**Title Page**

**Project Title:** Exercise Effects on Appetite-regulating Hormones and Cardiovascular Risk Factors

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Kingston University London

# DIABETES AND HEART DISEASE RESEARCH

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## Diabetes and cardiovascular heart disease risk: a global matter

According to previous studies, metabolic disorders such as impaired glucose tolerance, insulin resistance (IR) and dyslipidaemia are well recognised risk factors for the onset of atherosclerosis and cardiovascular diseases (CVD). The World Health Organisation (WHO) indicates CVDs are the leading cause of death and responsible for one third of deaths worldwide, especially in developed countries that are wealthy and industrialised.

Another alarming figure is how type 2 diabetes and its associated complications occur prematurely. Previous research reported that at the age of 40 years, men with diabetes and cardiometabolic diseases would on average have 23 years of reduced life expectancy and for women, the corresponding estimate was 20 years. These results highlight the importance of preventing heart disease and other metabolic complications amongst patients with diabetes which will have a positive impact on many people lives.

Kingston University is particularly committed to the prevention and cure of diabetes and cardiovascular diseases using the latest health technologies and through a group of expertise and researchers with different backgrounds who have the same purpose namely improving patient treatment and quality of life through inter-disciplinary research (http://sec.kingston.ac.uk/research/research-groups/drg/, and http://sec.kingston.ac.uk/research/research-groups/senphrg/).

In the following pages you will find all the information about the new research study conducted by the Sport, Exercise, Nutrition and Public Health Research Group (SENPHRG) of Kingston University entitled *Exercise and diabetes/cardiovascular risk factors in South Asian and European individuals.* The project will be led by a team of experts in exercise physiology, nutrition, diabetes and cardiovascular disease research and will benefit from a wide range of equipment for human and exercise physiology testing.

Please read carefully the Participants Information Sheet before agreeing to participate in the study. Moreover, the General Consent Form, the Informed Consent for sub-maximal Testing, the General Health, Physical activity and Food Intake questionnaire have to be respectively signed and filled in before starting any testing. Please email us all the relevant documents or bring them when you attend the physiology laboratory.

For participating in this project you will receive detailed physiological feedback regarding your health status and you will be also helping scientific research in improving prevention and treatment of diabetes and cardiovascular heart disease.

We look forward to seeing you!

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# Participants Information Sheet

**Title of the study: <u>Exercise effects on appetite-regulating hormones and cardiovascular risk disease factors in South Asian and White European men</u>**

**Ethics Code: 1617/034**

Thank you for considering your participation in this study. Below you will find a short background of the project, and an outline of what you would be required to do as a participant. As highlighted by previous studies [1], increasing burden of obesity, T2D and CVD amongst South Asian people rather than in Europeans has created an urgent need to organise health policies and intervention programs to tackle poor nutrition and physical inactivity in this high risk population.

The aim of this research project is to examine metabolic markers (e.g. glucose, insulin, cholesterol, etc.) and specific appetite hormones in response to a single bout of exercise, standardised meal and ad libitum buffet meal, with a comparison between South Asians and Europeans identifying potential relationships with genetic and other metabolic risk factors.

**Overview:** The literature has identified appetite hormones to be important for energy balance and weight control but also as potential predictors of diabetes and related complications. Similarly, exercise has been shown to influence the blood concentration of these hormones, appetite perception and food intake. However, to our knowledge there are no studies investigating the influence of exercise on appetite hormones or food intake in South Asians. Therefore, white European and South Asian participants will perform an acute bout of exercise and some health assessments to compare appetite hormone responses to exercise in these groups.

**Recruitment:** to take part in this study you must belong to ONE of the following ethnicities:

1. White European
2. South Asian (India, Pakistan, Sri Lanka, Nepal, Bangladesh, Maldives and Bhutan)

**What will be required of you:** You will be required to attend the laboratory on three different occasions (preliminary testing, exercise trial and control trial) separated by 1 week.

