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Increasing physical activity levels using e-bikes to enhance prostate cancer survival

Submission date
30/03/2022

Recruitment status
No longer recruiting

Registration date
08/04/2022

Overall study status
Completed

Last Edited
19/08/2024

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Prostate cancer is the most common male cancer in the UK. Regular physical activity has been shown to be beneficial throughout the cancer journey, leading to improvements in quality of life and physical function. Furthermore, higher levels of post-diagnosis physical activity are associated with reduced risk of all-cause mortality and cancer mortality. However, individuals diagnosed with prostate cancer 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, to a clinically significant level, while overcoming some of the commonly reported barriers to cycling. The impact of e-cycling on physical activity behaviour and associated health outcomes amongst individuals with prostate cancer has yet to be explored. This study will explore the feasibility of implementing an e-bike intervention in individuals with prostate cancer. This study will examine whether a 12-week individualised e-bike program is appropriate for individuals being treated for prostate cancer and if it is possible to complete such a program. The study will also examine if e-cycling can have a positive impact on a range of health outcomes including fitness and quality of life.

Who can participate?
Men aged 18 years and over with prostate cancer from a single NHS trust in the Southwest of England (UK)

What does the study involve?
Participants will be randomly allocated to a 12-week intervention, including e-bike training and the provision of an e-bike for 12 weeks, or a waitlist control group that will receive no intervention. Physical activity and associated health outcomes will be explored before and after the provision of an e-bike and 3 months later. Participants in the e-bike group will have training on how to ride the e-bike and how to ride on roads. Additional support will be provided to help overcome some of the challenges to becoming more active that people with cancer face. The researchers will lend people an e-bike, a bike lock, cycling helmet, a bike pannier, and lights for the duration of the 12-weeks. After the 12-week program participants will be provided with information on community-based e-bike schemes or information on where they can purchase an

e-bike. Participants will need to attend three research testing visits across the study period. These visits involve exercise tests and blood samples being taken as well as questionnaires to complete.

What are the possible benefits and risks of participating?
Potential risks in this research relate to the blood sampling, exercise testing procedures, engaging in physical activity in a free-living setting and transmission of COVID-19 through face-to-face contact. The potential benefits are an e-bike loan for 12 weeks, training on using an e-bike from qualified instructors, and increased physical activity levels.

Where is the study run from?
St Michael's Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2021 to July 2024

Who is funding the study?
Cancer Research UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307645

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51629, IRAS 307645

Study information

Scientific Title
Increasing physical activity levels using e-bikes to enhance prostate cancer survival: a randomised pilot study

Acronym
CRANK-P

Study objectives
The e-bike intervention is a feasible and acceptable method of increasing physical activity levels in individuals with prostate cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 15/03/2022, London – Dulwich Research Ethics Committee (Health Research Authority, 2nd Floor 2 Redman Place, Stratford, London, E20 1JO, UK; +44 (0)207 104 8241; dulwich.rec@hra.nhs.uk), ref: 22/LO/0036

Study design
Randomized; Interventional; Design type: Process of Care, Psychological & Behavioural, Complex Intervention, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Prostate cancer

Interventions
A randomized pilot study will be conducted and will consist of two trial arms: 1) an e-biking intervention and 2) a waitlist control (no intervention). While the primary aim of this study is to examine feasibility measures, the inclusion of a control group will enable the examination of descriptive statistics of the two conditions. In addition, estimates of associations between the intervention and health, behaviour and travel outcomes will be explored as change scores between groups. 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.

Screening in the uro-oncology clinic
All individuals that are referred to the uro-oncology clinic will be assessed by the research nurses to determine potential eligibility in the study. In addition, individuals who are nearing the end of their intensive cancer treatment will be reviewed for potential eligibility. Individuals who are deemed eligible will be provided with information about the research study by the research nurses. Individuals that desire further information about the study or are interested in participating will be invited to leave their contact details for a member of the urology nurse research team to contact them.

Telephone screening
A member of the research nurse team will contact potentially eligible individuals via telephone.

