PARTICIPANT INFORMATION SHEET

Project title: Sustained well-being benefits of red meat consumption and meat-analogue meals: a 10-week randomised clinical trial
Principal Investigator: Dr Andrea Braakhuis (The University of Auckland)
Research Team: Dr Scott Knowles (AgResearch Ltd), Dr Emma Bermingham (AgResearch Ltd), Dr Toan Pham (The University of Auckland), Nicola Gillies (The University of Auckland), Anna Worthington (The University of Auckland), Associate Professor Tamlin Conor (The University of Otago), Dr Rajshri Roy (The University of Auckland).

Research introduction and aim
Red meat is long-established as an important dietary source of protein and essential nutrients including iron, zinc and vitamin B12, yet recent reports that its consumption may increase the risk of chronic disease have led to a negative perception of the role of red meat in health. A substantial amount of evidence supports the role of lean red meat as a positive moderator of lipid profiles with recent studies identifying it as a dietary source of the anti-inflammatory long chain and conjugated linoleic acid. The aim of this trial is to understand the effects of moderate consumption of lean red meat as part of a balanced diet and its impact on biomarkers of long term health.

Project description and invitation
You can take part if you are between the age of 20 and 34 years and are willing to share meal kits with someone you currently live with (spouse, partner, or a flatmate you can cook with) who is also eligible and willing to participate in this trial. This study will involve you visiting the Research Facility at The University of Auckland on five separate occasions; the first will be a screening visit and take approximately 15 minutes. The following four will be clinic visits in the morning, and take approximately 2 hours for clinic visit 1, and 30 minutes for clinic visits 2-4.

Project Procedures
All interested participants will be asked to complete a pre-screening questionnaire which will ask for weight, height, physical activity, ethnicity, education, and eating habits. Participants will be excluded if they are smokers, have chronic health conditions (for example, cancer, diabetes, heart disease) or hyperlipidaemia, do not have access to a working mobile phone with a camera or demonstrated disordered eating habits. Eligible participants will be invited to a screening visit where responses to the questionnaire will be confirmed, and questions regarding the study can be discussed. If you are satisfied with everything and agree to take part, we will ask you to sign the consent form prior to randomisation to an intervention group.

Participating couples will commence the trial with a two-week pre-intervention period with their usual diet, and will be required to fill in two questionnaires regarding their diet and mood. These participating couples will then be asked to consume a balanced diet for 10 weeks, which will contain either NZ pasture-fed red meat (total 350-500g cooked weight per person per week) or plant-based protein alternatives. The meat and meat-alternatives will be provided to participants weekly along with a meal kit that provides 4 vegetarian meals a week. During these ten weeks, it is important that participants do not consume any meat or fake-meat alternatives other than those provided by the study. We will ask you to record

everything you eat and drink for the 10 weeks on a mobile phone application called Easy Diet Diary (Xyris Pty Ltd). On Sunday and Monday you are required to manually input all food and drink you consume on this app, while on Tuesday to Saturday you may take a photo or manually input the information. You will be asked to complete questionnaires that ask you about your well-being and mental health each fortnight, which will take around 20 minutes of your time. You will be sent text message reminders three times a week to complete your food diaries and questionnaires. We will also provide a nutrition education package to help you achieve a balanced diet which will involve group sessions with a dietitian and supporting emails.

Physical activity and sleep monitoring
You will be provided with a Huawei Band 4 Pro fitness band for the duration of the study. The watch has an optical heart rate monitor which will be set to continuous monitoring, and a sleep tracker which will be enabled during the study. You will be required to wear the fitness band most of the time during the 10 weeks, and will bring in the watch to all laboratory sessions.

Procedures for Test Days
Participating couples will visit the Research Facility on four occasions for clinic visits including (1) after the 2-week pre-intervention period, (2) at week 5 of 10-week intervention, (3) at week 10 of the 10-week intervention, and (4) at 3 months post-intervention.

The procedures for all four clinic visits will be the same. We will ask you to rest quietly for 20 minutes before we measure your blood pressure. You will be asked to fill in questionnaires. We will measure your body composition through a dual energy X-ray absorptiometry (DEXA) scan (Clinic visit 1, 3, and 4). We will measure your weight and height. We will then test your grip strength by having you squeeze a special device as hard as you can. Additionally, there will be a group education component (1 hour) in clinic visit 1.

