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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

Registration date
17/02/2011

Overall study status
Completed

Last Edited
27/07/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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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. Comorbitities 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
Resarch and Development Office
Tremona Road
Southampton
England
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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