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Participant information sheet - Effect of habitual diet on fuel utilisation during exercise

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Effect of Habitual Diet on Fuel Utilisation during Exercise

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study about the effects of habitual diet on fuel utilisation. This aims to identify how dietary patterns influence the amount of fat and carbohydrate used during endurance exercise.

You have been invited to participate in this study because you have expressed interest in this study. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don’t understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:
- Understand what you have read.
- Agree to take part in the research study as outlined below.
- Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is running the study?

The study is being carried out by the following researchers:
- Dr Kieron Rooney, Exercise and Sport Science, University of Sydney
- Dr Dale Hancock, School of Molecular Biology and Genetics, University of Sydney
- Mr Tom Gwinn, Exercise and Sport Science, University of Sydney
- Dr Dick Stevenson, Macquarie University
- Prof Nuala Byrne, Bond University
- Dr Kristen MacKenzie, Bond University

Anneliese Reeves is conducting this study as the basis for the degree of Masters of Applied Science (Research) at The University of Sydney. This will take place under the supervision of Dr Kieron Rooney, Senior lecturer.
(3) **What will the study involve for me?**

This study involves attending one laboratory session at the Faculty of Health Sciences, University of Sydney, Cumberland Campus, Lidcombe. You will be required to refrain from eating the morning of the test, and refrain from strenuous exercise and alcohol 24 hours prior to testing. There will also be two 24 hour food recall questionnaires conducted in the 4-6 weeks following testing, conducted via phone conversation.

At the session, you will undergo the following tests for analysis of health, fitness and habitual diet.

**Body composition:** We will measure your height, weight, waist and hip circumference. We will also conduct a Bioelectrical Impedance Analysis to determine body fat percentage.

**Blood and urine samples:** We will measure your resting heart rate and blood pressure. We will ask you to provide a urine sample two 5mL blood samples will be collected from the arm. The urine sample and one blood sample will be analysed for various blood biomarkers (specific compounds in your blood which will be used to determine habitual diet). The other blood sample will be used for a genetic screening (CD36 gene, associated with fat transportation in and out of cells) and health screening. We will also ask you to provide a fingerpick blood sample to measure blood lipids (the fat content in your blood) and ketones (a product of metabolism influenced by fat utilisation).

**Habitual diet questionnaires:** We will then ask you to complete four dietary questionnaires pertaining to habitual diet and a physical activity questionnaire.

**Aerobic exercise test:** You will then be asked to perform a multi-stage endurance performance test on a cycle ergometer. The exercise test involves a 5 minute warm up and then three minute increments of intensity until a certain point dependent upon your exercise response, where the intervals will increase every two minutes, which will continue until you reach exhaustion. During the exercise test, expired breath will be collected in a breathing tube to be analysed. Heart rate will be measured throughout the test. At the end of each three minute stage, blood lactate will be measured via an ear prick blood sample. This will occur approximately 2-4 times during the test, depending upon fitness.

(4) **How much of my time will the study take?**

The overall testing at Cumberland should take a maximum of 2.5 hours. It will be conducted in the morning between 6:30-11am. Each 24 food recall will take a maximum of 10-15 minutes.

(5) **Who can take part in the study?**

This study is open to anyone between the ages of 18 and 40.

You must have had a relatively consistent diet and maintained a stable weight (current weight +/- 3%) for a minimum of the six months preceding the test. This is to allow for ‘habitual diet’ to be accurately measured.
You are unable to participate if you: are pregnant, have diagnosed mental illness, have asthma, diabetes or cardiovascular disease, or are on medication for cardiovascular related symptoms (eg. hypertension, high cholesterol), or medication for insulin resistance (metformin). Maximal aerobic exercise tests are potentially unsafe for anyone falling into the above exclusion categories.

