

Chief Investigators:

Prof Paul Fournier

A/Prof Kym Guelfi

Researcher:

Zac Leow

School of Sport Science, Exercise and Health

The University of Western Australia
35 Stirling Highway, Crawley WA 6009

Phone + 61 86488 1356

Fax +61 8 6488 1039

Email paul.fournier@uwa.edu.au

Study 1: Effect of habitual food intake on glycaemic control in individuals with type 1 diabetes

- Participant Information Sheet -

Dear participant,

As part of the research work of my PhD candidate, Zac Leow, I would like to invite you to participate in the following research project.

Purpose of this study:

To determine if there is a relationship between daily carbohydrate intake and glycaemic control, frequency of hypoglycaemic events, fear of hypoglycaemia, insulin dosage, physical activity participation, body composition and blood lipoprotein profiles in individuals with T1DM in a free-living setting.

Procedures:

For this study, you will be asked to visit the Exercise Physiology Laboratory at the School of Sport Science, Exercise and Health, The University of Western Australia (35 Stirling Highway, Crawley, WA 6009) on two separate occasions, each separated by 7 days. Each conducted at the same time of the morning after an overnight fast, with at least 7 days between each session.

After an overnight fast and upon arrival at the laboratory, 2 ml of venous blood will be taken from an antecubital vein for analysis of fasting blood glucose and HbA1c levels. Following this, height and weight will be measured. Then, a whole body DEXA scan will be performed to analyse your body composition. Following this, you will be asked to complete a fear of hypoglycaemia and an anxiety rating questionnaire. Before leaving, participants will be provided with a food weighing scale and a diary to record all cases of hypoglycaemia, physical activity, insulin therapy, post-prandial blood glucose levels on your personal pre-calibrated glucometer, daily food and drink intake for the next 7 days under free-living conditions.



Risk:

The blood sampling procedure may cause some mild discomfort and may leave a small bruise at the sampling site. This procedure has been used often in our lab and causes no long-term harm. In addition, some of the taste solutions may be perceived as unpleasant, but they are also not harmful and their taste should disappear in a matter of minutes. All of the chemicals and procedures used in this study have been previously tested and have been found to be safe for use with human participants.

Although there is a slight risk of infection at the sites of blood sampling, this will be minimised by the adoption of sterilised equipment and procedures.

The DEXA test will require that you lie quietly on an x-ray bed for 5 min while a scanning arm assesses your body composition. This is a protocol in routine use in our School. DEXA is considered the laboratory 'gold' standard for validating measures of lean muscle mass. DEXA involves the use of low dose x-rays, with radiation levels approximately one thousandth of the background radiation received in one year from living in Perth. The background radiation exposure from the sun on a normal day is around $8.0\mu\text{Sv}$ and therefore you are at no major risk. However, an exclusion clause for DEXA scanning is pregnancy. For this reason, all female participants will be informed about this and will be required to undertake a pregnancy test prior to scanning.

Confidentiality:

Your confidentiality will be maintained throughout the study through random assignment of a number to de-identify your data. All data collected will be securely stored in a locked filing cabinet and password-protected computer accessible only to the chief investigator and PhD student (Zac Leow). The findings of this study may be published, however all information used will be non-identifiable.

Your Rights:

Participation in this research is voluntary and you are free to withdraw from the study at any time without prejudice. You can withdraw for any reason and you do not need to justify your decision. If you withdraw from the study and you are an employee or student at the University of Western Australia (UWA) this will not prejudice your status and rights as employee or student of UWA. If you do withdraw we may wish to retain the data that we have recorded from you but only if you agree, otherwise your records will be destroyed.

Your participation in this study does not prejudice any right to compensation that you may have under statute of common law. If you have any questions concerning the research at any time please feel free to ask the researcher who has contacted you about your concerns. Further information regarding this study may be obtained from Zac Leow on 0402 632 334 or zac.leow@research.uwa.edu.au



Approval to conduct this research has been provided by the University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time.

In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics Office at the University of Western Australia on (08) 6488 3703 or by emailing to humanethics@uwa.edu.au

All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.