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The regulate your sitting time (RESIT) study in type 2 diabetes

Submission date
23/07/2020

Recruitment status
No longer recruiting

Registration date
06/08/2020

Overall study status
Completed

Last Edited
26/04/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. High levels of sitting increase the risk of heart disease and early death in people with type 2 diabetes, regardless of the amount of time they spend exercising. Interventions that help reduce sitting time in this group are therefore needed. Our team has developed an intervention that is designed to reduce the time people with type 2 diabetes spend sitting. The intervention is based on previous work that the research team have carried out over the past few years. The intervention involves patients choosing from a list of tools designed to help reduce their sitting time (so it is tailored to each patient) and patients will also receive support from a health coach and complete an online education session on the risks of sitting and how sitting could be reduced. The aim of this research is to see whether people like and engage with the intervention and how easy it is for us to take some measurements to see how well it worked.

Who can participate?
People with type 2 diabetes aged 18 - 85 years.

What does the study involve?
Participants will be randomly allocated to a control or intervention group for 6 months. The control participants will receive normal diabetes healthcare as usual. Intervention participants will first complete an online interactive education module, which will include information on the health risks of sitting too much, the benefits of reducing sitting, think about their own sitting time and set goals for reducing sitting. This will be followed by access to a list of tools that participants will select from to use during the intervention (e.g. mobile phone and computer apps, and wearable devices that track and provide feedback on sitting). Support will also be given by a health coach at the start and then approximately 2, 6 and 12 weeks into the intervention to help reduce sitting. We will take measures of sitting, physical activity and health (including physical function, body fat, blood sugar and cholesterol, blood pressure, and questionnaires) before the intervention begins and then 3 and 6 months after the first set of measures. We will assess how many people we recruit for the study, how many complete the study and each of the measurements and gather participants' thoughts about the intervention and measurements we take.

What are the possible benefits and risks of participating?
Participants may experience improvements in the participant's health from receiving the intervention; this includes the control group who can have the intervention at the end of the study. We are hoping this study leads to a larger study that may help to change healthcare for people with Type 2 diabetes. Participants will receive £30 of shopping gift vouchers if participants take part in all of the data collection and return the activity monitor each time participants have worn it. Participants will be reimbursed travel expenses for any visits participants make to the university as part of this study.

There is a very small risk of cross-infection when taking blood samples. We will take these samples in line with best practice guidelines to minimise this risk. There is a small chance of skin irritation from the dressing used to attach the activity monitor to the participant's skin. If this happens, the activity monitor can be removed immediately and the problem discussed with the research team. When we measure how well the participant's body functions there may be a risk of injury. During these measures, participants will need to wear suitable footwear to minimise the risk of falling and do the tests without any obvious trip hazards.

Where is the study run from?
The study is being run by Brunel University London (UK)

When is the study starting and how long is it expected to run for?
August 2018 to March 2022

Who is funding the study?
Diabetes UK

Who is the main contact?
Dr Daniel Bailey, daniel.bailey@brunel.ac.uk

Study website
https://www.brunel.ac.uk/research/Projects/reducing-sitting-behaviour-in-people-with-type-2-diabetes

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
279157

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
22727-NHS-Apr/2020- 252, IRAS 279157

Study information

Scientific Title
A randomised-controlled feasibility study of the REgulate your SItting Time (RESIT) intervention for reducing sitting time in individuals with Type 2 diabetes

Acronym
RESIT

Study objectives
The RESIT intervention will be acceptable and it will be feasible to deliver and evaluate the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2020, West of Scotland National Health Service Research Ethics Committee 1 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC5@ggc.scot.nhs.uk), ref: 20/WS/0080

Study design
Mixed-methods randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Participants will be randomly allocated to a control or intervention group for 6 months (an independent researcher will use computer generated lists for randomisation of participants in a 1:1 (intervention:control) ratio with a fixed block size of four).

The control participants will receive normal diabetes healthcare as usual.
Intervention participants will first complete an online interactive education module, which will include information on the health risks of sitting too much, the benefits of reducing sitting, think about their own sitting time and set goals for reducing sitting. This will be followed by access to a list of tools that participants will select from to use during the intervention (e.g. mobile phone and computer apps, and wearable devices that track and provide feedback on sitting). Support will also be given by a health coach at the start and then approximately 2, 6 and 12 weeks into the intervention to help reduce sitting.

