PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: *Participants*

Plain Language Statement

Date: 26/11/24

Full Project Title: ALMOND ProFIT-PM- Almond Protein powder to enhance fitness training

Principal Researcher: Dr D. Lee Hamilton

Student Researcher: Vy Tran (PhD student)

Associate Researcher(s): Dr Charles Urwin, Dr Jackson Fyfe, Dr Simon Feros, Dr Gavin Abbott, Dr Sze Yen Tan, Prof Clinton Bruce, Dr Giselle Allsopp, Dr Greg Kowalski, Assoc. Prof Michael Tieland, Dr Rhiannon Snipe, Dr Shaun Mason, Dr Zoya Huschtscha

Who do I contact if I have questions about the project?

Ms Vy Tran
s223235429@deakin.edu.au
School of Nursing and Midwifery Melbourne Burwood Campus Deakin University

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Your Consent

Thank you for considering our invitation to take part in this research. Please read the following sections to understand what is required from you and where you can seek further information if required. Please know that your participation is completely voluntary, and you can withdraw from the project at any time. If you do decide to participate, we thank you for your contribution.

The student researcher, Vy Tran, is conducting this project as part of their PhD at Deakin University and will be involved in all aspects of the study.

What is this study about?

We are investigating whether almond protein powder can improve muscle mass in postmenopausal women participating in both strength and cardiovascular training. Almond protein, a plant-based, vegan alternative to whey protein may offer similar benefits in supporting muscle growth. This study will assess whether daily consumption of almond protein powder can help build muscle, increase strength, improve blood sugar levels, and promote heart health, as well as evaluate its impact on appetite and food choices..

Why is the study important?

We anticipate that almond protein will enhance muscle size, strength, fitness, blood sugar regulation, and cholesterol levels, contributing to overall better health.

After completing the consent form at the end of this plain language statement, the research team will email you a **participant ID number and a link to the first survey**.

You will be invited to participate in this study if you fit the following criteria:

- Aged 50-65 years
- Have undergone natural, surgical or medically induced menopause; no menstrual bleeds for 12 consecutive month
- Overweight (25–29.9 kg/m²) and obese class I (30–34.9 kg/m²)
- Not currently practicing progressive resistance training or challenging balance/mobility training (>1/week) in last 6 months
- Weight stable (no more than +/-2 kgs of weight change in last 2 months)
- Continuously using or not using hormone therapy for more than 12 months
- No nut allergy
- No uncontrolled high-blood pressure
- Untreated thyroid conditions
- No history of muscle, nerve, bone, or clotting disorders
- No recent treatment for conditions affecting muscle mass (e.g., cancer treatment, anabolic steroids))
- Do not have any current chronic disease including cancer, diabetes, cardiovascular disease, chronic liver disease, and gastrointestinal disorders that affects nutrient absorption.
- No injuries preventing exercise participation
- No anticipated absences longer than 1 week during the study
- Non- smoker

What you will be asked to do?

If you agree to participate:

- Fill out a consent form and provide medical and diet history information via an online questionnaire to check eligibility.
- Eligible participants must complete a Physical Activity Readiness (PAR-Q) questionnaire before engaging in any physical activity. This questionnaire will ask you questions about your general and physical health and determine your readiness for exercise. If the questionnaire indicates the need for medical clearance, they must obtain approval from a healthcare professional before proceeding.
- NOTE: If you are required to obtain medical clearance to participate in this study, please note that the study will **not** cover any costs associated with medical consultations, tests, or assessments. You will be responsible for any fees incurred. If you visit a GP who offers **bulk billing**, there may be no out-of-pocket expenses. However, if your GP or specialist charges a fee, you will need to cover this yourself.

We recommend checking with your healthcare provider about potential costs before booking an appointment.

- If eligible, you will be randomly assigned to one of two groups: one group will take almond protein powder, and the other will take a placebo (a non-protein supplement). You will not know which you are assigned to.
- Participate in a 12-week study with 10 weeks of strength training. Measurements will include muscle growth, fat loss, fitness, strength, blood sugar, cholesterol, appetite, and overall food intake.
- Attend Deakin University for **23 sessions** over **12 weeks** (approx. **38 hours total**). Testing will include hydration assessment, anthropometric measurements, hand grip strength, body composition (DEXA scan), oral glucose tolerance test (OGTT), food diary, strength tests, VO2 peak test, and appetite feedback.

