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**Participant Information Letter**

**Project title:** Effect of BoneBoost Gelato on musculoskeletal health
**Ethics Approval Number:** *2024-06029-SIM*
**Principal Investigator:** A.Prof. Marc Sim

## An invitation to participate in research

You are invited to participate in a project titled the **"Effect of BoneBoost Gelato on markers of musculoskeletal health"** which seeks to assess if the daily consumption of a specifically formulated ice-cream (BoneBoost Gelato) over 4-weeks improves musculoskeletal health. You are being asked to take part in this project because you are a woman aged between 60 and 80 years, identified as meeting the eligibility criteria and have expressed interest in participating in this clinical trial.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative or friend.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to be involved in the research described;
- Consent to the use of your personal information as described.

## What is this project about?

Older women are at a much higher risk for osteoporosis (weak bones) and fracture compared to men. When considering diet, often only calcium, vitamin D and protein are promoted for muscle and bone health. However, an overall balanced diet is critical to optimise musculoskeletal health. In addition to protein, calcium and vitamin D, our team has identified key nutrients from vegetables and fruits that also play an important role. However, improving dietary habits, such as increasing fruit and vegetable intake, is challenging. We have developed BoneBoost gelato to overcome this limitation.

Our team at the Edith Cowan University Future Foods & Digital Gastronomy Laboratory developed healthy Gelatos (Italian ice-cream) containing a variety of key nutrients that we have shown to support musculoskeletal health. Nutrient-packed freeze-dried powders from fruits and vegetables, in-combination with other beneficial nutrients (protein, calcium, vitamin D) have been incorporated into specifically formulated 'BoneBoost' Gelatos. Each serve/scoop of BoneBoost (~100 g) comprises of ~ 45% of the recommended daily intake (RDI) for calcium (~600 mg), ~ 90% of the RDI for vitamin D (~14 µg), 15% of the RDI for protein (~12 g), and the equivalent of 1.6 serves of green leafy vegetables and up to 0.5 serves of fruit (e.g., lemon., kiwifruit, lime).

This project seeks to examine if BoneBoost Gelato consumption improves markers of bone health.

## What does my participation involve?

Your participation in this research project will involve 3 clinical visits over an 8-week period, including at the start (T0 baseline), at 4 weeks (T1) and finally at 8 weeks (T2). Each visit is estimated to take a maximum of two hours at the Royal Perth Hospital Research Foundation Building and will include:

- A venous blood sample where 2x3ml and 3x5ml of blood (total 21ml) will be collected at PathWest.
- Blood pressure measurement
- Anthropometric measurement including body weight and height, as well as the estimation of lean and fat mass using an electronic scale (bioelectrical impedence).
- Perform simple muscle function tests including hand grip strength and the timed-up-and-go test
- Undertake a range of questionnaires relating to your habitual diet, physical and mental health as well as lifestyle

To determine whether you are eligible to participate in this study, we will ask you some questions about your health and dietary preferences, especially known food allergies in commonly used ingredients to create gelato (this is known as pre-screening). Gelato can contain many common food allergens, including dairy, eggs, nuts, soy, and gluten. If you are considered eligible and are interested in participating, we will provide you with an appointment letter, and a map of the venue for the first visit. If there are measurements (e.g., blood pressure) taken that indicate the possibility of significantly elevated risk for hypertension, you will be advised by the research team to take these to your GP for review

*Location: Royal Perth Hospital Research Foundation*

When you arrive for your clinical visit, the study will be explained to you in detail and any questions you have will be answered. You will be asked to sign a consent form if you wish to participate in the study. A consent form must be signed prior to any study assessments being performed. A copy of this consent form will be provided.

*Online questionnaires*

A link for an online questionnaire will be sent to you by email. You can complete this at home at a time that is convenient for you, using a computer, tablet or phone that has an internet connection (e.g. Wi-Fi). The questionnaire will include demographic questions (e.g. age, gender, ethnicity, marital status, occupation), medical questions (e.g. self-reported physical and mental health), and questions about your current lifestyle, including diet and physical activity behaviours.

*The 8-week trial*

*The entire duration of this study is 8 weeks, comprising 4 weeks of observation and 4 weeks of BoneBoost Gelato consumption.*

The 4-week period between your first (T0) and second clinic visit (T1) will serve as a 'control' to assess how your typical lifestyle (e.g. diet, exercise, medication) influences various markers of cardiovascular and musculoskeletal health, including bone markers. Immediately after your second clinic visit, you will be required to consume a daily serve of BoneBoost gelato for the next 4 weeks (28 days x 100 g per day which is the equivalent of 1 small scoop). Gelatos can be provided to you in two separate deliveries (14 cups per delivery) to ensure adequate storage space in your freezers at home. You will have your third and final clinical visit 4 weeks later (T2), after 28 days of daily gelato consumption.

Following the completion of this study, the research team intend to use the findings for research translation purposes (including, but not exclusive of; conference presentations, media releases, infographics etc.), guiding future research projects and for future research grant applications. No identifiable data will be included in any future uses of the findings from this study.

## Reimbursement of study costs?

None

## Do I have to take part in this research project?

Your participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any time. If you do withdraw your consent during the research project, we will not collect any additional information from you and all data collected from you will be destroyed. If the request for withdrawal occurs after data analysis, your data cannot be deleted.

If you do decide to take part, you will be given this Participant Information Letter and Consent form to sign and you will be given a copy of the information letter to keep. Your decision to take part, or to take part and later withdraw, will not affect your relationship with the research team and Edith Cowan University.

## Your privacy

By signing the consent form, you consent to the research team collecting and using personal information about you, or information about your health or dietary patterns, for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Identifying information from the focus group interviews will be removed when they are transcribed. All data records will be de-identified with a participant identification (ID) number assigned to you, instead of your name. Only members of the Edith Cowan University research team, and researchers listed on this project, will have access to your name and your corresponding participant ID number. Any data shared with the wider research team will only contain your participant ID. The online questionnaire will also use your participant ID number, so you will not be asked to enter any personally identifiable information such as your name or date of birth. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any form of publication and/or presentation, information will be provided in such a way that you cannot be identified, except where requested for specific reasons, and then you will be asked to provide written consent.

In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this letter if you would like to access your information.

All data collected will be kept in accordance with ECU's Data Management Policy. All blood samples will be used for the purposes of this research and future questions related to the broader objectives of this research. Stored blood samples will be individually re-identifiable (coded). Privacy and confidentiality will be maintained by using password-protected databases. Samples will be stored by PathWest during the study, and subsequently at the Edith Cowan University School of Medical, Health Sciences at Royal Perth Hospital Unit, until all appropriate tests are completed. In addition, blood samples provided will be stored for future research within the Edith Cowan University School of Medical, Health Sciences at Royal Perth Hospital Unit. The samples may only be used to investigate questions related to the broader objectives of this research. That is, research relating to the cause and prevention of cardiometabolic diseases. This may involve using samples and data collected in future studies aiming to understand factors that influence cardiometabolic health, including muscle and bone. This will allow for the investigation of research questions that require a larger number of participants than that required for this specific research study. You will be asked to provide consent for the collection of your blood prior to the commencement of this research project. Electronic data will be stored on a secure Microsoft SharePoint site provisioned by ECU's IT Services. All records will be stored as required in ECU's Records Management Policy. The

data will be retained for 15 years and destroyed, if appropriate at the end of the retention period. Data will be de-identified when stored and at the end of the retention period, the data will be destroyed, if appropriate under the State Records Act.

## Possible Benefits

This research may not provide any long-term benefits to you personally but may provide evidence in the development of a novel whole foods product to assist people with poor muscle and bone health. We aim to use the results of this study to determine in future work if the long-term consumption of BoneBoost Gelato can improve structural markers of bone strength (bone mineral density) to lower the risk of falls and fracture.

## Possible Risks and Risk Management Plan

BoneBoost Gelato can contain many common food allergens, including dairy, eggs, nuts, soy, and gluten. BoneBoost Gelato will also be created using commercially available food ingredients including protein powder, calcium carbonate and vitamin D3, as well as fruit and vegetables. In the rare event of an allergic reaction to the ingredients in the gelato, medical assistance must be sort immediately. The collection of venous blood can sometimes result in bruising and tenderness at the forearm. Medical staff within the Royal Perth Hospital Research Foundation can be sort to assist with any of these issues. Answering survey questions on your physical and mental health may cause worry or anxiousness. You may have significant, mild or no change in anxiety and overall quality of life. If you have any change, or are otherwise worried, please ask for help:

• You should talk to your General Practitioner (GP) or other health professional as soon as possible.

• In case of an emergency, please phone emergency services (000), Lifeline (13 11 14) or visit the local hospital emergency department.

• Further information on the signs and symptoms of depression and anxiety can be found on the Beyondblue website (https://www.beyondblue.org.au/).

- Further information on food allergies, including first-aid for anaphylaxis can be found here, as provided by the Australasian Society of Clinical Immunology and Allergy website.

## What happens when this research study is finished?

We intend to publish our results in research journals and present them at research conferences locally, nationally, and internationally. Your name or any other identifying information will not be included in any of the publications or presentations. At the end of the study, once all biomarkers have been measured, we will provide a summary of the study findings to you via email. Due to the nature of the study, we will not provide you with any individual study results.

## Has this research been approved?

This research project has received the approval of Edith Cowan University's Human Research Ethics Committee, in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*. The approval number is *2024-06029-SIM*

## Contacts

If you would like to discuss any aspect of this project, please contact the following people.

**Chief Investigator**
Associate Professor Marc Sim
Senior Research Fellow
Edith Cowan University
P: 6304 4605
E: boneboost@ecu.edu.au

**Associate investigators**
Dr Lie Zhou Zhong
Associate Professor Therese O'Sullivan
Professor Richard Prince
Miss Montana Dupuy

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

**Independent Person**
Research Ethics Support Officer
Edith Cowan University
P: 6304 2170
E: research.ethics@ecu.edu.au

If you wish to participate in this research, please sign the Consent Form upon your visit.

Sincerely,

*Marc sim*

Chief Investigator