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Prostate cancer intervention study for men with prostate cancer and their partners

Submission date
25/11/2012

Recruitment status
No longer recruiting

Registration date
15/01/2013

Overall study status
Completed

Last Edited
23/06/2016

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?
After completing treatment, men with prostate cancer and their partners can experience distress and have difficulties in coping with problems associated with prostate cancer. These problems can sometimes disrupt their lives and the lives of their families. The purpose of the study is to develop and test a programme of support which will aim to give men with prostate cancer and their partners the information they require and the skills they need to keep control over their lives and deal with some of the problems they will face.

Who can participate?
Men who have recently had treatment for prostate cancer (and their partner) will be invited to participate in this study. In total, over a six-month period, around 50 men and their partners will be invited to take part in the study.

What does the study involve?
If a man takes part in the study, he and his partner will be randomly assigned (like flipping a coin) to receive one of two programmes of care 1) Standard Care or 2) Standard Care plus the CONNECT Programme. The CONNECT programme is designed to help men with prostate cancer and their partners to manage prostate cancer and the treatments for it. The CONNECT programme consists of three group sessions and two telephone calls with a trained counsellor. During the sessions the trained counsellor will discuss ways that couples can work together to manage the illness and any problems associated with the cancer and its treatment. All participants will be invited to complete questionnaire packets four times, before and after the CONNECT programme and at one and six months after the programme. These group sessions will take place in local hotels. Those people who do not receive the CONNECT programme will be asked to complete the questionnaire packets at similar times. As well as testing whether or not the CONNECT programme helps men with prostate cancer and their partners; we also want to ensure the programme addresses all the concerns the men and their partners have. We will therefore invite 10 15 couples to be interviewed after the programme is finished to get their views on what they thought of the programme. With the permission of these couples these discussions will be tape recorded, so that the researcher does not miss anything important. The CONNECT programme is a self-contained, time-limited programme that all participants will complete. However, if a participant feels they need ongoing support, there are other prostate

cancer support groups organised by Cancer Focus (formerly the Ulster Cancer Foundation) that they can attend. Also if a participant feels they need to be referred to a counsellor to discuss any concerns this will be possible.

What are the possible benefits and risks of participating?
We cannot promise the study will help participants but the information we get from this study will help us learn more about the experiences of men with prostate cancer and their partners. This information will help us design programmes of care to assist other individuals with cancer and their partners, which may give participants a sense of personal satisfaction. In addition, we hope that those couples who participate in the CONNECT programme will benefit from the opportunity to discuss their feelings about the cancer and the treatments for it during the group and phone sessions.
Participants may feel a little uneasy responding to some questions on the questionnaires that ask about their personal experiences with cancer and the treatments for it. If participants are assigned to the CONNECT programme, they also may feel uneasy discussing some of their personal experiences with cancer and the treatment for it during the group or phone sessions with the trained counsellor. There may also be risks involved in taking part in this study that are not known to the researchers at this time. To protect against these risks, participants may refuse to answer any question in the questionnaire packets that makes them uncomfortable or that they chose not to answer for any reason. If participants are assigned to the CONNECT programme, they may refuse to discuss any issue that makes them feel uncomfortable for any reason during the group or phone sessions.

Where is the study run from?
The trial is being organised primarily by researchers from the University of Ulster, in collaboration with the NHS.

When is the study starting and how long is it expected to run for?
The study began on the 16 of May 2011 and the anticipated end date is 16th of April 2013.

Who is funding the study?
The study is funded by Cancer Focus (formerly the Ulster Cancer Foundation)

Who is the main contact?
Professor Eilis Mc Caughan
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Developing and evaluating a self-management psychosocial intervention for men with prostate cancer and their partners: a feasibility study

Study objectives
1. The intervention will lead to an increase in self efficacy among men and their partners in the experimental group when compared with the control group.
2. The intervention will lead to a higher quality of life among men and their partners in the experimental group when compared with the control group.
3. The intervention will lead to men and their partners in the experimental group experiencing less symptom distress than those in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 9 December 2010, REC reference 10/NIR02/59

Study design
Feasibility intervention 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 contact Professor Eilis Mc Caughan (em.mcaughan.ac.uk) to request a patient information sheet

