
APPENDIX B
PARTICIPANT INFORMATION SHEET – PART 1
INTENDED FOR ONLINE ADMINISTRATION

An Observational, Longitudinal, Psycho-Biological Study of Dieting in Young People

PARTICIPANT INFORMATION SHEET
Part 1 – Online Surveys & Diaries

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| Short Title | <i>My Diet Study</i> |
| Protocol Number | <i>X21-0181</i> |
| Project Sponsor | <i>University of Sydney</i> |
| Project Site | <i>Charles Perkins Centre, University of Sydney</i> |
| Coordinating Principal Investigator | <i>Assoc. Prof. Andrew Holmes¹</i> |
| Co-Investigators | <i>Assoc. Prof. Sarah Maguire² Professor Stephen Simpson¹ Professor Stephen Touyz² Dr Jane Miskovic-Wheatley² Sarah Barakat² Professor Ian Caterson^{1,2}</i> |
| Co-Investigators/ Study Coordinator/s | <i>Mirei Okada (PhD Candidate)¹ Melissa Pehlivan (PhD candidate)²</i> |
| Institutions | <i>¹School of Life and Environmental Science, Faculty of Science, USyd ²InsideOut Institute, Central Clinical School, Faculty of Medicine and Health, USyd</i> |
| Study Co-ordinators and contacts | <i>Mirei Okada & Melissa Pehlivan – usyddieting.study@sydney.edu.au</i> |

Are you thinking about starting a diet in the next few weeks? If so, we hope you will consider participating in this study that will track your experience with the aim of understanding the relationship between your motivations, your behaviour, and your biology.

What is this study about?

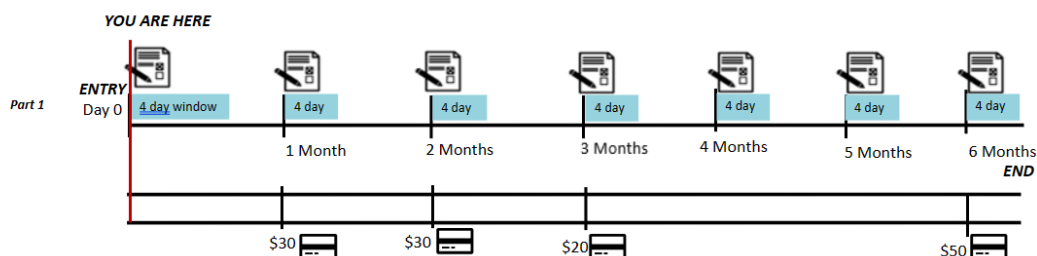
You are invited to take part in a research study – the first of its kind – investigating the natural dieting patterns/habits for young people. The aim of the study is to understand and identify what factors (biological and psychological) impact a person’s experience of dieting. This study does not provide specific dieting advice, and it does not matter if you decide to change your diet or stop dieting, we would just like the opportunity to follow you on your journey.

Emerging research has suggested strong implications that physiologic and metabolic changes in gut microbial communities can influence our feeding behaviours where multiple signals can be sent to the brain via various routes including the immune system, the nerves and cells which link your body's sensory system to the brain and the digestive system which determines gut movements, interacts with your immune system and releases some hormones. This will be the first study in a range of studies with the aim to better understand these processes, how to promote healthy eating, and how to avoid unhealthy dieting.

Who is running the study?

This study is being co-conducted by Mirei Okada and Melissa Pehlivan. Melissa is conducting this study to fulfill the requirements of a Doctor of Philosophy (PhD) in psychology, under the supervision of Assoc. Prof. Sarah Maguire and Prof. Stephen Touyz; Mirei Okada is conducting the study to fulfill the requirements for PhD in Science, under the primary supervision of Assoc. Prof. Andrew Holmes and co-supervision of Assoc. Prof. Sarah Maguire and Prof. Stephen Simpson.

What will the study involve for me? You will be asked to complete a number of online questionnaires, once a month for 6 months. We would also like you to keep some online diaries, one week a month. More details below:



- 1. First questionnaire – At the start** you will be asked some basic demographic information (e.g., gender, occupation), your history with dieting your basic health history. You will also be asked to complete some standardised measures relating to body shape/weight and eating habits, your mood, and motivations for dieting. This is the longest set of questions and will take about 30-45 minutes. You will then be asked to complete a daily diary for the next week (see below).
- 2. Check in – At week 1** the study co-ordinators will be in touch to see how you are progressing with your diet and the daily diaries
- 3. Daily Diaries – At the start of each month** you will be asked to complete a daily diary for 4-days (3 weekdays and 1 weekend day) to record the food you are eating, your stool/poo and your mood. We expect it will take you around 5-10 minutes a day to complete this online diary on your mobile phone device.

Hang on...why your poo?! Your bowel movements are a strong indicator of your digestive health, and our research team can tell a lot just by looking at your poo! We know this is an unusual request, but this information will help us learn about the gut-brain axis and holistic physiological and psychological changes as you diet.

- 4. Monthly questionnaires – Once a month** for the next 6 months, you will be asked to complete the following information:
 - Questions about your dieting, weight changes, motivation changes, etc.
 - Repeat of the standardised measures from the first questionnaire

These are briefer questionnaires than the initial one and will take about 15 minutes each time.

