

A randomised controlled trial assessing effectiveness of six sessions of brief cognitive behaviour therapy in reducing psychological distress in women who have completed a course of intravenous chemotherapy for ovarian cancer

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/02/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

N0063116010

Study information

Scientific Title

A randomised controlled trial assessing effectiveness of six sessions of brief cognitive behaviour therapy in reducing psychological distress in women who have completed a course of intravenous chemotherapy for ovarian cancer

Study objectives

The aim of this project is to carry out a randomised controlled trial, to assess the hypothesis and gain information regarding the acceptability of such a programme.

Please note that as of 11/08/2009 this record was extensively updated

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Ovarian cancer

Interventions

Current information as of 11/08/2009:

At the end of chemotherapy those who have consented to the study will be asked to complete a Hospital Anxiety and Depression Scale (HADS) to assess their suitability for randomisation.

Those scoring 7 will then be randomised into

1. Intervention arm - up to 6 30 minute sessions of cognitive behaviour therapy
2. No intervention

Initial information at time of registration:

Randomised controlled trial:

Arm A: no intervention

Arm B: intervention

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Added 11/08/2009:

Women in both arms of the study will be assessed using:

1. HADS and Worry About Cancer Scale
2. A Social Support Inventory (SSI)
3. an Impact of Events Scale
4. A scale assessing the beliefs about controllability and social worry

These will be administered at the end of chemotherapy and 3 months following completion of chemotherapy. These questionnaires will be administered by a member of the research team who will not be involved in the cognitive behaviour therapy sessions.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/2003

Eligibility**Key inclusion criteria**

Current information as of 11/08/2009:

1. Patients newly diagnosed with ovarian cancer, attending the outpatient clinic of Dr G Jayson
2. Age <55 years
3. Written informed consent
4. Hospital Anxiety and Depression Scale (HADS) score of 7

Initial information at time of registration:

Patients with ovarian cancer, who are less than 55 years of age, will be giving an information sheet outlining the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

26/04/2002

Date of final enrolment

31/10/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Christie Hospital NHS Trust

Manchester

United Kingdom

M20 4BX

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Christie Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration