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**Participant Information Sheet**

**High-Intensity Exercise Benefits to Blood Glucose Control – Is the Milk-Sugar Lactose better than Sucrose?**

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| Formal Study title: Effect of Carbohydrate Energy Replacement on Glycaemic Control Following High-Intensity Interval Training. Does Lactose Improve Glycaemic Control in Comparison to Sucrose? |
| Lead: Prof. David Rowlands  Study Site: School of Sport, Exercise and Nutrition, Massey University, Albany Campus  Contact phone number: +6492127050  Ethics committee referee: Dr Kaio Vitzel  **Purpose of the Study**  The primary aims of the study is to identify the extent to which replenishing the exercise-induced energy deficit with carbohydrate alters next day glycaemic control. Whilst, assessing if there is a difference in glycaemic control when ingesting lactose compared to when ingesting sucrose, two sugars with known different effects on the blood glucose response and on liver metabolism (i.e., breakdown).  This study will provide a Masters of Nutrition and Dietetics thesis and insight into how lactose can be used for increased athletic performance. Additionally, it will provide information for future studies to be completed regarding glucose control and the role of lactate in metabolism, health and performance.  **Voluntary Participation and Withdrawal from the Study**  You are invited to take part in a study on the effect of carbohydrate energy replacement on glycaemic control following high intensity interval training. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect any care you receive or future relationships with the University. If you do want to take part now, but change your mind later, you can pull out of the study at any time.  This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.  If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.  If you wish to withdrawal from the study then please inform Miss Rose Stirling, Masters Student. If you do withdrawal from the study after the second tests are completed then your data will be used in the study. However, if you withdrawal before this point then your data will not be used in the study and your information will be deleted.  Please make sure you have read and understood all the pages before proceeding to the consent form.  **Study Design and Involvement**  The study involves you to monitor blood glucose levels through a continuous glucose monitor for two days per trial over the course of the study period. Each trial period involves a short period of exercise testing and ingesting lactose, glucose, or placebo carbohydrate beverages, however, you and the researchers will not know which carbohydrate beverage being received to control for any pre-existing information that may influence outcomes. As a participant, you will be provided with standardised meals to be consumed at the given times on day 2 of each metabolic trial. You will also be asked to record this on a food diary provided. Additionally, you will be provided with standardised meal to be consumed at the laboratory after testing on day 1.  A standardised diet will be provided for the remainder of the testing day and the subsequent day after testing.  The study will be conducted over 3 days per month for 3 months per participant, comprising of 7 visits to the laboratory (Figure 1).  7 visits to the laboratory:   1. Study introduction, discussion, questions, consent. Laboratory and cycle ergometer familiarization with a short 3-5 min low intensity ride after bike fit. 2. Baseline measures – VO2 max, maximum power output, workload for high intensity interval exercise and body composition (bioelectrical impedance scales). Familiarisation trial of the high-intensity exercise protocol (3 x 1 min @90% of maximum power output). During all exercise sessions, you will breathe through an on-line gas analysis facemask that covers the mouth and nose, and is attached to a 0.2 micro filter system, which filters virus. At other times, participant will need to comply with the University requirements for COVID, at the time.   Trial #1:   1. Placement of the continuous glucose monitor (Day of Trial = Pre; either around 48h or 24 h prior, see Figure 1) 2. Exercise testing (Day of Trial = day 1). This day comprises:   You will consume a standardized meal at standardised times during this day: 9:00h (breakfast), 12:00h (lunch) and 15:00h (snack). You will then report to the laboratory at or before 17:00h, whereby you will perform a supervised session of high intensity interval exercise (10x1-min cycle intervals at 80 percent of maximal watts, with recovery in between, and collection of your effort level). For this visit, bring some clothing you are comfortable exercising in, and appropriate footwear (e.g., walking or gym shoes). Post-exercise, you will ingest the trial drink or placebo drink (lemonade flavour). After exercise and drink ingestion, you will be able to shower (if desired; bring towel) and rest seated in the laboratory prior to consuming a low-carbohydrate high-fat (LCHF) dinner meal at 19:00h. You will then leave the laboratory at around 20:00h, under instructions to abstain from consuming any food or drink other than water for the rest of the evening.  