***Visit 1 (Preliminary testing)***

You will be asked to arrive at the physiology laboratory in the morning and testing will take approximately 1 hour. **Any exercise above normal background activity the day before and on the same day is not permitted**. The following tests will be conducted:

1. Blood pressure measurement
2. Anthropometric assessment (mass, stature and waist circumference)
3. Body composition assessment (fat mass percentage and lean mass percentage)
4. Cheek buccal swab[2] (method to collect DNA from the cells on the inside of a person's cheek)
5. Fitness level assessment ($\dot{V}O_2$max measurement)

Before leaving the lab, you will receive a food diary to record food in the 24 h before the first main trial (visit 2) which you are requested to replicate before the subsequent trial (visit 3). Please return the food diary at the following visit (visit 2).

[1] Misra A, Shrivastava U. (2013). Obesity and dyslipidemia in South Asians. Nutrients, 5, 2708 2733.

[2] Cheek Buccal Swab sample will not be used for DNA sequencing but rather for determining Single Nucleotide Polymorphisms (SNPs) or genetic variants associated with Type 2 diabetes (T2D).

***Visit 2 (Exercise trial)***

You will be required to attend the laboratory after 9 h fasting and having drunk 500 ml of water the night before in order to be in a normal state of hydration. In addition, avoiding exercise, caffeine and alcohol consumption in the previous 24 h will be also requested. The second visit will begin in the morning at 8:00 and will last for 7 h (until 3:00) (Figure 2). Upon arrival at the laboratory, a fasting blood sample will be collected (baseline) followed by a standardised breakfast which will be consumed within 15 min. The 8 h trial will commence with the start of breakfast (0 h). Another blood sample will be collected immediately after breakfast. Sixty minutes of continuous cycling at 65-70% maximum oxygen uptake will be performed using a bicycle ergometer 2 hours after consuming breakfast. Before and after performing the exercise, a blood sample will be collected. After one hour of the exercise (4 h) participants will be given 30 minutes ad libitum access to a buffet meal. Before and after this meal, a blood sample will be collected. Once the second meal has been completed, participants will rest until the end of the trial (sitting reading, working or watching a movie). Another blood sample will be collected before participants leave the laboratory (7 h).

Blood samples will be used to determine metabolic markers, inflammatory markers and appetite hormones, such as cell count, glucose, insulin, total cholesterol , HDL-C, LDL-C, TAG, HbA1C, CRP, TNF-α, IL-6, acylated ghrelin, PYY, leptin and fatty acids. Blood sampling will be performed by venepuncture and cannulation (~ 100 ml, one fifth of a standard blood donation).

***Visit 3 (Control trial)***

The procedures in the control trial will identical to the exercise trial except that no exercise was performed. The blood samples will be collected at the same time of visit 2.

**Before starting any experimental procedures, you will be requested to carefully read the participant information sheet and sign the pre-participation informed consent form. Please, feel free to contact the investigators for any clarification related to the study.**

**Benefits:** You will receive physiological feedback regarding your health status. You will also be helping to add to the body of scientific literature investigating the relationship between exercise, appetite regulation and CVD risk factors.

**Queries** - We are happy to answer any queries that you may have about the study. In the event of detecting an abnormal blood analysis result or physical measurement, we will advise you to contact your GP for further screening and advice.

**Risks** - The risks of drawing blood via venepuncture and cannulation are small, but may include discomfort at the site of puncture, possible bruising around the puncture site and uncommonly, infection or faintness from the procedure. Maximum oxygen uptake test and continuous cycling risks are minimal and may include muscle cramps, muscle strain and/or joint injury and delayed muscle soreness (1 to 2 days afterwards).

**Withdrawal** - Participants are permitted to withdraw from the study at any time without giving reason. In such circumstances, their data will not be used.

**Confidentiality** - All information collected will remain confidential and no identifying information will be used in any publication of this research.

**Privacy and dignity** - Some procedures will involve minimal bodily contact such as the taking of blood samples or measurement of body fat percentage. In no situation will this contact violate your dignity ensuring the observance of factors such as respect, body protecting privacy and treating all participants alike.

**Exclusion criteria** - Participants should be male, non-smokers, aged between 18-50 years, no dieting, physically well to participate in the maximal testing following Physical Activity Readiness Questionnaire (PARQ) clearance, except for those participants that are taking any anticoagulant or anti-inflammatory medication the presence of which will be a reason for exclusion. Moreover, if the participant ticks yes to any of the questions on the PAR-Q form and does not seek GP clearance then they will be excluded from the study.

