PLAIN LANGUAGE STATEMENT AND CONSENT FORM

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): 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 pattern (e.g. eaten with breakfast vs. before each of the three main meals) will influence blood glucose 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, with Type 2 Diabetes (T2DM) accounting for 58% of these deaths. High blood glucose levels are a hallmark feature of T2DM, which increases the risk of cardiovascular disease (such as 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 throughout the day, particularly after mealtimes, 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 of the highest priority. Various dietary strategies have been shown to regulate 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, stimulate insulin release, and reduce 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 compare the effects of two nut ingestion patterns on the 24-hour blood glucose control 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.

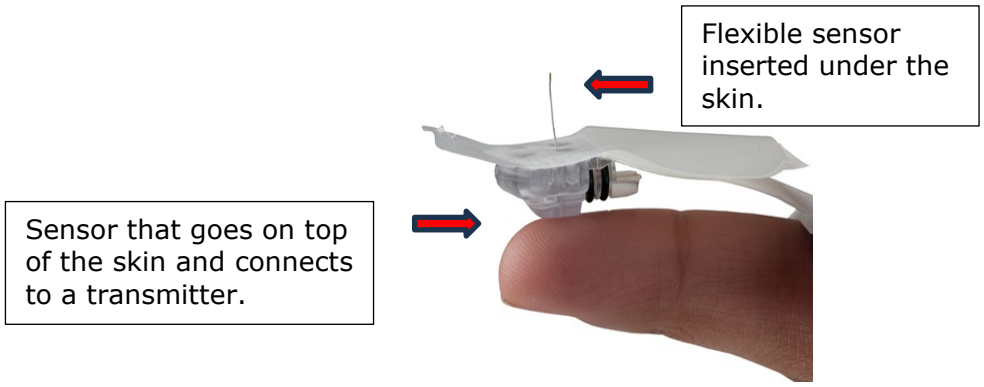
3. Procedures – what you will be asked to do

First, you will be asked to fill out a questionnaire to determine whether you are eligible to participate. If you meet all inclusion criteria, you will provide us with a written informed consent, after which you will be enrolled in the study officially. Once enrolled, you will attend a Baseline visit (Day 1) at Deakin University (Burwood), where we will ask you to complete questionnaires about yourself and your health, obtain some measurements, wear a device (like a watch) on your wrist that measures your activity levels, and a device that measures your blood sugar levels continuously for the next 5 days will be placed in your abdominal region or back of your upper arm. After the Baseline visit, you will be asked to eat 3 test diets (1 day each) in a random order for the next 5 days in the free-living environment. One diet will involve eating 42g of almonds with your breakfast, the second diet will involve eating 14g of almonds with all 3 main meals, while the final diet will not include any almonds. There will be a day in between these 3 test diets, where you just eat your usual diet. During the 3-day test diet period, you will be asked to eat only the foods provided to you. All foods provided to you are purchased from the supermarket as pre-portioned meals, plus some pre-packaged snacks and beverages In between these 3 diets, you will be asked to eat your usual diet (foods not provided). The 3-day test diet plus the 2-day washout period will be conducted in the free-living environment. After the 5-day test period, you will attend the Final visit on Day 7 at Deakin University (Burwood), where the measurements taken on Day 1 (at Baseline visit) will be repeated again, and you will be asked to provide feedback on the three test diets through a questionnaire. To summarise, you will be asked to attend 2 study visits at Deakin University

Burwood Campus, which is estimated to take about 4 hours in total, plus consuming the diets for 3 days at home.

During the first (Baseline) study visit at Deakin University (Burwood), you will be asked to complete a number of activities.

• Continuous blood glucose/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 back of your upper arm, which will record your 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



• 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. We will also ask you to complete a questionnaire about your perception of the diets you have followed.

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 when you have completed the study.

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 monitor will be placed by a trained staff at Deakin University. Almonds, foods and beverages provided in this study are commercially available in the supermarket and pose minimal risks. If you experience any adverse events during the study, you are advised to immediately stop consuming the foods provided to you, and advise the researcher of this adverse event.

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.

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 [2024-124]

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. You will also be informed that any of study data collected until the day of withdrawal may be used for data analysis as per informed consent; however, you will not be able to be identified from any published results. You may also request a summary of the overall study results, and your results at completion.

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 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.

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