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# Strategies for combatting sedentariness in type 1 diabetes

**Submission date**
30/10/2020

**Recruitment status**
No longer recruiting

**Registration date**
26/04/2021

**Overall study status**
Completed

**Last Edited**
03/04/2024

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Current plain English summary as of 12/05/2021:
Background and study aims
Sitting for long periods of time is harmful to our health. In people with diabetes, this has been shown to contribute to poorer glucose control and an increased risk of developing diabetes complications. Although the NHS and Diabetes UK recommend and encourage all people with diabetes to become more physically active, about 80% of people with type 1 diabetes (T1D) do not meet physical activity recommendations. Simple and acceptable methods that enable people to incorporate physical activity more easily into everyday life and reduce the amount of time spent sitting are urgently needed for people with T1D.

The study aims to assess the impact of breaking-up extended periods of time spent sitting with short frequent bouts of light-intensity walking on glucose levels and risk factors associated with diabetes complications in people with T1D.

Who can participate?
Patients with type 1 diabetes

What does the study involve?
Participants will attend two laboratory-based visits each interspersed by a minimum of one week. On each occasion participants will undergo one of two experimental conditions (Arm 1 and Arm 2), both of which will comprise of a prolonged period of seating with instruction to minimise excessive movement. In Arm 1, participants will remain seated for a total duration of 7-hours. In Arm 2, participants will periodically ‘interrupt’ sitting time with 3-minute bouts of light-intensity walking over the course of the 7 h period. Each experimental condition will involve the consumption of mixed macronutrient meals and periodic blood sampling to determine glycaemic, lipaemic, and vascular inflammatory parameters. In addition, participants will be fitted with a continuous glucose monitoring system which will record glucose levels, and an accelerometer which will monitor physical activity levels for 48-hours before and after each laboratory visit. In addition, participants will be fitted with a small device that will continuously record glucose levels (CGM) from the arm, a device that will monitor physical activity levels (accelerometer).

What are the possible benefits and risks of participating?
Our main aim from the study is to understand whether and how breaking-up prolonged sitting time with short frequent bouts of light-intensity walking impacts glucose levels and vascular health in people with T1D. If this helps to achieve better glucose control then this approach may help enable people with T1D to participate in physical activity safely. If this helps to improve vascular health, then this approach may reduce the risk of developing diabetes complications in the long-term. The research is likely to benefit the participants in the study directly, by providing the opportunity to learn about their individual glucose responses to low-intensity physical activity and the potential impact of this on their diabetes self-management. The information generated in this subsequent study has the potential to benefit the wider T1D population by refining the physical activity advice provided to them.

Importantly, this approach may be particularly useful for people who are unable or unwilling to engage in structured exercise. For some people with T1D this approach may be viewed as an important 'stepping-stone' towards more regular participation in physical activity or exercise, whereas for others, it may be a simple and acceptable intervention to achieve better glucose control in its own right and reduce the risk of future complications.

Participants may face potential risks while participating in the study, such as developing hypoglycaemia before, during, or after each experimental visit, developing hyperglycaemia due to postprandial sedentariness, and experiencing mild bruising or feel faint during venous blood sampling.

Where is the study run from?
The clinical laboratories at the School of Food Science and Nutrition, University of Leeds (UK)

When is the study starting and how long is it expected to run for?
From January 2020 to December 2022

Who is funding the study?
Diabetes UK (UK)

Who is the main contact?
Dr Matthew Campbell
matthewcampbell.sunderland.ac.uk

Previous plain English summary:
Background and study aims
Sitting for long periods of time is harmful to our health. In people with diabetes, this has been shown to contribute to poorer glucose control and an increased risk of developing diabetes complications. Although the NHS and Diabetes UK recommend and encourage all people with diabetes to become more physically active, about 80% of people with type 1 diabetes (T1D) do not meet physical activity recommendations. Simple and acceptable methods that enable people to incorporate physical activity more easily into everyday life and reduce the amount of time spent sitting are urgently needed for people with T1D.

The study aims to assess the impact of breaking-up extended periods of time spent sitting with short frequent bouts of light-intensity walking on glucose levels and risk factors associated with diabetes complications in people with T1D.

Who can participate?
Patients with type 1 diabetes

What does the study involve?
Participants will be fitted with a small device that will continuously record glucose levels (CGM) from the arm, a device that will monitor physical activity levels (accelerometer).

