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UNIVERSITY OF LEEDS

PARTICIPANT INFORMATION SHEET

The impact of breakfast consumption and exercise on appetite and health markers

We would like to invite you to take part in a research study. Before you decide to take part you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about this if you wish. Part 1 details the purpose of the study and what will happen if you take part and Part 2 provides more detailed information about the conduct of the study. Please ask if there is anything you are not sure of or would like further explanation about.

Part 1

What is the purpose of the study?

This study has been designed to investigate the effects of regular consumption of a yoghurt and jelly breakfast product during a 12-week exercise intervention on health markers in overweight and obese adults.

Why have I been invited?

You have been chosen because you fulfil the study requirements; we hope to recruit 30 participants in total to take part in the study.

Do I have to take part?

It is up to you to decide if you would like to take part. You will be asked to read this information sheet and then sign a consent form to show that you have agreed to take part. You may take as much time as you need to decide whether or not you would like to take part. It is important to note that you will be free to withdraw from the study at any time point without having to provide a reason.

What will the study involve for me?

The study will be 14 weeks in total, with 12-weeks of exercise 5 times per week. The exercise will be individually prescribed for you to burn 500 calories per session by an exercise physiologist. This usually takes around 60 minutes for most women. The exercise will be built up slowly and you will be shown how to use all of the gym equipment. In addition, during the 12-week exercise intervention, you will be required to consume a yoghurt and jelly breakfast product at home 4 times per week.

You will also have 2 assessments of your weight, waist and hip circumference, body composition, resting metabolic rate, blood pressure and resting heart rate. These measurements will be taken once during week 1 of the study before you start exercising and once upon completion of the full 12-weeks of exercise and product consumption.

You will also be required to wear a physical activity monitor and accelerometer and complete a physical activity diary for 7 consecutive days at 4 time points throughout the study. These will be; once during week 0 before you start exercising, once during the first week of exercising (week 1), once during the last week of exercising (week 12) and lastly once at the end of study when the exercise intervention is complete (week 13).

You will also be required to have breakfast, lunch and dinner within the research unit on 4 occasions throughout the 14 weeks. This will involve 2 days prior to the start of the study, and 2 days in week 12. However, you will be able to leave the research unit between meals. You will also have your fitness measured on 3 occasions. All the measurements that we will be taking are detailed further below.

Measurements that will be taken during the study:

Fitness assessment

Fitness assessments will be done at week 0 (before starting the exercise), week 6 during the intervention and at week 12. The assessment procedure will be as follows:

You will be shown to the changing facilities by a researcher so that you can change into your exercise clothes. You will then be shown the fitness test, which will involve exercising on a treadmill until you feel that you cannot perform any more exercise. During the test the researcher will need to collect your expired air for 1-min every 3-4 mins. You will be required to wear a sterile breathing tube in your mouth throughout the test.

The information we get from this test will give us a measurement of your fitness. From this test the researcher will be able to advise you for how long you need to exercise for to burn 500 calories per session.

MEASUREMENT DAYS – BEFORE ARRIVAL:

Please do not eat or drink anything after 10pm on the evening before each measurement day. **Do not drink any alcohol on the day prior to the measurement day**. Please arrive at the research unit in the morning having had nothing to eat or drink except water. **Please remember to bring some tight clothing with you for the assessment of body composition**. A swimming costume is ideal.

MEASUREMENT DAYS – ON ARRIVAL:

Resting Metabolic Rate

This machine measures how many calories you burn whilst you are resting. It is a very simple procedure which measures how much oxygen you are breathing in and how much carbon dioxide you are breathing out. For this to be measured you will need to lie on a bed for 30-40 minutes relax and breath normally with a large plastic dome which is placed over your head. There is fresh air pumped into the dome at all times.

Blood Pressure and resting heart rate

A trained researcher using an inflatable cuff will take your blood pressure and resting heart rate. For this you can relax on the bed and this will take no more than 2 minutes.

Body Composition
This machine measures the amount of fat and muscle you have in your body. For this to be measured you will be required to wear a swimming costume (or other very tight clothing) and sit in a carbon fibre pod, relax and breath normally for 5 minutes.

Meals
The meals will be given at intervals 4 hours apart throughout the day and these include breakfast, lunch and dinner. Between breakfast and lunch you will be required to remain in the research unit however between lunch and dinner you will be free to leave the research unit if you wish. You must, however, not have anything to eat or drink (except water) between the meals. You will be required to have 4 meal days with us throughout the 14-week study period.

Blood samples
Before having breakfast on the meal days you will be fitted with an intravenous cannula by a trained researcher. Eight 8ml blood samples will be drawn between breakfast and lunch. One will be taken before breakfast is served and then at the following time points after breakfast - 10 minutes, 20 minutes, 30 minutes, 60 minutes, 90 minutes, 120 minutes and 180 minutes. The cannula will then be removed.

Questionnaires
At the start of the meal day, and after each meal you will be asked to fill in a short questionnaire about your appetite, mood and gastrointestinal sensations. You will also be asked to complete this questionnaire at hourly intervals throughout the meal day. In addition, you will complete a food preference questionnaire before and following lunch on the meal days, and before and following the fitness assessment. At the start and end of the study we will ask you to complete some questionnaires about yourself and your behaviours. Finally, at the end of each week you are exercising will we ask you to complete a questionnaire about your experience of food cravings and mood.

EXERCISE DAYS

On the exercise days you will be required to attend the Human Nutrition Research Unit 5 days a week to expend 500kcal per session. You will need to wear a heart rate monitor during all exercise sessions. You are advised to wear comfortable clothing that you will not get too hot in and trainers or pumps. Drinking water is available near the exercise room, or you may prefer to bring a water bottle. Shower facilities are available within the Unit.

Are there any risks associated with taking part?

There are risks associated with exercising, which include, fainting, dizziness, muscle cramps and pulls. These risks are greatly reduced when the correct precautions are taken and the exercise is undertaken in a controlled and supervised environment. There is also a very small risk of exercise inducing a heart attack; again this is rare and especially rare when there is no pre-existing heart condition.

There are also risks with eating food, which include food allergies and food contamination. To minimise the risk of these anyone who has a nut allergy or is allergic to any of the foods that we are using will not be eligible to participate in the study. All staff that will prepare food for participants will be required to pass a food hygiene and safety course. Staff will adhere to food safety regulations at all times.

The final risks of taking part are those associated with blood samples being taken. The risks include; fainting, bruising and irritation. All researchers taking blood samples will be fully trained, and qualified first aiders. We will take every step to minimise any of the potential risks.

What are the benefits of taking part?
Undertaking regular moderate exercise has been associated with a reduction in resting heart rate, waist circumference, blood pressure, body fat and an increase in fitness. All these factors have been strongly associated with a reduced risk of many health problems including; strokes, heart conditions, some cancers, obesity, diabetes and many others.

Volunteers will be compensated £240 on completion of all study procedures and will receive detailed information about themselves such as information on their metabolism, body composition and fitness levels.

Part 2 – the general conduct of the study

Will my information be kept confidential?
It is important to note that all measurements taken will be kept confidential. After initially completing the consent and contact details form you will be given a unique identity number. All data will then be recorded safely using this number and not your name. The only people who will have access to your data are the researchers on the project and yourself. If any of the data is published, no participants will be referred to by name. If you join the study, authorised personnel will look at some parts of your data. This might include the persons sponsoring the project and collaborators on the project.

What happens if I no longer want to take part in the study?
If you decide at any time that you no longer wish to take part you will be free to withdraw at any time without giving a reason.

What if there is a problem?
If you have a problem with the way you have been treated or have a concern about the study this will be addressed. There are a number of ways you can complain. You can talk to the researchers Dr Michelle Dalton or Dr Catherine Gibbons (0113 343 5753) or the senior investigators Professor John Blundell (0113 343 5742) or Dr Graham Finlayson (0113 343 7601). If you remain unhappy and wish to complain formally, this can be done through the University complaints procedure.

Should my GP be informed of my participation?
Yes, we will be sending out letters to your GP, which will inform them of your participation in an exercise intervention study. They will be informed that you will be exercising 5 times per week at a moderate intensity and that you will be required to undertake a maximal fitness test. We will ask them to sign to say that they give their permission for you to participate. You may also wish to consult with your GP about your involvement.

What will happen to the samples I give?
The blood samples that are to be taken will be sent off to a third party where they will be analysed for chemicals associated with the regulation of appetite. The blood plasma will be sent over to the third party

and the remaining red blood cells will be destroyed. The samples will be labelled by number only, and only the research technician and surgeon collaborating on the project will have access to the data. Any unused plasma will be destroyed. There will be no genetic testing carried out on the samples.

What will happen to the results of the study?
The overall results of the study will be published in scientific journals. In the journal there will be no mention of individuals and confidentially will be maintained. If you would like to read any of the publications arising from this research you can contact us to have a copy sent to you. In addition, personal results can be discussed with a researcher upon completion of the intervention and any questions will be answered fully.

Who is funding the research?
The research has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under Collaborative Project, Grant agreement number 289800.

Who has reviewed the study?
The plans and procedures for this research study have been rigorously scientifically and ethically reviewed. The study has been reviewed by the Institute of Psychological Sciences Ethics Committee and an NHS Research Ethics Committee to protect your rights, safety and well-being.

Contact details
If you have any questions or concerns please contact one of the following:

Dr Michelle Dalton (m.dalton@leeds.ac.uk, 0113 343 5753)
Dr Catherine Gibbons (c.gibbons@leeds.ac.uk, 0113 343 5753)
Dr Graham Finlayson (g.s.finlayson@leeds.ac.uk, 0113 343 7061)
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