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Positive Psychology Interventions in Patients with Advanced Cancer

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 02/08/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544187603

Study information

Scientific Title

Study objectives
To see if simple positive psychology interventions will improve well being and quality of life in persons with advanced cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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 use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer: Breast & prostate

Interventions
Theoretical framework: psychological interventions have been known to improve quality of life, functioning, well being and immunity in early stage cancer. Similar studies are needed in late stage cancer.

Purpose of the study: to see if simple, easy to use, cost effective strategies of positive psychology can be used to improve quality of life in people with advanced cancer.

Study design: pilot study for a Randomised Control trial. Methodological evaluation study. Methodology: patients attending the oncology clinic at Addenbrookes Hospital will be invited to participate in the trial. An initial screening will be conducted and suitable candidates will be recruited after obtaining written consent when they come to attend their oncology clinic appointment. This is expected to take 15-30 minutes.

If they agree to take part, they will be randomly allocated into one of two groups:
1. Fast-track group who will start immediately
2. A delayed start group who will start 6 weeks later

The fast track group will be interviewed on the same day and asked to fill some baseline questionnaires. They will also be given written information about positive psychology methods and also verbal explanation. They will be given diary sheets to be filled out on a daily basis and tapes or CDs to listen to for their relaxation/meditation exercises. This can be done in 30-45 minutes. They will then be contacted on phone 1, 2 and 4 weeks after the first meeting in order to clarify any doubts they may have and also to encourage them to complete their daily tasks. Each phone conversation is not expected to last more than 10 minutes. After this, there will be no further phone contact. Face to face interviews will take place at 6, 12, and 18 weeks after the initial interview. Each is expected to last 30 minutes and will coincide with clinic appointments. Patients will be asked some questions and requested to fill out questionnaires at these meetings. The delayed start group will undergo an identical process, after a lag of 6 weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Well being

Secondary outcome measures
Quality of life, functioning.

Overall study start date
01/08/2006

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Age above 18 (age of consent)
2. Women with advanced breast cancer (study involves cancer patients and breast cancer is one of the commonest forms of cancer in women)
3. Men with advanced prostate cancer (study involves cancer patients and prostate cancer is one of the commonest forms of cancer in men)

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Minimum of 10 in each group

Key exclusion criteria
1. Significant psychological distress - it is not ethical to include them as they may benefit from treatment with medication.
2. Current treatment with medication for psychological distress, unless they have been stable on them for more than a year - inclusion of such people will confound the results of the study as it would be difficult to say whether improvement is due to medication or the intervention.
3. Those who are unable to understand, read or write in English - a currently all the material is only available in English.
4. Those who have severe memory impairment - as they may not be able to learn and use the strategies.

Date of first enrolment
01/08/2006

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Palliative Care Team
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK), Own Account NHS R&D Support Funding

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	results	01/12/2009		Yes	No