University of South Australia

PARTICIPANT INFORMATION SHEET

Study: The effects of low versus high egg diets on blood cholesterol and lipid levels

Alliance for Research in Exercise, Nutrition and Activity (ARENA), University of South Australia.

Purpose of Study

The purpose of this study is to compare the effects of eating three different diets, each with varying amounts of dietary cholesterol and saturated fats (animal and/or coconut fats). The proposed research will examine if a low-saturated fat diet containing eggs changes blood cholesterol or other blood lipid levels when compared to a high saturated fat, low cholesterol diet (without eggs) or an average Australian control diet (high saturated fat and cholesterol).

What it involves

Participants will consume three diets, in random order, for five weeks each:
1) **Control diet** (representative of typical Australian diet)- High saturated fat + high cholesterol diet,
2) **Egg diet** - High cholesterol + low saturated fat diet,
3) **Egg Free diet** - Low cholesterol + high saturated fat diet.

You will be provided with weekly meal plans and be asked to follow the patterns of eating described by the dietitian. Foods that will be consumed during these diets include dairy, fish and seafood, meat and eggs. These diets will be easiest to follow if you are able to cook for yourself or have someone cook for you, following the meal plan.

The study will be conducted by the Alliance for Research in Exercise, Nutrition and Activity (ARENA), University of South Australia.

Given the social distancing restrictions, we have undertaken the following measures to keep you and ourselves safe.

- All room surfaces and equipment will be disinfected between sessions.
- Study participants and investigators will be asked to wear a mask during sessions.
- All investigators will wash and sanitize hands prior to each session and at end of session (products available inside door). We will ask participants to do the same.
- Where possible we will maintain 1.5m distancing and appropriately sized room (>4m^2).
- All equipment given for your use at home will be sanitised prior to handing it out and after it is bought back.
- All staff working in the Clinical Trial Facility are COVID vaccinated.

If you would like to participate in the study, we will conduct a screening appointment at the **Clinical Trials Facility** in the Bonython Jubilee Building **(UniSA City East Campus on Frome Road)** to determine whether the study is suitable for you. If you meet the criteria and you are eligible, we will invite you to attend further appointments. In total there will be **5 (five) visits to the Clinical Trials Facility** over 16 weeks; one screening appointment (45 mins), and four data collection visits (1 hour each). There will also be 9 (3 sessions per diet phase) one-on-one dietitian consults (via videoconference) (20-30 min each). We will be recruiting approximately 52 participants and anticipate the study will be completed by the end of 2023.

Who is eligible for the study?

In order to be included in the study you will need to meet the following criteria:

- Aged 18-60 years.
- Non-smoker (or other nicotine products) (minimum 6 months cessation).
- LDL-cholesterol (LDL-C) ≤3.5 mmol/L (measured at the screening appointment via a finger prick blood sample).

People that are not suitable to be involved in this study are those who:

- Have cardiovascular disease (including uncontrolled high blood pressure) or a chronic disease, including Type-1 or -2 diabetes, kidney or liver disease, gastrointestinal disorders requiring medical nutrition therapy (e.g., Crohn's disease, irritable bowel, coeliac disease) or any other condition that might impact the study outcomes.
- Allergies or strong aversion to eggs or other components in the diet plans (diets contain meat).
- Eat more than 5 eggs a day in the month prior to commencing the trial.
- Have changed medication or supplementation, that will impact the study outcomes, in the last 3 months.
- Take vitamin, mineral or herbal supplementation that may impact on study outcomes.
- Unwilling to stop dietary supplements that influence the outcomes of the trial.
- Are already involved in another research project within 30 days of commencement of the present study that in the opinion of the investigators will be unsuitable for this study.
- Are pregnant or breastfeeding.
- Show unwillingness to be randomised to either experimental group.
- Are unwilling or unable to provide written informed consent.
- Failure to satisfy the investigator regarding suitability to participate for any other reason.

What happens if I participate in the study?