Health condition(s) or problem(s) studied
Prostate Cancer

Interventions
This feasibility study will involve men with a diagnosis of prostate cancer and their partner. Couples will either be invited to participate in a self-management intervention programme over the course of nine weeks, or receive usual care. The overall aim of the study is to develop and evaluate a self-management psychosocial intervention programme for men with prostate cancer and their partners. There are three stages to the evaluation of the intervention (Donabedian's1978 framework):

1. Evaluating the structure (the resources used in developing and delivering the intervention)

2. Evaluating the process
The evaluation will consist of two parts:
2.1. The perceptions and experience of the men and their partners of taking part in the intervention.
2.2. The perceptions and experience of facilitators in delivering the intervention. This will be explored through semi- structured interviews with the facilitators.

3. Evaluating the outcome
The intervention will be tested by means of a randomised controlled trial. The intervention will be based on a modified version of the FOCUS program (Northouse et al., 2007).

The intervention consists of three group meetings (approx. 2 hours per week) on week one, week three and week nine. Men and their partners will also be contacted by telephone on two occasions (week five and week seven). The groups will be facilitated by counsellors from Cancer Focus (formerly the Ulster Cancer Foundation) who will be trained specifically for this purpose. However, while this intervention will be professional led active participation from the patient and their partner will be encouraged.

Topics to be covered in the intervention (CONNECT):
1. Couple care: encourage active involvement of men and their partners in a planned programme of care.
2. Optimistic Outlook: assist men and their partners to maintain a positive outlook as they live with the illness and consider their future.
3. Navigating the Journey: assist men and their partners to obtain information that will reduce their uncertainty about the illness and/or treatments.
4. New Normality: teach men and their partners ways to manage reactions and side effects associated with the illness, treatment and adjustment.
5. Empowering Self: facilitate men and their partners to become effective self managers. Underpins the intervention.
6. Change Lifestyle: encourage men and their partners to adopt or maintain healthy living strategies.

7. Target Setting: assist men and their partners to set personal targets in relation to their illness, treatment and adjustment.
Information and support booklets relevant to each of the topics will be developed for the men and their partners. The telephone sessions will be considered booster sessions, content from the previous two group sessions will be reinforced, very little new content will be introduced. These sessions provide the opportunity for the intervention to be individualised as participants are encouraged to set their own personal targets. Although there are concrete themes to be addressed (couple care, optimistic outlook, new normality and changing lifestyle), there is a degree of fluidity to the intervention. During each group session there will be a constant movement to and from each of the topics. The group sessions will be conducted in a way that facilitates personal/couple needs. The intervention allows them to attain targets at the level they want to attain them at. A further opportunity to individualise the intervention occurs with the telephone sessions. At this stage, the couples will be invited to set their own personal targets in relation to the intervention.

The control arm of the study will receive usual care. The usual care group may avail of the services of the voluntary cancer organisations in Northern Ireland.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To test the feasibility of a self-management intervention developed for men with prostate cancer and their partners

Secondary outcome measures
1. To investigate the impact of the intervention on the quality of life of men with prostate cancer and their partners
2. To determine the effectiveness of the intervention programme in improving the self-efficacy and health behaviours and reducing the uncertainty of men with prostate cancer and their partners
3. To investigate the ability of the intervention programme to reduce the level of symptom distress reported by individuals with prostate 4. To investigate the impact of the intervention programme on caregiving and communication within the couple
5. To evaluate the cost of developing and evaluating the intervention
6. To evaluate the process of the intervention

Overall study start date
16/05/2011

Completion date
16/04/2013

Eligibility

Key inclusion criteria
Men:
1. Over the age of 18

2. Diagnosed with localised adenocarcinoma of the prostate
3. Immediately post surgical / radiation treatment with curative intent, with or without hormonal treatment
4. Physically and mentally (based on consultants assessment) able to participate
5. Provide fully informed written consent
6. Able to communicate in English
7. Have a spouse or cohabiting partner residing in Northern Ireland

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Target number of participants 96 (48 men with prostate cancer and their 48 partners)

Key exclusion criteria
1. Couples will be excluded if the spouse/partner has been diagnosed with cancer within the past year
2. Individuals who are unable to speak English

Date of first enrolment
16/05/2011

Date of final enrolment
16/04/2013

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Institute of Nursing Research
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
University of Ulster (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Charity

Funder Name
Ulster Cancer Foundation (now known as Cancer Focus) (UK)

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