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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Mrs Karen Maughan

#### Contact details

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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 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### 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