ISRCTN95243663 https://doi.org/10.1186/ISRCTN95243663

Mindfulness in ovarian cancer

Submission date 05/12/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 05/12/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/01/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Ovarian cancer is a common form of cancer that often returns after treatment.Having cancer return can be traumatizing, causing mental distress. Mindfulness is a technique that aims patients live life in a present moment and could help patients with recurrent ovarian cancer. The aim of this study is to explore the feasibility of delivering a 6-week mindfulness based group support intervention to a cohort of ovarian cancer patients who have experienced disease recurrence.

Who can participate?
Woman aged 18 and older who have a confirmed ovarian cancer.
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What does the study involve?
All participants receive a 6-week mindfulness-based intervention comprising a total of 8.5 contact hours. The programme has been specifically adapted and modified for cancer patients based around extensive qualitative research to ensure its applicability and acceptability and in this capacity it has been successfully trialled in a population of stage 4 breast cancer patients.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Queen Alexandra Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2016 to May 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Sam Watts (Scientific)
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Contact information

Type(s)
Scientific

Contact name
Dr Sam Watts

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32108

Study information

Scientific Title
A six-week programme of group mindfulness sessions to improve mental health and wellbeing in patients with recurrent ovarian cancer: a feasibility study

Acronym
MOVA

Study objectives
The aim of this study is to explore the feasibility of delivering a 6-week mindfulness based group support intervention to a cohort of ovarian cancer patients who have experienced disease recurrence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee, 30/08/2016, ref: 16/SC/0415

Study design
Non-randomised; Interventional; Design type: Treatment, Complementary Therapy, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Specialty: Cancer, Primary sub-specialty: Gynaecological Cancers; UKCRC code/ Disease: Cancer/ Malignant neoplasms of female genital organs

Interventions
All participants receive a 6-week mindfulness-based intervention comprising a total of 8.5 contact hours. The intervention has been specifically adapted and modified for cancer patients based around extensive qualitative research to ensure its applicability and acceptability and in this capacity it has been successfully trialled in a population of stage 4 breast cancer patients.

Intervention Type
Other

Primary outcome measure
Feasibility outcomes:
1. Recruitment rate
2. Response rates
3. Number of patients completing the intervention
4. Number of patients completing the 6 month follow-up
5. Qualitative assessment of the intervention
6. Quantitative data analysis

Secondary outcome measures
1. Anxiety
2. Depression
3. Quality of life
4. Diurnal cortisol variations

Overall study start date
01/05/2016

Completion date
09/05/2017

Eligibility

Key inclusion criteria
1. Any confirmed recurrence of OvCa at any stage
2. Aged 18 years and above
3. Willing to participate and provide informed consent
4. Fluent English (questionnaires validated and interviews conducted in English)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Additional cancer diagnoses
2. Any significant mental illness (i.e. overt psychosis, history of suicidal ideation) but not to include clinical depression and/or anxiety
3. Receiving any other psychological therapy

Date of first enrolment
09/11/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham

Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

Sponsor details
De La Court House
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
England
United Kingdom
PO6 3LY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
09/05/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No