ISRCTN61403534 https://doi.org/10.1186/ISRCTN61403534

Exercise for type 1 diabetes (EXTOD) education

Submission date
18/05/2016

Recruitment status
No longer recruiting

Registration date
27/07/2016

Overall study status
Completed

Last Edited
08/07/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes mellitus is a life-long condition where a person is unable to control their blood sugar levels. There are two main types of diabetes, type 1 (around 10% of cases) and type 2. In type 1 diabetes (T1DM) the body is unable to produce a hormone called insulin, which is responsible for breaking down glucose and turning it into energy. This means that people suffering from T1DM have to regularly inject insulin in order to keep their blood sugar levels in a healthy range. Exercising regularly has huge benefits for people with T1DM but less than 40% undertake regular exercise. People with T1DM say they do not exercise because they are scared of their blood sugar levels falling, and because they aren't sure what changes to food and insulin-dose should be made when exercising to prevent this. In a previous study, it was found that almost all (96%) T1DM adults felt that education about nutritional adjustments for safe exercise is important, but only one in five felt they had received this information. It was also found that healthcare professionals (HCPs) feel ill-equipped to educate T1DM patients around exercise. The aim of this study is to develop and test the UK's first education programme for people with T1DM, to help them learn how to manage their glucose levels around exercise so that they can safely increase their exercise levels. It will also involve developing training for health care professionals supporting people with Type 1 diabetes using the new education programme.

Who can participate?
Healthcare professionals who look after people with T1DM and people with T1DM can take part in phase one of the study. Adults with T1DM who are on insulin treatment who have attended their local approved T1DM education programme and exercise for at least 30 minutes two a week can take part in phase two of the study.

What does the study involve?
In phase one of the study, groups of 6-8 heathcare professionals (HCPs) and patients meet for focus groups at a local venue. This takes place in a two hour session in which managing Type 1 diabetes, nutrition and exercise is discussed. The session is audio-recorded to capture all of the information and help with the development of the education sessions. Once the draft education programme has been developed enough to be tested, participants are invited to attend an education session as part of the 'development testing cycle'. They then receive the new education programme as part of a group of up to 10 people who have Type 1 diabetes. Participants then provide feedback to the development team, to make the programme the best it can be.

In phase two of the study, participants with T1DM are randomly allocated to one of two groups. Those in the first group receive an update of their usual local Type 1 education course. Those in the second group attend the newly developed education programme. The programme is delivered by a specialist diabetes nurse, a specialist diabetes dietician and a doctor who specialises in diabetes. It provides information about how different exercises affect blood sugars and what other factors influence what happens to blood sugars during and up to 12 hours after exercise. Participants also learn how to adapt their insulin and food intake to keep blood sugar stable during and after exercise. Participants are followed up at six months to assess their blood sugar control. The amount of patients recruited to the study and who remained in the study until the end are also recorded.

What are the possible benefits and risks of participating?
Participation in the trial may provide a benefit, in that increased knowledge gained in managing carbohydrate intake and insulin levels for exercise might in turn improve the stability of participants' blood sugar levels during exercise. Exercising can increase the chances of hypoglycaemia (very low blood sugar levels) during or after exercise. It is hoped that this new programme will help to reduce the chance of this happening. By using the techniques taught on the education course there remains a small chance that participants may have more hypos. To minimise this risk further education will be provided about how participants should manage hypoglycaemia; in addition training can be provided to partners and/ or relatives on how to manage severe hypos. Daytime and out or hours numbers will be provided to participants to ring if they are experiencing frequent hypos and need advice on how to manage these.