(6) Do I have to be in the study? Can I withdraw from the study once I’ve started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, Low Carb Down Under, I Quit Sugar Program, Low Carb Downunder, 360 Nutrition, Bond University or any of the investigators.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting Anneliese Reeves (email: aree5635@uni.sydney.edu.au, phone: 0405 645 498) or Kieron Rooney (email: kieron.rooney@sydney.edu.au, phone: 9351 9135). There are no consequences for withdrawing from this study.

Questionnaires: Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses if you change your mind about having them included in the study, up to the point that we have analysed and published the results.

If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results. This also includes whether or not you want blood, urine and DNA samples to be disposed.

(7) Are there any risks or costs associated with being in the study?

Anthropometry: It is possible that some degree of psychological distress may be associated with the measurement of body weight and mass index parameters.

Blood testing: This can elicit slight pain in the arm. All attempts will be made to make this as painless as possible.

Gene testing: We will be screening your CD36 genotype for a specific type we have previously associated with changes in rates of fat oxidation during exercise. This is not directly associated with health issues however some people may feel distress if they are identified to have a genotype associated with reduced rates of fat oxidation. You will have the right to consent to how this information is handled for future use.

Aerobic exercise test: Maximal exercise testing is considered low risk to healthy populations. This study is conducted on a bicycle which is low impact and has a low chance of injury. Throughout the test, you will be encouraged to push yourself, however you are able to terminate this test at any point. Towards the higher intensities, you might experience discomfort due to sweating, a high heart rate, soreness in your legs and general fatigue. At the conclusion of the test, we will monitor these symptoms to ensure they have subsided.

Time: We will try and fit the testing in around your schedule to the best of our ability.
If you experience distress from any of our procedures, then we advise you to contact your usual care GP and/or any one of the following free counselling services:

- NSW Government “Get Healthy Information & Coaching Service

Are there any benefits associated with being in the study?

Testing your VO₂max will give you an accurate measure of your aerobic fitness. You will also be measured for other general health outcomes, including blood lipids and anthropometry. These results will be compiled into a report and sent to you.

This study will help the broader community by investigating the link between diet and exercise, potentially identifying areas for future diet research and exercise performance research.

What will happen to information about me that is collected during the study?

The types of information collected about you during the study will be as follows; anthropometry measurements, genetic screening, urine and blood biomarkers, dietary and exercise questionnaire and fuel utilisation data during exercise. By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. The results from the study will be published in Anneliese Reeves’ Masters thesis and the research will be submitted for journal publication. The data may also be used for conference presentations. You will not be individually identifiable in these publications. Your results from the study will be emailed to you from Anneliese Reeves if you elect to be made aware of your results.

All hard copy data will be stored securely at the University of Sydney. Electronic data will be on password protected computers. Tissue samples will be kept in secured laboratory freezers. Only researchers will have access to this information. Your information will be kept strictly confidential, except as required by law.

These samples and data will be kept for 20 years after the completion of the project.

Optional consent for future use

All participants will be given the option for their data and DNA to be kept in a tissue bank for future use. There is a separate consent form for tissue banking. By providing your consent you are allowing us to keep the information and DNA we collect for this study for potential future use.

Ethical approval is required before any studies using your data and DNA. You will be contacted to obtain consent before any additional use of your DNA and data.

The future use of stored samples that we intend to implement would be to identify any further genes of interest that are related to fat oxidation during exercise. It is highly unlikely that any information gathered in future studies would provide conclusive evidence for concern regarding
health issues. You will have the option of whether or not you would like to be informed of the results of any further study.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study. You are welcome to provide fliers to friends or family who may be interested in participating.

(11) What if I would like further information about the study?

When you have read this information, Anneliese Reeves will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Anneliese Reeves, student researcher (aree5635@uni.sydney.edu.au) (+61405 645 498) or Dr Kieron Rooney (kieron.rooney@sydney.edu.au) (+61-9 351 9135).

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one page summary, via email. You will receive this feedback after the study is finished.

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney (2015/597). As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:
- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep