

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

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

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

Contact name

Dr Caroline Eyles

Contact details

Complementary and Integrated Medicine Research Unit
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton
United Kingdom
SO16 5ST
+44 (0)23 80 241089
C.G.Eyles@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

06/12/2010

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

Age group

All

Sex

Female

Target number of participants

Planned sample size: 35

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

England

United Kingdom

Study participating centre

University of Southampton

Southampton

United Kingdom

SO16 5ST

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

Sponsor details

Research and Development Office

Tremona Road

Southampton

England

United Kingdom

SO16 6YD

Sponsor type

Hospital/treatment centre

Website

<http://www.suht.nhs.uk/home.aspx>

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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
Plain English results			27/07/2022	No	Yes