Comparing the health impact of bioactive compounds in different meal environments (Turmeric study)

INFORMATION SHEET

Researcher(s) Introduction

Study purpose: To investigate the impact of turmeric in different meal environments on blood markers of inflammation, oxidation and metabolic health after a fatty meal.

Investigators:

I am Dr Noha Ahmed Nasef (PhD, BSc (Hons) biomedical sciences). I am a Postdoctoral Researcher in the Riddet Institute, Palmerston North, New Zealand. My interest is in how food affects your health and specifically in relation to metabolic disease and type 2 diabetes.

Other people involved in the study are:

Professor Manohar Garg PhD, MND, RNutr, MSc (Biochem), BSc (Hons) Director, Nutraceuticals Research Group, School of Biomedical Sciences and Pharmacy, University Drive, Callaghan, Australia. Honorary Professor, Riddet Institute, Massey University

Professor Jane Coad PhD, PGCEA, BSc, Professor in Nutrition, Massey Institute of Food Science and Technology, leader in the Human Nutrition expertise group, Massey University, Palmerston North, New Zealand

Professor Matt Golding, Professor in Food Colloids, Massey Institute of Food Science and Technology, Massey University, Palmerston North, New Zealand

Dr Simon Loveday Senior Research Officer, Massey Institute of Food Science and Technology, Massey University, Palmerston North, New Zealand

Distinguished Professor Harjinder Singh, Director of Massey Food Science and technology innovation, Massey Institute of Food Science and Technology and Riddet Institute, Massey University, Palmerston North, New Zealand

Distinguished Professor Paul Moughan Co-Director of Massey Institute of Food Science and Technology and Riddet Institute, Massey University, Palmerston North, New Zealand

Project Description and Invitation

Curcumin from turmeric (a curry spice) is thought to have many health benefits such as reducing inflammation and reducing the risk of type 2 diabetes and heart disease. But it is still unclear whether these effects are due to curcumin itself or whether there are other components in the whole turmeric that also contribute to the benefit of consuming these foods.

To investigate this, we are inviting you to take part in a study that will test 3 different meals where the curcumin is incorporated into meals in slightly different ways. The study will involve 1x1 hour assessment visit and 4 study visits. In the study visits, you will be eating 1 of 3 test meals or a control meal. We will then collect blood from you immediately before you eat the meals and then every hour for 6 hours after eating the meal. The blood will then be measured for markers of inflammation, oxidation, triglycerides and metabolic function.

Participant Identification and Recruitment

We will be advertising for this study in Massey University through lecture announcements, noticeboards and staff and students email lists. We will also be advertising in local newspapers, social media and external organisations. In addition, we will be inviting people to participate from the Human Health participant database and directly approaching people in public areas such as cafes and University grounds.

To take part in this study you must be:

- Male aged between 18 and 40 years old and with normal body weight (body mass index between 18 and 30 kg/m^2) at initial assessment.

You are NOT eligible to participate if you:

- Are currently taking any blood pressure medication;
- Are dieting or have any eating disorders;
- Have allergy or intolerance to dairy products or spices;
- Have a history of congestive heart failure, stroke, myocardial infarction, coronary artery bypass graft, or atherosclerotic CVD;
- Have a history of diabetes, high blood pressure or high cholesterol;
- Have history of gastrointestinal disorder, renal or liver disease;
- Vigorously active
- Smoke;

Participation in this research is voluntary. Only those people who have given their written informed consent will be included in this study. If you do decide to participate you may withdraw from the project at any time without giving a reason.

We aim to recruit 26 participants for this study to get statistically significant results.

You will be provided with lunch after each study visit and reimbursed for travel expenses (see 'Compensation').

Participants will acquire knowledge and contribute to the scientific advancements of nutrition in the prevention of chronic diseases. In addition, feedback of results from the overall investigation and other information regarding the outcome of the research will be made available to you and will be posted as an individual letter at the completion of the study.

Risks: Some people may find it uncomfortable to give blood samples. As with all blood sample donation some individuals may feel dizzy or faint, if you have previously experienced these symptoms when having blood samples taken please inform the study researcher or medical personnel. There is a chance that you will see minor bruising around the cannula site. However, the bruising is temporary and will fade away over time.

