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Increasing physical activity levels using e-bikes to enhance breast 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
Breast cancer is the most 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 breast 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 breast cancer has yet to be explored. This study will explore the feasibility of implementing an e-bike intervention in individuals with breast cancer.

Who can participate?
Women aged 18 years or older, with early breast cancer who have completed their primary breast cancer treatment, and who currently exercise less than 150 minutes per week.

What does the study involve?
Individuals will be randomly assigned to a 12-week intervention, including e-bike training and the provision of an e-bike for 12-weeks, or a waitlist control who will receive no intervention. Physical activity and associated health outcomes will be explored before and after provision of an e-bike and at 3-months post intervention.

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.
Potential benefits include e-bike loan for 12-weeks, training on using an e-bike from qualified instructors, increased physical activity levels.

Where is the study run from?
University of Bristol (UK) the research testing will take place in the Clinical Research facility in St. Michael's Hospital. Training for the e-bike will take place from the Life Cycle UK headquarters.

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

Who is funding the study?
Cancer Research UK and Integrative Cancer Epidemiology Programme (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310422

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 310422, CPMS 51692, CRUK 29019

Study information

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

Acronym
CRANK-B

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/03/2022, London – Dulwich Research Ethics Committee (Health Research Authority, 2nd Floor 2 Redman Place, Stratford, London, E20 1JO; +44 (0)207 104 8241; dulwich.rec@hra.nhs.uk), ref: 22/EM/0010

Study design
Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Breast cancer survival

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, 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 Bristol Breast Care centre
Following primary treatment all individuals treated with breast cancer receive a holistic needs assessment. Prior to this assessment a list of potentially eligible individuals will be prepared by the research nurses following discussions at the multi-disciplinary team meeting. At the holistic needs assessment the research will be introduced to potential participants. Individuals who are deemed eligible and would like more information on the study will be provided with information about the research study at this assessment. 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 nurse research team to contact them. Individuals who are deemed eligible but who are not interested in participating will be invited to share their decision not to participate if they feel comfortable doing so with the clinical team.

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, 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 travel diary to complete over the upcoming seven 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 onto 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 2 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 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 min 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 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 of 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 min)
Participants in the e-bike condition will be invited to participate in a 60 min 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 min 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, the fidelity of intervention delivery will be measured through observation checklists during the study intervention period
4. Perceptions of the intervention for the deliverers, recruiters, and participants through qualitative interviews after the study intervention
5. Safety or maintenance issues will be measured by record of incidents throughout the study intervention

Secondary outcome measures
1. Anthropometric outcomes including BMI calculated using weight measured using the digital scale, height measured using the stadiometer, and waist circumference measured using the non-stretch tape measure at baseline, post-intervention, and 3-month follow-up
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 measured from blood samples obtained by venipuncture at baseline, post-intervention, and 3-month follow-up
3. Generic quality of life measured using the EuroQol-5 Dimension-5 level survey (EQ-5D-5L) at baseline, post-intervention, and 3-month follow-up
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) at baseline, post-intervention, and 3-month follow-up
5. Fatigue measured using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) at baseline, post-intervention, and 3-month follow-up
6. Self-efficacy to cope with cancer measured using the Cancer Behaviour Inventory- Brief version (CBI-B) at baseline, post-intervention, and 3-month follow-up
7. Cardiorespiratory fitness measured using Cardiopulmonary exercise testing (CPET) and the Ergoselect bicycle ergometer (Ergoselect 100, Love Medical, Manchester, UK) at baseline, post-intervention, and 3-month follow-up
8. Hand-grip strength measured using Jamar Hand Dynamometer (USA) at baseline, post-intervention, and 3-month follow-up
9. E-bike activity measured using the 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
10. Physical activity measured using the Axivity AX3 wrist-worn triaxial accelerometer at baseline and during the final week of intervention, and at 3-month follow-up

11. Travel behaviour measured using the spatial location data will be collected using a personal GPS receiver (QStarz International Co. Ltd, Taiwan) at baseline, the final week of intervention,n and 3-month follow-up
12. Barriers and facilitators to e-biking to understand potential determinants of e-biking behaviour measured using participant interviews at post-intervention

Overall study start date
01/07/2021

Completion date
31/08/2024

Eligibility

Key inclusion criteria
1. Women with early breast cancer who have completed their primary breast cancer treatment (i. e., surgery, chemotherapy and/or radiation therapy)
2. Aged ≥18 years
3. Cleared for engaging in physical activity by the treating surgeon

For the instructor/coordinator interviews the inclusion criteria is that individuals have coordinated the CRANK project or delivered e-bike training to participants in the CRANK trial. For health care professionals the inclusion criteria for participating in the interviews is that they have been involved in identifying and/or recruiting individuals for the CRANK-B trial.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

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

Key exclusion criteria
1. Engage in ≥150 minutes of moderate-to-vigorous physical activity per week
2. Individuals with metastatic disease
3. Uncontrolled hypertension (systolic blood pressure (BP) >160 mmHg and/or diastolic BP >90 mmHg), for which the individual is not taking medication
4. Comorbidities including myocardial infarction or stroke within the past six months or evidence of end-stage renal failure or liver disease, uncontrolled congestive heart failure or angina
5. Use of a mobility aid preventing cycling

6. No previous experience riding a bicycle
7. Any other contra-indications to exercise
8. 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
Life Cycle UK
CREATE Centre
Smeaton Road
Bristol
United Kingdom
BS1 6XN

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

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Sponsor information

Organisation
University of Bristol

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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

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

Funder Name
Integrative Cancer Epidemiology Programme

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