Research Participant Information and Consent Form

Title of the study: Feasibility of Egg White Pudding Supplementation for Individuals in Personal Care Home Centres Needing Dietary Supplementation

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Chronic Disease Innovation Centre

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. Participation in this study is voluntary.

Purpose of Project

Sarcopenia is an age-related condition, involves the loss of muscle, strength and physical function. A medical condition characterized by heightened vulnerability and functional decline. Persons with frailty often need assistance to complete daily living activities. According to a study conducted in a multiple

Canadian home care centers, the prevalence of frailty was approximately 44%, significantly higher than that observed among older adults living in the community.

The intake of protein has been shown to be critical for the maintenance of muscle mass. Protein consumption triggers muscle protein synthesis, primarily due to ingestion of essential amino acids. This is likely because essential amino acids activate the mammalian target of rapamycin signaling pathway which regulates muscle protein synthesis in skeletal muscle. Aging appears to be associated with resistance of muscle protein synthesis in relation to ingestion of essential amino acids. This could be a contributing factor in the onset of sarcopenia and frailty.

Malnutrition is another critical issue, affecting older adults in home care and institutional settings.. It has been linked to reduced physical function and an increased risk of mortality in this population. A large Canadian study found that 21% of newly referred home care patients were malnourished. Key contributing factors include dysphagia (difficulty swallowing) and poor food intake, often associated with acute or chronic illnesses, which significantly elevate the risk of malnutrition in these vulnerable groups.

Moreover, many dietary supplement options are high in sugar, not very palatable, and are hard to chew or swallow. These factors make current products unsuitable for many older adults who require supplementation. Older adults may also have chronic diseases with dietary restrictions on sugar, phosphorus, sodium, potassium and fluid. This population is often older and may also have issues with swallowing and chewing. Recently, the Chronic Disease Innovation Centre with the Food Development Centre in Portage la Prairie and supported by Manitoba Egg Farmers, formulated an egg white protein pudding. Egg white is made up of albumin, which makes a great protein source.

The purpose of this study is to assess the feasibility of providing a high-protein egg white pudding to residents in home care centers and to evaluate its acceptability and overall liking as a nutritional intervention

Study Procedures

If you are interested in this study, a research team member will book a meeting with you to go through study details and answer any study related questions you may have. A copy of signed consent form will be given to you afterwards.

After this, the study team will go through the inclusion/exclusion criteria with you and determine your eligibility for this study. We will also review your medication/supplement information and collect your personal contact information including name, email and phone number for study related communication.

Study flow:

This study will last 8 weeks. Before you begin the study, it will be decided whether you will be a part of the egg pudding group or Resource 2.0 group. You will only join one of these groups. If placed in the pudding group, will consume 1 treatment 5 days a week for 8 weeks. If placed in the Resource 2.0 group,

you will consume three 60 ml drinks 7 days a week for 8 weeks. The home care staff or research staff will record if you consumed it fully or not. There will be two study visits which are outlined below.

Week 1	**Week 8**
Height, weight, waist, and calf measurement Hand Grip Strength test Diet Recall ASA24 Questionnaire Feedback on study pudding	Height, weight, waist, and calf measurement Hand Grip Strength test Diet Recall ASA24 Questionnaire Feedback on study pudding Product consumption logs

Nutritional Information:

Treatment	Serving size	Calories	Protein	Carbohydrates	Potassium	Phosphorous	Sodium
Egg Pudding	50 ml	180kcal	22 grams	12 mg	100 mg	20 mg	135 mg
Resource 2.0	180 ml	360kcal	15 grams	40 grams	318mg	189mg	130 mg

The egg pudding ingredients: concentrated egg white, water, sugar, canola oil, modified corn starch, maltodextrin, Arabic gum, natural flavor, and stevia leaf extract.

Resource 2.0 Ingredients: Water, Glucose Syrup, Milk Protein, Proteins (Calcium and Sodium Caseinates), Vegetable Oil (Low Erucic Acid Rapeseed), Sucrose, Minerals (Potassium Phosphate, Potassium Chloride, Sodium Citrate, Magnesium Oxide, Potassium Citrate, Sodium Chloride, Calcium Phosphate, Ferrous Sulphate, Zinc Sulphate, Manganese Sulphate, Copper Sulphate, Chromium Chloride, Sodium Molybdate, Sodium Selenate, Potassium Iodide). Acidity Regulators (Citric Acid E330, Potassium Hydroxide E525). Emulsifier (Soy Lecithin E322). Stabilizers (Cellulose E460, Cellulose Gum E466), Choline Manganese j.lg 345 818 Chloride, Vitamins (C, E, Calcium Panto-Selenium j.lg 12.2 28.9 the nate, Nicotinamide, B6, A, B1, B2, Folic Acid, K1, Biotin, D3, B12). Natural and Artificial Flavourings.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first.

