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Please note: All information is provided based on the pre-approved ethics, approved on 26th Feb 2019 (approval confirmation attached at the end of this document).

Study title: Effects of Breaking up Prolonged Sitting on Postprandial Cardiometabolic Disease Risk Markers in Normal Weight Versus Overweight and Obese South Asian Adults

Brief Title: Effects of Breaking up Prolonged Sitting on Postprandial Cardiometabolic Disease Risk Markers in South Asian Adults

Study aim:

The purpose of this study is to examine whether breaking up prolonged sitting with short regular bouts of walking can reduce blood sugar and cholesterol levels after eating, which are risk markers for Type 2 diabetes and heart disease. This study will compare these responses in normal-weight versus overweight/obese South Asian adults.

Methods
Study overview
This two-condition randomised crossover study was conducted according to the Declaration of Helsinki principles and approved by the University of Bedfordshire Institute for Sport and Physical Activity Research Ethics Committee (2019ISPAR003). Participants provided written informed consent prior to taking part in any study procedures. The study was conducted and reported in line with the Consolidated Standards of Reporting Trials (CONSORT) guidance (Moher et al. 2012); see checklist in Supplementary Material S1. The trial was registered with clinicaltrials.gov/ (NCT03898206). Experimental condition order was randomised using an online computer-generated randomisation method (https://www.randomizer.org/). Following a preliminary testing visit, participants completed two experimental conditions separated by ≥ 3 to 28 days to eliminate potential carryover effects (Mikines et al. 1988). Female participants were tested between 1 and 10 days into their follicular phase to minimise the influence of hormonal fluctuations on glucose metabolism (Pulido and Salazar 1999). The study was interrupted by the COVID-19 pandemic, affecting the ability to continue data collection; the associated impact on the study protocol is described below. All testing procedures took place at the University of Bedfordshire Sport and Exercise Science Laboratories.

Participants
South Asian adults aged 18 to 75 years who were normal-weight (BMI 18.0–22.90 kg.m−2) or overweight/obese (BMI > 23 kg.m−2) were eligible to take part. These BMI thresholds were used in line with recommendations for South Asian populations (Bays et al. 2022). Body mass index was calculated as body mass (kg) ÷ height (m)2. ‘South Asian’ was defined as anyone identifying themselves as South Asian or British South Asian (Bays et al. 2022). Exclusion criteria were self-reported CVD, diabetes, any known blood borne disease, pregnancy, recent or current smoker, allergies to the test meals, other known health issues (e.g., neurological disorders), or any injuries that might limit the ability to perform light walking. Participants were recruited from the local community (Luton and Bedford, UK) using adverts through social media posts (e.g., Facebook and Twitter) and distribution of flyers.

Preliminary measures
Height (cm) was measured to the nearest 0.1 cm using a stadiometer (Harpenden 98.602, Crymych, UK). Body mass (kg) was measured to the nearest 0.1 kg, and the percentage of body fat (BF %) was estimated

after fasting for 4 h, using the Tanita BC-418 Segmental Body Composition Analyzer (Tanita Corp., Tokyo, Japan). Waist circumference (cm) was measured at minimal inspiration to the nearest 0.1 cm (Lohman et al. 1988). Resting blood pressure (BP; mmHg) and heart rate (HR; beats.min−1) were measured using an automatic device (Omron M5-I; Omron Matsusaka Co. Ltd., Matsusaka, Japan). Participants were familiarised with the Borg Rating of Perceived Exertion (RPE) scale (Borg 1982) and the Woodway motorised treadmill (Woodway PPS55Med-i, GmbH, Germany). An exercise protocol to determine the walking speed for each participant in the relevant experimental condition began at a speed of 1.2 km.h−1 and increased by 0.5 km.h−1 every 2-min until an RPE of 9 (very light) was reached. This speed was recorded for each participant (Bailey and Locke 2015).

Experimental protocol

Participants attended two separate laboratory visits at 08:30 am in the fasted state (Henson et al. 2016). They were asked to refrain from food and drink containing alcohol and caffeine for 24-h before and to avoid moderate-to-vigorous exercise 48-h before each condition to exclude possible acute influences on insulin sensitivity (Mikines et al. 1988). Participants were asked to weigh and record all food and beverages consumed for 24-h before their first experimental condition and then consume the same volume of food and beverage at the exact times in the 24-h before their second experimental condition. This was to minimise the influence of chronobiological aspects of dietary intake (e.g., timing, and frequency) and macronutrient intake on cardiometabolic risk marker responses (Ekmekcioglu and Touitou 2011). Participants were instructed to travel by car and park as close as possible to the laboratories to minimise physical activity in the hours before each condition. Upon arrival, participants sat for 5-min and resting BP and HR were measured. Afterwards, resting expired air was collected continuously for 5-min using a Metalyzer 3B (Cortex Biophysik, Leipzig, Germany). A fasting blood sample was then taken immediately before consuming a standardised breakfast. The 5-h experimental condition began immediately after the breakfast was consumed. The conditions were as follows, as illustrated in Fig. 1:

(1) SIT: Participants remained seated at a desk for 5-h and were instructed to reduce excessive movement.

