

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

Submission date 31/10/2011	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 31/10/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/11/2017	Condition category Cancer	☐ Individual participant data ☐ 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

Primary study design

Interventional

Study design

Non-randomised interventional treatment

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