

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
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/10/2011	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Gynaecological cancer

Interventions

Nurse counselling versus standard care.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Patient well being, quality of life, sexual functioning.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/07/1998

Eligibility

Key inclusion criteria

Diagnosed gynaecological cancer having a surgical procedure with curative intent.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

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?
Results article	results	01/03/2001		Yes	No