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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 14/02/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

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
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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
26/04/2002

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

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Christie Hospital NHS Trust
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Christie Hospital NHS Trust (UK)

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