(2) INT-SIT: Participants interrupted their sitting every 30-min with walking on a motorised treadmill at a light-intensity for 5-min. Participants started the walking breaks at 30, 60, 90, 120, 150 and 180-min into the breakfast postprandial period and 30, 60 and 90-min into the lunch postprandial period. The walking breaks were undertaken on nine occasions, providing a total of 45-min of light walking.

A standardised lunch meal was provided at 3 h into each condition. Participants were permitted to read books, newspapers, and magazines, or work on a laptop/computer throughout the conditions. When participants needed to use the toilet, they were transported in a wheelchair to avoid physical activity.

Statistical analysis plan

Statistical analyses were performed using SPSS version 26.0 (SPSS Inc., NY, USA). Data were tested for normality using Q–Q plots prior to statistical analysis. Linear mixed models were used to determine the main effect of condition (INT-SIT vs. SIT) for the AUC variables and the condition × time (i.e. sample time points during each condition) interaction for all other outcomes. All models were adjusted for condition order and the baseline value of each outcome. Condition, time and covariates were included as fixed factors and participants were a random factor in each model. Two-tailed statistical significance was set at $p \leq 0.05$. Cohen's d effect sizes were calculated with 0.2, 0.5, and 0.8 indicating a small, medium or large effect, respectively (Cohen 1988). All data are presented as mean (95% confidential interval [CI]) unless stated otherwise.

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Participant Information Sheet

Study title: Effects of breaking up prolonged sitting on postprandial cardiometabolic disease risk markers in normal weight versus overweight and obese South Asian adults.

Principal Investigators: Kamalesh Dey, University of Bedfordshire
Dr Daniel Bailey, University of Bedfordshire

Project date: April 2019 – July 2020

Email: kamalesh.dey@study.beds.ac.uk ; daniel.bailey@beds.ac.uk

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Study title
Effects of breaking up prolonged sitting on postprandial cardiometabolic disease risk markers in normal weight versus overweight and obese South Asian adults.

Invitation paragraph
Dear Participant,

You are being invited to take part in a research study. Before you decide 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. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

The purpose of this research project is to examine whether breaking up prolonged sitting with short regular bouts of walking can reduce blood sugar and cholesterol levels after eating, which are risk markers for Type 2 diabetes and heart disease. We want to test this in normal weight and overweight/obese South Asian adults as South Asians have a higher risk of these diseases. Breaking up sitting may help lower blood sugar and cholesterol levels but we need to test if this happens in South Asians.

What type of participant is needed?
This study requires participants who meet all of the following criteria:
- 18-65 years old
- Male and female
- Has not been diagnosed with diabetes or heart disease.
- Does not smoke
- Is not currently pregnant or given birth in the past 6 months.
- No other issues identified in the health screen questionnaires that may be affected by study participation (e.g. pacemakers fitted, allergies to the test meals).

Do I have to take part?
It is up to you to decide whether or not to 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. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?
You will be invited to attend a preliminary testing session, where you can become familiar with walking at a light intensity on a treadmill and have your height, weight, and body fat measured. After completing this session, you will be invited to two main trials. Trials days will be at least 3 days apart and will start at approximately 9:00 am at the Sport and Exercise Science Laboratories at the University of Bedfordshire (Bedford Campus).

In the 48 hours leading up to a main trial, you will be required to avoid exercise, and in the 24 hours beforehand also avoid alcohol and caffeine. You will also be asked to record the weight and timings of what you eat in a food diary for 24 hours before your first main trial, and replicate your recorded diet exactly before your second trial. You will be asked to fast overnight before you attend (except drinking water). In addition, women will be asked to complete both of their trials during their follicular phase of their menstrual cycle (this is 1-10 days after the start of menstruation/period). Trial days will last be 5 hours long but allow up to 6½ hours as we need to take measures from you before and after. Please bring laptops, books, magazines, newspapers, and DVDs to keep you busy during rest time.

Upon arrival to the two main trial days, your resting blood pressure will be measured and a finger- prick blood sample will be taken. Afterwards, you will be provided with a breakfast meal. Following these procedures, the trial will begin:

> **For trial 1***:* you will be asked to remain seated for the whole duration (5 hours).
>
> **For trial 2**: you will be asked to remain seated for the whole duration, but complete light intensity walking for 5 minutes every 30 minutes.

During each main trial, blood pressure will be taken 11 times and blood samples will be taken 10 times. You will also be asked to wear a face mask for 5 minutes 11 times throughout the main trials, so we can measure how much carbohydrate and fat you are burning.

