Temasek POLYTECHNIC

Participant Information Sheet

We are inviting you to participate in a research study. Before participating in the study, we will explain the study to you. You will have the chance to ask questions and your questions will be answered clearly and to your satisfaction. You do not have to immediately decide whether or not you will participate in the study. Please read the information provided in this Participant Information Sheet and the attached Consent Form carefully. We encourage you to ask questions about anything you do not understand before deciding whether or not to participate in the study.

If you agree to participate, please sign the Consent Form attached. You will receive a copy of this document.

STUDY INFORMATION
Study title: Effect of Preload Oathie biscuits on glucose metabolism in healthy and pre-diabetic females.
Principal Investigator: Name: Kalpana Bhaskaran School/Department: Centre for Applied Nutrition Services Organisation: Temasek Polytechnic Contact details: 6780 5355/ Kalpana_BHASKARAN@TP.EDU.SG **Co-investigators:** Name: Ong Jing Ting School/Department: Centre for Applied Nutrition Services Organisation: Temasek Polytechnic Contact details: 6780 5350/ ONG_Jing_Ting@TP.EDU.SG Name: Saihah Mohd Salleh School/Department: Centre for Applied Nutrition Services Organisation: Temasek Polytechnic Contact details: 6780 1849/ Saihah_MOHAMED_SALLEH@TP.EDU.SG Name: Sharifah Fatanah Bte Syed Abdullah School/Department: Centre for Applied Nutrition Services Organisation: Temasek Polytechnic Contact details: 6780 6409/ Sharifah_Fatanah_SYED_ABDULLAH@TP.EDU.SG
PURPOSE OF THIS RESEARCH STUDY
You are invited to participate in a research study. This information sheet provides you with information about the research. The Principal Investigator (the research doctor or person in charge of this research) or her representative will also explain this research to you and answer all of your questions. Read the information below and ask questions about anything you do not understand before deciding to take part. You are being asked to participate in the test to determine the effect of Preload Oathie biscuits on glucose metabolism (sugar levels in your body) in healthy and pre-diabetic females.

The preload Oathie biscuits contains 0at, coconut oil, oat fiber, agave syrup (nectar), salt, vanilla flavor. 1 biscuit weighs approximately 18g.

STUDY PROCEDURES

The effect of the biscuits on blood sugar metabolism (levels) will be determined in **15 healthy fertile females, aged 25 – 40 years and 15 females with pre-diabetes, aged 25-60 years.** The recruitmentperiod will be from August 2021 to July 2022.

There will be a total of 3 visits namely Screening, Control and Treatment visit. You will be asked to visit Temasek Polytechnic, Glycemic Index Research Unit for this study. HbA1c test (three-month average blood sugar level) will be conducted during the Screening visit. Fingerprick blood (~2µl) will be taken to measure your HbA1c level. The other inclusion and exclusion criteria are as follows:

Inclusion criteria

1. Subjects must be females at least 6 weeks post-delivery, non-lactating and aged 25-60yrs old.
    1) Healthy fertile females:
        i. 25-40years
        ii. HbA1c reading during screening: ≤5.6%
        iii. BMI: 18.5- 25kg/m^2
        iv. They should not suffer from any chronic diseases
    2) Females with pre-diabetes
        i. 25-60 years old
        ii. HbA1c reading during screening: 5.7-6.4%
        iii. BMI: ≥18.5kg/m^2
        iv. Existing conditions such as hypercholesterolemia (high blood cholesterol)and hypertension (high blood pressure) are acceptable
2. They should not smoke.
3. They should not have any known food allergy and intolerance to the ingredients in thebiscuits.
4. They should not consume any medications known to affect glucose tolerance (excludingoral contraceptives).

    Note: stable doses of oral contraceptives, acetylsalicyclic acid, thyroxin, vitamins and minerals supplements or drugs to treat hypertension or osteoporosis are acceptable
5. Subjects should have completed both doses of COVID-19 vaccine at least 2 weeks before the enrolment for the study.

Exclusion criteria

1. Age less than 25 years old and greater than 60 years old.
2. HbA1c reading during screening: ≥6.5%
3. Known history of diabetes mellitus or the use of anti-hyperglycemic drugs or insulin totreat diabetes and related conditions.
4. Subjects with glucose intolerance
5. Known history of AIDS, hepatitis, renal or any other serious complications that mayinterfere with glucose metabolism.
6. Subjects using any medication (e.g. steroids, protease inhibitors or antipsychotics, etc.)that would interfere with the digestion and nutrient absorption.
7. Subjects having gastrointestinal diseases that may interfere with nutrient absorption,distribution, metabolism, excretion and have no known food allergies.
8. Major medical or surgical event requiring hospitalisation within the preceding 3 months.
9. Subjects who are not fully vaccinated against COVID-19

10. Subjects who have taken their second dose of COVID-19 vaccination within the past 2 weeks.
11. In addition, subjects will be excluded if they are unable to comply with experimentalprocedures or did not follow safety guidelines.

You will be enrolled in the study if you meet the inclusion and exclusion criteria.

During the Control and Treatment visit, you are to visit the GI unit after a 10-14hr overnight fast on separate mornings between 8am to 12pm. The interval between the mornings should at least 2days.

Finger prick capillary blood sample (~210µl) will be obtained using a sterile lancet device from warmed hands at fasting state. During the Treatment visit, you will be asked to consume Preload Oathie biscuit with 200ml of water within 5-10 minutes. 3 biscuits will be given in females with pre- diabetes while 1 biscuit will be given to healthy fertile woman. During the Control visit, there will be no preload of biscuits. After 30mins, another blood sample will be drawn followed by the intake of glucose solution (75g of glucose in 300ml of water). This should be consumed in 5 minutes. There will not be any additional water provided beyond this period until the test is completed. Further capillary blood (~210µl) samples will be drawn at 15, 30, 45, 60, 90 and 120 minutes. Visual Analog Scale (appetite) will be administered at every timepoint during the two visits to determine your appetite rating.

During each test visit, a total of 1.8ml (~1/4 tsp) of capillary blood will be drawn from you.The blood samples collected will be strictly for blood sugar analysis.

All human biological materials collected in this study will be in a de-identified form at the point ofcollection.

Any human biological materials obtained during this study will be stored, used and analysed only for the purposes of this study, for a period not exceeding the duration of the study, as approved by TP IRB. The human biological materials will be destroyed after completion of the study and willnot be used for future research. They will also not be used in restricted human biomedical research involving human-animal combinations.

INCIDENTAL FINDINGS

During this study, we might unintentionally come to know of new information about your health condition from the biochemical tests performed on blood collected from you that were conducted as part of the study. The new information is unrelated to the purpose or objectives of this study but may impact your current or future life and/or health insurance coverage. This is known as an 'incidental finding'. Examples of potential incidental findings that may be discovered during the course of this study include, but are not limited to, out of range laboratory results for the test conducted.

You can choose whether you wish to be re-identified and notified in the case of a clinically significant incidental finding that is related to you. If you agree to be re-identified and notified, please inform the Principal Investigator or any of the study team members listed in this document whenever there are changes in your contact details. You are advised to seek advice from a qualified healthcare professional to explain the incidental finding to you and discuss about the next steps to follow. The costs for any care that will be needed to confirm, diagnose or treat an incidental finding will not be borne by this research study. These costs will be your responsibility.

YOUR ROLE IN THIS STUDY

You are required to adhere to the study schedules and instructions.

During the Control and Treatment visit, you are to visit the GI unit after a 10-14hr overnight fast on separate mornings between 8:00am to 12:00pm. It may range from 1 week to a month or more. The interval between mornings should be a minimum of 2 days. You should not smoke, consume alcohol or involve in any form of unusual vigorous physical activity 24hrs prior to the testperiod. Please ensure that you eat a meal which is low in fat, high in carbohydrate and contains nolegumes (e.g. of legumes include soy bean, soy-based products like tofu, taukwa, tempeh, soy milk, green bean, red bean, peas etc.). Investigators will remind you to ensure that you follow a similar evening meal pattern the day before each test. Please make sure that you follow this meal pattern one day before each test and have adequate rest before test.

COVID-19 safety measures:

- Screening activities (Use of TraceTogether app/token while entry, temperature screening),hand sanitation procedure and declare on travel history as well as health status on every visit.
- Subjects have to complete both doses of COVID-19 vaccine at least 2 weeks before enrolment for the study.

COMPENSATION FOR PARTICIPATION

You will be reimbursed $20.00 for screening and $50.00 per test visit. You may be asked to repeat tests if the results are poor and will be reimbursed the appropriate amount ($50.00 accordingly). If you withdraw from the study or become ineligible and is withdrawn by the investigator prior to completing the full study, you will be reimbursed for the portions of the study you have completed to that point.

ANTICIPATED EXPENSES FROM PARTICIPATION

You will not be expected to incur additional expenses from participation in this study.

WITHDRAWAL FROM STUDY

Participation in this study is entirely voluntary. You are free to withdraw your consent, refuse to participate or withdraw from the study at any time, with no penalty or repercussion. If you decide to stop taking part in this study, you should inform the Principal Investigator in writing. Upon study withdrawal, the PI will not re-contact you for the purpose of this study.

If you withdraw from the study, it will not affect the research information obtained before the consent is withdrawn and such information may be retained and used for the research.

For human biological materials, however, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if the biological material(s) is individually-identifiable, or re-identifiable, and has not been used for the research, or it has been used for research but it is practicable to discontinue further use of the biological sample(s) for the research.

The Principal Investigator may stop your participation in the study at any time if you do not follow the study procedure or our safety guidelines.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

There are no potentially fatal risks of infection from this test as the following precautions will be ensured.

- Use of single use lancets only.
- Swabbing the finger with alcohol and using a new sterile lancet for each finger prick.
- Disposing the lancets after use immediately into the sharps container provided.

The finger pricks are sometimes associated with sharp pain, which may persist for a day. But most of the time the finger prick will not be so painful/ noticeable. In the unlikely event that the finger prick test results show an error in measurement, there may be a need to repeat this. You will be given an option of whether you would like to repeat the finger prick test. If the test is not repeated, we may not be able to use the data as it will not be complete. However, you will be able to continue with the rest of the study if you are willing to do so.

Every precaution will be taken to prevent injury to you during your participation in this study. If you think you suffered an injury or discomfort directly related to your participation in the study, you must inform the Principal Investigator or study team, and the IRB Secretariat as soon as possible. Contact details are found at the front of this Participation Information Sheet.

COMPENSATION AND TREATMENT OF RESEARCH STUDY RELATED INJURY

As this is a low-risk research study, there will be no compensation given. However, first aid treatment from trained personnel will be available in the event of any study related injury. Should there be complications such as infection at the finger prick site, you should inform the principal investigator, Dr Kalpana Bhaskaran.

Temasek Polytechnic does not make any provisions to compensate study subjects for study related injury. In the unlikely event that you are injured as a direct result of taking part in this research study, Temasek Polytechnic, its agents and employees will assume whatever responsibility as required by law. By signing this Informed Consent Form, you will not waive any of your legal rights or release the parties involved in this Research Study from liability for negligence.

POTENTIAL BENEFITS

There is no direct benefit to you by participating in this research. The knowledge gained will help consumers make careful choices about the selection of food to lead a healthy life.

STATEMENT OF CONFIDENTIALITY

De-identification of data and/or human biological materials

This study involves the collection of data and/or human biological materials from you in an individually-identifiable form. To protect your confidentiality, all individually identifiable data and/or human biological materials will be de-identified (i.e. only identified with a code) for the purpose of further processing at the earliest possible stage of the research. Only assigned personnel outside of the study team will have access to the re-identification key and be able to access individually-identifiable data and/or human biological materials. The re-identification key will be kept for two years after the study ends, after which it will be destroyed.

During the study, any personnel who has access to individually-identifiable data and/or human biological materials during the study will store them in a locked cabinet (if in physical form), or store the data with password protection, and the password(s) known only to the assigned personnel (if in electronic form). Only the assigned personnel will have access to the confidential information being collected.

Disposal of research information containing "Personal Data" and/or human biological materials

"Personal Data" refers to data about you that makes you identifiable (i) from such data, or (ii) from such data and other information to which we have or likely to have access to, or (iii) tissue specimen,

blood and other organic materials provided by you, but only when such materials are linked with data that can lead to identification of the data subject.

All human biological materials obtained from you during this study will be disposed/destroyed in a proper manner upon completion of this study and will not be used for future biomedical research.

All research information containing "Personal Data" obtained in physical form will be stored in a locked cabinet, or, if in electronic form, will remain in password-protected computer files. These will be kept for 6 years after completion of this study, after which it will be disposed/destroyed in a proper manner and will not be used for future research.

Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Your identity will remain confidential in the event of any publication arising from this study. However, in the event of adverse events during the study or during on-site monitoring and audits the TP IRB and/or regulatory authorities/study monitors will be granted direct access to your study information and data to check study procedures and data, without making any of your records public.

All materials collected, including data entered into data collection forms and/or case report forms, biological materials collected and findings from this study are property of Temasek Polytechnic and Gloobe AB and will remain in Singapore. Under the Personal Data Protection Act, the study team shall be responsible to make reasonable security arrangements to protect your personal information collected in this study.

By signing the Informed Consent Form attached, you are authorizing (i) collection, access to, use and storage of your "Personal Data", and (ii) disclosure to authorised service providers and relevant third parties.

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

If any new information becomes available during the study that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the Principal Investigator and/or study team.

The donation of human biological materials/tissues by you is voluntary. You will not have any rights to the donated human biological materials/tissues and intellectual property rights that may be derived from the use of the human biological materials/tissues. You will also not have any right or claim to any share in the commercial gain derived from the research (if any).

By signing this consent form, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time and will not release the parties involved in this study from liability for negligence.

FURTHER CONSENT

You are being asked for permission to be contacted again under the following circumstances:

a) Changes to the current research study, including those arising from adverse events.
b) You are found eligible for future research studies.

If you agree to be contacted, your information and contact details will be entered and stored in a secured database in TP. Your information and contact details will not be released to any parties outside TP without your permission.

When investigators from TP identify you to be suitable for a particular research study, the investigators or authorised personnel from TP will contact you to inform you about the research study.

Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this study. Your decision will not affect any benefits to which you are entitled. You may change your mind at any time by contacting the Principal Investigator and/or co-investigators.

WHO TO CONTACT IF YOU HAVE QUESTIONS OR CONCERNS ABOUT THE STUDY

If you have any questions about the content of this Participant Information Sheet or the study, please contact the Principal Investigator and/or co-investigators of this study. Contact details of the Principal Investigator and/or co-investigators can be found at the front of this Participant Information Sheet.

The Temasek Polytechnic Institutional Review Board (TP IRB) has reviewed this study. If you have questions about your rights as a participant, you can call the TP IRB Secretariat at 67804011 during office hours (8:30 AM to 6:00 PM) or email at irb@tp.edu.sg.