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Study title: Substituting Sitting with standing and Walking in Free-living Conditions Improves Daily Glucose Concentrations in South Asian Adults Living with Overweight/Obesity

Brief Title: Substituting sitting with standing and walking in Free-living Conditions improves daily glucose profile in South Asians

Study lay title: Effects of substituting sitting with standing and at least light intensity activity in free-living conditions on glycaemia (sugar levels in the blood) in overweight/obese South Asian adults.

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Consent form for participants: see page 5

Participant information sheet

School of Sport Science and Physical Activity
Institute for Sport and Physical Activity Research (ISPAR)
University of Bedfordshire
Polhill Avenue, Bedford, MK41 9EA

Participant Information Sheet

Study title: Effects of substituting sitting with standing and at least light intensity activity in free-living conditions on glycaemia (sugar levels in the blood) in overweight/obese South Asian adults.

Principal Investigators: Kamalesh Dey, University of Bedfordshire
Dr. Julia Zakrzewski-Fruer, University of Bedfordshire

Project date: November 2020 –July 2021

Email: kamalesh.dey@study.beds.ac.uk ; julia.fruer@beds.ac.uk

Telephone: 01234 793053/ 07574748607

Dear Participant,

You are being invited to take part in a research study in free-living conditions. 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.

What is the aim of the project?
South Asians have the highest risk of heart disease and diabetes of any ethnicity in the UK. The purpose of this research project is to examine whether replacing your sitting with standing and light-intensity physical activity can reduce Type 2 diabetes and heart disease risk marker in overweight/obese South Asian adults. The study will compare two activity regimens: 1) Participants will be instructed to restrict walking to ≤1 h/day and standing to ≤1 h/day and the remainder of waking day will be seated apart from visiting the toilet, and 2) Participants will be instructed to substitute minimum 5h/day of sitting with ≥2 h of at least light-intensity physical activity and ≥3 h of standing. Participants will rise from the seated position for 2-5 min every 30 min with standing /light-intensity physical activity.

This research project will be undertaken as part of a PhD degree.

What type of participant is needed?
This study requires participants who meet all the following criteria:
This study requires participants who meet all of the following criteria:

- 18-75 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.
- Has a Body Mass Index (BMI) ≥23 kg/m2. Your BMI is your weight relevant to your height.
- No other issues identified in the health screen questionnaires that may be affected by study participation (e.g. pacemakers fitted).

What will participants are asked to do?

You will be screened by research team for temperature assesment using infared (IF) forehead temperature at the begining of the session. If temperature above 37.8ºC then session will be postponed and if temperature below 37.8ºC then session will go ahead.This safety procedures will be in place to protect the participant and researcher.

You will be invited to attend one visit to our Sport Science Laboratories to complete the following steps; alternatively, all equipment with instructions i.e., glucose monitor, activity monitor and anthropometric measurement materials can be posted to your home address if you are unable to visit laboratory. The steps and measurements will be as follows:

1. **Preliminary testing session:** Your height, weight, and waist circumference will be measured. You will also be familiarised to perform a set of light-intensity physical activities including walking at a slow pace, walking on the spot, and standing. After preliminary testing, you will then be fitted with a physical activity monitor on your thigh and asked to perform a try-out day over the next 24 hours (i.e., substitute a minimum 5 h/day of sitting with ≥2 h of at least light-intensity physical activity and ≥3 h of standing breaks).
2. **Fitting of devices to start the physical activity regimens:** After preliminary session, you will be fitted with a physical activity monitor on your thigh and a small sensor which goes into the skin on the back of your arm that will measure your blood sugar levels continuously. You will be asked to wear the blood sugar monitor for 11 days continuous days. You will need to wear activity monitor for four days continuous days. Afterwards, you need to take off your activity monitor (activPAL) for days 5 to 7 (wash out period) to recharge the activPAL device. You will need to wear activPAL again for 4 days (from days 8 to 11) continuously. During the 11 days, you will be asked to scan the blood sugar monitor attached to your arm 3 times a day using a small device that we will provide to you. You will be shown how to do this and have an opportunity to practice doing it with the research team and provided with written instructions.

During the 11 days that you are fitted with the blood sugar and activity monitors, you will be asked to complete the two conditions described below. The first regimen will be undertaken on days 1-4 and the second regimen will be undertaken on days 8-11. There will be a 3 day wash out period between each of these conditions where you continue your normal daily routines. The two activity regimens are:

Activity regimen 1 – 'Sit regimen' (4 days): Participants will be instructed to restrict walking to ≤1 h/day and standing to ≤1 h/day and the remainder of the waking day will be seated apart from visiting the toilet.

Activity regimens will be separated by at least three days

Activity regimen 2 – 'SitLess regimen' (4 days): Participants will be instructed to substitute a minimum 5 h/day of sitting with ≥2 h of at least light-intensity physical activity and ≥3 h of standing. You will be advised to rise from the seated position for 2-5 min every 30 min as well, so you are regularly breaking up your sitting time.

During each activity regimen, you will also be asked to record all of the activities you do in an activity logbook. In addition, you will be asked to weigh, using standard kitchen scale, and record food and beverage consumption in a diary for the first four days (day 1-4) interventions and replicate the dietary intakes and timings for the second four days (day 5-8) intervention, ensuring that each meal contains at least 50% carbohydrate (examples will be provided to help you). Kitchen scales and a food diary will be provided by research team.

Throughout the 11 days, you will be required to avoid exercise, alcohol and caffeine.

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What are the possible risks of taking part in the study?

This research project involves prolonged sitting for 4 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 screen questionnaire before participation is essential, as this will identify any potential issues with you being able to do the activity or take part in this study. Also, please note that prolonged sitting over the long term can have adverse health effects, so we will provide you with a debrief at the end of the study to encourage you not to follow this regime in everyday life.

The strict safety procedures will be in place to protect the participant and researcher from COVID-19. Therefore, you will be screened by research team for temperature assessment using infrared (IF) forehead temperature at the beginning of the session. If temperature above 37.8ºC then session will be postponed and if temperature below 37.8ºC then session will go ahead. In addition, vigorous hand sanitising facilities will be available throughout your lab session to minimise the possible spreads of COVID-19 infection.

There is a small risk of inflammation or infection at the site of insertion of the blood sugar sensor in your

arm. This will be minimised by only using sensors that have been kept secure in their sterile packaging and ensuring the skin is appropriately cleaned before insertion of the sensor. There is a small risk that the medical grade dressing used to attach the activity monitor to the skin could cause irritation. Please remove the device and attachment if this occurs and contact the research team to discuss an alternative dressing withdrawal from the project. Please contact the research team if you have any queries regarding the blood sugar or activity monitors during the study.

What if you decide you want to withdraw from the project?
It is up to you to decide whether 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; 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. You will be able to withdraw your data up to one calendar month following your final data collection. You can do so by contacting the researcher.

What will happen to the data and information collected?
Everyone that takes part in the study will receive their results for the tests that they complete. All information and results collected will be held securely on a password-protected device or locked filing cabinets at the University of Bedfordshire and will only be accessible to related University staff. Results of this project may be published, but any data included will in no way be linked to any specific participant. Any information about you will have your name and any other identifying material removed so that you cannot be recognised from it.

What if I have any questions?
Questions are always welcome, and you are free to ask the research student (Kamalesh Dey), or the study director (Dr. Julia Zakrzewski-Fruer), 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

School of Sport Science and Physical Activity
Institute for Sport and Physical Activity Research (ISPAR)
University of Bedfordshire
Polhill Avenue, Bedford, MK41 9EA

Participant Consent Form

Study title: Effects of substituting sitting with standing and at least light intensity activity in free-living conditions on glycaemia (sugar levels in the blood) in overweight/obese South Asian adults.

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To be completed by participant

Please select the box

1	I confirm that I have read and understood the study full information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that relevant sections of my medical records and data collected during the study may be looked at by individuals from the University of Bedfordshire or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4	I understand that the information collected about me may be used to support other research in the future, and maybe shared anonymously with other researchers.	☐
5	I agree with my General Practitioner being informed of my participation in the Study or I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my GP and the research team.	☐
6	I agree to take part in the above study.	☐

.....	.....	.....
Name of Participant	Date	Signature

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

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