Breakfast will consist of cornflakes, whole milk, white bread, orange juice, spreadable butter, and strawberry jam. Lunch will be provided consisting of a chicken or cheese sandwich, ready salted crisps, Lucozade drink, and milk chocolate bar. Let us know if you are unable to eat any of these foods and we will find some alternatives for you instead. In addition, Halal and vegetarian option will be available for participants in this study.

What are the possible benefits of taking part?
Everyone that takes part in the study will be provided with a summary of the study findings. In addition, participants will be provided their individual body mass index, blood sugar, and cholesterol) levels.

What are the possible risks of taking part in the study?
This research project involves sitting for 5 hours uninterrupted on one of the trial days. Although there will be no immediate risk to your health from this period of sitting, there will be the possibility it might cause feelings of discomfort, such as back pain. If this happens the trial will be stopped.

The completion of a health screening questionnaire prior to participation is essential, as this will identify any potential issues with you being able to do walking. The walking will be completed on a motorised treadmill, which could cause injury if used incorrectly. To prevent this, you will have a practice session with the treadmill machine and you will need to wear appropriate footwear.

You will have finger prick blood samples taken 10 times during each trial day. To minimise the risk of cross-infection, which is very rare, individuals with a known blood-borne disease will not be allowed to take part in the study and blood samples will be taken by a trained person following best

practice guidelines. During both of the main trial days, you will be provided with a breakfast and a lunch meal. If you are allergic to any of the foods being provided you will be excluded from the study or we will attempt to find suitable alternative foods for you to consume.

What will happen to the data and information collected?
All information and results collected will be kept strictly confidential and also held securely on a password-protected device or locked filing cabinets at the Sport and Exercise Science Laboratories, University of Bedfordshire and will only be accessible to University staff involved with the project. Any information about you will have your name and address removed so that you cannot be recognised from it. In addition, a unique ID code will be used for each participant in this study to maintain their confidentiality.

What will happen to the results of the research study?
Results of this research study may be published, but any data included will in no way be linked to any individual participant and you will not be identified in any publication.

Contacts for further information?
Questions are always welcome, and you are free to ask the research student (Kamalesh Dey), or the supervisory team (Dr Daniel Bailey), any questions at any time. See below for specific contact details.

Many Thanks

Contact Details

Kamalesh Dey
Email: kamalesh.dey@study.beds.ac.uk Phone: 01234 793053

Dr Daniel Bailey
Email: daniel.bailey@beds.ac.uk Phone: 01234 793237

Alternatively, if you would like to speak with someone independent from the research study please contact:

Dr Andrew Mitchell
Head of School of Sport Science and Physical Activity

Phone: 44 (0)1234 793363
Email: andrew.mitchell@beds.ac.uk

Thank you for taking your time to read this information letter. Please keep this form for your records.

Consent form for participants

Study title: Effects of breaking up prolonged sitting on postprandial cardiometabolic disease risk markers in normal weight versus overweight and obese South Asian adults.

Principal Investigators: Kamalesh Dey, University of Bedfordshire
Dr Daniel Bailey, University of Bedfordshire

Project date: April 2019 – July 2020

Email: kamalesh.dey@study.beds.ac.uk ; daniel.bailey@beds.ac.uk

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To be completed by participant

Name of the participant: ……

I have read the information sheet concerning this project and understand what is about. All my further questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:

- My participation in the project is entirely voluntary and I am free to withdraw from the project at any time without disadvantage or prejudice.
- I will be required to attend three sessions to complete the project.
- As part of the study I will have to:
    - Sit for 5 hours on two occasions (on separate days), once prolonged sitting and once with walking breaks where I will complete light intensity walking for 5 minutes every 30 minutes;
    - Have finger-prick blood samples taken a total of 10 times, expired air sample taken 11 times, and blood pressure taken 11 times during each main trial day;
    - Consume one breakfast and lunch meal for each of the main per trial days.
- I am aware of any risks that might be involved with the project.
- All information and data collected will be published but anonymity will be preserved.

Signed: …… (Participant) Date: ……..

Thank you for your participation! Please complete and return this form to the research staff.

Ethical approval confirmation:

26/02/19

ISPAR Ethical Approval Confirmation

Proposer: Kamalesh Dey

Proposal title: Effects of breaking up prolonged sitting on postprandial cardiometabolic disease risk markers in normal weight versus overweight and obese South Asian adults.

Dear Proposer

Your research proposal has now received ethical approval from the Institute for Sport and Physical Activity Research (ISPAR) Ethics Panel and you are now able to proceed with the data collection for the project.

Approval number: 2019ISPAR003

Please note that if it becomes necessary to make any substantive change to the research design, the sampling approach or the data collection methods a further application will be required.

Please be advised that your research project may be subject to an ethical audit at any given time. If you require any further information please contact the ISPAR Ethics Chair, Dr Laura Charalambous.

Kind Regards

Dr Laura Charalambous (ISPAR Ethics Chair)