

I volunteer to be in this study at my own free will and without being pressured by the study doctor or the study staff knowing I have the opportunity to leave at any time without giving a reason and without affecting my health care. The risks involved with participating in this study are clear to me. I agree to follow the study instructions provided to me by the study doctor and study staff and understand I may not participate in another study while I am enrolled in this study.

It is clear to me that my data derived from this study will be kept anonymous and may be reviewed by the Sponsor, their agents, the Institutional Review Board (Research Ethics Review Board), Health Canada and other foreign regulatory agencies. I understand that all my personal information will be treated as strictly confidential, except where disclosure is required by law, and will not be made publicly available; however, absolute confidentiality cannot be guaranteed.

By signing and dating this document, I do not waive any of my rights under the law or release the study doctor or Sponsor from their legal and professional obligations.

I know that the study product is for my use only. I will not share it with anyone and will store it in a safe place away from children, pets or others for whom it is not intended. I understand that I will receive an email and be asked to download a copy of this electronically signed and dated consent form to keep for my record.

For Electronic Consent:

For electronic consent your digital signature will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document. By signing this informed consent document, you acknowledge that you have read and fully understand all the information presented in it.

_____

Printed Name of Participant

_____	_____	_____ AM/PM
Signature of Participant	Date (mmm dd, yyyy)	Time (00:00)