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Participant Information Sheet/Consent Form

Interventional Study - Adult providing own consent

Title	IMAGINE for better diabetes management: modifying delay discounting and physical activity via episodic future thinking.
Short Title	IMAGINE
Study ID Number	To be inserted
Project Sponsor	Western Sydney University
Coordinating Principal Investigator/ Principal Investigator	Prof David Simmons
Associate Investigator(s)	A/Prof Carina Chan A/P Milan Piya Professor Timothy Skinner A/Professor Brett Gordon Dr Jessica Triay A/Professor Mark Savage Dr Amy Harding Dr Sathya Vijayanand Mr Dan Persson Dr Wendell Cockshaw
Locations	To be inserted

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have a diagnosis of Type 2 Diabetes. This study aims to examine mental imagery techniques and how they can help people manage diabetes.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the details of your involvement. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Being part of this study is voluntary. You can read the information below and decide at the end if you do not want to participate. If you decide not to participate this won't affect your relationship with **[Insert Site name]**

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 have the technology and network connections that are described

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This study aims to examine mental imagery techniques, their role in the way people perceive time and future, and how they can help people with their diabetes care, for example increasing physical activity.

3 Who is being asked to participate?

You have been asked to participate because you:

- Are a person with Type 2 diabetes (with HbA1c >= 7.0%)
- Are over the age of 18
- Own a smartphone
- Are not currently completing any health improvement program
- Are not pregnant and/or have a psychiatric condition
- Have no medical condition that would limit participation in light- to moderate-intensity physical activity.

4 What does participation in this research involve?

If you agree to take part in this intervention, you will be asked to complete one short questionnaire. You will then be randomly put into one of two groups. People in each group will then attend a face-to-face or virtual session (of your choice) where you will learn about the mental imagery that you will be asked to practice.
You will be asked to practice this technique 3 times a day for the next 4 weeks. You will be given access to a mobile app which will remind you how and when to perform the imagery technique. There will be 1-, 3- and 6-month follow-up questionnaires that will be sent to you via email or post. The study as a whole will take 6 months. During the first month of your participation in the study, 15 minutes of your time will be required each day and 45 minutes will be required of you to complete each of the three surveys.

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

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 stage.
If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.
Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment or your relationship with those treating you or your relationship with your health service.

6 What are possible benefits of taking part in this study?

The benefit of you taking part in this study is that you may learn a technique that may help you to better manage your

diabetes. If the imagery skills you learn do have a benefit, then this knowledge can be offered to other people. You will also receive a $10 voucher as a token of appreciation for your participation.

7 What are the possible risks or disadvantages of taking part?

There is no major risk that we are aware of. Some minor risks are listed below for your information:

- Risk of surveys/intervention causing discomfort or potentially being triggering. Trigger warning: Surveys will include questions about food, exercise and general health.

8 What if I withdraw from this research project?

If you consent to participate but then change your mind you can withdraw your consent and stop participation at any time. Please contact Dr Karen Mathews and request a Withdrawal of Participation form if you wish to do so. If you withdraw consent you can indicate on the form whether or not you wish your data to be removed from the study. There are no health risks associated with withdrawal from this project. If you do withdraw your consent during the research project, we will not collect additional personal information from you.

9 Could this research project be stopped unexpectedly?

The project team do not anticipate this project stopping unexpectedly.

10 What happens when the research project ends?

After the data is analysed you will be provided with a summary of the results in a brief report provided via email or hard copy depending on your preference.

Part 2 How is the research Project being conducted?

11. What will happen to information about me?

By signing the consent form, you consent to the research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

The data collected and information from surveys and interview will be stored on a password protected drive at La Trobe University. Any hard copies will be shredded once data are entered into the computer.

All data and information collected will be retained for a period of 7 seven years then deleted as per research protocol. 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.

Publication and any other dissemination of results from this research will involve summaries of grouped data only. No individual data will be published so that you cannot be identified in any way.

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

The storage, transfer and destruction of your data will be undertaken in accordance with the Research Data Management Policy https://policies.latrobe.edu.au/document/view.php?id=106/.

12 Who is organising and funding the research?

This research has been funded by La Trobe University and is being conducted by Western Sydney University, in collaboration with La Trobe University.

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of South Western Sydney Local Health District. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

14 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project, you can contact: the study coordinator, Karen Mathews, on (02) 4634 4596 or email k.mathews@westernsydney.edu.au

15 Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / email SWSLHD-ethics@health.nsw.gov.au, website: http://www.swslhd.nsw.gov.au/ethics/default.html and quote project number **[Insert]**

Thank you for taking the time to consider this study. If you wish to take part, please sign the attached consent form. This information sheet is for you to keep.

Insert site logo

IMAGINE for better diabetes management: modifying delay discounting and physical activity via episodic future thinking.

Consent Form – *Adult Providing own Consent*

Consent Agreement

I …… have read the Participant Information Sheet or someone has read it to me in a language that I:

□ Understand the purposes, procedures and risks of the research described in the project.

□ Have had an opportunity to ask questions and I am satisfied with the answers I have received.

□ Freely agree to give consent for the research team to use my screening data as described

□ Freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

□ Understand that I can withdraw at any time until four weeks following the final collection of my data.

□ Agree information provided by me or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that I cannot be identified.

□ Understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____