Measures of sitting, physical activity and health (including physical function, body fat, blood sugar and cholesterol, blood pressure, and questionnaires) will be taken before the intervention begins and then 3 and 6 months after the first set of measures.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcome measures calculated at the end of the study:
1. Participant eligibility will be calculated as: participants eligible/participants assessed for eligibility x 100
2. Recruitment rate will be calculated as: participants randomised / number of eligible participants screened x 100
3. Retention rate will be calculated as: participants completing the intervention/participants enrolled x 100)
4. Completion rates for the data collection measures will be calculated as: participants providing full outcome data/participants completing the study x 100
5. Acceptability of the intervention will be evaluated using self-report questionnaires that include closed and open-ended questions around engagement with the different intervention components. Self-report questionnaires will be completed by all participants to explore if the data collection measurements affected their behaviour. Semi-structured interviews will be completed with a subset of intervention participants to examine acceptability of the intervention. Semi-structured interviews will also assess the suitability of data collection procedures with a subset of control and intervention participants

Secondary outcome measures

1. Sitting, standing and stepping: this will be measured using the activPAL4 activity monitor worn on the thigh for 24 hours/day for eight consecutive days
Measured at baseline, 3 months and 6 months:
2. Body composition, anthropometry and blood pressure:
2.1. Height will be measured using a stadiometer
2.2. Weight and body fat % will be measured using a bioelectrical impedance analysis device
2.3. Blood pressure will be measured on the right arm in a seated position using an automatic monitoring device
3. Biochemical measures: A finger prick sample technique will be used to collect fasting capillary blood samples to measure glycated haemoglobin, lipid profile and glucose concentrations
4. Psychological, sleep, musculoskeletal and wellbeing measures:
4.1. Perceived fatigue will be measured using the Chalder Fatigue Scale
4.2. Self-efficacy for reducing sitting will be assessed using an adapted Physical Exercise Self-Efficacy Scale
4.3. A perceived sense of control over one's actions and outcomes will be assessed using the Generalised Self-Efficacy Scale and the Cohen Perceived Stress questionnaire will assess perceived stress
4.4. The Positive and Negative Affect Scale will measure positive and negative mood
4.5. The World Health Organization Five Well-Being Index will measure psychological wellbeing and quality of life will be measured using the WHOQOL-BREF questionnaire
4.6. The Pittsburgh Sleep Quality Index questionnaire will assess sleep quality and duration and musculoskeletal symptoms will be measured using the Standardised Nordic Questionnaire.
5. Physical function: this will be assessed using the Short Physical Performance Battery (which includes standing balance, walking speed and rising from a chair) and handgrip strength

Overall study start date
01/08/2018

Completion date
10/03/2022

Eligibility

Key inclusion criteria
1. Aged 18 - 85 years
2. Diagnosed with type 2 diabetes
3. Able to ambulate unassisted (with or without the use of a walking aid)
4. Self-report sitting for ≥7 h/day

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Using insulin medication
2. Unable to communicate in English
3. Pregnant
4. Cognitive or physical conditions interfering with the ability to stand and ambulate

Date of first enrolment
10/09/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brunel University London
Kingston Lane
Uxbridge
United Kingdom
UB8 3PH

Sponsor information

Organisation
Brunel University London

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Sponsor type
University/education

Website
https://www.brunel.ac.uk/

ROR
https://ror.org/00dn4t376

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
Findings will be disseminated to lay, academic, practice, and policy-based audiences including:
- Summary of findings to participants via a newsletter
- Dedicated University webpage, newsletters and social media
- Summary report to key stakeholders in our networks e.g. GP practices, Diabetes UK Support Groups, Leicester Diabetes Centre
- Publication in a scientific journal
- Presentation at conferences

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v4	26/06/2020	07/08/2020	No	Yes
Protocol article		19/03/2021	08/03/2022	Yes	No
Participant information sheet	version 6.0		23/01/2023	No	Yes
HRA research summary			26/07/2023	No	No
Results article		24/04/2024	26/04/2024	Yes	No