Risks and Discomforts

There may be unknown risks associated with taking the investigational product in this study. Some participants may experience minor gastrointestinal discomfort, such as flatulence, abdominal pain, or

bloating in with study treatment consumption. There is also the risk of allergic reaction to the treatment product which could occur, but this risk is unlikely as we are excluding any participants with known egg allergies.

Although there will be instructions to participate provided by research personnel, if you have any reason to believe that you will be at physical risk of harm/injury by participating in any portion of the study, you will have the opportunity to decline to participate.

Benefits

This product will be provided to you alongside your routine medical care. There may or may not be direct benefit to you from participating in this study. You may learn more about healthy nutrition recommendations while you are in this study. However, your participation provides valuable information to researchers about patient health and well-being.

Costs

There will be no cost to participate in this study.

Reimbursements

As an appreciation of your time, you will be given a small gift bag as a thank you.

Confidentiality

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information (such as phone number, address and email) will not be used or revealed in the publications or presentations. Your personal information and personal health information is being collected under the authority of The University of Manitoba Act. The information you provide will be used for the purpose of this research project. Your personal information and personal health information will not be used or disclosed for other purposes, unless permitted by The Personal Health Information Act (PHIA) or The Freedom of Information and Protection of Privacy Act (FIPPA). If you have any questions about the collection of your personal information or personal health information, contact the Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) at CHIPER@researchmb.ca or call 204-775-1096.

Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Organizations that may inspect your research records, including digital records, for quality assurance and data analysis include study staff and staff from groups such as: The Chronic Disease Innovation Center (CDIC) at Seven Oaks Hospital. Representatives from The Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) may access your confidential records for quality assurance purposes; however, they are committed to confidentiality as well.

We will employ a unique numerical coding system that will not contain any direct identifiers, such as your name or initials to de-identify the data collected in this study. All research data collected throughout the study will be inputted into the study database using this unique code. A master list record that will link your name, home and email addresses, phone and participant code will be retained in a locked cabinet in CDIC and/or on a password protected CDIC shared drive.

The data collected from you during this study may be shared in a de-identified form to academic journals for publication purposes, or academic researchers for the purpose of meta-analysis and further data analysis. The data may also be stored by the academic journal or other open-access repositories under an open access policy in which case it may be used by other researchers for further data analysis and research purposes.

Your email address will be used to communicate with you during the study, this includes booking study visits and sending study related forms and questionnaires. Furthermore, please note that the name and delivery address you provide will be used for the delivery of study treatments or forms. Participant consent forms will be signed on paper and stored at CDIC in a locked cabinet and electronic copies on a password protected shared drive. Other study documents and logs will be organized in a study binder and kept in CDIC.

All paper study records will be kept in a locked secure area and only those persons authorized by the study investigators will have access to these records. CDIC is secured 24 hours per day and has controlled access. No personal identifying information such as your name, address, or contact information will leave Seven Oaks Hospital, except in relation to the delivery of trial related goods to your home.

This study will be registered on a publicly available Registry Databank. ClinicalTrials.gov is a website that provides information about federally and privatively supported clinical trials. A description of this clinical trial will be available on http://ClinicalTrials.gov. This website will not include information that can identify you. At most the website will include a summary of the results. You can search this website at any time.

Voluntary Participation/ Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. If the Principal Investigator feels that it is in your best interest to withdraw you from the study, the Principal Investigator can remove you without your consent.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the study staff:

Principal Investigator: Dr. Navdeep Tangri ntangri@sogh.mb.ca

Research Coordinator: Maryem Zahra mzahra@sogh.mb.ca

For questions about your rights as a research participant, you may contact The Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) at CHIPER@researchmb.ca or call 204-775-1096. Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you wish to have the study findings, you can contact the research personnel listed on the consent form.

Statement of Consent

1.I have read this consent form. I have had the opportunity to discuss this research study with Dr Tangri and/or his study staff.

2. I have had my questions answered by them in language I understand.

3. The risks and benefits have been explained to me.

4. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements.

5. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate.

6. I understand that I will be given a copy of this consent form after signing it.

7. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time.

8. I freely agree to participate in this research study.

9. I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed.

10. I hereby consent to undergo all necessary assessments that may be required in the course of this study.

11. I authorize the inspection of my research records by the Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER).

13. By signing this consent form, I have not waived any of the legal rights that I have.

Participant Printed name _____ Date _____

(day/month/year)

Participant Signature: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

Printed Name: _____ Date _____

(day/month/year)

Signature: _____ Role in the study: _____