Where is the study run from?
Musgrove Park Hospital (lead centre) and Queen Elizabeth Medical Centre (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Miss Niamh Quann (public), niamh.quann@leicester.ac.uk
(updated 08/07/2020, previously: Ms Pattie Laikos (public), pl120@le.ac.uk)
2. Dr Robert Andrews (scientific), r.c.andrews@exeter.ac.uk

Contact information

Type(s)
Public

Contact name
Miss Niamh Quann

Contact details
Leicester Clinical Trials Unit
College of Life Sciences
University of Leicester
Maurice Shock Building
University Road

Leicester
United Kingdom
LE1 7RH
+44 (0)116 229 7243
Niamh.quann@le.ac.uk

Type(s)
Scientific

Contact name
Prof Robert Andrews

ORCID ID
https://orcid.org/0000-0003-4939-1738

Contact details
Department of Diabetes and Endocrinology
Taunton and Somerset NHS Foundation Trust Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA
+44 (0)1823 344986
r.c.andrews@exeter.ac.uk

Additional identifiers

Protocol serial number
30478

Study information

Scientific Title
Supporting adults with Type 1 Diabetes (T1DM) to undertake exercise; Developing and piloting an Education programme for exercise in Type 1 diabetes

Acronym
EXTOD Education

Study objectives
The aim of this study is to develop and pilot an education programme for such people (with accompanying training for health care professionals to deliver this programme) to guide insulin and carbohydrate adjustment for safe exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Coventry & Warwickshire Research Ethics Committee, 16/03/2016, ref: 16/WM/0034

Study design
Interventional; Design type: Process of Care, Education or Self-Management

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Specialty: Diabetes, Primary sub-specialty: Type 1; UKCRC code/ Disease: Metabolic/Diabetes mellitus

Interventions
In the first phase of the study, a structured group education programme to provide adults with T1DM with the skills, knowledge and confidence to manage their diabetes before, during and after exercise will be developed. This involves the conduction of two focus groups, one with people with T1DM, another comprising multidisciplinary Health Care Professionals, to carry out focus group discussions facilitated with a flexible topic guide. Focus groups will take place at each recruiting site (Taunton and Somerset NHS FT, and University Hospitals Birmingham NHS FT), and will be audio-recorded. Analysis of the focus group discussions will follow on from the above process. The education intervention is then developed.
Accompanying resources supporting the developed education intervention will also be developed (including web-based tools), before iteratively testing the intervention in small groups of people with T1DM (n=8 -10) at each site. Using action research methodology, this initial education intervention will be refined according to structured observation and patient feedback. This will be an iterative process of three cycles at each centre. Feedback from each cycle will be collated and used to refine the intervention.
A web-based survey will also be conducted to collect data on current practice regarding education of patients with Type 1 around activity and to identify education gaps. This survey will also be used to collect information on the type of resources that are provided to patients or information that is sign posted to patients. This survey will be highlighted to health care professionals throughout the world through their national healthcare professional groups.

In the second phase of the study, participants will be randomised to receive either usual care (updated local education course) or the newly developed education course, with 40 participants in each group.

Intervention group: The EXTOD education programme will be delivered by a specialist diabetes nurse, a specialist diabetes dietician and a doctor who specialises in diabetes. It will explain about how different exercises affect blood sugars and what other factors influence what happens to blood sugars during and up to 12 hours after exercise. The participants will also learn how to change their carbohydrate intake or insulin doses during this time period to adapt to these factors so that their blood sugars remain within the ideal range. During the programme participants are also asked to to work through some case studies so that they can have a go at thinking about how they would use these new skills in different circumstances. At the end of the programme participants will be provided with a file containing all the information covered and a link to a website. On this website the participants will be able to review the talks given on the programme, get more detailed information about how to manage specific sports and exercises and do more case studies.

Control group: Participants receive usual care as well as an update of their usual local Type 1 education course (e.g. DAFNE, BERTIE, Living with Diabetes).

Updated as of 31/07/2017:
Follow up for all participants involves three more visits (visits 6, 7 and 8).

Visit 6 involves an appointment with the multidisciplinary team comprising a nurse, doctor and dietitian, for a review. No clinical outcomes taken at this visit.

Visit 7 involves a 6-month assessment of the participant. Blood samples will be taken, plus physical measurements. Questionnaires will be completed, an activity monitor fitted and (if using) a continuous blood glucose monitor. Blood glucose and insulin diaries will be given to the participant.

Visit 8 will be the final follow up visit, during which the devices fitted at visit 6 are returned and the data captured.

Previous:
Follow up for all participants involves three more visits ('visits 4, 5 and 6') :

Visit 4 involves an appointment with the multidisciplinary team comprising a nurse, doctor and dietitian, for a review. No clinical outcomes taken at this visit.

