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Psycho-educational interventions for gynecological cancer patients

Submission date 07/09/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 08/09/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 27/01/2020	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Being diagnosed with gynecological cancer (cancer that affects the female reproductive system) and the related treatments can be a difficult experience for women, and can lead to problems with sexual functioning. In addition, the unpredictability of the disease can lead to high levels of anxiety, which may have a negative effect on quality of life. Psycho-educational interventions (programs which combine education and counseling) for gynecological cancer patients were found to have positive effects on sexual functioning and mental health status. This type of program is still rare in Hong Kong however. The aim of this study is to find out whether a nurse-delivered psycho-educational intervention could help to improve sexual function and mental wellbeing in gynecological cancer patients in Hong Kong.

Who can participate?
Women over the age of 18 with a new diagnosis of gynecological cancer who are planning to have surgical treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive four sessions of the psycho-educational program, delivered by a trained nurse. The first session takes place before the operation and involves being given information about gynecological cancer. The second session is 1-2 days after surgery and involves meeting with the nurse. The third session is arranged for after the patient is discharged from hospital, and involves talking about how they are recovering and if they are experiencing any discomfort. The fourth session involves individual counseling 3-4 months after the operation. Those in the second group receive the same amount of contact without the information and counseling. Participants in both groups complete a number of questionnaires before and after the program in order to assess sexual functioning and mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their sexual function, mental wellbeing and quality of life. There are no risks associated with participating in this study.

Where is the study run from?
Department of Obstetrics and Gynecology at Queen Elizabeth Hospital and Prince of Wales Hospital (Hong Kong)

When is the study starting and how long is it expected to run for?
March 2015 to July 2018

Who is funding the study?
Health and Medical Research Fund (Hong Kong)

Who is the main contact?
Dr Ka Ming Chow

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
study protocol version 1

Study information

Scientific Title
A randomized controlled trial of psycho-educational interventions for reducing uncertainty and anxiety, and improving sexual functioning among gynecological cancer patients in Hong Kong

Study objectives
Compared with an attention control (AC) group, participants in the intervention group will have:
1. A statistically significant lower level of uncertainty after the completion of the program

2. A statistically significant lower level of anxiety after the completion of the program
3. A statistically significant improvement in sexual functioning after the completion of the program

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Kowloon Central Cluster / Kowloon East Cluster Research Ethics Committee (KCC / KEC REC), 08/12/2015, ref: KC/KE-15-0206/ER-1
2. Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC), 27/01/2016, ref: 2014.501-T

Study design
Single-blinded prospective randomized 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
Gynecological cancer

Interventions
The participants will be assigned randomly to participate in a psycho-educational intervention program or to an attention control group:

Psycho-educational intervention group: Participants will receive four sessions of the program by the research nurse who is a qualified registered nurse with rich clinical experience and will receive two days of training, and each lasts for 30 to 60 minutes. The first session will be provided before the operation. Information about gynecological cancer will be provided. The second session will be on post-operative day 1 or 2, the participants will be met with the nurse intervener. The third session will be arranged after discharge, a telephone call will be made at 4 weeks afterwards by the nurse intervener to ask about their recovery status and any discomfort encountered. It takes about 15 to 30 minutes. At 3 months after operation, the fourth session will be arranged for individual counseling. Semi-structured interviews will also be conducted for selective participants after the individual counselling. The interviews will be audio-taped for data analysis.

Attention control group: Participants will receive the same amount of attention by the nurse intervener. Before the operation, they will be met for completing a questionnaire. On post-operative day 1 or 2, the nurse intervener will visit them about their post-operative condition. After discharge, a telephone call will be made at 4 weeks afterwards by the nurse intervener about their recovery status and any discomfort encountered. At 3 months after operation, they will receive a telephone call from the nurse intervener for completing a questionnaire, it takes about 20 minutes.

All the participants will answer a set of questionnaires measuring uncertainty, anxiety and sexual functioning on recruitment and after the completion of the psycho-educational intervention program. It takes about 15 to 20 minutes.

Intervention Type
Behavioural

Primary outcome measure
Level of uncertainty will be measured using the Chinese version of Mishel Uncertainty in Illness Scale (C-MUIS) at baseline and the completion of the intervention (3-4 months).

Secondary outcome measures
1. Level of anxiety will be measured using the Chinese version of the anxiety subscale in the Hospital Anxiety and Depression Scale (HADS) at baseline and the completion of the intervention (3-4 months)
2. Sexual functioning will be measured using the Chinese version of Sexual Function-Vaginal Changes Questionnaire (SVQ) at the completion of the intervention (3-4 months)

Overall study start date
20/03/2015

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Women with a new diagnosis of primary gynecological cancer including uterine, ovarian and cervical cancers over the past three months
2. Planning for surgery as the first-line treatment
3. Older than 18 years
4. Able to understand spoken Cantonese and to read all materials printed in Chinese
5. Able to consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200 subjects

Total final enrolment
202

Key exclusion criteria
Patients with known psychiatric morbidity.

Date of first enrolment
09/09/2016

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Hong Kong

Study participating centre
Queen Elizabeth Hospital
Department of Obstetrics and Gynecology
30 Gascoigne Road
Yau Ma Tei
Hong Kong
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Study participating centre
Prince of Wales Hospital
Department of Obstetrics and Gynecology
30 Ngan Shing Street
Sha Tin
Hong Kong
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Sponsor information

Organisation
Food and Health Bureau, The Government of the Hong Kong Special Administrative Region

Sponsor details
Secretary for Food and Health
18/F, East Wing, Central Government Offices
2 Tim Mei Avenue
Tamar
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Sponsor type
Government

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Government

Funder Name
Health and Medical Research Fund

Alternative Name(s)
, HMRF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Hong Kong

Results and Publications

Publication and dissemination plan
The study results will be disseminated in international conferences within one year after the completion of the study. Publications will be planned in high-impact peer reviewed journals.

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2020	27/01/2020	Yes	No