You will be sent an email prompt when the questionnaires are due, and then up to three email reminders. We will need to collect an email address so we can stay in contact with you.

What do I benefit from participating in the study?

Though there are no direct benefits from your participation, we understand that this study may take some time to complete and would like to offer you an incentive.

- If you complete all measures up to 1 months (inclusive), we are pleased to offer you a \$30 gift card for online purchases.
- If you complete all measures up to 2 months (inclusive), we are pleased to offer you a \$30 gift card for online purchases
- If you complete all measures up to 3 months (inclusive), we are pleased to offer you a \$20 gift card for online purchases.
- If you complete all measures to 6 months, we are pleased to offer you an additional \$50 gift card (\$100 in total).

We will also keep you engaged with the research via a regular newsletter.

Who can take part in the study?

You can take part in this study if you are aged 16-25 years, an Australian resident and intend to start a diet within the next month. For this study, you will need your own device or computer, have reliable internet access, and able to read/write English.

You cannot participate if you are pregnant or lactating, if you have a formal diagnosis of malnourishment, a BMI of <17.5, or major medical condition that creates medical imperative for diet compliance. Additionally, since this study is focused on longer term dietary changes, you will need to be planning to make dietary changes that last for longer than a couple of weeks.

You also cannot participate if you have or have had a clinically diagnosed eating disorder. As part of the initial study screener, you will complete a standard measure for eating disorder risk. If you do score in the clinical range, you will not be eligible to continue. We will contact you with this information and suggest you make contact with your GP about further assessment.

Participation in this study is completely voluntary.

Are there any risks associated with participating in the study?

There may be some risk associated with completing standard psychological measures. If at any time you feel distressed, you can call the NSW Mental Health Access Line at 1800 011 511. Alternatively, we encourage you to speak to your friends or healthcare professional (GP, psychologist, psychiatrist).

What if I decide to withdraw from the study once I've started?

Being in this study is completely voluntary, your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney. 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 emailing study coordinators, Mirei Okada and Melissa Pehlivan at usyddieting.study@sydney.edu.au

If you decide to withdraw from the study, we will not collect any more information from you. Any information already collected will be kept in our study records and may be included in the study results.

The gift card incentive will not be made available for anyone who does withdraw from the study prior to completion. For University of Sydney students, course credit is only available with study completion.

If we need to exclude you from the study for medical reasons, we cannot offer the study incentive, however we would contact you to explain the situation and to assist you with contacting your GP for ongoing assessment and care. Being part of this study could be helpful to identify any future risk.

What happens to my information collected during the study?

Once collected, all data will be deidentified. The study co-ordinators will allocate you a study ID number so your identifying information (such as your email address) will be kept separately from your questionnaire data. Any presentations and publications of this research will only report deidentified group data.

Only Mirei Okada (PhD Candidate/Study coordinator), Melissa Pehlivan (PhD Candidate/Study Coordinator), Assoc. Prof. Andrew Holmes (Coordinating Principal Investigator), Assoc. Prof. Sarah Maguire (Co-investigator), Sarah Barakat (Co-investigator) and Prof. Ian Caterson (Co-investigator) will have access to sensitive information to assess inclusion/exclusion criteria and risk. A separate database will be available to other researchers who may be involved with the study, with all identifying data removed and participants only identified by their study ID.

Storage of Data

All information collected online will be via the secure online platform REDCap and TeamsScope App stored in the Research Data System (RDS) compliant with data security guidelines of the University of Sydney. Unless you decide you want to exit the study, files will be retained for 7 years from the day the study is completed, then destroyed, as per guidelines.

Future use of Data

The data collected in this project may be used for future research purposes. After removing any identifying information, the data will be published in a public, online data-store, Sydney eScholarship repository. This is in line an open science approach and enables other researchers to independently verify findings and permit the testing of new research questions. You can indicate your agreement to this during the consenting process.

Can I tell other people about the study?

Of course, yes! We encourage you to tell people about this study, and you can also invite others to participate.

Will I be told the results of the study?

It is anticipated that the results of this research study will be published in academic journals and be presented at local and international scientific conferences. Results will also be communicated to the wider community through public talks, social media networks and print media as well as via the InsideOut website. In any publication and/or presentation, information will be provided in such a way that you cannot be identified as we will not use any of your personal information as part of this research study. Participants will be sent a copy of all academic publications pertaining to this study.

How is this study funded?

By a fabulous philanthropic donation from the M.A.S.T foundation, a not-for-profit family organisation which seeks to help medical research that aims to enhance human health and wellbeing, and education, training and employment initiatives assisting children and young people in Australia.

Ethics Approval and Complaints

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Human Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. 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.

Any person with concerns or complaints about the conduct of the study should contact the Executive Officer on (02) 9515 6766 and quote protocol number **X21-0181**.

What if I would like further information?

If you would like to know more at any stage, please feel free to contact study coordinators at usyddieting.study@sydney.edu.au

*Please feel free to download this participant information sheet for your records.
If you decide to consent, we will also email one to you.*