Project Procedures

If you agree to participate in this study, you will be asked to visit The Human Nutrition Research Unit (HNRU) at Massey University, Oteha Rohe Campus (Albany, Auckland) 5 times. On your first visit, you will be asked to fast the night before. During your first visit, we will get you to answer questions about your eating habits, medical history, physical activity and assess your availability for the study. We will measure your height, weight and blood pressure and take a small blood sample (about 4 drops) using a finger prick. The first visit will take about an hour.

On visit 2 to 5 you will be asked to fast the night before and not eat or drink anything before your visit. When you arrive to the unit, you will be asked to eat a test meal prepared by the research team. The test meal will contain mashed potato, cream, corn starch and turmeric or curcumin. You will remain in the HNRU for 7 hours (from 8am to 3pm) while 6 blood samples are collected (time 0 and 1, 2, 3, 4 and 6 hours after you eat the meal). The blood will be collected from a cannula inserted into your forearm by an experienced Massey University staff member. The cannula will remain in your forearm for the duration of the visit. We will take around 15ml (1 tablespoon) of blood every hour so that at the end of the study visit we will have taken 90ml (6 tablespoons) of blood.

In the event that the cannula becomes blocked before the final blood collection is taken at the 6 hour time point, a needle will be inserted into your forearm to collect the final 15ml of blood. This will only be done once and only if needed.

The day before visits 2-5, you will be asked to refrain from strenuous exercise and alcohol. You will be asked to pick up your dinner from the unit to eat at 8pm the night before the study visit. You will then be asked to stop eating or drinking (except for drinking water, which is OK) from 10pm the night before the study visit until the study visit is over (you will be provided with lunch at the end of the study visit around 2.30pm).

In the morning of visit 2-5 you will be asked to complete a 24-hour food recall. This involves recording all the food and beverages you have eaten in the last 24 hours. You will be given instructions on how to record this information when you arrive at the HNRU.

Test meals: Cream, turmeric/curcumin, mashed potato and corn starch

Visit 2-5 will be 1 week apart where the same procedure will be repeated for each visit.

Dr Noha Ahmed Nasef is a certified first aider and will be able to respond appropriately in the unlikely event of any emergency.

The blood will be measured for markers of inflammation, oxidation and metabolic function in the Riddet Institute, Massey Manawatu Campus, Palmerston North. Levels of curcumin in the blood will be analysed in the University of Newcastle, Australia as they have established methods to undertake this analysis on a regular basis.

Any unused blood samples will be disposed of following standard bio-hazardous waste procedures. If participants have indicated in their consent form that they want any unused samples back, Dr Noha Ahmed Nasef will organise for any samples stored in New Zealand to be returned.

Compensation

You will be reimbursed for your time and travel with a $10 Westfield voucher for the screening visit and $90 Westfield voucher for each study visit you attend.

Data Management

Results of this research will be published in scientific journals. Individual participants will not be identified in any report arising from the project.

Your information will be treated with the same respect for privacy and confidentiality as is undertaken for all medical information collected about you during your visits to your local doctor. Access to the collected information will be limited to the named investigators only.

All information collected from participants will be stored in the original paper copy in a locked filing cabinet at the Riddet institute at Massey University accessible only to the investigators. Data will only be identifiable by a participant identification number with

no other identifying details on file. During statistical data analysis the database will be stored in a password protected computer file.

All data for the study will be kept by the Chief Investigator for the period of 5 years following the completion of the study. Only the investigators conducting this research will have access to this information.

Feedback of results from the investigation and other information regarding the outcome of the research will be made available to you and will be posted as an individual letter at the completion of the study.

Note: If you elect to receive the results of your own individual tests or you give the test results to your GP (we will give you a letter and a summary of your test results to give your GP if we find any 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.

Participant's Rights

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

- *decline to answer any particular question;*
- *withdraw from the study;*
- *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

Further information about this project can be obtained from Dr Noha Ahmed Nasef 0800 MASSEY (0800 627 739) ext. 86421 or spice@massey.ac.nz).

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Statements

This project has been reviewed and approved by the Massey University Human Ethics Committee: Southern A, Application 17/10. 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 humanethicsoutha@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. Entitlements may include, but not be limited to, treatment costs, travel costs for rehabilitation, loss of earnings, and/or lump sum for permanent impairment. Compensation for mental trauma may also be included, but only if this is incurred as a result of physical injury.

If your ACC claim is not accepted you should immediately contact the researcher. The researcher will initiate processes to ensure you receive compensation equivalent to that to which you would have been entitled had ACC accepted your claim.