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PRO-MAN study: To determine whether nutrition counselling and self-help resources will affect body weight and quality of life of prostate cancer patients

Submission date
20/12/2013

Recruitment status
No longer recruiting

Registration date
25/02/2014

Overall study status
Completed

Last Edited
08/02/2017

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study among prostate cancer patients to assess the feasibility of monthly individually-tailored telephone calls and the engagement of the patients in web-based self-help resources following recommendation by physicians. We will assess the effectiveness of nutrition counselling and self-help resources on the maintenance of healthy body weight. The findings should help to inform clinical practice.

Who can participate?
Men aged at least 16 years diagnosed with prostate cancer in the Grampian region from the Urological Cancer Charity (UCAN) database.

What does the study involve?
At your first visit we will measure your weight and height and ask you to complete a quality of life questionnaire. You will be randomly assigned to Group A or Group B. If you are assigned to Group A, you will not be given any instruction on diet and exercise on the first visit. We will arrange for you to come to the UCAN Care Centre for a second visit 12 weeks later when your weight will be measured and you will be asked to complete a second quality of life questionnaire. You will be provided with a weighing scale, a pedometer and will also receive a letter giving you access to a self-help weight management resource on the UCAN website. We will ask you to weigh yourself and complete a quality of life questionnaire again at 24 weeks and return this information to us by mail. If you are assigned to Group B you will attend a 1-hour group session on your first visit. This will involve 12-15 men in the same group; partners /caregivers are welcome to join in this group. A dietitian will give information about diet and exercise after prostate cancer treatment, and there will be an opportunity for discussion. You will also be given a pedometer for monitoring your activity. You will receive a letter giving you access to a self-help weight management resource on the UCAN website for 12 weeks. The dietitian will contact you by telephone in the next week to obtain a diet history and pedometer reading, and set goals for changing your diet and exercise. The dietitian will contact you by

telephone after 4 and 8 weeks to review your progress and set new goals for change. You will be asked to come to the UCAN Care Centre or CLAN House for the second visit at the end of 12 weeks, where we will measure your weight and you will complete a second quality of life questionnaire and we will ask some questions about your experience of the group meeting, the dietitian counselling and the self-help resources. You will be provided with weighing scale and asked to weigh yourself 12 weeks later. At this point we will send a third quality of life questionnaire, and will ask you to return this and your recorded weight to us by mail.

What are the possible benefits and risks of participating?
You will have the opportunity to learn more about healthy eating and healthy lifestyle and in some cases may lose weight. We do not anticipate any disadvantages or risks in taking part.

Where is the study run from?
The University of Aberdeen in collaboration with NHS Grampian.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in October 2013. Participants will be enrolled on the study for a period of 24 weeks. The study will end in June 2014.

Who is funding the study?
Funding has been provided by Malaysian Government through University of Aberdeen PhD student budget.

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Protocol serial number
Version 1.4

Study information

Scientific Title
The effect of nutrition counselling and self-help resources on body weight and quality of life in overweight men treated for prostate cancer: the PROstate cancer weight MANagement (PRO-MAN) pilot trial

Acronym
PRO-MAN

Study objectives
Patients who received nutrition counselling and self-help resources will have greater weight loss and better quality of life compared to controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 02/08/2013, ref: 12/NS/0126

Study design
Single centre randomised pilot trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Obesity and prostate cancer

Interventions
This is a 12-week randomised controlled trial to compare an intervention with telephone-based nutrition counselling plus provision of group based and self-help resources for diet and physical activity with a Control Group.

The intervention group will receive the weight management programme package which includes: -
1. A 1-hour group session with a dietitian at the beginning of the 12-weeks programme: partners or caregivers are welcome to join in this group.
2. A recommendation letter from their individual consultant to encourage them to comply with dietary modification and to engage in regular physical activity. The letter also includes the link and password to UCAN website for them to get access to the self-help resources.
3. A pedometer with complete instruction manual and guidelines for exercise are provided. Participants are asked to provide a baseline reading and will set the physical activity goals for the following four weeks. They will be asked to provide a pedometer reading during each follow-up telephone call which will be used as a review for their goals achievement and to re-set new goals.
4. The patients are contacted by telephone by a dietitian to give an individually tailored dietary

consultation based on diet history, at their own convenient time in the following week. A written summary of the advice and goals set are sent out by mail to each participant. Two follow-up telephone calls to review and reset goals are carried out at the 5th and the 9th week. All telephone calls are recorded.
5. A digital weighing scale with instructions for measuring body weight at 24 weeks

The men in the wait-list control group will not be given any instruction on diet and exercise at the start of the study but they get access to the website, pedometer and weighing scales at the end of 12 weeks.

All participants are followed up 12 weeks after intervention end point so total duration of study is 24 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Changes in body weight. Body weight will be measured at baseline, 12 weeks (end of the intervention) and 24 week (end of follow-up)
2. Quality of life will be measured by questionnaire administered at baseline, 12 weeks (end of the intervention) and 24 week (end of follow-up)

Key secondary outcome(s))
Acceptability and feasibility of the intervention will be assessed by analysing the recruitment rates, drop-out rates, engagement in self-help resources (time & frequency of access will be automatically captured) and participants' feedback and suggestions (through short questionnaire) after 12 weeks (end of intervention)

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Men diagnosed with localized and locally advanced prostate cancer
2. Age at least 16 years
3. Body mass index greater than 25 kg/m2 (those aged <70 years) or greater than 30 kg/m2 (those aged >70 years)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Known distant metastases
2. Currently participating in any weight loss programme
3. Currently involved in other study

Date of first enrolment
02/10/2013

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Academic Urology Unit,
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Government of Malaysia - through University of Aberdeen (UK) PhD student budget

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes