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Knowledge and barriers related to physical activity in type 1 diabetes

Submission date 17/10/2020	**Recruitment status** No longer recruiting	[ ] Prospectively registered [X] Protocol
Registration date 04/11/2020	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 12/01/2023	**Condition category** Nutritional, Metabolic, Endocrine	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Type 1 diabetes causes the level of glucose (sugar) in the blood to become too high. It happens when the body cannot produce enough of a hormone called insulin, which controls blood glucose.

There are many clear health benefits from regular physical activity; including reduced risks for heart disease, loss of bone strength, obesity, lower back pain, and depression.

Recent publications have shown that in general, people with type 1 diabetes participate in less regular physical activity than non-diabetic populations.

Barriers to physical activity have been shown to reduce physical activity levels, thus it is important to identify the most restrictive and most common barriers experienced by those with type 1 diabetes.

We want to find out the most significant barriers to physical activity, and why they exist. This survey will ask participants about any personal barriers they may have, physical activity habits, and overall knowledge regarding physical activity and type 1 diabetes.

Who can participate?

Those aged 18 or over that are able to read and write in English and have been diagnosed with type 1 diabetes.

What does the study involve?

The study involves the completion of a 61-question anonymous survey that will take about 5-10 minutes to complete.

What are the possible benefits and risks of participating?

None.

Where is the study run from?

Clinical Research Centre Tayside, Ninewells Hospital & Medical School (UK)

When is the study starting and how long is it expected to run for?

September 2019 to January 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Alex St. John,
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Study website
https://dundee.onlinesurveys.ac.uk/kbpa-t1d

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

280818

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 280818

Study information

Scientific Title

Assessing disease management knowledge and barriers related to physical activity in type 1 diabetes via online questionnaire.

Acronym

KBPA T1D

Study objectives

1. What are the most prevalent barriers to physical activity in people with type 1 diabetes?
2. What are the most common health benefits seen in type 1 diabetes as a result of physical activity?
3. What are the best ways for healthcare practitioners to discuss physical activity with people with type 1 diabetes?
4. What are the best recommendations for sport participation for people with type 1 diabetes?
5. What impacts do socioeconomic status have on physical activity and type 1 diabetes?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 09/10/2020 London - Harrow REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8057; harrow.rec@hra.nhs.uk), ref: 20/PR/0081

Study design

Observational cross-sectional survey

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Identification of the most prevalent barriers to physical activity in patients with type 1 diabetes

Interventions

The link to the online survey (https://dundee.onlinesurveys.ac.uk/kbpa-t1d) will be shared on various social media outlets (Twitter, Facebook, Instagram). Upon arriving at the above link, the participant will be directed towards downloading/reading the Patient Information Sheet (PIS) within the first page of the online survey. The following page will act as an acknowledgement of the PIS and the participant's opportunity to ask the research team any questions. The third page of the survey includes definitions of terms within the survey that some participants may not know. Pages 4-10 include the survey body, with the 11th page being a "thank you" message. The total duration of the online survey will be no longer than 10 minutes, with a majority of participants thus far taking 5-6 minutes to complete it. There will be no follow-up within this study.

The survey consists of five main sections as well as an introductory 'Definitions' section.

The 'Definitions' section will outline specific terms and phrases used within the survey with which some participants may be unfamiliar.

Section 1, 'Demographics' will ask participants their age range, gender, location, length of T1D diagnosis, and most recent HbA1c.
Section 2, 'Physical Activity Barriers' will ask participants to indicate how likely an item would keep them from participating in PA during the next six months. Items will include potential barriers to PA.
Section 3, 'Diabetes Management' will ask participants about their current treatment of their T1D, the information they discuss in clinic visits and their knowledge on PA information resources and condition management around PA.
Section 4, 'Exercise' will ask participants about their participation frequency of various forms of exercise, as well as changes from euglycemia around exercise.
Section 5, 'Sport' will ask participants about their participation frequency of sport, as well as changes from euglycemia around sport. It will also ask participants to indicate the degree to which they agree with statements pertaining to PA enjoyment, and the effects of their condition on their sport participation.

Intervention Type

Other

Primary outcome measure

Measured using a 61 item questionnaire at a single time point:
1. Demographics: age range, gender, location, length of T1D diagnosis, and most recent HbA1c
2. Physical Activity Barriers: participants indicate how likely an item would keep them from participating in PA during the next six months. Items will include potential barriers to PA
3. Diabetes Management: current treatment of T1D, the information they discuss in clinic visits and their knowledge on PA information resources and condition management around PA
4. Exercise: participation frequency of various forms of exercise, as well as changes from euglycemia around exercise
5. Sport: participation frequency of sport, as well as changes from euglycemia around sport.

Participants indicate the degree to which they agree with statements pertaining to PA enjoyment, and the effects of their condition on their sport participation

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

03/09/2019

Completion date

01/01/2021

Eligibility

Key inclusion criteria

1. Person with type 1 diabetes
2. Aged 18 or over
3. Able to read and write in English

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Participant is unable to complete the survey.

Date of first enrolment

21/10/2020

Date of final enrolment

01/01/2021

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Clinical Research Centre Tayside
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/12/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	10/07/2020	12/01/2023	No	No
HRA research summary			26/07/2023	No	No