# Can activating muscles by breaking up time spent sitting improve blood glucose control for people with type 2 diabetes?

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
22/04/2024		Protocol		
Registration date	Overall study status Completed  Condition category Nutritional, Metabolic, Endocrine	Statistical analysis plan		
23/04/2024		Results		
Last Edited		Individual participant data		
14/01/2025		[X] Record updated in last year		

# Plain English summary of protocol

Background and study aims

Research studies conducted in laboratories and workplaces have shown that regularly interrupting the time that people spend sitting has health benefits. This is especially so for people with type 2 diabetes. A few minutes of upright activity such as walking or doing simple resistance exercises can have significant benefits, especially for their blood-sugar control. It seems likely that the activity of large muscle groups in the upper legs and buttocks is important for these benefits, but this has not been examined directly. It is possible to do so now, using unique "electromyographic shorts" developed in Finland .The aim of this laboratory study is to directly assess the electrical characteristics related to different muscle activity patterns (underdesk pedalling, more standing time, or making sit- to- stand transitions) as interruptions to the prolonged sitting time. The findings will be important for understanding the kinds of simple activities that will be most beneficial for overweight adults with type 2 diabetes.

# Who can participate?

People aged 35 years or older, with type 2 diabetes.

# What does the study involve?

This study involves participants attending a three hour screening visit and four separate laboratory sessions, each lasting approximately seven hours, where their sedentary behavior is modified by specific activities designed to interrupt sitting. Participants will experience different conditions including extended sitting and sitting interrupted by standing, under-desk pedaling, or sit-to-stand transitions, with activities tailored to equalize muscle activation as measured by electromyography.

What are the possible benefits and risks of participating?

Participants may benefit from personalized feedback on muscle inactivity and activity during different working strategies and how these affect their blood sugar levels. Possible risks include mild discomfort from the catheter used for blood sampling and muscle soreness similar to that experienced after typical exercise.

Where is the study run from? South Eastern Finland University of Applied Sciences

When is the study starting and how long is it expected to run for? January 2021 to November 2024

Who is funding the study? Research Council of Finland

Who is the main contact?

Dr Arto J Pesola, arto.pesola@xamk.fi

# Contact information

## Type(s)

Public, Scientific, Principal investigator

#### Contact name

Dr Arto J Pesola

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

475/2021

# Study information

#### Scientific Title

Efficacy of interrupting prolonged sitting with varied muscle activity patterns on glycemic control in type 2 diabetes: a randomized crossover trial

## Acronym

#### **OPTIMUS**

## **Study objectives**

The active sitting interruption conditions (pedaling, standing, or sit-to-stand transitions) will differ to a prolonged sitting condition for primary and secondary outcomes.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 17/03/2021, The Research Ethics Committee of the Northern Savo Hospital District (Kuopio University Hospital, Kuopio, FI 70029, Finland; +358 44 717 2102; tutkimuseettinentoimikunta@kuh.fi), ref: 475/2021

#### Study design

Acute four-armed randomized cross-over trial conducted in a single-centre laboratory

#### Primary study design

Interventional

# Study type(s)

Treatment, Efficacy

## Health condition(s) or problem(s) studied

Overweight/obese inactive and sedentary adults with type 2 diabetes not using insulin medication

#### **Interventions**

Following baseline assessment and familiarisation participants will be scheduled to visit the laboratory for four acute experimental conditions each 7 hours in duration. These conditions are: prolonged sitting (SIT, the reference condition), and prolonged sitting interrupted by different countermeasures—sit-to-stand transitions (SIT-TO-STAND), seated pedaling (PEDAL), and standing (STAND). The duration of each countermeasure is tailored to match the average EMG (aEMG) amplitude observed during the STAND condition. Each participant will be required to complete all four conditions in a randomized order. To randomize four conditions there are 26 possible order permutations, meaning the first 26 participants will be assigned to each of the 26 possible orders (randomization.com). Given the obvious differences between conditions, blinding of research staff and participants is impractical and unnecessary. If in the event of participant withdrawal, exhausting the original batch; new participants will be randomly assigned a permutation from a new batch of 26 permutations sampled without replacement.

The four conditions are as follows:

- 1. SIT: after a 30 min seated steady-state, participants will remain seated for 6,5 hours.
  2. SIT-TO-STAND transitions: after a 30 min seated steady-state, participants first sit 53-58 minutes and then interrupt sitting with 2-7-min bout of sit-to-stand transitions at high intensity (Instruction: do sit-to-stand transitions continuously as quickly as you can [for 2-7 minutes] as many times as you can within this time). This one cycle will be repeated six times, followed by 30 minutes of sitting in the end.
- 3. PEDAL: after a 30 min seated steady-state, participants first sit 45-53 minutes and then use elliptical pedaling while seated for 7-15 minutes (Cubii Pro, Chicago, USA). This one-hour bout

will be repeated six times, followed by 30 minutes of sitting in the end.