If you are interested in participating in this study, please complete the confidential questionnaire (Diet and Lifestyle Questionnaire), either online or request a copy to be emailed or posted to you to be completed in hard copy.

You are welcome to discuss your participation in this study with your doctor, family members or friends. If the information provided by you in the returned Diet and Lifestyle Questionnaire suggests that you may be eligible, you will be asked to attend a screening appointment at the Clinical Trials Facility, Bonython Jubilee Building of the UniSA, City East Campus, Frome Road, Adelaide.
Please see the study timeline (Appendix 1) at the end of this document for an overview.

Screening Visit (45 min)

The screening visit will take approximately **45 minutes**.

During the screening visit you will: -

- Have the project explained to you by one of the study investigators, you can ask questions and then sign a consent form, should you choose to participate in the trial.
- Confirm your medical history and any current medications you are taking. It is important to tell the research staff about all treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture, or other alternative treatments.
- Have your height and weight measured.
- Have a finger prick blood sample taken to measure LDL-C levels in your blood.

If you meet the required criteria and you are deemed eligible, you will:-

- Be given a five-day weighed food diary to be completed prior to the next visit. We will provide you with kitchen scales and ask you to record your food and drink intake for 5 days.
- Be given an activity watch to wear on your non-dominant wrist for 7 days. This will be used to monitor your activity and sleep patterns.
- Be given a sleep diary to complete for 7 days.
- Arrange a date and time for you to come for your next clinic visit (Baseline).

Baseline clinic visit

This will take **approximately 1 hr.** Prior to this visit we will ask you to fast overnight and avoid drinking alcohol for 24 hours (hr) prior.
During this visit you will:

- Return your activity watch, sleep diary and food diary.
- Have your height, weight and waist circumference measured.
- Have your blood pressure measured.
- Have a fasting blood sample collected (approximately 15 mL).

The first of the diet phases will then be explained to you by a dietitian. You will receive financial support to purchase the foods required for following this diet plan. This diet plan will be followed for 5 weeks. You will be given daily checklists to complete to aid in following this diet.

Diet Review Visits (Week 1, 2, 4)

During each diet phase, you will also be asked to participate in 3 x online diet review consults (via videoconference) for individualised dietary advice (20-30 minutes each). The study dietitian will meet (online) with participants weekly to assess dietary compliance and provide strategies to maintain dietary

compliance. You will be asked to maintain your current weight, and your body weight will be checked. You will be given advice to assist with weight maintenance if required.

Week 5 clinic visit

This will take **approximately 1 hr.** Prior to this visit we will ask you to fast overnight and avoid drinking alcohol for 24 hrs prior.

At the end of the first 5-week diet plan you will again attend the Clinical Trial Facility**.** We will repeat the assessments performed at the baseline visit (as described above). In week 4 you will again be asked to wear an activity watch and fill in the sleep diary for 7 days. You will also record your food and drink intake for 5 days prior to this appointment. These will be posted to you prior to the beginning of the 4th week. The dietary strategy for the second 5-week diet phase will be described in detail to you and you will receive more financial support to purchase diet foods.

Diet phases 2 and 3 (Week 6-15)

The following diet phases will follow the visit structure and data collection plan as described above, with diary and accelerometer wear at **week 9 and week 14** for diet 2 and 3, respectively. **Clinic visits** for data collection and the beginning of third diet phase will occur at **week 10** and then the final data collection at **week 15** (appendix 1).

Description of Procedures

Weight, height, waist circumference (5 min)

Your height and weight will be recorded to calculate body mass index (BMI). Height will be measured whilst barefoot. Body weight and waist circumference will be measured with participants wearing light clothing.

Blood samples

A fasting venous blood sample (15 mL, less than a tablespoon) will be collected. This will be used to assess fasting blood glucose, cholesterols, lipids, and other molecules that are indicators of vascular health. Blood samples will be taken on 4 occasions.

Investigators will wear gloves and mask, throughout the blood draw.

Blood pressure (10 min)

Blood pressure will be assessed using an inflatable cuff on your upper arm. These assessments are repeated 3-4 times to ensure measures are consistent. You will be asked to sit quietly whilst these measures are collected.

