

An intervention to decrease sedentary behaviour in young adults at risk of type 2 diabetes: project STAND (sedentary time and diabetes)

Submission date 22/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/02/2011	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 20/10/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

An intervention to decrease sedentary behaviour in young adults at risk of type 2 diabetes: project STAND (sedentary time and diabetes)

Acronym

DRN 465 (STAND)

Study objectives

An intervention to decrease sedentary behaviour in young adults at risk of Type 2 Diabetes Mellitus

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/H0403/13; First MREC approval date 07/05/2010

Study design

Randomised interventional process of care

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Type 2, Not Assigned; Disease: All Diseases, Education

Interventions

Structured education, based on the PREPARE and DESMOND programmes, with the aim of reducing sedentary behaviour. The structured education programme will incorporate movement technology to facilitate participant feedback and self-monitoring.

Intervention Type

Behavioural

Primary outcome measure

Reduced sedentary behaviour measured by an accelerometer at 12 months

Secondary outcome measures

Not provided at the time of registration

Overall study start date

17/11/2010

Completion date

28/02/2013

Eligibility

Key inclusion criteria

1. Age 18-40 years with a BMI >30 (>27.5 for South Asian participants) or age 18-40 years with a BMI >25 (>23 for South Asian participants) plus one additional risk factor:
 - 2.1. Family history of diabetes or cardiovascular disease (in a first degree relative)
 - 2.2. Previous gestational diabetes
 - 2.3. Polycystic ovarian syndrome
 - 2.4. HbA1c >5.8% or previous impaired glucose regulation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Both

Target number of participants

Planned Sample Size: 178; UK Sample Size: 178;

Key exclusion criteria

1. Physical condition which limits full participation in the study
2. Active psychotic illness or an significant illness which, in the view of the investigators, would prevent full participation
3. Steroid use
4. Inability to communicate in verbal and written English
5. Diabetes

Date of first enrolment

17/11/2010

Date of final enrolment

28/02/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Leicester Royal Infirmary

Infirmery Square

Leicester

United Kingdom

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Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Diabetes Research

Level 1 - Victoria, Leicester Royal Infirmary , Infirmery Square

Leicester

England

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Sponsor type

University/education

Website

<http://www.uhl-tr.nhs.uk/>

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/12/2011		Yes	No
Results article	results	01/05/2013		Yes	No
Results article	results	01/12/2015		Yes	No
Other publications	process evaluation	14/01/2017		Yes	No