4. STAND: after a 30 min seated steady-state, participants first sit 30 minutes and then stand at a height-adjustable desk for 30 minutes. This one-hour bout will be repeated six times, followed by 30 minutes of sitting in the end.

Average EMG amplitude (aEMG) will be matched between the active conditions (SIT-TO-STAND, PEDAL, STAND) based on reference tests. aEMG measured during 30 minutes of sitting and standing will be the reference, and other active conditions' aEMG will be tailored to match the reference aEMG by modifying their duration.

After a condition is completed, participants adhere to a 3 – 10 day washout period before attending the next condition. During this period the participant's habitual living will be monitored with body worn devices to investigate post-condition effects, ensure trial fidelity, and to explore habitual activity and its association with daily glycaemic control (exploratory outcomes).

### Intervention Type

Behavioural

#### Primary outcome(s)

Glucose and insulin 6,5h iAUC collected every 30 minutes using an indwelling catheter inserted into an antecubital vein

## Key secondary outcome(s))

During experimental conditions:

- 1. Triglycerides 6,5h iAUC
- 2. Quadriceps, hamstring and gluteal usual EMG bout amplitude, usual EMG bout duration; EMG duration
- 3. Systolic and diastolic blood pressure
- 4. Central (aortic) systolic blood pressure (aoSBP), central (aortic) pulse pressure (aoPP), aortic augmentation index (aoAix), and aortic pulse wave velocity (aoPWV) 6,5h iAUC
- 5. Self-perceived energy, mood, alertness, productivity, focus, fatigue

#### Sustained effects post experimental conditions:

6. CGM (during 24h post-condition): Average 24 hour glucose, 24-hour net iAUC, Time in range TIR & time above range >=10 mmol/l TAR, Glucose variation (CV; SD; CONGA), average at different times: pre-breakfast post-breakfast, iAUC and peak at different times: pre-breakfast / post-breakfast

Exploratory outcomes during habitual living:

- 7. EMG: Quadriceps, hamstring and gluteal average EMG amplitude (aEMG), usual EMG bout amplitude, usual EMG bout duration; EMG duration
- 8. Sitting, standing, and physical activity metrics (Fibion, Fitbit)
- 9. CGM (after 24h post-condition): Average glucose, net iAUC, time in range (TIR) & time above range ≥10 mmol/l (TAR), Glucose variation (CV; SD; CONGA)

# Completion date

22/11/2024

# **Eligibility**

## Key inclusion criteria

- 1. Aged 35 or more years;
- 2. Have a body mass index (BMI) between 25-50 kg/m<sup>2</sup>;
- 3. Be medically diagnosed with T2D for at least three months
- 4. T2D to be treated by diet alone or with oral hypoglycaemic agents or GLP1 agonists and be on stable treatment regimen for > 3 months
- 5. Inactive (less than 150 minutes per week of self-reported moderate-to-vigorous physical activity and regularly sits for > 7 hours per day for > 3 months)

## Participant type(s)

Other

# Healthy volunteers allowed

No

## Age group

Other

## Lower age limit

35 years

#### Sex

All

#### Total final enrolment

26

#### Key exclusion criteria

- 1. Using insulin to treat T2D
- 2. HbA1c >10% (reflects uncontrolled glycemic levels);
- 3. Current smoker
- 4. Pregnant
- 5. Women of childbearing potential not currently using adequate contraception
- 6. Major illness/physical problems (acute or chronic) that may limit participation in the intervention.
- 7. Unable to communicate in Finnish
- 8. Unable to provide written informed consent

#### Date of first enrolment

21/08/2023

#### Date of final enrolment

31/05/2024

# Locations

# Countries of recruitment

Finland

# Study participating centre Active Life Lab

Raviradantie 22b Mikkeli Finland 50100

# Sponsor information

#### Organisation

South Eastern Finland University of Applied Sciences

#### **ROR**

https://ror.org/051v6v138

# Funder(s)

# Funder type

Government

#### **Funder Name**

Research Council of Finland

#### Alternative Name(s)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

#### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

Research institutes and centers

#### Location

Finland

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

# IPD sharing plan summary

# Data sharing statement to be made available at a later date

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes