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A psycho-educational intervention for Chinese gynecological cancer patients

Submission date	Recruitment status	[_] Prospectively registered
19/04/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/04/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/04/2025	Cancer	

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 uncertainty and anxiety, which may have a negative effect on the 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 China, however. The aim of this study is to find out whether a nurse-delivered psycho-educational intervention could help to improve sexual functioning and mental wellbeing in Chinese gynecological cancer patients.

Who can participate?

Women over the age of 18 with a new diagnosis of gynecological cancer who are planning to have surgical treatment in Hong Kong and Hunan.

What does the study involve?

Participants are stratified by study location (Hong Kong and Hunan) and randomly allocated to the intervention or attention control group. Those in the intervention group will 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 to receive information on wound management, coping skills and relaxation exercises. The third session is arranged after the patient is discharged from the 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 attention control group receive the same amount of contact without the intervention components. 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 in their sexual functioning, 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) and Hunan Provincial People's Hospital (Hunan)

When is the study starting and how long is it expected to run for?
March 2015 to June 2021

Who is funding the study?
Health and Medical Research Fund (Hong Kong), no funding (Hunan)

Who is the main contact?
Dr Ka Ming Chow, kmchow@cuhk.edu.hk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Multicenter randomized controlled trial of a psycho-educational intervention for reducing uncertainty and anxiety, and improving sexual functioning among Chinese gynecological cancer patients

Study objectives
Compared with an attention control (AC) group, participants in the intervention group will have:
1. A statistically significant lower level of uncertainty in illness 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. Approved 08/12/2015, Kowloon Central Cluster / Kowloon East Cluster Research Ethics Committee (KCC / KEC REC; Room 533, 5/F, Block J, Princess Margaret Hospital, Hong Kong; +852 (0)2990 1017; kwcrec@ha.org.hk), ref: KC/KE-15-0206/ER-1
2. Approved 27/01/2016, Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC; 8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; +852 (0)3505 3935; crec@cuhk.edu.hk), ref: 2014.501-T
3. Approved 18/07/2018, Hunan Provincial People's Hospital (The First Affiliated Hospital of Hunan Normal University) ethics committee (61 Jiefang West Road, Furong Changsha, Hunan, 410005, China; + 86 (0)731 84913336; no email provided), ref:[2018]-30

Study design
Multicenter single-blinded prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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, each lasting 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 postoperative day 1 or 2, the participants will be met by a 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 the 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 from the nurse intervener. Before the operation, they will be met for completing a questionnaire. On postoperative day 1 or 2, the nurse intervener will visit them about their postoperative 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 the operation, they will receive a telephone call from the nurse intervener for completing a questionnaire, which 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(s)
Level of uncertainty in illness measured using the Chinese version of the Mishel Uncertainty in Illness Scale (C-MUIS) at baseline and the completion of the intervention (3-4 months)

Key secondary outcome(s))
1. Level of anxiety 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 measured using the Chinese version of the Sexual Function-Vaginal Changes Questionnaire (SVQ) at the completion of the intervention (3-4 months)

Completion date
02/06/2021

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
402

Key exclusion criteria
Patients with known psychiatric morbidity

Date of first enrolment
09/09/2016

Date of final enrolment
10/03/2021

Locations

Countries of recruitment
China

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

Study participating centre
Hunan Provincial People's Hospital
Department of Obstetrics and Gynecology
61 Jiefang West Road
Furong Changsha

Hunan
China
410005

Sponsor information

Organisation
Chinese University of Hong Kong

ROR
https://ror.org/00t33hh48

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

Individual participant data (IPD) sharing plan
Current participant level data sharing plan as of 17/12/2024:
The datasets generated during and/or analysed during the current study are available from Dr Ka Ming Chow (kmchow@cuhk.edu.hk) on reasonable request.

Previous participant level data sharing plan:
The datasets generated during and/or analysed during the current study are not expected to be made available due to the nature of the data being sensitive and all the results will be disseminated in publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/04/2025	24/04/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes