

A qualitative (feasibility) study of mindfulness based stress reduction (MBSR) for the treatment of fatigue, anxiety and depression in women with metastatic breast cancer

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|--------------------------|----------------------------------|--|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 17/02/2011 | No longer recruiting | <input type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 17/02/2011 | Completed | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 27/07/2022 | Mental and Behavioural Disorders | |

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-mindfulness-as-way-of-helping-with-fatigue-anxiety-and-depression-in-secondary-breast-cancer-mfab>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

9766

Study information

Scientific Title

A qualitative (feasibility) study of mindfulness based stress reduction (MBSR) for the treatment of fatigue, anxiety and depression in women with metastatic breast cancer

Acronym

Mindfulness for Fatigue in Breast cancer

Study objectives

In the UK 8 - 12% of women develop breast cancer and of those 20 - 30% progress to metastatic breast cancer (MBC). Cancer related fatigue is one of the most common symptoms experienced by those with persistent or advanced cancer and may be related to treatments (radiotherapy, chemotherapy and endocrine therapy), the cancer itself, menopausal symptoms and anxiety and depression. Fatigue has been poorly investigated and there are few effective treatments.

Mindfulness based stress reduction is a non-religious approach to meditation that has been used in clinical settings for many years and can be taught in a structured 8 week course. MBSR has been shown to help people manage chronic pain and fatigue and also anxiety and depression. Although MBSR has been investigated in women with early stage breast cancer it has not been explored in MBC. Therefore a mixed method feasibility study will be conducted in order to assess the impact of MBSR in this population and to assess the feasibility of conducting a RCT.

3 groups of approximately 10 women will be identified by their oncologist. Participants eligible for the study must have an Eastern Cooperative Oncology Group (ECOG) score of 0 - 1 and a life expectancy of more than 6 months. Potential participants will undergo further assessment by the mindfulness practitioner and if eligible then recruited onto the study. Two qualitative interviews will be undertaken with each participant to elicit experiences before and after attending a MBSR group. Questionnaires (BFI, HADS, TMS, EORTC QLC C30, EuroQol EQ5D) will also be completed by participants at baseline, during the MBSR course at 1 month and 2 months and post MBSR course at 3 months and at 5 months.

Three focus groups involving, service commissioners (including psychological services for cancer) and mindfulness instructors will be held at the end of the MBSR intervention. Groups will systematically explore feasibility and acceptability issues of MBSR in MBC within the NHS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Isle of Wight, Portsmouth & South East Hampshire Local Research Ethics Committee, 21/07 /2010, ref: 10/H0501/18

Study design

Multicentre non-randomised interventional pilot/feasibility study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions

Mindfulness based stress reduction (MBSR) was developed by Jon Kabat Zinn (University of Massachusetts Medical Center) and is a "specific structured psycho educational and skills based package" that employs taught patient "self management" using mindfulness meditation exercises.

The key goals are to encourage non-judgemental attention to what goes on in the present moment in your body mind, and the world around you.

Study entry: Other

Details: Patients will be identified by their Oncologist

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Brief Fatigue Inventory, measured prior to intervention at baseline, during the intervention at months 1 and 2 and post-intervention at months 3 and 5

Key secondary outcome(s)

1. EORTC-QLQ-C30, measured prior to intervention at baseline and post-intervention at month 5
2. EuroQol EQ5D, measured prior to intervention at baseline, during the intervention at months 1 and 2 and post-intervention at months 3 and 5
3. Hospital Anxiety and Depression Scale, measured prior to intervention at baseline, during the intervention at months 1 and 2 and post-intervention at months 3 and 5
4. Toronto Mindfulness Scale, measured prior to intervention at baseline, during the intervention at months 1 and 2 and post-intervention at months 3 and 5

Completion date

01/10/2012

Eligibility

Key inclusion criteria

1. After diagnosis of metastatic breast cancer and stable enough to have a real likelihood of completing the study as assessed by the recruiting oncologists
2. Eastern Cooperative Oncology Group (ECOG) Performance Score of 0 - 1, thus excluding bed bound and frail patients
3. Estimated life expectancy of at least 6 months to enable retention and minimise group disruption
4. Able to provide informed written consent
5. Fluent English; the questionnaires are written and validated in English
6. Assessed as eligible by the mindfulness instructor following the clinician's initial approval
7. Female subjects, no age range

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Sex

Female

Total final enrolment

20

Key exclusion criteria

1. Substance misuse or other issues that may jeopardise the health of individuals participating in the intervention will be excluded
2. Comorbidities that makes it unlikely that participants will complete the study (including borderline personality disorder, major psychotic illness)
3. Participants who are felt to be too distressed to be approached will be excluded (this will be determined by the clinicians)

Date of first enrolment

06/12/2010

Date of final enrolment

01/10/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Southampton

Southampton

United Kingdom

SO16 5ST

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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 | 01/01/2015 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Plain English results | | 27/07/2022 | | No | Yes |