Eligible patients will attend two separate 7 h morning visits to the dedicated clinical testing facility at the School of Food Science and Nutrition at the University of Leeds, with the visit one week apart. Before these visits, participants will be instructed to fast overnight. Participants will have a cannula inserted into the vein of their non-dominant arm for the collection of blood samples. Following the first blood sample, patients will be given a standardised breakfast meal which will be identical at each visit. At 3.5 h after breakfast, participants will be provided with a standardised lunch meal. Participants will remain in the laboratory under observation for a further 3.5 h before being discharged home. Blood samples will be collected hourly, over a total of 7 h.

The participants will be randomly chosen to be in one of two groups. All participants will have baseline measurements collected. In the first visit, the first group will sit in a lounge chair for 7 h, with breakfast provided upon beginning the experimental trial and lunch after 3.5 h. Except for bathroom breaks, participants will be seated in a comfortable lounge-chair and instructed to minimise excessive movement during these visits. In their second visit, the participants in the first group will follow the same instructions during their first visit but will complete a 3 min bout of light-intensity walking on a treadmill (zero gradient, 3.2 km/h) at 1 h after breakfast, then return to the seated position. The second group will complete the 3 min of exercise in their first visit and will remain seated for their second visit.

What are the possible benefits and risks of participating?
Our main aim from the study is to understand whether and how breaking-up prolonged sitting time with short frequent bouts of light-intensity walking impacts glucose levels and vascular health in people with T1D. If this helps to achieve better glucose control then this approach may help enable people with T1D to participate in physical activity safely. If this helps to improve vascular health, then this approach may reduce the risk of developing diabetes complications in the long-term. The research is likely to benefit the participants in the study directly, by providing the opportunity to learn about their individual glucose responses to low-intensity physical activity and the potential impact of this on their diabetes self-management. The information generated in this subsequent study has the potential to benefit the wider T1D population by refining the physical activity advice provided to them.

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Participants may face potential risks while participating in the study, such as developing hypoglycaemia before, during, or after each experimental visit, developing hyperglycaemia due to postprandial sedentariness, and experiencing mild bruising or feel faint during venous blood sampling.

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Who is funding the study?
Diabetes UK (UK)

Who is the main contact?
Dr Matthew Campbell
matthewcampbell.sunderland.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Matthew Campbell

### ORCID ID
http://orcid.org/0000-0001-5883-5041

### Contact details
Faculty of Health Sciences and Wellbeing
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
279434

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
IRAS 279434

# Study information

### Scientific Title
Can frequent activity breaks from prolonged sitting improve glucose control and vascular health in people with type 1 diabetes?

## Study objectives
Frequent bouts of low-intensity activity during prolonged sitting will be associated with improved glycaemic control and parameters of vascular health without increasing the risk of hypoglycaemia.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 04/06/2020, London - Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8376; surrey.rec@hra.nhs.uk), ref: 20/LO/0650

## Study design
Single-centre interventional randomized and counter-balanced two-arm cross-over study

## Primary study design
Interventional

## Secondary study design
Randomised cross over trial

## Study setting(s)
Other

## Study type(s)
Prevention

## Participant information sheet
Please use the contact details (email) to request a participant information sheet (matthew.campbell@sunderland.ac.uk)

## Health condition(s) or problem(s) studied
Prevention of hyperglycaemia and vascular risk factors in patients with Type 1 diabetes mellitus

## Interventions
Current interventions as of 12/05/2021:
Participants will attend two laboratory-based visits each interspersed by a minimum of one week. On each occasion participants will undergo one of two experimental conditions (Arm 1 and Arm 2), both of which will comprise of a prolonged period of seating with instruction to minimise excessive movement. On Arm 1 participants will remain seated for a total duration of 7 h. On Arm 2 participants will periodically ‘interrupt’ sitting time with 3-minute bouts of light-intensity walking over the course of the 7 h period.

Before each visit to the laboratory, participants will be instructed to fast overnight. After arriving at the laboratory, participants will have a cannula inserted into the vein of their non-dominant arm for the collection of blood samples. Following the first blood sample, patients will be given a standardised breakfast meal which will be identical at each visit. At 3.5 h after breakfast, participants will be provided with a standardised lunch meal. Participants will remain in the laboratory under observation for a further 3.5 h before being discharged home. Blood samples will be collected hourly, over a total of 7 h. The participants will be randomly chosen to

be in one of two groups. All participants will have baseline measurements collected. In the first visit, the first group will sit in a lounge chair for 7 h, with breakfast provided upon beginning the experimental trial and lunch after 3.5 h. Except for bathroom breaks, participants will be seated in a comfortable lounge-chair and instructed to minimise excessive movement during these visits. In their second visit, the participants in the first group will follow the same instructions during their first visit but will complete a 3 min bout of light-intensity walking on at 1 h after breakfast, then return to the seated position. The second group will complete the 3 min of exercise in their first visit and will remain seated for their second visit.