During this telephone conversation the research nurse will answer any questions the individual may have and confirm eligibility. Individuals deemed eligible and wishing to participate in the study will have their information passed to the research team at the University of Bristol who will contact them and book them in for baseline assessments.

Consent and baseline testing (Visit 1)
Baseline testing will occur at the Clinical Research Facility, Bristol. Potentially eligible individuals will arrive fasted. At this time informed consent will be obtained and the following measures will be collected: Anthropometrics, baseline fasting blood samples and questionnaires, cardiopulmonary exercise testing (CPET) and hand-grip strength. Prior to conducting the CPET participants will receive a 12-lead ECG. This will be fitted by a research nurse. Once the ECG has been conducted the reading will immediately be sent to the study consultant/cardiologist who will identify whether the participant is cleared for completing the CPET during that visit. Prior to leaving the facility participants will be provided with a physical activity monitor and GPS receiver to wear and a travel diary to complete over the upcoming 7 days. Participants will be provided with a pre-stamped, addressed envelope to return the devices after 7-days of wear. Following completion of this visit participants will be randomly assigned into one of the two conditions using the methods outlined above. Participants will be informed of their allocation by telephone by a member of the research team. Individuals in the waitlist control condition will be informed that they will have e-bike training and access to the e-bikes for 12 weeks in approximately 6 months. Individuals in the study will be asked for consent for their name, telephone number and email to be passed on to Life Cycle UK.

Intervention
Individuals in the e-bike condition will then commence e-bike training with Life Cycle UK (CREATE centre, Bristol). This will consist of up to two one-to-one training sessions (Session 1 will be mandatory and session 2 will be optional). 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 study researcher will provide individuals in all conditions with an activity monitor, personal GPS, and a 7-day travel diary for completion over the upcoming 7 days. The e-bikes will be collected from participants by Life Cycle UK at the end of week 12 or participants can drop the e-bike off with Life Cycle UK.

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

Post testing (Visit 2)
Participants will attend the clinical research facility for post testing. This will be conducted by the research team. Individuals will arrive fasted and the following assessments will be collected: anthropometrics, fasting bloods, questionnaires, CPET and hand-grip strength. The participant will return the activity monitor, GPS, and travel diary at this time.

One-to-one interviews
Participants in the e-bike condition will be invited to participate in a 60-minute one-to-one interview to discuss experiences of using an e-bike and thoughts and feelings regarding the support received during the 12-week loan period. In addition, participants will be asked about their experiences of participating in the study. Individuals in the control condition will be invited to participate in a 30-minute one-to-one interview to discuss their experience of participating in the study.

Three-month community e-bike loan
Following completion of the intervention, all individuals in the e-bike condition will be provided with information on how to access community-based e-cycling initiatives. In addition, a pool of

five e-bikes will be available for participants to loan for 12 weeks from the University of Bristol. These e-bikes have been loaned to the university by Bristol City Council. These e-bikes will be allocated on a first-come, first-serve basis.

Individuals in the waitlist control will have no contact during this time.

At week 10 of the follow-up period, the researcher will send participants in both conditions a physical activity monitor, GPS and travel diary to wear and complete respectively for one week.

Three-month follow-up (Visit 3)
Three months after post-testing participants in both conditions will be invited back for follow-up testing. They will arrive fasted and the following assessments will be collected: anthropometrics, fasting bloods, questionnaires, CPET and hand-grip strength. The participants will return the activity monitor at this time.

One-to-one interviews (e-bike condition only: 60 minutes)
Participants in the e-bike condition will be invited to participate in a 60-minute one-to-one interview at a time of their choosing after the 3-month follow-up testing to discuss their barriers and facilitators to e-cycling during the follow-up time period.

