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The effect of interrupting sitting with regular active breaks on vascular function in adults with type 1 diabetes

Submission date
29/07/2025

Recruitment status
Not yet recruiting

Registration date
05/08/2025

Overall study status
Ongoing

Last Edited
30/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with type 1 diabetes (T1D) are advised to stay physically active to help manage their blood sugar and reduce the risk of heart disease. However, many people with T1D spend long periods sitting during the day — for example, while working or watching TV. New research suggests that sitting for long stretches could affect blood flow and increase the risk of health problems, even in people who are otherwise active. This study will look at how long periods of sitting, compared with sitting that is regularly interrupted with short bouts of light walking, affect blood sugar and blood vessel function in adults with T1D who use a hybrid closed-loop (HCL) insulin delivery system. These systems automatically adjust insulin delivery in response to blood glucose. The aim of the study is to find out whether breaking up sitting time improves glucose levels, reduces inflammation, and helps blood vessel function.

Who can participate?
Patients aged 18 or older who have had type 1 diabetes for more than 3 years and use a hybrid closed-loop insulin delivery system

What does the study involve?
Each participant will take part in two separate 7-hour sessions in a laboratory. The sessions will be spaced at least four days apart, and the order will be random. In one session, participants will sit for the full 7 hours without interruption. In the other, they will break up their sitting every 30 minutes with a 3-minute light walk.
Before each visit:
• Participants will wear a small physical activity monitor (called activPAL4) for 48 hours
• They will record their meals using a free app (MyFitnessPal)
• Standardised meals will be provided to eat the night before and morning of the visit
• They will continue using their continuous glucose monitor (CGM) and insulin pump
During the lab visits:
• Blood vessel health will be measured using ultrasound scans
• Blood pressure and heart rate will be recorded
• Brain blood flow will be monitored using an ultrasound of the head and neck

• Blood samples will be taken to measure inflammation markers (such as interleukin-6 and VCAM-1)
• Glucose levels and insulin use will be tracked continuously using the participant's own devices
After each visit:
• Participants will wear the activity monitor for another 48 hours
• They will continue to record their meals and glucose levels
The main outcome will be a measure of blood vessel function in the leg (called flow-mediated dilation). Other outcomes include blood glucose trends, brain blood flow, and inflammatory markers.

What are the possible benefits and risks of participating?
Participants will help researchers understand how sitting and light movement affect blood sugar and blood vessel health in people with type 1 diabetes.
There are no expected direct health benefits for participants. Risks are low but include discomfort from wearing activity monitors and mild side effects from blood pressure cuffs or blood draws. Blood sugar will be closely monitored throughout, and fast-acting carbohydrates will be given if levels fall too low.

Where is the study run from?
The study is being run by the University of Birmingham, in collaboration with:
• Liverpool John Moores University (LJMU)
• Manchester Metropolitan University (MMU)
Testing will take place in university research laboratories at all three sites.

When is the study starting and how long is it expected to run for?
October 2024 to April 2027. Recruitment will run for 18 months.

Who is funding the study?
The University of Birmingham, UK

Who is the main contact?
Dr Katie Hesketh, Principal Investigator, k.hesketh@bham.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
338230

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Protocol number: RG_24-066

Study information

Scientific Title
Acute effect of breaking up sitting on peripheral and cerebral blood flow in adults with type 1 diabetes using closed-loop systems insulin systems

Study objectives
The primary aim of this research is to investigate the influence of breaking up prolonged sitting with scheduled active breaks on peripheral vascular function, as measured by superficial femoral artery flow-mediated dilation (FMD), in adults with T1D who use HCL systems.

The secondary aims include investigating the impact of scheduled active breaks on peripheral blood flow (superficial femoral artery blood flow and shear rate), cerebral vascular function, continuous glucose monitor (CGM) derived endpoints (as outlined in the most recent consensus (Battelino et al., 2019)), insulin dose and serum concentrations of endothelin-1 (ET-1), vascular cellular adhesion molecule concentrations (VCAM-1), intracellular adhesion molecule (ICAM-1) and interleukin-6 (IL-6).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/02/2025, London - City & East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048171; cityandeast.rec@hra.nhs.uk), ref: 25/PR/0098

Study design
Interventional randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Improvement of vascular health in people with type 1 diabetes.