For the duration of study involvement participants will be fitted with a continuous glucose monitoring system which will record glucose levels, and an accelerometer which will monitor physical activity levels for 48 h before and after each laboratory visit.

Previous interventions:
Participants will attend two laboratory-based visits each interspersed by a minimum of one week. On each occasion participants will undergo one of two experimental conditions (Arm 1 and Arm 2), both of which will comprise of a prolonged period of seating with instruction to minimise excessive movement. In Arm 1, participants will remain seated for a total duration of 7-hours. In Arm 2, participants will periodically 'interrupt' sitting time with 3-minute bouts of light-intensity walking over the course of the 7 h period. Each experimental condition will involve the consumption of mixed macronutrient meals and periodic blood sampling to determine glycaemic, lipaemic, and vascular inflammatory parameters. In addition, participants will be fitted with a continuous glucose monitoring system which will record glucose levels, and an accelerometer which will monitor physical activity levels for 48-hours before and after each laboratory visit.

### Intervention Type
Other

### Primary outcome measure
Current primary outcome measure as of 12/05/2021:
48 h glycaemic control measured using continuous glucose monitoring for 48 h before and after each laboratory visit

Previous primary outcome measure:
48 h glycaemic control measured using continuous glucose monitoring for 48 h prior to the intervention and for 48 h after the intervention

### Secondary outcome measures
Vascular inflammatory responses to each intervention measured using biochemical analysis techniques at baseline and 1, 2, 3, 4, 5, 6, and 7 h during the laboratory observation window

### Overall study start date
06/01/2020

### Completion date
01/12/2023

## Eligibility

### Key inclusion criteria

1. Diagnosed with type 1 diabetes for a minimum of 5 years
2. Aged between 18-60 years
3. Currently being treated on a stable insulin regimen for ≥6 months consisting of continuous subcutaneous insulin infusion (CSII) or multiple daily insulin (MDI) of a combination of rapid-acting and long-acting insulin
4. Able to understand written English and provide a written consent form
5. Do not currently meet the recommendations for moderate-to-vigorous physical activity (150 min/week) in adults

## Participant type(s)
Patient

## Age group
Adult

## Lower age limit
18 Years

## Upper age limit
60 Years

## Sex
Both

## Target number of participants
32 participants

## Total final enrolment
32

## Key exclusion criteria
1. Newly diagnosed with T1D (<5 years)
2. Not on a stable insulin regimen consisting of CSII or MDI of a combination of rapid-acting and long-acting insulin
3. Currently pregnant or seeking to become pregnant within study timelines
4. Diagnosed with overt diabetes complications (except for mild retinopathy)
5. Presenting with hypoglycaemia unawareness
6. Established and/or diagnosed medical conditions (e.g. haematological disorder, gut mobility or digestion)
7. History of eating disorders (e.g. anorexia, bulimia)
8. History of deep vein thrombosis
9. History of stroke or heart attack (within 6 months before recruitment)
10. History of malignancy
11. History of existing medical or psychiatric conditions
12. Recent history of diabetic ketoacidosis (<6 months)
13. Severe functional limitations (e.g. back pain, and walking difficulties)
14. Dietary allergies or intolerance

## Date of first enrolment
01/06/2021

**Date of final enrolment**
01/06/2023

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Diabetes Centre at Leeds Teaching Hospitals NHS Trust**
Beckett St
Leeds
United Kingdom
LS9 7TP

# Sponsor information

**Organisation**
University of Leeds

**Sponsor details**
Faculty of Medicine and Health Offices
Level 9
Room 9.29
Worsely Building
Leeds
England
United Kingdom
LS2 9NL
+44 (0)1133434897
governance-ethics@leeds.ac.uk

**Sponsor type**
University/education

**Website**
http://www.leeds.ac.uk/

**ROR**
https://ror.org/024mrxd33

# Funder(s)

### Funder type
Charity

### Funder Name
Diabetes UK

### Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Scientific reports will be published in peer reviewed journals and data presented at scientific and patient conferences/meetings.

### Intention to publish date
01/12/2022

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be publicly available upon request from Dr Matthew Campbell (matthewcampbell.sunderland.ac.uk), in anonymised raw form, after the date of publication and for a duration of 3 years. All requests for data should be accompanied with a research proposal which will be reviewed by the institutional ethics committee prior to any decision to release data'

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | | | 30/09/2022 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 01/04/2024 | 03/04/2024 | Yes | No |