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| **PLAIN LANGUAGE STATEMENT AND CONSENT FORM** | Deakin University logo |

TO: Participants

**Plain Language Statement**

Date:

Full Project Title: Effects of nut consumption patterns on the 24-hour glucose homeostasis of adults with type 2 diabetes mellitus (T2DM): A pilot study

**Principal Researcher:** Dr Sze Yen Tan

**Associate Researcher(s):** Michelle Keske, Lewan Parker, Shaun Mason, Elena George, Jeew Hettiarachchi

**1. Your Consent**

You are invited to take part in this research project which will investigate how nut consumption structure (e.g. eaten in one sitting vs. timed before meals) will influence glycaemic control over a 24-hour period in people with T2DM.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker or doctor. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information you have read, consent to take part in the study, consent to have the tests and treatments that are described and consent to the use of your personal and health information as described.

You will be given a copy of the Plain Language Statement and Consent Form to keep as a record if you wish to.

*Participation in this study is voluntary.* If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether or not to participate will not affect your relationship with Deakin University.

**2. Purpose and Background**

In 2021, 1 in 20 Australians had diabetes. According to the National Mortality Database, diabetes accounted for 19,300 deaths (11.2% of all deaths) in Australia in 2021 (ABS 2021), with Type 2 Diabetes (T2DM) accounting for 58% of these deaths. High blood glucose levels are a hallmark feature of T2DM, which accelerates the risk of cardiovascular disease (heart attack and stroke). These cardiovascular complications start to develop in people at risk of T2DM (i.e. people with blood glucose levels higher than normal but not considered T2DM). The variability of blood glucose during the day, particularly during mealtime, is a stronger predictor of cardiovascular disease risk than fasting blood glucose levels. Hence, finding effective intervention strategies to reduce blood glucose excursions during mealtimes is the highest priority. Various dietary strategies have been shown to modulate blood glucose levels after eating a meal and they include reducing the carbohydrate content and increasing the protein and fat content of a meal to reduce the availability of glucose, increase insulin release, and slow digestion rates. In our previous study, eating foods high in protein and fat (i.e. nuts) have been shown to reduce the blood glucose levels after a meal.

The purpose of this study is to understand the effects of two nut ingestion patterns on the 24-hour blood glucose homeostasis of adults with T2DM.

The outcomes of this study include glycaemic control and well-being indicators. A total of 10 adults with T2DM (5F & 5M) will participate in this project.

This study is funded by IPAN seed funding from, the Institute for Physical Activity and Nutrition at Deakin University. This trial has been initiated by Dr Sze Yen Tan, the Principal investigator of the study.

**3. Procedures – what you will be asked to do**

If you decide to volunteer in this study, you will first be asked to fill out a questionnaire to determine whether you are eligible to participate. If you meet all inclusion criteria, you will provide written informed consent and be enrolled in the study. Once enrolled, you will be randomly assigned (like flipping a coin) to one of the three study groups, where one group will receive and consume 1 preload of 42g almonds before the first meal i.e. breakfast, the second group will receive 14g almonds (total 42g) consumed before each of 3 main meals while another group will not receive any almond and will serves as the comparison group (no intervention). In addition, you will receive foods and beverages with known macronutrient breakdown to consume for five days. Regardless of which group you are allocated into, you will be asked to attend 2 study visits at Deakin University Burwood Campus. We estimate that the total time commitment for the study is approximately 3 hours spread over the 2 study visits.

During the first (baseline) study visit, you will be asked to complete a number of activities.

(A) At Deakin University Burwood Campus, you will complete the following:

• Continuous blood sugar monitoring. This allows us to record your blood sugar levels continuously for up to 7 days. To do this, we will place a tiny flexible sensor under the skin of your abdomen or the back of your arm (refer to below picture), which will record you blood glucose levels for up to 7 days. You may feel a minor stinging sensation when this is inserted (similar to taking a finger prick blood sample), but after the initial placement there is unlikely to be any ongoing pain or discomfort. The sensor will be covered by a plastic adhesive waterproof cover, and as such can be worn at all times discretely under your clothes and does not impede your day-to-day activities including showering. All blood sampling and continuous blood sugar monitoring has a small risk of infection and/or bruising but this is rare and will be minimised by the use of strict sterile procedures performed by experienced research investigators

Flexible sensor inserted under the skin.