Diet diaries (approximately 10 minutes per day for 5 days on 4 occasions)

You will be asked to complete a five-day food diary. During the 5 days you will record all foods and drinks consumed. You will be asked to record weights or estimate volumes using standard measures where possible and provide as much detail as possible about branded products. You will also be given checklists to record daily consumption of the diet foods.

Activity monitors (7 days on 4 occasions)

You will be asked to wear an activity monitor on your non-dominant wrist to measure activity for 7 consecutive days prior to your baseline, week 5, week 10 and week 15 clinic appointments.

Sleep diaries (approximately 5 minutes per day for 7 days on 4 occasions)
You will be asked to complete a sleep diary. During the 7 days you will record the times that you went to bed and awoke from sleep. You will also record any times that you were not wearing the activity watch (non-wear times). These diaries are paired with the activity watch data.

Dietary advice (video conference, approximately 20-30 minutes, on 9 occasions)
A dietitian will provide detailed dietary instruction for each diet over 3 sessions in each of the dietary phases. They will also assist with weight maintenance if required. These can be either by videoconference (Zoom) or telephone consult.

Are there any risks involved?

All procedures will be carried out by qualified personnel and in accordance with strict occupational, health and safety guidelines. The risks associated are outlined below.

Finger prick blood sample
A small drop of blood will be taken from your finger after a small prick from a lancet. This might result in a small amount of bruising or soreness at the site.

Blood collection
Blood samples will be taken by inserting a needle into a forearm vein (i.e., venipuncture). The potential risks associated with this procedure are:

- *Infection* - although all the needles will be sterile, and all reasonable precautions will be taken, in any situation involving penetration of the skin there is a slight risk of infection.
- *Blood clotting* - insertion of a needle into a blood vessel involves a risk of a blood clot forming which can travel through the circulation and block a smaller blood vessel somewhere else. However, the danger of this occurring is remote.
- *Bruising* - it is possible that you may experience slight bruising around the area where the needle was inserted. This is nothing to worry about as any such bruising should clear up within a few days. To minimise the risk of bruising, you can (only if advised by your doctor) cease taking blood thinning agents, such as aspirin and ginko, three days prior to sampling.

Test food consumption
There are no known risks to consuming the test foods (unless you have an unknown allergy). If you have any adverse effects whilst at home, you will be asked to immediately discontinue consuming the foods and report your difficulties to the researchers.

How will my privacy be protected?

After completing the screening questionnaire, you are given an identification (ID) number and only this ID number will be used for all subsequent data collection. You will not be identified in any way in the analysis of the data or when the results are published in scientific journals. In addition,

information will be grouped for reporting and individual responses will not be presented in any way. All records containing personal information will remain confidential and no information which could lead to identification of any individual will be released, unless required by law. The information collected in this study will be stored on a USB at the Alliance for Research in Exercise, Nutrition and Activity's secure data store in the Bonython Jubilee Building, Frome Rd for a period of 15 years. Participants will be provided with a copy of their personal results and a summary of the research findings within 6 months of the study completion.
Biological samples will be stored frozen until analysed. The biochemical analysis will be performed at the completion of the study. Analysed samples will be treated as biological waste and disposed of accordingly.

What are the benefits to participating in this study?

You will be providing a valuable contribution to the scientific knowledge. You will receive financial support to purchase the study foods required to follow the prescribed diet. Participants who complete all aspects of the study will receive an honorarium of $600 to compensate for your time and travel expenses. Participants who withdraw from the study will be provided with a pro rata of the $600 reimbursement for participation.

We will provide you with as many of your personal results as possible. However, the clinical utility of some results from the study are not yet clear and therefore can only be used for research purposes. Expressly, this means that some blood analysis results will not be provided to you as a meaningful context cannot be given.

Participants may not personally benefit by participating in the study. At the completion of the project (anticipated to be late 2023) all participants will receive a summary of the study findings.

What if I want to withdraw from the study?

