ISRCTN95931417 https://doi.org/10.1186/ISRCTN95931417

Prostate and Diet Study (ProDiet Study): dietary interventions for men at high risk of prostate cancer - feasibility study

Submission date 27/02/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/03/2009	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 11/07/2019	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/trials-search/a-study-men-at-risk-prostate-cancer-can-increase-levels-lycopene-and-green-tea-prodiet

Contact information

Type(s)
Scientific

Contact name
Dr Athene Lane

Contact details
Department of Social Medicine
Bristol University
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01105338

Secondary identifying numbers
Protocol version 1.1 (07/07/2008)

Study information

Scientific Title
The feasibility of a randomised controlled trial of dietary interventions for men at high risk of prostate cancer: the ProDiet study

Acronym
ProDiet

Study objectives
This study aims to investigate the feasibility of recruiting men identified with an increased risk of prostate cancer into a randomised trial of dietary modification. Secondly, to investigate whether dietary modification results in elevated serum levels of the biological active dietary agents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Multi-centre Research Ethics Committee (MREC), approved on 16/12/2008 (ref: 08/H0405/61)

Study design
Randomised 3 x 3 factorial design double-blind feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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 three lycopene-based/matched placebo interventions, and one of three green-tea-based/placebo interventions. Men will be asked to follow their allocated interventions for six months.

Lycopene-based interventions:
1. Dietary advice regarding a daily portion of cooked tomatoes (rich in Lycopene) plus matched placebo tablets
2. Tomato-derived lycopene supplement capsules (oral) daily (30 mg) with control dietary advice recommending five daily portions of fruit and vegetables
3. Control dietary advice recommending five daily portions of fruit and vegetables plus matched placebo tablets

Green-tea-based interventions:
A. Green tea capsules (oral) at 800 mg daily
B. Matched placebo supplement capsules
C. Advice to increase consumption of green tea

Intervention Type
Supplement

Primary outcome measure
Serum lycopene and epigallocatechin-3-gallate (green tea) levels at six months following randomisation

Secondary outcome measures
1. Trial recruitment and randomisation rates (measured at each stage of the study flowchart)
2. Intervention tolerability (adverse event reporting during the six months of follow-up)
3. Compliance (returned tablet counts and self reported counts at six months)
4. Trial retention (participants completing the six month follow-up and the questionnaires)
5. PSA values (measured at one and six months)
6. Dietary compliance with recommendations (dietary questionnaire completed at six months and participant data reporting dietary change)
7. Weight and body mass index (measured at one and six months) to assess whether the interventions have beneficial or deleterious effects on weight
8. Blood pressure (measured at one and six months) to assess whether there are any overall health benefits to the healthy diets
9. Attitudes and views of men and their spouses about dietary modification and participation in long term trials. Only a subset of participants will be included in this part of the study (one qualitative interview per participant; conducted throughout the study).
10. Anxiety, depression and pschycological state - measured by the Hospital Anxiety and Depression Scale and the Profile of Moods States at enrolment, one month and six months
11. Urinary symptoms - measured at enrolment, one month and six months by the International Continence Society 'male short-form' (ICSmaleSF) questionnaire, which includes voiding and incontinence scores, nocturia, frequency and urinary-specific quality of life care data sources

Overall study start date
01/04/2009

Completion date
30/09/2010

Eligibility

Key inclusion criteria
1. Age 50-69 years on the date of preparation of the list at the general practice of potential participants for the ProtecT study (registered with ISRCTN20141297)
2. Male gender
3. ProtecT participants with a prostate-specific antigen (PSA) test between 2.5 to 2.95 ng/ml or a PSA level of at least 3.0 ng/ml with a negative biopsy (10 core procedure) from the ProtecT study
4. Enrolled in the ProMPT study and willing to be contacted about further studies
5. Able to give informed written consent to participate
6. Registration with the participating general practice

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
126

Total final enrolment
128

Key exclusion criteria
1. A PSA >=20 ng/ml (indication of prostate cancer or prostatitis)
2. History of allergic reactions to green tea or lycopene containing products (including guava, watermelon)
3. Concurrent medication with finasteride or dutasteride (elevates PSA values)

Date of first enrolment
01/04/2009

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Bristol University
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
c/o Anna Brooke
Research Governance Officer
University of Bristol
Research and Enterprise Development
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

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

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (ref: C11046/A10052)

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
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?
Results article	nested interview study results	03/05/2014		Yes	No
Results article	nested interview study results	05/11/2014		Yes	No
Results article	results	15/04/2019	11/07/2019	Yes	No