Visit 5 involves a 6-month assessment of the participant. Blood samples will be taken, plus physical measurements. Questionnaires will be completed, an activity monitor fitted and (if using) a continuous blood glucose monitor. Blood glucose and insulin diaries will be given to the participant.

Visit 6 will be the final follow up visit, during which the devices fitted at visit 5 are returned and the data captured.

Intervention Type
Behavioural

Primary outcome(s)
1. Eligibility rate is determined as the percentage of patients who are contacted about the study who meet the eligibility criteria
2. Recruitment rate is determined from as the percentage of eligible patients who consent to be involved in the study
3. Adherence rate, determined as the percentage of consented patients that attend the education days and all study visits, and drop out rate, determined as the percentage of consented patients who are lost to follow up

Key secondary outcome(s))
1. Acceptability of outcome measures collection, determined from interviews conducted at the end of the study
2. Acceptability of the intervention, determined from interviews conducted at the end of the study
3. Estimates of statistical properties of potential outcome measures that are needed for sample size calculations for the definitive trial. The potential outcomes that will be measured are (all will be measured at baseline and 6 months):
3.1. BMI(Kg/m2)

3.2. Waist circumference (cm)
3.3. Blood pressure
3.4. Percentage fat (bioimpedence)
3.5. Long term glucose control (HbA1c)
3.6. Hypoglycaemia awareness (Gold score, Edinburgh hypo survey, and hypoawareness score, The Hypoglycaemia Fear Survey, Clarke's Hypoglycaemia Awareness Questionnaire)
3.7. Frequency of hypoglycaemia (Blood Glucose monitoring (Roche Xpert Meter) and Continuous Glucose monitoring (dexcom)
3.8. Physical activity measured with an accelerometer (Actigraph model GT3X, Actigraph, Pensacola, Florida, USA)
3.9. Barriers to exercise measured with the “Barriers to Physical Activity in Type 1 Diabetes' (BAPAD-1) scale.

Completion date
12/07/2019

Eligibility

Key inclusion criteria
Health care practitioners inclusion criteria (phase 1):
1. Any HCP involved in the care of patients with type 1 diabetes
2. Testable knowledge about carbohydrate counting and insulin adjustment

T1DM inclusion critera (phase 2):
1. Type 1 diabetes
2. Aged 18 - 70 inclusive
3. On basal bolus insulin regime
4. Knowledge of carbohydrate counting
5. Have attended their local approved T1DM education programme (DAFNE, BERTIE, Living with diabetes or equivalent)
6. Doing more than 30 minutes of exercise twice a week or have signed up to do a sporting event (run or cycle event for example) that will take place in the next 3-6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

T1DM exclusion critera (phase 2):
1. Pregnancy
2. On insulin pump
3. Hypoglycaemia unawareness
4. Inability to provide informed consent
5. Aged under 18 years or 71 years and over
6. Unable to understand English
7. Any psychological disease likely to interfere with the conduct of the study
8. Unable to exercise

Date of first enrolment
23/06/2016

Date of final enrolment
09/05/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Musgrove Park Hospital
Parkfield drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Queen Elizabeth Medical Centre
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Taunton and Somerset NHS Foundation Trust

ROR

https://ror.org/02y5f7327

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be captured on paper case report forms and entered into a purpose built Macro database, designed and managed by the LCTU and hosted by the University of Leicester servers. Information capable of identifying individuals and the nature of treatment received will be held in the database with passwords restricted to the EXTOD education study staff. Information capable of identifying participants will not be removed from the LCTU or clinical centres or made available in any form to those outside the study. Access to the database will be via a secure password protected web-interface. If study data is required to be transferred electronically between the LCTU and the CI/PI for the purposes of analysis or reporting, this will be done a secure network in an encrypted form.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative results	19/02/2019	08/07/2020	Yes	No
Protocol article	protocol	30/12/2019	07/01/2020	Yes	No

HRA research summary			28/06/2023	No	No
Other publications	paper on developing the intervention	01/06/2020	08/07/2020	Yes	No
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