 

Sensor that goes on top of the skin and connects to a transmitter.



• Questionnaires on age, sex, general health and medication use.

• Have your weight, height, waist, body fat and blood pressure measured. For weight and body fat measurements, you will be asked to stand on a set of scales that have special foot and hand sensors that will send a low, safe signal though the body. It takes less than a minute and will provide a measure of how much muscle and fat is in your body. The test is painless and so you will not feel anything during this assessment.

During the final visit, you will be asked to repeat all measurements taken at the initial (baseline) visit. Participants in the intervention groups will also complete a questionnaire about their perception of the study intervention.

**4. Possible Benefits**

We cannot guarantee or promise that you will receive any benefits from this project, but the knowledge generated from this study will benefit the public in the future. As an appreciation for your time to participate in this study, we will provide you with a $50 voucher.

**5. Possible Risks**

The risks are minimal as most measurements taken in this study are non-invasive methods. You may feel a minor stinging sensation when the continuous glucose monitor sensor is inserted (similar to taking a finger prick blood sample), but after the initial placement there is unlikely to be any ongoing pain or discomfort. The Continuous glucose monitoring will be conducted by trained personnel from a Deakin University. Almond and food and beverage in the intervention and control group is sourced from a certified company and commercially available.

6. 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, diets, vitamins or herbal remedies and any changes to these during your participation in the study.

**7. Privacy, Confidentiality and Disclosure of Information**

Any personal information provided by you to the researchers involved with this project will remain confidential. It will only be disclosed with your permission, subject to legal requirements.

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. All data that we collect from you from online questionnaires will be kept secure with Qualtrics online survey software. All paper copies of this information will be kept in a locked filing cabinet in the researcher’s office at Deakin University or in a password protected computer. The information collected from this study will be kept until the end of the project and then placed in archives for 10 years from the publication of 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.

The results of this project will be discussed at national and/or international conferences. In all cases your identity and personal information will not be disclosed. Information will be provided in such a way that you cannot be identified. In accordance with the *Freedom of Information Act* 1982 (Vic), you have the right to access and to request correction of information held about you by Deakin University.

**8. 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.

**9. Results of Project**

Upon completion of the project it is anticipated that the results will be submitted for potential peer-review and journal publication in the field of nutritional science. The results may also be presented orally to a scientific meeting in Australia or internationally. Upon completion of the study, all participants will be invited to a group presentation conducted by the researchers who will outline the main findings from the study. In addition, all participants will receive a copy (booklet) of their key results.

**10. Further Information or Any Problems**

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the principal researcher or associate researcher below.

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| --- | --- |
| **Contact Person** | **Telephone Number** |
| Dr Sze Yen Tan | 03 9246 8977 |

**11. Complaints / Other Issues**

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 [2021-XXX]

**12. Participation is Voluntary**

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with Deakin University. You will also have the option to withdraw your data and tissues from the research project if you wish to do so.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team or complete and return the Revocation of Consent Form attached. This notice will allow the research team to inform you if there are any health risks or special requirements linked to withdrawing.

**13. 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 …

**14. 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:** Participants

**Consent Form**

**Date:**

**Full Project Title:** Effects of nut consumption patterns on the 24-hour glucose homeostasis of adults with type 2 diabetes mellitus (T2DM): A pilot study

**Reference Number:**

I have read, or have had read to me in my first language.

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.

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 …………………………

**PLAIN LANGUAGE STATEMENT AND CONSENT FORM** 

**TO:** Participants

**Withdrawal of Consent Form**

*(To be used for participants who wish to withdraw from the project)*

**Date:**

**Full Project Title:** Effects of nut consumption patterns on the 24-hour glucose homeostasis of adults with type 2 diabetes mellitus (T2DM): A pilot study

**Reference Number:**

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*.*

Participant’s Name (printed) …………………………………………………….

Signature ………………………………………………………………. Date ……………………

**Please post or email this form to:**

Dr Sze Yen Tan

School of Exercise and Nutrition Sciences

Deakin University

221 Burwood Highway

Burwood, Victoria 3125