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Mindfulness Based Stress Reduction in the management of psychological distress in prostate cancer

Submission date 31/10/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/10/2011	**Overall study status** Completed	
Last Edited 16/11/2017	**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
10897

Study information

Scientific Title
Understanding depression and anxiety in prostate cancer: a feasibility study and qualitative evaluation of Mindfulness Based Stress Reduction (MBSR) for the management of depression and anxiety in men with prostate cancer undergoing active surveillance

Acronym
MBSR

Study objectives
To assess the effectiveness of MBSR as an adjuvant treatment for depression and anxiety in a population of prostate cancer patients during active surveillance. This will be the first study to use a mixed methods approach (qualitative and quantitative methods) to evaluating and understanding the mechanism of MBSR in a population of cancer patients and thus will provide a rigorous foundation for further studies in this area, adding significantly to our knowledge base.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 11/SC/0355

Study design
Non-randomised interventional treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Prostate cancer patients undergoing active surveillance

Interventions
MBSR is a psycho-educational treatment for the management of depression and anxiety

Follow Up Length: 4 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depression and anxiety scores measured at baseline and monthly for 4 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
09/01/2012

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. HADS>8
2. English fluency (questionnaires only validated in English)
3. Diagnosed > 2 months to avoid the period of initial 'shock of diagnosis'
4. No other current serious life threatening co-morbidity an ECOG score of 0 or 1 (i.e. patients are fully active or with restricted mobility but are ambulatory and be able to carry out work of a light or sedentary nature
5. Male participants

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 30

Key exclusion criteria
Secondary cancer sites

Date of first enrolment
09/01/2012

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Cancer Care Directorate
B Level, Mailpoint WRE
Royal South Hants Hospital
Graham Road
Southampton
England
United Kingdom
SO14 0YG

Sponsor type
Hospital/treatment centre

Website
http://www.suht.nhs.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research (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