

Positive Psychology Interventions in Patients with Advanced Cancer

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 02/08/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pranathi Ramachandra

Contact details
Palliative Care Team
Box 193
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

Well being

Key secondary outcome(s)

Quality of life, functioning.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

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

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?
Results article	results	01/12/2009		Yes	No