Interventions
The study will use a randomised, crossover design, in which participants will complete two 7-hour experimental conditions, each separated by at least 4 days. One condition will involve participants sitting uninterrupted for 7 hours (sedentary), while the other will involve participants breaking up 7 hours of sitting with 3 minutes of low-intensity walking every 30 minutes (active breaks).
The order of the two trials will be randomised and counterbalanced using a computer-generated random allocation sequence (www.randomization.com). Due to the nature of the study, blinding of the participants or researchers is not possible. However, participants and researchers will be blinded to experimental condition order (by keeping the order in a sealed envelope) until 07:00 on the morning of the first experimental visit.

Intervention Type
Behavioural

Primary outcome measure
Peripheral vascular function, as measured by superficial femoral artery flow-mediated dilation at pre-intervention (0h) and post-intervention (7h)

Secondary outcome measures

1. Peripheral blood flow as measured by superficial femoral artery blood flow and shear rate at pre-intervention (0h) and post-intervention (7h)
2. Cerebral blood flow as measured by common carotid artery and internal carotid artery blood flow at pre-intervention (0h) and post-intervention (7h)
3. Cerebral vascular function as measured by middle cerebral artery blood velocity and CO2 reactivity at pre-intervention (0h) and post-intervention (7h)
4. Blood pressure as measured using automated resting blood pressure measurement at pre-intervention (0h), 1.75h, 3.5h, 5.25h and post-intervention (7h)
5. Heart rate measured using continuous heart rate monitoring throughout the intervention
6. Markers of glycaemia as measured using a continuous glucose monitor time in range (3.9–10.0 mmol/L) measured via, mean glucose, % time in hypoglycaemia (<3.0 and 3.0–3.9 mmol/L), % time in hyperglycaemia (10.0–13.9 and >13.9 mmol/L), glycaemic variability hypoglycaemia /hyperglycaemia episodes, area under the curve measured
7. Insulin dose as measured using an insulin log of a closed-loop insulin pump, the mean insulin dose of the intervention
8. Serum markers of vascular function as measured using endothelin 1 concentrations, vascular cellular adhesion molecule 1 concentrations, intracellular adhesion molecule 1 concentrations, interleukin-6 concentrations at pre-intervention (0h) and post-intervention (7h)

Overall study start date
01/10/2024

Completion date
01/04/2027

Eligibility

Key inclusion criteria
1. Having been diagnosed with T1D for more than 3 years
2. Aged 18-66 years
3. Not currently meeting physical activity guidelines of > 150 min/week of moderate-intensity exercise or >75 min/week of high-intensity exercise
4. Are sedentary (normally spend more than 5h per day sitting or lying down)
5. Use a closed-loop insulin delivery system

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
66 Years

Sex
Both

Target number of participants
24

Total final enrolment
30

Key exclusion criteria
1. Pregnant or planning to become pregnant
2. <6 months postpartum or stopped breastfeeding <1 month before recruitment
3. Having been diagnosed with cerebrovascular or cardiovascular disease
4. Having a significant history of uncontrolled hyperglycaemia (HbA1c >85 mmol/L)
5. Having a history of severe hypoglycaemia requiring third-party assistance within the last 3 months
6. Cold or flu within the last 2 weeks

Date of first enrolment
01/10/2025

Date of final enrolment
01/03/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences, Y14, Edgbaston
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Study participating centre
Liverpool John Moores University
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Study participating centre
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Sponsor type
University/education

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ROR
https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
University of Birmingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
On completion of the study, the data will be analysed, and results will be disseminated via publication in clinical and physiological journals, presented at National and International conferences and in the form of participant feedback sheets.

Intention to publish date
01/10/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Principal Investigator, Dr Katie Hesketh, k.l.hesketh@bham.ac.uk.

The type of data that will be shared: Data that underlie the results reported, after deidentification (text, tables, figures, and appendices).

Timing for availability: Beginning 3 months and ending 5 years following article publication.

Whether consent from participants was required and obtained: Consent from participants will be required and obtained to access this data

Comments on data anonymization: All files will be pseudonymised at the time of collection and will remain pseudonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	10/02/2025	30/07/2025	No	Yes
Protocol file	version 2	10/02/2025	30/07/2025	No	No