



MASSEY UNIVERSITY
COLLEGE OF HEALTH
TE KURA HAUORA TANGATA

The LOCA Study

Participant Information Sheet

We are looking for men and women aged between 20 and 45 years of age to take part in the low carbohydrate study. We want to understand how following a low carbohydrate diet is related to health and quality of life. Please read this information sheet carefully before deciding whether or not to participate.

What is this research about?

Here in New Zealand, we are experiencing an epidemic of obesity and related diseases, such as diabetes and heart disease. These diseases can lead to a lower quality of life, increased mortality, and a higher economic burden for the country. A key contributing factor is our diets and the type of food we eat. Diets low in carbohydrates have been popular for weight loss. However, people follow different varieties of a low carbohydrate diet and use different types of food to replace carbohydrates with, which can have different effects on health. All the long term risks and benefits are also not yet known. We want to know what the practices of low carbohydrate diet followers in NZ are, and the reasons behind their diet choices. This new knowledge will help us understand different varieties of low carbohydrate diets and how it impacts on people's lives in NZ.

Who are we looking for?

We are looking for men and women to participate in this study. To take part in this study you need to:

- Be between 20 and 45 years of age.
- Be following a low carbohydrate diet for at least 4 months.
- Not have chronic conditions or use medications that may affect our results (e.g. cancer, kidney, liver disease, or take medication that changes blood lipids/ cholesterol, blood sugar or blood pressure etc.).
- Not be pregnant or are breastfeeding.
- Not have had bariatric surgery.

What is involved in the study?

If you decide to take part in the study, you will be asked to complete a screening questionnaire (online or over the phone) that will assess your eligibility. If you meet these eligibility criteria you will be invited to take part in the study, which includes a visit to the Massey University Human Nutrition Research Unit in Albany (which will take about an hour and 30 minutes) and completing questionnaires at home. In total, you would need to give 3.5 - 4 hours of your time (including the visit to Massey University and doing some questionnaires at home), spread out over a timeframe of about one week.

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At home (approximately 30 minutes and additionally 30 minutes a day over 4 days)

You will be asked to:

- Complete online questionnaires about your physical activity and diet (approximately 1 hour in total).
- Record your food intake for 4 days (approximately 30 minutes per day over 4 days).
- We will ask you to provide a small urine sample.

At the Human Nutrition Research Unit (approximately 1 hour and 30 minutes)

You will have to visit the Human Nutrition Research Unit early in the morning (between 7:30 and 8:30am), without having eaten breakfast. The following procedures will take place during this visit:

- Your height, weight and body composition will be measured.
- Your blood pressure will be taken.
- A blood sample will be taken from a vein in your arm by a trained person (a phlebotomist). For this blood sample you need to have fasted overnight. **You should not eat or drink anything (other than water) from 10 pm the previous evening until after the blood sample has been taken.** We will use the blood samples to measure cholesterol and glucose levels, markers of inflammation, and small molecules related to carbohydrate, fat and protein usage and storage.
- We will provide breakfast for you.
- You will complete some questionnaires.
- You will have a short interview to make sure we have all the necessary information from your questionnaires.

What are the benefits and risks of taking part in this study?

There will be no charges made for any of the tests that you undertake. In recognition of your participation, you will receive a \$50 supermarket or petrol voucher at the end of the visit to the Human Nutrition Research Unit. Once the study is completed, you will receive information regarding your own individual measurements if you choose (blood results including blood sugar, cholesterol, blood pressure, percentage body fat and BMI). Note: If you elect to receive the results of your tests or agree that they be sent to your GP if they show abnormalities, and you seek life or health insurance you or your GP can be asked to disclose them by the insurer. Failure to disclose them could invalidate any insurance policy issued where disclosure has not been made. You will also receive a brief report summarising the main findings of the project via mail or email after analysis of the data has been completed as well as some healthy eating guidelines and nutritional information to fit into your lifestyle.

Some people may have a fear of having a blood sample taken, or experience discomfort when the blood samples are taken. Occasionally, a slight bruise will result. We will take every measure to ensure you are comfortable and respected. You may also be accompanied by a support person if required.

Project procedures

Sample Handling and Storage

Samples will be stored in a secure laboratory freezer at the Human Nutrition Research Unit until completion of the study for a maximum of 10 years. Samples will be analysed by fully accredited laboratories in NZ. The data will be used only for the purposes of this project, and no individual will be identified. Only the investigators and administrators of the study will have

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access to personal information, and this will be kept secure and strictly confidential. Participants will be identified only by a study identification number, to ensure anonymity and confidentiality of these samples. After analysis, any additional blood will be destroyed following usual procedures. However, if you prefer to rather have your blood samples, it can be returned to you if you request it.

Data Handling

Results of this project may be published or presented at conferences or seminars. No individual will be able to be identified. At the end of this study, the list of participants and their study identification number will be disposed of. Any raw data on which the results of the project depend will be retained in secure storage for 10 years, after which it will be destroyed.

Who is funding the research?

The research is funded by the Massey University Research Fund.

Participant's rights

You are under no obligation to accept this invitation. If you decide to participate, you have the right to:

- Withdraw from the study at any time
- Ask any questions about the study at any time during participation
- Provide information on the understanding that your name will not be used unless you give permission to the researcher
- Be given access to a summary of the project findings when it is concluded

Project contacts

If you have any further questions or concerns about the project, either now or in the future, please contact the research team on studyemail@massey.ac.nz or www.studywebsite.com.

The lead researchers for this study are Dr Marilize Richter and Associate Professor Rozanne Kruger. If you have any concerns, please contact Marilize m.richter@massey.ac.nz phone +649 213 6659 or Rozanne r.kruger@massey.ac.nz phone +649 213 6661.

Committee approval statement

This project has been reviewed and approved by the Massey University Human Ethics Committee: Southern A, application 18/22. If you have any concerns about the conduct of this research, please contact Dr Lesley Batten, Chair, Massey University Human Ethics Committee: Southern A, telephone: 06 356 9099 x 85094, email: humanethicssoutha@massey.ac.nz.

Compensation for injury

If physical injury results from your participation in this study, you should visit a treatment provider to make a claim to ACC as soon as possible. ACC cover and entitlements are not automatic and your claim will be assessed by ACC in accordance with the Accident Compensation Act 2001. If your claim is accepted, ACC must inform you of your entitlements, and must help you access those entitlements. If your ACC claim is not accepted you should immediately contact the researchers.