

Study title: Gut Health and Diet Study.

Research team: Angela Genoni (chief researcher), with co-supervisors; Assoc. Prof. Amanda Devine, Assoc. Prof. Philippa Lyons-Wall, Assoc. Prof. Mary Boyce, Dr. Claus Christophersen and Dr. Johnny Lo.

You are invited to take part in a study examining the long term effect of two different dietary patterns on gut health. This study is being undertaken as part of the requirements for a Doctor of Philosophy at Edith Cowan University (ECU).

Study aims

There is an increased awareness in the medical community about the role of the gut flora in promoting health and disease. This study will examine two different eating patterns and assess their effect on the gut flora and markers of glucose metabolism and cardiovascular health.

The study is a cross sectional study. We are recruiting long term followers of either the Paleolithic diet or a standard, western style of healthy eating.

We will be comparing the differences in biomarkers of gut health and general health between the two dietary patterns. This will help us determine the long term effect of both diets on gut and general health.

Study details

There are two stages of the study: data collection and analysis. If you choose to participate in the study, you will be involved in the data collection stage. This will take place over a 1-week period.

102 men and women will be recruited for participation in this study. There will be 51 men and women recruited from each dietary pattern.

What we will ask you to do

1. Complete an examination to record height, waist circumference, body fat percentage and blood pressure. A Bod Pod will be used to estimate your levels of body fat and muscle. It involves sitting inside an air chamber for a period of approximately 2 minutes. The chamber is harmless and painless. You will be required to wear tight fitting bathers or gym wear and hair cap, which we will provide.

2. Complete a diet history and food frequency questionnaire interview with the chief researcher. This interview will take approximately 45-60 minutes.
3. Complete a questionnaire on your physical activity level. This questionnaire might take you 5-10 minutes.
4. Complete a questionnaire on your bowel health. This questionnaire might take you 5-10 minutes.
5. Complete blood tests at a Pathwest collection centre. These blood tests will require you to attend a Pathwest pathology centre after an overnight fast.
6. Collect a 24 hour urine sample. This involves collecting all your urine for a 24 hour period.
7. Collect a 48 hour stool sample. This involves collecting all bowel movements for a 48 hour period. Containers and freezers for storage of the samples will be provided.
8. Complete a 3 day weighed food record. You will be given scales, measuring cups, spoons, recording sheets and instructions by the researcher. You do not need to alter the way you eat for this three day period.

Possible risks of the study

You may experience some anxiety or inconvenience associated with having your measurements taken, disclosing personal information in the questionnaires, or completing the weighed food record.

The physical risks of this intervention are those associated with blood sampling. Such risks occur infrequently and may include local bruising, inflammation of the vein, local thrombosis and possible infection of the sampling site.

Possible benefits of the study

You will receive feedback about your general and gut health from physical examinations and laboratory tests performed in the study. Information obtained from this study will advise researchers and public health educators on the long term health effects of diets containing carbohydrate and Paleolithic style diets. Scientific results of this study will be published in Medical and Health Journals.

Consent to Participate in the Study

If you choose to participate in the study, you are required to sign the Informed Consent document and return it to the chief investigator.

Confidentiality of Information

Access to all data will be limited to the chief researcher and supervisors of the study. A confidentiality agreement has been signed by all members of the research team. Confidentiality will be maintained by de-identifying all data. Hard copies of data will be stored in a secure, lockable cabinet at Edith Cowan University (ECU) or at the chief researcher's home and data will be transferred in a secure manner. Computer files will be stored on the ECU secure servers and on an external hard drive and all files will be password protected. After five (5) years of the finished project, all electronic data files will be deleted and any paper based records will be destroyed using ECU's confidential waste. It should be noted that there are legal limits to confidentiality. The data and/or samples collected for the purposes of this research may be used in further approved researcher projects. Your name and other identifying information will be removed.

Results of the Study

You will receive individual feedback on your laboratory and body composition measures by way of a written report. The findings will be used to develop a thesis and may be presented at conferences and as a journal article. No individual data will be made available.

Voluntary Participation in the Study

Your decision to participate in this study is entirely voluntary. No explanation or justification is needed if you choose not to participate. A decision not to participate will not disadvantage you or involve any penalty.

Withdrawing from the Study

You are free to withdraw from the study with no further involvement at any time. There will be no consequences of withdrawing from the study at any time. Information or material that has been collected will be used unless you request otherwise.

Questions or Further Information

If you have any questions or require any further information about the study, please contact:

Chief Researcher:

Angela Genoni, Edith Cowan University
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If you have any concerns or complaints about the study and wish to talk to an independent person, you may contact:

Research Ethics Officer

Edith Cowan University
270 Joondalup Drive JOONDALUP WA 6027
Phone: (08) 6304 2170 Email: research.ethics@ecu.edu.au

This project has been approved by the ECU Human Research Ethics Committee.