

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.

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**Protocol serial number**

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

Primary study design

Interventional

Study design

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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**

United Kingdom

England

Study participating centre

Queen Alexandra Hospital

Southwick Hill Road

Cosham

Portsmouth

United Kingdom

PO6 3LY

Sponsor information**Organisation**

Portsmouth Hospitals NHS Trust

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

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