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Prostate Cancer Evidence of Exercise and Nutrition Trial: nutritional and physical activity interventions for men with localised prostate cancer - feasibility study

Submission date 30/10/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 17/11/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 16/09/2021	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-diet-and-exercise-after-surgery-for-prostate-cancer-prevent

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Protocol Version 1.1, 13.08.2014

Study information

Scientific Title
The feasibility of a randomised controlled trial of dietary and physical activity interventions for men with localised prostate cancer: the PrEvENT trial

Acronym
PrEvENT

Study objectives
This study aims to investigate the feasibility of recruiting and randomising men, diagnosed with localised prostate cancer who are to be treated with radical prostatectomy, into a cohort study and nested RCT of physical activity and nutrition modification

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Cornwall & Plymouth, 09/07/2014, ref: 14/SW/0056

Study design
Feasibility cohort study with a nested 2 x 3 factorial design open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Prostate cancer

Interventions
Participants will each be randomly allocated to one of two physical activity interventions, and one of three nutritional interventions. Men will be asked to follow their allocated interventions for six months.

Physical activity interventions:
1. Brisk Walking - Walking at a brisk pace for 30 minutes, on at least 5 days a week, on top of your normal physical activity
2. Physical Activity Control - Carrying on with your normal levels of physical activity, if you request physical activity advice, standard, publically available, information will be provided as per usual care

Nutritional interventions:
1. Lycopene Supplement Capsules - Taking one lycopene capsule daily (this will be provided)
2. Plant Based Diet - Eating as many portions of fruit and vegetables per day as you can, aiming for at least 5 daily portions. In addition, swapping dairy milk for non-dairy alternatives, for example soy milk, almond milk or rice milk, as often as you can
3. Nutrition Control - Carrying on with usual diet, if you request nutritional advice, standard, publically available, information will be provided as per usual care

Intervention Type
Behavioural

Primary outcome measure
1. As a feasibility trial, the dual primary outcomes will be randomisation rates and adherence to the intervention at six months following randomisation
2. Randomisation rates will be calculated as the proportion of eligible men, who agree to be randomised
3. Adherence to the intervention arms will be calculated independently for the two levels i.e. nutrition and physical activity
4. Adherence to the nutrition intervention will be assessed by analysis of mean serum, plasma or tissue levels, collected at cohort baseline, true trial baseline and 6 months post randomisation. Self-reported nutritional data will also be collected
5. Adherence to the physical activity intervention will be assessed via daily step count, recorded by pedometer and reported by the participants during the 6 month intervention phase. Self-reported physical activity data will also be collected

Secondary outcome measures
1. Intervention tolerability (qualitatively collected data, reporting of adverse events)
2. Trial retention (number of participants successfully followed-up at the end of the 6 month trial, as a proportion of those who we recruited to the trial and randomised into a study arm at the start of the trial)
3. Change in prostate specific antigen (PSA) level (Change in participants absolute PSA level, from randomisation to 6 month follow up, collected via blood sample)
4. Change in insulin-like growth factor I (IGF-I) (Change in participants IGF-I, from randomisation to 6 month follow up, collected via blood sample)
5. Change in general nutrition (self-reported at baseline, 3 and 6 months, food frequency questionnaire (FFQ), Willett et al, 1985)
6. Change in general physical activity levels (self-reported at baseline, 3 and 6 months, Recent Physical Activity Questionnaire, Besson et al, 2010, accelerometers worn for two one week periods at cohort baseline and 6 month follow up)
7. Acceptability and ease of use of accelerometer (self-reported)
8. Urinary symptoms (collected at cohort baseline, true trial baseline, 3 and 6 month follow up, International Continence Society male - Short Form, (ICSmale-SF), Donovan et al., 2000)
9. Psychological factors (collected at cohort baseline, true trial baseline, 3 and 6 month follow up, Profile of Mood States - Short Form (POMS-SF), McNair et al, 1992 and Benefit Finding Scale,

Antoni, 2001)
10. Health beliefs (collected at cohort baseline, true trial baseline, 3 and 6 month follow up, adapted from Prochaska & DiClemente, 1983; Ajzen, 1991)
11. Quality of life measures (collected at cohort baseline, true trial baseline, 3 and 6 month follow up, (Functional Assessment of Cancer Therapy - Prostate) FACT-P, Cella, 1997)
12. General health data (collected at cohort baseline, true trial baseline, 3 and 6 month follow up)
13. Cancer related fatigue (collected at cohort baseline, true trial baseline, 3 and 6 month follow up, Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue), Cella, 1997)
14. General lifestyle factors (Self-reported levels of smoking and drinking)
15. Weight, body mass index and body fat (nurse measured)
16. Attitudes and views of men and their spouses about nutrition and physical activity modification and participation in long term trials (Qualitatively collected data at 6 months follow up)

Overall study start date
01/08/2014

Completion date
01/08/2016

Eligibility

Key inclusion criteria
1. Localised prostate cancer
2. To be undergoing radical prostatectomy
3. Be due to receive treatment at the Urology Centre, Southmead Hopsital, 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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
120 for the randomised controlled trial (150 for the cohort/pre-surgery phase)

Total final enrolment
108

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. Co-morbidities which could prevent participation in the intervention (RCT only) ie. this could include uncontrolled congestive heart failure or angina, recent myocardial infarction or breathing difficulties requiring oxygen use or hospitalisation. Additionally, the use of a mobility aid other than a walking stick
4. Allergies which would prevent participation in the intervention (RCT only) ie. allergy to lycopene
5. Religious beliefs that constrain them from participating in any aspect of the intervention (RCT only)
6. Any other additional reason for not being able to participate in any aspect of the intervention (RCT only)
7. Current heavy consumers of the nutritional element of the intervention, as judged by the research team (RCT only) ie. those who have been taking lycopene supplements daily for more than three months or eat more than five portions of fruit and vegetables every single day
8. Those who routinely exercise vigorously may not be suitable for the intervention (RCT only)

Date of first enrolment
08/08/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Bristol Education Centre
Bristol
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Sponsor information

Organisation
University of Bristol (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) Bristol Nutritional Biomedical Research Unit based at University Hospitals Bristol NHS Foundation Trust (UK)

Funder Name
University of Bristol (UK)

Alternative Name(s)
Universitas Bristolliensis, bristoluniversity, bristoluni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/03/2016		Yes	No
Results article	results	07/03/2017		Yes	No
Results article	results	06/11/2019	11/11/2019	Yes	No
HRA research summary			28/06/2023	No	No