The following day, you will be required to consume standardised meals that we will provide you at the given times: 7:00h, 10:00h, 13:00h and 18:00h. Breakfast at 7:00h, will be a high glucose meal consisting of 75g of glucose in the form of white bread, butter and jam. The remaining meals will be mixed macronutrient meals. Some of the study meals will contain animal products (meat, dairy) are not suitable if you are following a vegetarian or vegan diet.  Trial #2:   1. Repeat visit 3 2. Repeat visit 4   Trial #3:   1. Repeat visit 3 2. Repeat visit 4   As part of participating in the study your responsibilities will include:  1. recording of diet and time of consumption; diet diaries will be provided.  2. Ingest meals at given times; meals and drinks will be provided.  3. Arrive on time at the lab; a reminder the evening prior.  4. Keep continuous glucose monitor in for the intervention period.  5. Maintain your pre-study level of background physical activity (i.e., sedentary) and not to take up any sports during 9 week study period.  6. Maintain same dietary pattern throughout study, outside of the study meals.    *Figure 1.* Research design and partition of weekly exercise and diet.  *Figure 2.* Metabolic and performance test protocol  **Who can take part in the study?**  50-70 year old male and females (post-menopausal) who complete less than 150 minutes of purposeful exercise per week of more than walking, and have a VO2max ≤43.9 ml·kg·min-1. You must be tolerant to lactose and have no known heart and respiratory conditions.  Participants and researchers involved in face-to-face procedures will be required to be non-symptomatic to COVID-19 prior to each laboratory visit. If have recently tested positive for COVID-19 or are unwell with a normal cold or the flu, or other infection, you will be excluded or participation postponed until you are well again, which is also normal practice outside of current pandemic conditions. Participants and researchers will also be required to comply with the University COVID19 requirements.  **Potential Risks of the Study**  As a result of heavy physical exercise there is a very small increase in the risk of a heart attack, and a small increase in risk of a muscle, tendon, or ligament injury, such as a strain. You may also experience fatigue and may experience muscle cramps, and there is a chance of gut discomfort.  **Potential Benefits of the Study**  The direct benefit of this study is identifying your blood glucose level across the day; resting and after consumption of food and drink. As well as, how this differs between different meals of the day and different foods consumed. Furthermore, you will gain insight of your glycaemic control following exercise. This study may therefore help you to maintain good health or critical information to seek help from a healthcare professional.  The indirect benefits of this study are contributing to scientific research that is intended for publication in an international journal, and assisting in a study contributing towards the completion of Master of Nutrition and Dietetics thesis. Additionally, contributing to this study provides the foundation data for future research into glucose control and the role of lactate in metabolism, health and endurance performance.  **Reimbursement**  Participation in the study may incur some travel costs. The study will reimburse a total of $100 to contribute to travel at the completion of the entire study.  **What if something goes wrong?**  If you were injured in this study, you will be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.    **What will happen to my information?**  During this study Drs David Rowlands, Wendy O’Brien and Claire Badenhorst and masters student, Miss Rose Stirling, as well as other on-site staff will record information about you and your study participation. This includes the results of any study and the pre-screening health assessments. You cannot take part in this study if you do not consent to the collection of this information.  Identifiable Information  Identifiable information is any data that could identify you (e.g., your name, date of birth, or address). However, only Drs David Rowlands, Wendy O’Brien and Claire Badenhorst and masters student, Miss Rose Stirling will have access to your identifiable information.   1. Only research staff and masters student will complete study assessments. 2. Research staff, to process and report your screening and safety tests. 3. The ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct. 4. Your usual doctor, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged. 5. The Medical Officer of Health, if you return a positive test for COVID-19. 6. Rarely, it may be necessary for Dr David Rowlands to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.   De-identified (Coded) Information  To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by Drs David Rowlands, Wendy O’Brien and Claire Badenhorst and masters student, Miss Rose Stirling (researchers). Instead, you will be identified by a code. Researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed. All information will be stored in password protected files and computers with access only by the researchers on the project.  The following groups may have access to your coded information:   1. Other researchers through open-source data repositories or request for data for further analysis (for example, meta analyses), regulatory or other governmental agencies worldwide.   