If you would like to take part in this investigation or have any questions, please do not hesitate to contact the researcher or project supervisor:

**Name of Researcher: Simone Benedetti**
**Email: k1442446@kingston.ac.uk**
**Tel: 020 8417 2476**

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# Informed Consent Form

**Title of the study: Exercise effects on appetite-regulating hormones and cardiovascular risk factors in South Asian and White European men**

**Ethics Code: 1617/034**

**Statement by participant**

I ..... give my consent to the research procedures that are outlined above, the aim, procedures and possible consequences of which have been outlined to me

- I confirm that I have read and understood the information sheet/letter of invitation for this study. I have been informed of the purpose, risks, and benefits of taking part.

*Study title:* **Exercise effects on appetite-regulating hormones and cardiovascular risk factors in South Asian and European individuals**

- I understand what my involvement will entail and any questions have been answered to my satisfaction.
- I understand that my participation is entirely voluntary, and that I can withdraw at any time without prejudice.
- I understand that all information obtained will be confidential.
- I consent the Cheek Buccal Swab sample collection for genotyping analysis[1]
- I understand that although the genotyping analysis that will be performed will not give me significant information about the risk of disease, I would like to be informed about the results anyway
- I agree that research data gathered for the study may be published provided that I cannot be identified as a participant.
- Contact information has been provided should I (a) wish to seek further information from the investigator at any time for purposes of clarification (b) wish to make a complaint.

[1]*Genotyping is the process of determining differences in a specific sequence of the DNA, known as Single Nucleotide Polymorphisms (SNPs) associated with Type 2 diabetes (T2D).*

Participant Signature: ..... Date: .....

Participant Name: .....

Participant ID: .....

**Statement by investigator**

- I have explained this project and the implications of participation in it to this participant without bias and I believe that the consent is informed and that he/she understands the implications of participation.

Researcher Signature: ..... Date:.....

Researcher Name: .....

**Pre Screening for Blood Sampling**

**This form must be completed prior to any work involving blood sampling**

**Title of the study: Exercise effects on appetite-regulating hormones and cardiovascular risk factors in South Asian and White European men**

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- ☐ Fingertip capillary blood
- ☐ Earlobe capillary blood
- ☐ Venous whole blood

- Please indicate the trained phlebotomist who will be performing the venepuncture: .....

- ☐ Lactate (Biosen/Lactate Pro)
- ☐ Glucose (Biosen /Accutrend)
- ☐ HCt measurement (Hawksley capillary tubes and centrifuge)
- ☐ Hemoglobin (HemoCue)
- ☐ Cholesterol
- ☐ Other chemistries
- ☐ Any other; please specify .....

| **Please answer the following questions:** | **YES** | **NO** |
|---|---|---|
| 1. Are you suffering from any known active, serious infection? | ☐ | ☐ |
| 2. Have you had jaundice within the previous year? | ☐ | ☐ |
| 3. Have you ever had any form of hepatitis? | ☐ | ☐ |
| 4. Have you any reason to think you may be HIV positive? | ☐ | ☐ |
| 5. Have you ever been involved in intravenous drug use? | ☐ | ☐ |
| 6. Are you a haemophiliac? | ☐ | ☐ |
| 7. Is there any other reason you are aware of why taking blood might be hazardous to your health? | ☐ | ☐ |
| 8. Is there any other reason you are aware of why taking your blood might be hazardous to the health of the technician? | ☐ | ☐ |

I have been fully informed of and understand:

- **The procedure for the sampling and analysis of blood for the above**
- **The possible risks of contamination to myself and participants**
- **The benefit of being inoculated against Hepatitis B**

I agree to undertake all necessary health and safety procedures and precautions during blood sampling to avoid contamination and accept that I will be excluded from the laboratory should I neglect to demonstrate sufficient care and responsibility.

I have read and understood the University guidelines on the management of needlestick injuries and am aware of what to do in the event of such an accident.

Signed: ..... Date: .....

Name .....

Signed by supervising member of staff: .....