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E-bikes for individuals with type 2 diabetes

Submission date
17/12/2018

Recruitment status
No longer recruiting

Registration date
03/01/2019

Overall study status
Completed

Last Edited
26/04/2023

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
By 2040, approximately 642 million individuals worldwide will be diagnosed with diabetes, of which 90% will be type 2 diabetes mellitus (T2DM). Regular physical activity has been shown to be beneficial in the management of T2DM, with guidelines recommending that adults with T2DM aim to accumulate 150 minutes of moderate to vigorous physical activity per week. However, individuals with T2DM have lower levels of physical activity than their healthy counterparts. Electrically assisted bicycles (e-bikes) have been highlighted as a method through which to increase physical activity while overcoming some of the commonly reported barriers to cycling. The impact of e-cycling on physical activity behaviour and associated health outcomes among individuals with T2DM has yet to be thoroughly explored. This study will explore the feasibility of implementing an e-bike intervention in individuals with T2DM. The overarching aims of this study are a) to assess the feasibility of an e-bike intervention in individuals with type 2 diabetes mellitus and b) to examine the association between the intervention and outcome measures.

Who can participate?
Patients aged 30-70 with type 2 diabetes mellitus

What does the study involve?
Participants are randomly allocated to a 12-week intervention, including e-bike training and the provision of an e-bike for 12 weeks, or to a waiting list to be provided with e-bike training and the option to use an e-bike free of charge for three months at the end of the study. Physical activity behaviour and associated health and transport outcomes are explored before and after provision of an e-bike.

What are the possible benefits and risks of participating?
There are no significant benefits or risks expected as a result of participation in this study.

Where is the study run from?
1. The University of Bristol
2. Life Cycle UK
3. The University of Bath

When is the study starting and how long is it expected to run for?
November 2018 to March 2020 (updated 16/12/2019, previously: January 2020)

Who is funding the study?
NIHR Bristol Biomedical Research Centre (UK)

Who is the main contact?
Ms Jessica Bourne
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
39186

Study information

Scientific Title
Promoting electrically-assisted cycling in people with type 2 diabetes: a randomized pilot study

Study objectives

The main objectives for this study are to:
1. Identify effective methods of recruiting individuals with type 2 diabetes mellitus
2. Determine participants willingness to be randomized
3. Determine study retention rates (i.e., number of individuals that completed the study) and adherence to the intervention and data collection methods
4. Assess intervention fidelity (i.e., was the intervention delivered as intended)
5. Examine the association between the intervention (based on condition allocation) and outcome measures
6. Determine standard deviations of outcome measures to inform sample size calculation for a main trial
7. Assess experiences of intervention delivery from the perspectives of the instructors to evaluate intervention feasibility and sustainability
8. Assess experiences of the intervention from participants perspectives to a) understand the acceptability of the intervention and b) inform further intervention development

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Central Bristol Research Ethics Committee, 13/09/2018, ref: 18/SW/0164

Study design
Randomised; Interventional; Design type: Process of Care, Psychological & Behavioural, Physical

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
Type 2 diabetes mellitus

Interventions
A randomized pilot study will be conducted and will consist of two trial arms; 1) e-biking intervention and 2) waitlist control (no intervention). While the primary aim of this study is to examine feasibility measures, the inclusion of a control group will enable examination of descriptive statistics of the two conditions. In addition, estimates of associations between the intervention and health and travel outcomes will be explored using random-effects linear regression models. Effect estimates will be presented with confidence intervals, but no hypothesis tests will be performed as this is a feasibility study. In addition, this design was

chosen to mirror the design that would be used in a future large-scale randomized controlled trial if appropriate.

Telephone Screening
Prior to entry to the study, the participant will have a telephone conversation with the chief investigator (CI) to establish eligibility. At this time the CI will ask for the individual's age, sex, physical activity level, diabetes history, medication status and cycling experience and confidence. If it is established that the individual may be eligible for the study he/she will be asked to visit their general practitioner for clearance to participate in the study. The CI will provide the individual with an information letter for the GP and a clearance form to be completed. Once the form has been returned to the researchers (either directly from the surgery or via the individual) the CI will contact the potential participant to arrange a time and date for baseline testing. This will mean the CI has no access to potential participant's personal records without their knowledge.

Baseline testing will occur at two locations:
Visit 1: Clinical Research and Imaging Centre, Bristol. Potential participants will attend the Clinical Research and Imaging Centre and will arrive fasted. At this time, informed consent will be obtained, and the following assessments will take place: a) anthropometrics (height, weight, WC), b) baseline fasting blood tests and c) frequent sample oral glucose tolerance test. Two hours after consuming the glucose drink participants will be given breakfast (granola bar and fruit) and will then be provided with the Actiheart monitor and personal GPS device to wear over the upcoming seven days. Participants will also be given a 7-day travel diary to complete. This visit will take approximately 180-minutes

Visit 2: The University of Bath. Seven days after visit 1 the participant will visit the University of Bath for the following measures; cardiorespiratory fitness and verification, full-body scan, peripheral quantitative computed tomography, food preferences task, the motivation for food reward task and a survey. This visit will take approximately 120-minutes.

After this visit individuals will be randomly assigned to one of two conditions. Randomization will be stratified based on gender and will be performed using computer-generated random numbers by the company sealed envelope (https://www.sealedenvelope.com/). Individuals will be informed of their condition allocation via telephone.

Individuals in the e-bike condition will then commence e-bike training with Life Cycle UK (CREATE center, Bristol). This will consist of up to 2 one-to-one training sessions. After completion of the training individuals will be loaned an e-bike for 12 weeks. They will be free to take the bike home and ride as they wish.

In week 10 of the e-bike loan period, the CI will provide individuals in all conditions with an activity monitor, personal GPS, and 7-day travel diary for completion over the upcoming 7-days. At the end of this time, the CI will collect the devices and the diary. The e-bikes will be collected from participants by Life Cycle UK at the end of week 12.

All participants will commence post testing as soon as possible after the end of the intervention.

Visit 3: Clinical Research and Imaging Center, Bristol Measurements to be taken will include anthropometrics, baseline fasting blood and a frequent sample oral glucose tolerance test. This visit is expected to take approximately 180-minutes.

Visit 4: At the University of Bath where the following measures will be taken; cardiorespiratory fitness and verification, full body scan, peripheral quantitative computed tomography, food preferences task, the motivation for food reward task and a survey. This visit will take approximately 120-minutes.

After this time individuals in the e-bike condition will be invited to participate in a one-to-one interview either face-to-face or on the telephone with the study researcher. This is expected to take approximately 60-minutes.

Individuals in the waitlist control will be invited to e-bike training, followed by loaning of the e-bike.

Intervention Type
Device

Primary outcome measure
The feasibility of the intervention and research methods assessed through measurement of:
1. Recruitment to the trial
2. Willingness of participants to be randomized
3. Retention rates
4. Adherence to the intervention and research procedure methods including data collection
5. Intervention fidelity
6. Participants experiences of being part of the trial
These outcomes will be measured at the end of the study. Recruitment, willingness to be randomized, retention rates and intervention fidelity will be descriptively described. Adherence to intervention and research procedures will be measured through calculating the number of participants who complete each research procedure. Participants experiences of being part of the trial will be assessed through analysis of data collected through qualitative interviews conducted after post-intervention testing.

Secondary outcome measures
Secondary outcome measures:
1. BMI and waist circumference measured at pre and post intervention
2. Glycated haemoglobin, glucose, insulin, lipids and C-reactive protein and response to an oral glucose tolerance test measured at pre and post intervention
3. Health-related quality of life measured using the short form SF-36 collected at pre and post intervention

Tertiary outcome measures:

Physiological mechanistic outcome measures:
1. Cardiorespiratory fitness measured using a continuous incremental ramp maximal exercise test pre and post intervention
2. Body composition measured using dual energy X-ray absorptiometry at pre and post intervention
3. Muscle quality, density and area measured using peripheral quantitative computer tomography pre and post intervention

Behavioural outcome measures:
1. E-cycling activity measured using a GPS device throughout the intervention
2. Total physical activity measured using accelerometers pre and just before the end of the

intervention
3. Travel behaviour measured using GPS pre and just before the end of the intervention

Psychological outcome measures:
1. Barriers and facilitators to e-cycling assessed through qualitative interviews post intervention

Overall study start date
01/11/2018

Completion date
01/03/2020

Eligibility

Key inclusion criteria
1. Clinical diagnosis of type 2 diabetes mellitus
2. Aged 30 to 70 years
3. Do not currently engage in 150-minutes of moderate-to-vigorous physical activity per week (assessed by the Get Active Questionnaire; CSEP 2017)
4. Cleared for engaging in physical activity by their General Practitioner
5. Can read, write and speak English

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
40

Key exclusion criteria
1. Currently taking exogenous insulin
2. Uncontrolled hypertension (systolic blood pressure (BP) > 160 mmHg and/or diastolic BP > 90 mmHg), for which the individual is not taking medication
3. Myocardial infarction or stroke within the past six months or evidence of end-stage renal failure or liver disease
4. Any other contra-indications to exercise

Date of first enrolment
12/11/2018

Date of final enrolment
23/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol (lead centre)
NIHR Bristol BRC Nutrition Theme
Bristol
United Kingdom
BS2 8AE

Study participating centre
Life Cycle UK
CREATE Centre
Smeaton Road
Bristol
United Kingdom
BS1 6XN

Study participating centre
University of Bath
1 West University of Bath
Claverton Down
United Kingdom
BA2 7AY

Sponsor information

Organisation
University of Bristol

Sponsor details
Research Governance, Research & Enterprise Development (RED)
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Bristol Biomedical Research Centre; Grant Codes: BRC-1215-20011

Results and Publications

Publication and dissemination plan
It is anticipated that the study protocol will be published in 2019. Planned publication of the study results in a high-impact peer reviewed journal is anticipated for October 2020. This research will be disseminated as part of a PhD thesis.

Intention to publish date
01/05/2022

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/11/2019	05/12/2019	Yes	No
Results article	results	18/04/2023	26/04/2023	Yes	No
HRA research summary			28/06/2023	No	No