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Nutrition and physical activity trial in prostate cancer patients

Submission date 09/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/10/2009	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-diet-exercise-hormone-therapy-prostate-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial to evaluate the efficacy of a 6 month dietary and physical activity intervention for prostate cancer patients receiving androgen deprivation therapy

Acronym
Prostate Nutrition Study

Study objectives
Hypothesis is that the diet and physical activity intervention will;
1. Prevent or reduce weight gain, and prevent or reduce the increase in body fat mass typically found in patients treated with androgen deprivation therapy compared to the controls
2. Improve fatigue scores for those in the intervention group compared to those in the control group
3. Improve quality of life scores for those in the intervention group compared to those in the control group

As of 01/03/2011 the anticipated end date for this trial has been updated from 30/09/2010 to 01/07/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland, approved on 21/05/2009 (ref: 09/NIR03/41)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Prostate cancer patients receiving androgen deprivation therapy

Interventions
The intervention will consist of two components, a dietary intervention and a moderate physical activity intervention.

Dietary modification: The intervention group will meet individually with a nutritionist to receive dietary advice based on their usual diet measured at baseline in order to encourage them to adopt a diet to meet current dietary guidelines listed below:
a. Eat 5 or more servings of vegetables and fruits per day
b. Reduce total fat intake 30%-35% of total energy, with <10% saturated fat intake
c. Limit polyunsaturated fat intake to 10% of daily total energy intake
d. Limit consumption of processed meats
e. Eat fibre-rich foods. Aim to consume 25 to 35g of fibre daily.
f. Limit alcohol intake 28 units/ week
g. Limit intake of foods high in salt and/or sugar

Moderate physical activity: Brisk walking at least 30 min per day, in addition to usual activities on 5 or more days of the week.

The control group will receive usual care only.

Details of Joint Sponsor:
Queens University Belfast
Research and Regional Services
Room 103, Lanyon North
Belfast, BT7 1NN
United Kingdom

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Body Composition: Anthropometric measurement at baseline, mid-time (3 months) and end (6 months)
2. Fatigue: Self administrated Fatigue Severity Scale (FSS) questionnaire at baseline, mid-time (3 months) and end (6 months)
3. Quality of life: Self administrated Functional Assessment of Cancer Therapy-General (FACT-G) and Functional Assessment of Cancer Therapy-Prostate (FACT-P) questionnaire at baseline, mid-time (3 months) and end (6 months)

Secondary outcome measures
The feasibility of dietary and physical activity intervention will be assessed by drop-out and effectiveness of intervention at the end of intervention.

Overall study start date
06/08/2009

Completion date
01/07/2011

Eligibility

Key inclusion criteria
1. Histologically proven adenocarcinoma of prostate
2. Commencing Lutenising Hormone Releasing Hormone Agonist (LHRHa) therapy for at least 6 months OR already being treated with LHRHa and planned to continue for at least a further 6 months
3. No age limit

Participant type(s)
Patient

Age group
Other

Sex
Male

Target number of participants
94

Total final enrolment
94

Key exclusion criteria
1. Co-morbid condition that limits physical activity such as severe cardiac disease, recent myocardial infarction, severe asthma or breathlessness, uncontrolled hypertension (blood pressure >160/95 mm/Hg) or severe pain
2. Medical conditions that requires a reduced fruit and vegetable diet (e.g. kidney failure)
3. Life expectancy of less than 2 years

Date of first enrolment
06/08/2009

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre

Centre for Public Health
Belfast
United Kingdom
BT12 6BJ

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Knockbracken Healthcare Park
Saintfield Rd
Belfast
Northern Ireland
United Kingdom
BT8 8BH

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
University/education

Funder Name
Queen's University Belfast (UK)

Alternative Name(s)
QUB

Funding Body Type
Private sector 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
Not provided at time of registration

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	12/08/2010		Yes	No
Results article	results	01/09/2015		Yes	No
Plain English results			26/10/2022	No	Yes
HRA research summary			28/06/2023	No	No