Blood
You are required to go to any LabPlus on the day of your clinic visits in order to have a fasted blood test. Your blood will be used in the analysis of proteins, lipids, and sugars and markers of inflammation. These will provide vital insights into whether there are differences in the digestive responses to 10-week meal intervention period. We will be measuring metabolites (digested products of the meat and markers of your body's metabolic process) including amino acids (the digested products of proteins), lipids (the digested products of fats), sugars such as glucose (digestion products of carbohydrates), and hormones involved in digestion and absorption such as insulin.

Some analysis techniques will take place in the laboratories of the Liggins Institute (University of Auckland). Your samples will also be sent to AgResearch Limited (Palmerston North, New Zealand) for analyses that we are unable to do in Auckland. After these analyses have been performed, it will not be possible to return any unused samples to you. You can request the return of your blood prior to any analysis; this would mean we would not use your information in the study.

The information collected in this study will be kept for a total of 10 years. Your samples will be kept until the end of the analysis. At the end of this time a medical waste contractor will

dispose of your tissue. If you would like a karakia said at this time, please indicate so in the consent portion of this form. Cremation and karakia ceremonies take place through the Auckland District Health Board, and occur every 2 months during the year.

Many iwi, hapu, and whānau disagree with transport of blood samples due to issues with the loss of rights to your whakapapa. However, it is acknowledged that individuals have the right to choose. These concerns may also apply to non-Māori. We encourage you to consult with your family or whānau before agreeing to participate, if you think this might apply to you.

What are the potential benefits and risks to taking part in the research?
There is some risk associated with the radiation received during the dual energy X-ray absorptiometry (DEXA) scan. However, the amount of radiation received (as reported by the equipment manufacturer) is less than 0.1 mrem for a single whole-body scan. This is about the same as four (4) hours of normal background radiation, or about 1/100th of a typical dental Xray. There is minimal risk in other procedures associated with the trial, but the trial will require time each day to commit to logging food intake, completing questionnaires and preparing healthy food. The benefit to participating is you are provided 3 serves of protein (either red meat or a vegetarian meat-alternative) a week, 4 vegetarian meal kits each week, and group support from a dietitian to follow a healthy diet. You will also be reimbursed up to $30 for each visit to the laboratory to support your travel costs.

Detection of Abnormalities
Some blood markers analysed in this research can be early indicators of diseases such as diabetes and heart disease. Any blood results outside of the normal healthy range will be provided to you. We will also inform your usual doctor of any results that might be significant for your health, so follow-up can be arranged if appropriate.

What if Something Goes Wrong?
As this research study is for the principal benefit of its commercial sponsor (Meat Industry Association), if you are injured as a result of taking part in this study you won't be eligible for compensation from ACC.
However, Dr Andrea Braakhuis (PI) has satisfied the Northern Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.
New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme. Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines). These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own they are not legally enforceable and may not provide ACC equivalent compensation.
- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:

- The Sponsor may not accept the compensation claim if:
    - Your injury was caused by the investigators, or;
    - There was a deviation from the proposed research plan, or;
    - Your injury was caused solely by you. An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial. You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you. 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.

You may have your friend, family, or whānau support help you understand the risks and/or benefits of this study or any other explanation you require. You are also welcome to have a friend, family, or whānau support with you during every session.

Right to Withdraw from Participation
You may withdraw your consent for the collection and use of your information at any time, by informing any of the research staff. 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.

Anonymity and Confidentiality
All samples and the measurements will be coded and recorded to keep your identity confidential. Coding will be numerical and you will not be identifiable by this code. The only person able to link the code with your name is Dr Andrea Braakhuis who will keep the coding list in a locked filing cabinet. When the analysis is completed the researchers will analyse the whole group's data and report on averages. This data will be used for scientific publication and presentations. No person will be identifiable from the analysis.

Data storage
Data recorded on the Research Diet Diary application uses an industry standard cloud data storage, largely using Amazon Web Services. Their Amazon Web Services data (which includes Research Food Diary users' data) is stored in the Sydney, Australia data centre, however, we understand that for disaster recovery purposes the data is replicated in other data centres, possibly overseas. All other data generated in this study is only seen by research staff related to this project.

Availability of data and materials
Access to data will be granted to appropriate members of the research team and to authorised representatives from the host institution to monitor and/or audit the study and ensure compliance with regulations. Data will be made available to external academics on reasonable request.

Contact Details

For more information please contact either:

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Email: c.wall@auckland.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
Website: https://www.advocacy.org.nz/

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324.

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

APPROVED BY THE HEALTH AND DISABILITY ETHICS COMMITTEE ON (Jan 28th 2021), Reference Number (Ref: 20/STH/157)