Testing day (at Deakin):

You will attend Deakin for **3 days**, each lasting about **5-6 hours**, for various testing procedures. The following assessments will be conducted:

1. **Hydration Assessment**: A urine sample will be collected.
2. **Anthropometric Measurements**: Your height and weight will be measured using standard techniques.
3. **Hand Grip Strength**: Your grip strength will be tested with a specialised grip tool.
4. **Body Composition Analysis**: A DEXA scan will measure muscle and fat composition in the whole body as well as specific regions (arms and legs).
5. **Oral Glucose Tolerance Test (OGTT)**:
    - A fasting blood sample will be taken to measure baseline glucose levels.
    - You will consume a glucose drink containing **75 g of glucose**. Blood samples will be drawn at **15-minute intervals** over a period of **2 hours and 15 minutes** to assess how your body processes sugar.
6. **Food Diary**: You will complete a 3-day food diary (2 weekdays and 1 weekend) using the EasyDietDiary app.
7. **Strength Testing**: You will perform a 3-repetition maximum (3RM) test on both the leg press and chest press.
8. Blood pressure monitoring: We will monitor blood pressure at rest prior to exercise testing, with a cut-off of ≥160/100 mmHg for inclusion in the study. If a participant's blood pressure exceeds this threshold, they will not undergo exercise testing until cleared by their GP.
9. **VO2 Peak Test**: This test will measure the maximum amount of oxygen your body can use during intense exercise while cycling at progressively harder levels, monitoring your oxygen intake and carbon dioxide output. We will also measure your heart rate using a heart rate monitor (a strap on your chest).
10. **Appetite and Food Acceptability**: You will provide feedback on your hunger levels and enjoyment of the food and supplements offered during the study.

During the study:

Exercise Training

For **10 weeks**, you will attend Deakin campus at Burwood **2 days per week** for approximately **1 hour** of group supervised weight and cardio training sessions on non-consecutive days.

Supplement and Placebo Drinks

Throughout the study, you will consume one of two daily drinks:

1. **Supplement Drink**: Contains almond protein powder.
2. **Placebo Drink**: Similar in flavour but does not contain almond protein powder.

You will not know which drink you are assigned to until the study concludes. Please refrain from discussing your assigned supplement with other participants. You will be instructed on when to consume the drinks, including an additional supplement to take after your training sessions.

You will need to record your supplement intake using the EasyDietDiary app by taking a photo of your finished drink and uploading it. Please bring back all empty or unused supplements at the end of the trial.

Additional Measurements

Throughout the study, you will also be required to:

- Keep a food diary for **3 days** at multiple time points (e.g., weeks 1, 2, 5, 8, and 12).
- Complete a quick questionnaire regarding your appetite and enjoyment of the supplement at the same time points. You will receive a QR code to scan and fill out these questions on your own phone.

Are there any risks associated with participating in this project?

- **Mild discomfort from blood tests:** Only qualified phlebotomy trained researchers with experience at performing this procedure will collect blood samples. The amount of blood collected during each trial (~40 ml) will not impact upon normal physiological functioning. There may be discomfort experienced from having blood tests with the use of needles, some participants may find this procedure creates a bruise around the puncture site. Fainting may also occur in 'at risk' participants. We will familiarise you with the blood sample collection procedure during the initial assessment and will determine if you are an 'at risk' participant for fainting during blood sampling. If you do start to feel faint during the blood sampling, we will immediately stop and recline the phlebotomy chair, so you are fully reclined with your feet elevated. We will then get you to stay there for 10-minutes and sit up slowly to prevent any falling. Using your blood samples, we will be measuring markers of hormones and inflammation markers associated with muscle mass and ageing.

- **Muscle soreness from training sessions:** You may experience muscle soreness or fatigue as a result of the training sessions involved in the study. This discomfort is expected to be temporary and will be monitored by our research team.

- **Time commitment:** Participation in this study requires a significant time commitment for assessments, training sessions, and follow-up visits. We appreciate your dedication and will strive to accommodate your schedule as much as possible.

- **Radiation exposure*:** This research study involves exposure to a very small amount of radiation from DEXA. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose you will receive from all the DEXA of your body will be approximately 0.02 mSv. At these dose levels, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. The risk is believed to be minimal and is similar to a long-haul flight. **Please keep this Patient Information and Consent Form that includes information about your exposure to radiation in this study for at least five years. You will be required to provide this information to researchers of any future research studies involving exposure to radiation**
- Cardiac event: It is estimated that for adults without existing heart disease, the risk of a cardiac event or complication ranges between 1 in 40,000 – 800,000 hours of exercise. For patients with existing heart disease, an event can occur an average of once in 62,000 hours. To ensure the safety all participants must undergo the following pre-screening:
    - **Physical Activity Readiness Questionnaire (PAR-Q):** A self-screening tool to identify individuals who may require medical clearance before engaging in physical activity. It assesses factors such as history of heart conditions, dizziness, or joint issues.

    - **Blood Pressure Monitoring:** Blood pressure should be measured before exercise testing. Elevated readings may indicate a need for further medical assessment before participation.
    - **Medical Clearance:** Individuals with known cardiovascular conditions, high-risk factors, or concerning responses in the PAR-Q may require clearance from a doctor before starting an exercise program, particularly one involving high-intensity or strenuous activity.

*If you have been involved in any other research studies that involve radiation, please inform us. Please keep this Patient Information and Consent Form that includes information about your exposure to radiation in this study for at least five years. You will be required to provide this information to researchers of any future research studies involving exposure to radiation.

- **Reactions to OGTT:** Some participants may experience mild symptoms such as nausea or dizziness after drinking the glucose solution. These symptoms usually subside quickly.

Health results: The OGTT is a routine procedure used to assess how your body processes glucose, and the results may help identify any potential risks for conditions such as prediabetes or diabetes. You have the option to consent to be notified if your results are of concern. If there are any concerns regarding your results, a healthcare professional (Dr Zoya Huschtscha) will contact you to discuss the findings in detail and recommend any necessary follow-up actions- such as seeing your GP for follow

up. It's important to understand that elevated glucose levels may indicate that your body is not processing sugar effectively, which could lead to further health complications if not addressed.

What are the potential benefits of participating in this study?

The primary purpose of this study is to contribute to scientific knowledge, rather than to provide direct health benefits. **We cannot guarantee or promise that you will receive any benefits from this project**. But we expect that the following benefit might occur:

- Resistance training may enhance muscle mass gains, strength and power as a result of the training.
- Contribution to scientific knowledge on the benefits of almond protein powder.
- You will be provided with a $100 Coles electronic gift voucher upon the completion of the trial.

Other treatments whilst on study

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies and any changes to these during your participation in the study.

How will my information be handled?

All collected information will be labelled with a unique study code, and not with your name or any other identifying information, which will be kept separate from the information collected. Only the principal investigators/study coordinator on the study will have the ability to re-identify the data. All paper copies of this information will be kept in a locked filing cabinet in at Deakin University or in a password protected computer or on a secure server managed by Deakin. Apart from basic personal information (e.g., name, contact information), your information will be coded with a unique study identifier to preserve privacy. The information collected from this study will be kept until the end of the project and then placed in archives for a minimum of 15 years from the final publication of the findings. All data will also be kept in a database stored on a computer which will be password-protected and only accessible to the research staff involved in this study and may be used in future research which is closely related to this project. In the future, we may also wish to share some non-identifiable aggregate research data with other groups that obtain relevant ethics approval that are not immediately involved in this project, but your information will be non-identifiable.

It is the intention of the researchers to publish the results of this project. In such circumstances your identity will not be disclosed. In all cases, information will be provided in such a way that you cannot be identified. In addition, any information collected will be coded and de-identified, and stored securely in electronic format where only researchers will have access to the data.

New Information Arising During the Project

Although unlikely, during the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this

research.

Similarly, as you will be monitored during each testing session, if it appears for any reason that you or the research staff are at risk by your continuing participation in the testing session, the person(s) supervising the research will stop your participation. In all cases you will be offered all available care to suit your needs and medical condition.

Do I have to take part?
Your participation in the study is voluntary. If you do not wish to take part, there is no obligation. If you decide to take part and later change your mind, you are free to withdraw your participation from the study at any time. There will be no adverse consequences should you wish to withdraw.

Non-participation or withdrawal from the study will not affect your employment or your relationship with your professional organisation or Deakin University. Should any of the researchers withdraw from the study, you will be notified.

How do I withdraw?
Send an email to: zoya.huschtscha@deakin.edu.au

How can I get involved?
For further information or to take part, please contact the study coordinator (zoya.huschtscha@deakin.edu.au) and student researchers **Ms Vy Tran** **s223235429@deakin.edu.au**The study team will assist you to complete screening and other study procedures.

Will I be able to find out the results of the project?

A summarised report of the findings will be available for participants to read at the completion of the study. The study findings will also be presented at conferences and published in peer-reviewed journals that you will be able to access. If you wish to receive a copy of the manuscript, please contact the research team via email and they will send one to you.

What if I have a complaint or any concerns?

Complaints
If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number 2024/HE000126.

Funding for the Research

The project is funded by California Almonds, Almond Board of California ($225,348.11)

Organisational consent

We have obtained organisational consent which has been approved by the Deputy Vice Chancellor – Research (DVC-R) to recruit Deakin Staff.

To mitigate the risks associated with recruiting participants in unequal relationships:

1. Your decision to participate or not, will have no impact on your employment, academic standing, or relationships with your supervisors .
2. Any researcher or supervisor who holds a direct hierarchical relationship with a potential participant will not be involved in recruitment, obtaining consent, or conducting data analysis for that participant. This ensures that hierarchical relationships do not influence participation or data handling processes.
3. Participants will be asked to confirm on the consent form if they have a direct hierarchical relationship with any member of the research team. This declaration is mandatory for participation in the study.

Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project are being reviewed by the Deakin University Human Research Ethics Committee for approval. (2024/HE000126).

New Information Arising During the Project

Although unlikely, during the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. Similarly, as you will be monitored during the testing session, if it appears for any reason that you or the research staff are at risk by your continuing participation in the testing session, the person(s) supervising the research will stop your participation. In all cases you will be offered all available care to suit your needs and medical condition.

Termination of the Study

This research project may be stopped for a variety of reasons. These may include reasons such as unacceptable side effects.

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participant

Consent Form

Date:

Full Project Title: ALMOND ProFIT-PM- Almond Protein powder to enhance fitness training

Reference Number: 2024/HE000126

☐I have read, or have had read to me and I understand the attached Plain Language Statement.

☐ I freely agree to participate in this project according to the conditions in the Plain Language Statement.

☐ I have been given a copy of the Plain Language Statement and Consent Form to keep.

☐ If my oral glucose tolerance results indicate that I have a health concern with glucose control, I agree to have my results discussed with a member of the research team and agree to organise a follow-up with my GP.

☐ I Understand that if I have pre-existing hypertension, or if my pre-exercise screening indicates that I need a medical clearance prior to exercise, that I must provide a letter from my GP indicating that I am fit for exercise. I also understand that any costs associated with obtaining this medical clearance are my responsibility and will not be covered by the study.

☐I understand that my participation is completely voluntary, and I can withdraw from this study at any time without any consequences.

For Deakin staff only:

Organisational Consent:
Do you have a direct hierarchical relationship with any member of the research team?

☐ Yes

☐ No

If **Yes**, please specify the name(s) of the individual(s) to ensure they are not involved in the recruitment, assessment, or analysis of your data:

☐ I understand that if I do have a direct hierarchical relationship with a member of the research team, that researcher will not be involved in my recruitment, consent, or data analysis processes.

☐ I understand that my decision to participate or not participate in this study will not impact my employment, academic standing, or professional relationships at Deakin University.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.

Participant's Name (printed) ……
Signature ……Date ……

CONSENT WITHDRAWAL FORM

Full Project Title: ALMOND ProFIT-PM- Almond Protein powder to enhance fitness training

Reference Number: 2024/HE000126

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Deakin University or any other organisation.

Participant's Name (printed) ……..

Signature …… Date ……

Please return this withdrawal form to:

Email: Ms Vy Tran s223235429@deakin.edu.au

or Dr Zoya Huschtscha at zoya.huschtscha@deakin.edu.au