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

At the end of the study all cycling instructors will be invited to take part in a 60-minute one-to-one interview. In addition, members of the clinical teams involved in recruitment will be invited to take part in one-to-one interview.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment, measured by the number of participants recruited by the end of the recruitment period
2. Retention rates, measured by retention of sample by the end of the intervention
3. Adherence to the intervention and data collection methods and the fidelity of intervention delivery measured through observation checklists during the study intervention period
4. Perceptions of the intervention for the deliverers, recruiters, and participants assessed with qualitative interviews after the study intervention
5. Safety or maintenance issues measured by recording incidents throughout the study intervention

Secondary outcome measures
The pilot study will include the following clinically relevant secondary outcome measures, assessed at baseline, post-intervention and 3-month follow-up:
1. Anthropometric outcomes (BMI: weight measured using a digital scale, height measured using a stadiometer, waist circumference measured using a non-stretch tape measure)
2. Cardiometabolic outcomes including fasting glucose and insulin, prostate-specific antigen, insulin-like growth factor (IGF-1 and IGF-II), ICFBP-2 and IGFBP-3 obtained by venepuncture
3. Generic quality of life measured using the EuroQol-5 Dimension-5 level survey (EQ-5D-5L)
4. Cancer specific health-related quality of life measured using the European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30)

5. Urinary health measured using the International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms Module (ICIQ-MLUTS)
6. Erectile dysfunction measured using the International Index of Erectile Function (IIEF)
7. Fatigue measured using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)
8. Self-efficacy to cope with cancer measured using the Cancer Behaviour Inventory- Brief version (CBI-B)

Physiological mechanistic outcomes assessed at baseline and post-intervention and 3-month follow-up:
1. Cardiorespiratory fitness measured using cardiopulmonary exercise testing (CPET); Ergoselect bicycle ergometer (Ergoselect 100, Love Medical, Manchester, UK).
2. Hand-grip strength measured using Jamar Hand Dynamometer (USA)

Behavioural outcomes:
1. E-bike activity: number and duration of e-bike journeys per week (assessed throughout the intervention) assessed using the Fitbit Charge 5 worn during the study intervention period
2. Physical activity assessed using the Axivity AX3 wrist-worn triaxial accelerometer at baseline and during the final week of intervention and at 3-month follow-up
3. Travel behaviour: spatial location data collected using a personal GPS receiver (QStarz International Co. Ltd, Taiwan) and assessed at baseline, the final week of intervention and 3-month follow-up

Psychological outcomes
1. Barriers and facilitators to e-biking to understand the potential determinants of e-biking behaviour, assessed using interviews post-intervention

Overall study start date
01/07/2021

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. Men with high-risk localised prostate cancer (PSA >20 or clinical stage ≥cT2c or Gleason 8/9/10 (NICE Guidance definition)), OR men with locally advanced prostate cancer (in addition to the above, T3b and T4, N0 prostate cancer; and any T, N1 prostate cancer), OR men with metastatic prostate cancer (stage M1)
2. Aged 18 years or over
3. Cleared for engaging in physical activity by the treating consultant

For the instructor/coordinator interviews the inclusion criterion is that individuals have coordinated the CRANK project or delivered e-bike training to participants in the CRANK trial.

For healthcare professionals the inclusion criterion for participating in the interviews is that they have been involved in identifying and/or recruiting individuals for the CRANK-P trial.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

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

Total final enrolment
30

Key exclusion criteria
1. Engage in ≥150 minutes of moderate-to-vigorous physical activity per week
2. Uncontrolled hypertension (systolic blood pressure (BP) >160 mmHg and/or diastolic BP >90 mmHg), for which the individual is not taking medication
3. Comorbidities including myocardial infarction or stroke within the past 6 months or evidence of end-stage renal failure or liver disease, uncontrolled congestive heart failure or angina
4. Use of a mobility aid preventing cycling
5. No previous experience riding a bicycle
6. Any other contra-indications to exercise
7. Are unable to read and communicate in English

Date of first enrolment
25/04/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
University of Bristol

Sponsor details
Research Governance Team, Research & Enterprise Division
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Sponsor type
University/education

Website
http://bristol.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: 29019

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/07/2025

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		24/04/2023	25/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	The development of the CRANK intervention	16/08/2024	19/08/2024	Yes	No