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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Depression and anxiety scores measured at baseline and monthly for 4 months

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
Secondary cancer sites

Date of first enrolment
09/01/2012

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration