

# Increasing physical exercise to preserve beta cell function in adult patients with type 1 diabetes mellitus (T1DM)

**Submission date**

21/04/2011

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☒ Protocol

**Registration date**

18/10/2011

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

14/02/2018

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Parth Narendran

**Contact details**

Institute of Biomedical Research

University of Birmingham

Edgbaston

Birmingham

United Kingdom

B15 2TT

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PB-PG-0609-19093

# Study information

## Scientific Title

Increasing physical exercise to preserve beta cell function in adult patients with type 1 diabetes mellitus (T1DM): a randomised controlled trial

## Acronym

T1DM

## Study objectives

Intensive exercise preserves beta cell function in patients with T1DM

On 04/10/2013, the anticipated end date was changed from 31/03/2013 to 31/12/2014.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Birmingham, East, North and Solihull Research Ethics Committee, February 2010, ref: 10/H1206/4

## Study design

Phase 1: Quantitative study, Phase 2: Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

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

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

Type 1 diabetes mellitus

## Interventions

Exercise will be supervised, graded and for a minimum of 150 min/week aiming for 240 min /week over a 1-year period versus control group (no exercise)

## Intervention Type

Other

## Phase

Not Applicable

### **Primary outcome measure**

1. The proportion of patients with T1DM who started the intervention
2. The proportion who adhered to the required intensity of exercise
3. The proportion who dropped out
4. The rate of exercise uptake in the non-intervention arm, an effect which is important to incorporate into the trial design because it will dilute the effect of the intervention observed within the trial
3. The rates of loss of beta cell function (effect size) in the intervention and control arm to enable the power calculations for the definitive trial to be refined

### **Secondary outcome measures**

Beta cell function-measured using a meal stimulate C peptide assay at the study onset, 6 months and 12 months time intervals.

### **Overall study start date**

01/04/2011

### **Completion date**

31/12/2014

## **Eligibility**

### **Key inclusion criteria**

1. A clinical diagnosis of T1DM made within the previous 3 months
2. Age 16-60 years at time of diagnosis
3. Willing to monitor and adjust insulin in order to safely undertake exercise programme

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

92

### **Key exclusion criteria**

1. Pregnancy
2. Inability to give informed consent
3. Inability or unwilling to exercise
4. Any psychological disease likely to interfere with the conduct of the study
5. Patients on beta blocker therapy or other therapies that affect heart rate

### **Date of first enrolment**

01/04/2011

**Date of final enrolment**

31/12/2014

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Institute of Biomedical Research

Birmingham

United Kingdom

B15 2TT

**Sponsor information****Organisation**

University of Birmingham (UK)

**Sponsor details**

University of Birmingham

Edgbaston

Birmingham

England

United Kingdom

B15 2TT

**Sponsor type**

University/education

**Website**

<http://www.rcs.bham.ac.uk>

**ROR**

<https://ror.org/03angcq70>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Programme

## 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?
<a href="#">Protocol article</a>	protocol	18/06/2013		Yes	No
<a href="#">Results article</a>	results	24/01/2018		Yes	No