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Implications of physical activity on CPET in a prostate cancer sample

Submission date 22/09/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/10/2017	**Overall study status** Completed	
Last Edited 14/09/2022	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public

Contact name
Dr Luke Robles

ORCID ID
http://orcid.org/0000-0003-2882-9868

Contact details
NIHR Bristol BRC Nutrition Theme
Level 3, University Hospitals Bristol Education and Research Centre
Upper Maudlin Street
Bristol
United Kingdom
BS2 8AE
+44 117 342 1765
luke.robles@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2839

Study information

Scientific Title
Feasibility randomised controlled trial to explore implications of a physical activity intervention on Cardiopulmonary Exercise Testing (CPET) and other outcomes in men with localised prostate cancer prior to radical prostatectomy

Study objectives
The aim of this study is to explore the impact of moderate-vigorous physical activity on anaerobic threshold, in men with localised prostate cancer, as measured by Cardiopulmonary Exercixe Testing (CPET).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands – Nottingham 2 Research Ethics Committee, ref:17/EM/0446, 31/01/2018

Study design
Two arm randomised control feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Localised prostate cancer

Interventions
Participants are randomised (1:1) into a physical activity intervention arm or the control arm. This is carried out using a computer generated programme by a member of university staff unrelated to the research study.

Men in the intervention arm are asked to carry out moderate-vigorous physical activity. Participant interventions are asked to walk at a brisk pace for 30 minutes, on at least 5 days a

week, on top of normal physical activity, with the additional aim to walk 10,000 steps every day. Participants are provided with a wrist worn activity monitor which provide real time feedback and motivational reminders. The participants are instructed to do this by the research nurse at their research appointment. They are asked to carry out the intervention from randomisation until their surgery which are approximately 4-6 weeks in duration.

Participants in the control arm are asked to carry on with normal physical activity. Baseline takes place at randomisation, follow up is done just prior to surgery approx. 4-6 post randomisation.

Intervention Type
Behavioural

Primary outcome measure
CPET quantitative measures for fitness pre- and -post exercise intervention are measured using peak oxygen uptake (VO2) and surrogate measures of lung efficiency of ventillatory equivalents for CO2 and O2, as well as the AT
Quantitative measures for fitness pre- and -post exercise intervention will include peak oxygen uptake (VO2) and surrogate measures of lung efficiency of ventilatory equivalents for CO2 and O2 measured using Cardiopulmonary exercise testing (CPET) monitoring at baseline and prior to surgery (approx. 4-6 weeks post randomisation / baseline).

Secondary outcome measures
1. Effects on markers of proliferation and metabolic pathways, including p AMPK/AMPK, p IGF-I receptor/ IGF-I receptor, FASN, PTEN, IGFBP-2, Ki67 and pACCA/ ACCA are measured using blood and prostate tissue at baseline and prior to/during surgery (approx. 4-6 weeks post randomisation/baseline)
2. Randomisation rates are measured using the proportion of eligible men approached who agree to be randomised baseline
3. Retention rates measured using the number of participants successfully followed-up, as a proportion of those who were randomised just prior to surgery (approx. 4-6 weeks post randomisation/baseline)
4. Change in prostate specific antigen (PSA) level collected via blood sample at baseline and prior to surgery (approx. 4-6 weeks post randomisation/baseline)
5. Change in insulin-like growth factor (IGF-I) level collected via blood sample at baseline and prior to surgery (approx. 4-6 weeks post randomisation / baseline)
6. Change in Quality of life collected via validated questionnaire (The Functional Assessment of Cancer Therapy – Prostate subscale (FACT-P) and Functional Assessment of Chronic Illness Therapy – Fatigue subscale (FACIT-F) questionnaires) at baseline and prior to surgery (approx. 4-6 weeks post randomisation/baseline)

Overall study start date
12/06/2017

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Localised prostate cancer
2. Be due to undergo radical prostatectomy

3. Be due to receive treatment at Southmead Hospital, North Bristol NHS Trust
4. Capacity to consent for themselves as judged by a member of the research team with appropriate training and experience
5. Be aged 18 or over, there is no upper age limit
6. Have sufficient understanding of the English language, including being able to read and speak English at a basic level
7. Be physically able to undergo the brisk walking intervention and CPET static bike assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
20

Key exclusion criteria
1. Inability to give informed consent or unavailability for follow-up
2. Being identified as unsuitable to participate following guidance of their clinician
3. The use of a mobility aid other than a walking stick that would prevent them from carrying out the brisk walking intervention
4. Any co-morbidities or other reason for not being able to participate in any aspect of the intervention
5. Participants already achieving physical activity levels over the physical activity intervention level

Date of first enrolment
01/04/2018

Date of final enrolment
20/08/2018

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
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 2PS

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Bristol Biomedical Research Centre (Nutrition Theme)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and via national and international conferences at approximately 30/09/2019.

Intention to publish date
30/09/2019

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?
HRA research summary			28/06/2023	No	No