

Yoga and quality of life study

Submission date 06/07/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/07/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Yoga has been practiced for thousands of years to improve emotional and physical well being. It involves the adoption of various postures and controlled breathing to gently exercise and relax the body. Several studies have shown that practicing yoga can have beneficial effects on the quality of life of cancer patients, although this has yet to be proved conclusively. We are planning to carry out a clinical trial to determine if yoga has positive effects on gynaecological cancer patients at Royal Derby Hospitals. If the results of this study are positive, then future patients could benefit from an improved cancer care service.

Who can participate?

Women aged 18 or over diagnosed with gynaecological cancer and undergoing treatment or about to undergo treatment in the form of surgery, chemotherapy or radiotherapy (or a mixture of these).

What does the study involve?

Participants will be randomly allocated into one of two groups. One group will attend 1-hour weekly yoga classes for 10 weeks, whereas the other group will receive standard care and will be asked to not practise yoga for a period of 10 weeks. The classes will be run on Thursday evenings between 6 and 7 pm at the University of Derby, Kedleston Road campus.

Both groups will be asked to complete a quality of life questionnaire before the study and at the end of the study. Patients will also be contacted 4 months after the study to complete a further quality of life questionnaire to see if there are any long-term benefits of practicing yoga. Both groups will be asked to keep a diary over the 10-week period so we can see their thoughts and feelings over the 10 weeks. Furthermore, patients who take part in the yoga will also be asked to take part in a focus group (a group discussion) to find out their thoughts and feelings about taking part in yoga as a gynaecological cancer patient and both the positives and negatives of the study will be discussed. This will help us decide whether offering yoga as a complementary therapy is a suitable service for the NHS.

What are the possible benefits and risks of participating?

Currently, there are no side effects reported by cancer patients who have practiced yoga. The yoga classes that patients will be offered are taught by a qualified teacher who has considerable experience, and will be designed to include gentle stretches and poses. The classes will be adapted from Hatha yoga, which allows participants to work at their own pace. Patients will be

encouraged to listen to your own body and not attempt poses that you feel are uncomfortable or strained.

We are trying to find out if yoga can benefit cancer patients by helping to manage symptoms of the disease such as fatigue, anxiety and pain, and these in turn are thought to have an impact on quality of life. We cannot promise that this study will help you, but the information we get from this study could help to improve the care of future gynaecological cancer patients.

We do not believe that participation in this study will harm you in any way. In the unlikely event that you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someones negligence, however, then you may have grounds for legal action which you may have to pay for.

Where is the study run from?

University of Derby (UK)

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

January 2011 to June 2012

Who is funding the study?

The Gynaecological Cancer Research Fund, which is part of the Derby Hospitals Charity.

Who is the main contact?

Dr Heidi Sowter

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Contact information

Type(s)

Scientific

Contact name

Dr Heidi Sowter

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomized controlled clinical trial to investigate whether practising Yoga improves the quality of life for gynaecological cancer patients

Study objectives

To develop a randomised controlled trial to investigate the impact of Yoga on quality of life (QoL) of gynaecological cancer patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS REC committee (Nottingham REC2), 11/11/2010, ref: DHRD/2010/085

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please contact s.archer@derby.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied

Gynaecological cancer

Interventions

A gentle course of Hatha Yoga vs standard care

The classes lasted for one hour and patients attend once a week for 10 weeks.

The control group had care as normal.

Both groups were followed up (complete the original questionnaire pack) at 4 months.

Intervention Type

Behavioural

Primary outcome measure

1. Quality of Life measured using the European Organisation for Research and treatment of Cancer
2. Quality of Life Questionnaire Core 30 measured Pre/Post intervention and at 4 month follow up.

Secondary outcome measures

1. Mental Adjustment to Cancer measured Pre/Post intervention and at 4 month follow up.
2. Acceptance of Illness measured Pre/Post intervention and at 4 month follow up.
3. Pain, anxiety and Fatigue measured on a weekly basis whilst on the trial, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain)

Overall study start date

01/01/2011

Completion date

30/06/2012

Eligibility**Key inclusion criteria**

1. Aged 18 or above
2. Diagnosed with cancer of the ovary, cervix, vulva, fallopian tube, or peritoneum
3. Undergoing treatment or about to undergo treatment in the form of surgery, chemotherapy or radiotherapy (or a mixture of these)
4. Able to engage with a gentle programme of yoga

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

54

Key exclusion criteria

1. Diagnosed with a benign condition such as ovarian cyst
2. Patients with the mental incapacity not to be able to give informed consent
3. Patients unable to understand verbal or written English
4. Patients who already practice yoga who would be unwilling to enter the control arm of the trial

Date of first enrolment

01/01/2011

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Derby

Derby

United Kingdom

DE22 1GB

Sponsor information

Organisation

University of Derby (UK)

Sponsor details

Kedleston Road

Derby

England

United Kingdom

DE22 1GB

Sponsor type

University/education

Website

<http://www.derby.ac.uk/>

ROR

<https://ror.org/02yhrrk59>

Funder(s)

Funder type

Charity

Funder Name

Gynaecological Cancer Research Fund (UK) - part of the Derby Hospitals Charity

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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?
Results article	results	01/02/2015		Yes	No