The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you. All information will be presented as summarised statistics rather than individual data. This therefore limits your data from being identified when presented.  Future Research Using Your Information.  If you agree your coded information may be used for future research related to lactose or other metabolic or nutrition studies. This is outlined in the consent form also.  This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.  You will get a short report about any research that is done using your information. This will be provided by the email provided.  Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.  Security and Storage of Your Information.  Your identifiable information is held at exercise science laboratory at Massey University, Albany Campus during the study. After the study, it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic spreadsheets and stored in a secure sever and kept by the researchers indefinitely. All storage will comply with local and/or international data security guidelines.  Risks.  Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g., making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.  This research includes basic information such as your geographic region and. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.  Rights to Access Your Information.  You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.  Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study’s scientific integrity.  If you have any questions about the collection and use of information about you, you should ask Dr David Rowlands or Miss Rose Stirling.  Rights to Withdraw Your Information.  You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.  If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.  Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.  **Accessing Study Results**  At the end of the intervention, participants will be emailed a document with the full breakdown of the results with relevant explanations.  **Study Funding**  The study has received funding from the Massey University Research Funding (MURF).  **Study Approval**  This study has been approved by Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards.  **Who do I contact for more information or if I have any concerns?**  If you have any questions, concerns or complaints about the study at any stage, you can contact:  Prof *David Rowlands*  *Professor of Nutrition, Metabolism and Exercise. School of Sport, Exercise and Nutrition. Massey University, Albany*  *Telephone number: 0272099383*  *Email: d.s.rowlands@massey.ac.nz*  If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:  Phone: 0800 555 050 Fax: 0800 2 SUPPORT (0800 2787 7678) Email: [advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz)  Website: https://www.advocacy.org.nz/  For Maori health support please contact:  *Dr Geoffery Kira, Senior Lecturer, School of Health Sciences*  *Telephone number: +6449793974*  *Email:* [*G.Kira@massey.ac.nz*](mailto:G.Kira@massey.ac.nz)  For Pacific health support please contact:  *Mr Jack Scanlan, Lecturer, School of Social Work*  *Telephone number: +6492136353*  *Email: J.Scanlan@massey.ac.nz*  You can also contact the health and disability ethics committee (HDEC) that approved this study on:  Phone: 0800 4 ETHIC  Email: hdecs@health.govt.nz ransparent massey university logo jpg - Google SearchConsent Form **Glucose Control after Exercise.**  **Comparing Lactose vs High-Fructose Carbohydrate.**    \*An interpreter is available on request  *Please tick to indicate you consent to the following:*   |  | | --- | | I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. | | I have been given sufficient time to consider whether or not to participate in this study. | | I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | | I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | | I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | | I consent to the research staff collecting and processing my information, including information about my health. | | I understand that my coded information may be used for future research related to lactose or other metabolic or nutrition studies. | | If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | | I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | | I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | | I understand the compensation provisions in case of injury during the study. | | I know who to contact if I have any questions about the study in general. | | I understand my responsibilities as a study participant. | | I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 | |  |  |  |   **Declaration by participant:**  I hereby consent to take part in this study.   |  |  | | --- | --- | | Participant’s name: | | | Signature: | Date: |   **Declaration by member of research team:**  I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.  I believe that the participant understands the study and has given informed consent to participate.   |  |  | | --- | --- | | Researcher’s name: Dr David Rowlands | | | Signature: | Date: | |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: Dr Claire Badenhorst | |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

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| Researcher’s name: Dr Wendy O’Brien | |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

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| Researcher’s name: Rose Stirling | |
| Signature: | Date: |