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A prospective evaluation of the effect of a nurse counsellor on psychological and sexual morbidity in gynaecological cancer patients

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 19/10/2011	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
F1005 MAUGHAN R&D

Study information

Scientific Title

Study objectives
Psychological sequelae following the diagnosis and treatment of cancer are common. The treatment of gynaecological tumours is however recognised to present particular difficulties in relation to altered fertility, changes in body image and sexual dysfunction. There is evidence to indicate that improvements in sexual function and reduction in psychological morbidity in breast cancer patients can be achieved through counselling. Some previous studies evaluating sexual dysfunction in gynaecological oncology have been flawed due to the failure to use control subjects, the exclusion of partners or the limited duration of follow-up. The Northern Centre for Gynaecological Oncology provides the opportunity to conduct this study due to the centralisation of surgical treatment. The applicant also has the support and supervision of nursing, clinical psychology and medical colleagues, thus providing the skill range necessary to complete the project.

Aims :
1. To analyse the impact of surgery for gynaecological cancer on the well being of patients and their lived experience of illness.
2. To identify areas in which nursing practice may be developed across the Primary/Secondary care interface, in relation to the adaptation and rehabilitative process following surgery.
3. To provide clear evidence which demonstrates the benefits of a 'nurse counsellor' for women with gynaecological cancer.

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)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Gynaecological cancer

Interventions
Nurse counselling versus standard care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patient well being, quality of life, sexual functioning.

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/01/1997

Completion date
31/07/1998

Eligibility

Key inclusion criteria
Diagnosed gynaecological cancer having a surgical procedure with curative intent.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Advanced disease/palliative intent.

Date of first enrolment
08/01/1997

Date of final enrolment
31/07/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Gynaecological Oncology Centre
Newcastle upon Tyne
United Kingdom
NE9 6SX

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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United Kingdom
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+44 (0)20 7307 2622
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2001		Yes	No