**A comparison of daily energy expenditure when breakfast cereal with milk is consumed as a breakfast or a supper.**

**Participant Information Sheet**

You are being invited to take part in a research project. Before you decide whether or not you wish to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If you would like more information about any aspect of the study or have any questions you wish to ask please contact us by e-mail or telephone. Take time to decide whether or not you wish to take part. Thank you for reading this.

**What is the research about?**

The consumption of breakfast is declining in the UK, especially in young people, and it is thought this may have adverse health consequences. A recent study in young women has shown that the regular consumption of cereal with milk increases the intake of some vitamins and minerals, whether consumed in the morning, as a breakfast, or in the evening, as a supper. However, in this study the women who consumed their cereal as a supper put a small amount of weight on (less than 1kg over 12 weeks), and this was statistically significant. No difference in energy intake could be detected between morning and evening consumers.

*We wish to find out whether the consumption of cereal with milk as a breakfast leads to greater energy expenditure in the day than when the cereal with milk is consumed as a supper.*

If you decide to take part in the study you will have to make 5 short visits to the Human Nutrition Unit in the Medical School over a period of three weeks.

**Am I eligible for the study?**

We wish to carry out the study in 20 young women aged between 18 and 24 yr inclusive, who regularly skip breakfast and have a BMI in the healthy range (18.5-25 kg/m2). If you satisfy these criteria then you will be eligible for the study.

**Do I have to take part?**

It is up to you whether you take part. If you do decide to take part you will be given this information sheet to keep, and be asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving a reason.

**What will I be asked to do if I take part?**

If you take part in this study you will be given cereal and milk to eat as a breakfast for four days and as a supper for four days. You will complete a diary in which you record all that you eat and drink during this time. You will also be given a monitor that you will wear like a watch during each day. The monitor will continuously record movement; the information is stored in the monitor and can be downloaded onto a computer to allow us to calculate how much energy you have expended each day you wore the monitor. A schedule to show when you will need to visit the Human Nutrition Unit in the Medical School is shown below. Each visit will take between 10 and twenty minutes.

*Visit 1: Pre-intervention meeting*. You will be asked to complete a short questionnaire about your date of birth and exercise habits. We will confirm your eligibility for the study and ask you to sign the consent form, if you wish to take part. You will receive a diet diary and shown how to complete for 4 weekdays. Your height and weight will be measured.

*Visit 2:* The completed diet diary will be reviewed and you will be asked to complete a further 4 days of diary. You will receive four days’ supply of cereal and semi-skimmed milk and told how much to eat either as a breakfast or a supper, for 4 days. You will be given an activity monitor and shown how to use it. You will be weighed.

*Visit 3:* You will return your completed food diary and bring any leftover cereal. You will return the activity monitor. You will have your weight measured.

*Visit 4:* After about 9 days, you will return to the Unit to receive a second batch of cereal and milk, a new food diary and a new activity monitor. This time you will eat the cereal at a different time of day (if you had it as a breakfast before you will have it as a supper now). You will complete the diet diary and use the activity monitor for 4 weekdays. You will be weighed.

*Visit 5*: This is the last visit. You will return the completed diary, the activity monitor, and any leftover cereal. You will be weighed.

**What are the possible disadvantages and risks of taking part?**

It is not anticipated that there are any risks in taking part. If at any point in the study you have concerns or anxieties, you can talk with the researcher.

**What are the possible benefits of taking part?**

There is no intended benefit to the participants. However, the findings will help us understand more about the possible health benefits of breakfast consumption in terms of maintaining a healthy weight.

**What if something goes wrong?**

Should you have any complaint about the way the research has been conducted you should contact the main supervisor who will discuss the matter with you. In the unlikely event of a serious incident you should contact the Head of the Department (Professor Tim Skerry, whose secretary can be contacted on: 0114 2713112, email: s.patel@sheffield.ac.uk).

**Will my taking part in this project be kept confidential?**

Yes. When you register for the study your name and contact details will be held on a computer in the principal supervisor’s office, which is kept securely locked when not in use. You will be given a study ID number which will be used throughout the study. No measurements will be traceable to your name.

**What type of information will be sought from me and why is the collection of this information relevant for achieving the research project’s objectives?**

We will record information about your age, height and weight. to ensure that you are eligible to take part in the study and to monitor any weight change. We will collect information about your food and beverage intake at the beginning of the study and throughout the cereal and milk intervention, to see whether your diet changes as a result of the intervention.

**What will happen to the results of the research project?**

The research is being carried out as part of a Master’s degree in Human Nutrition at the University of Sheffield. The results will be reported in a thesis, and possibly as a paper in a learned scientific journal. The results may be presented at a scientific meeting. You will not be identified in any presentation or publication.

**Using the findings of this research in the future.**

It is possible that other researchers will find the data collected useful in answering future research questions. The consent form allows you to decide whether you agree for your data to be shared in this way on the understanding that it will not be possible to trace your data back to you.

**Who is organising and funding the research?**

The research is supported by the University of Sheffield, through part of the students’ fees. Kelloggs Company of Great Britain have donated a small amount of money to support the study. The research was conceived of and organized by academic staff in the Human Nutrition Unit at the University of Sheffield.

**Who has ethically reviewed the project?**

The project has been reviewed by the Medical School Ethics Committee.

**Contact for further information**

**Should you require further information please contact either of the following people:**

The researchers:

The primary supervisor: Prof Hilary Powers, 0114 2261346, h.j.powers@sheffield.ac.uk

The secondary supervisor: Dr Elizabeth Williams, 000142159065, e.a.williams@sheffield.ac.uk

**You will able to keep a copy of this Information sheet.**

**Thankyou for the time you have taken to read this.**

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