Participation in this study is voluntary, and you may withdraw from the study at any time without prejudice. If you choose to withdraw, you will be given the option at the time to decide whether you also withdraw consent for the use of your data which has already been collected.

In the event of a pregnancy occurring, please notify the investigator as soon as is practically possible as you will be withdrawn from the study. You should tell the research staff about any changes to your general health or prescribed medications during participation in the research. You may also be withdrawn if you have a change to your medications or health which is likely to adversely affect the results of the study or if you fail to comply with consuming the appropriate quantities of the test foods.

Are there any costs involved?

There are no additional costs involved in participating in this project as the test foods are provided to you free of charge.

Your obligations as a participant

You will need to inform a study staff member of any changes to your health, medications, or your ability to complete the requirements of the trial as some changes could influence your participation in the study and the study findings. You must also be able to undertake all relevant procedures during the study period.

Study Funding

The study is funded by a grant from the American Egg Board. While the grant funder has a financial interest in the outcomes of this project, please be aware that the design and conduct of this study has, and will, occur independent of any input from the sponsors. The company will only be provided with aggregated, group-level results and there will be no restrictions on publication of these results, regardless of outcomes.

Further information required?

If you, or any member of your family, require more information about this project to help you arrive at a decision, please contact:

Clinical Trial Facility; Louise Massie: Ph: 8302 2097 Email: unisa.researchvolunteers@unisa.edu.au

Trial Dietitian; Dr Sharayah Carter: Ph: 8302 1115 Email: sharayah.carter@unisa.edu.au

Clinical Trial Co-ordinator: Dr Catherine Yandell: Ph: 8302 2109 Email: catherine.yandell@unisa.edu.au

Principal Investigator: Prof. Jon Buckley: Ph: 8302 1853 Email: jon.buckley@unisa.edu.au

Please note: The consent form on the last page is for your information only. If you are eligible and wish to participate, this form will be signed at the screening visit.

Research Team:

Name	Phone	Email
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The University of South Australia's Human Research Ethics Committee has reviewed this study and have given approval for it to commence (ID 204327). Should you wish to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study, or your rights as a participant please contact the Executive Officer of UniSA HREC. Participants or third parties who wish to lodge a complaint about either the study or the way it is being conducted should contact the Executive Officer of UniSA HREC by email: humanethics@unisa.edu.au or telephone 83023118.

Project Consent Form

Project Title: Independent effects of high-cholesterol (high-egg) and high-saturated fat diets on LDL-cholesterol

In signing this form, I confirm that:

1. I consent to take part in the research project entitled: "Independent effects of high-cholesterol (high-egg) and high-saturated fat diets on LDL-cholesterol".
2. I have read the Participant Information Sheet, and the nature and purpose of the project and the risks inherent in my participation have been explained to me. I understand and agree to take part.
3. Although I understand that the purpose of this research project is to examine the effects of eating eggs on cholesterol and lipid levels, it has also been explained that my involvement may not be of any direct benefit to me.
4. I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.
5. I have been informed that, while information gained during the study may be published, I will not be identified, and my personal results will not be divulged, unless required by law. Following the publication of results, data will be housed in a secure off-site storage facility run by the university and will be destroyed after 15 years.
6. I understand that I am free to withdraw from the project at any time and that this will not affect my rights or the responsibilities of the researchers in any respect.
7. I understand that if I withdraw from the study, I can choose at the time to withdraw consent for my data which has already been collected to be included.
8. I understand that I will receive an honorarium of $600 as a thank you for my assistance in this research project upon completion of the study. However, if I do not complete the full protocol, I will receive compensation on a pro-rata basis
9. I am aware that I should retain a copy of this Consent Form, when completed, and the attached Participant Information Sheet.

Name of participant: ……

Signed …… **Date**…..……

Witness

I have provided …… (Name of participant) information about the research to the research participant and believe that he/she understands what is involved.

Researcher's Name ..……

Researcher's signature ……..... **Date** .....

Role in the project……

Appendix 1 Study timeline