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A nurse-led sexual rehabilitation intervention for gynaecological cancer survivors

Submission date
04/09/2019

Recruitment status
No longer recruiting

Registration date
06/09/2019

Overall study status
Completed

Last Edited
02/06/2023

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Gynaecological cancer (GC) refers to cancers that originate in the female reproductive tract, such as cervical, uterine or ovarian cancers. GC is the third most common female cancer and the fifth leading cause of cancer death in women in Hong Kong. With advances in medical technology and improved treatment, more women with GC now live extended lives and become long-term survivors. As the GC survival rate increases, more attention has been paid to the quality of life of GC survivors, where issues of intimacy and sexuality are regarded as essential components. This project proposes a nurse-led sexuality rehabilitation intervention for GC survivors in Hong Kong, and evaluate their effects on uncertainty, sexual functioning and marital satisfaction.

Who can participate?
Women who are newly diagnosed with primary GC (uterine, ovarian or cervical cancers) over the past three months, not in the terminal stage of the disease, with a regular sexual partner, over 18, able to understand spoken Cantonese and to read Chinese, and consenting to participate in the study.

What does the study involve?
This study is a single-blinded randomised controlled trial. Participants are randomly assigned to intervention or attention control groups. The intervention group receives sexual rehabilitation intervention which is delivered in four sessions scheduled: 1) before the commencement of cancer treatment, 2) one month after the completion of treatment, 3) two months post-treatment and 4) six months post-treatment. Each session lasts 45 to 60 minutes, all being individual or couple-based, with the provision of information, cognitive-behavioural therapy and counselling in motivational interviewing skills. Those in the attention control group receive attention from the research nurse on four occasions in the same period as the intervention group.

What are the possible benefits and risks of participating?
The potential benefits of participating in the study are to improve sexuality and intimate relationship with partners to GC survivors and ultimately improve their marital satisfaction, psychological adaptation to illness and quality of life. There is no risk to the participants.

Where is the study run from?
The study is run in three acute regional hospitals in Hong Kong.

When is the study starting and how long is it expected to run for?
The study is started in July 2019 and expected to run for 20 months.

Who is funding the study?
The study is funded by Health and Medical Research Fund (HMRF) from the Food and Health Bureau, the Government of the Hong Kong Special Administrative Region.

Who is the main contact?
The main contact is Dr Ka Ming Chow via email to kmchow@cuhk.edu.hk.

Contact information

Type(s)
Scientific

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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
Rebuilding sexuality and intimacy after treatment for gynaecological cancer, through a nurse-led sexual rehabilitation intervention: a randomised controlled trial

Acronym
N/A

Study objectives
There are three research hypotheses: GC survivors participating in the intervention will have:
1. Better sexual functioning,
2. A lower level of sexual distress
3. Better marital relationships
after the completion of the intervention than those in the attention control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 08/05/2018, Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, N.T., Hong Kong; crec@cuhk.edu.hk; +852-35053935), Ref: 2018.112
2. Approved 05/09/2018, Research Ethics Committee (Kowloon central/ Kowloon East) (Room 414, Nurses Quarters, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon, Hong Kong; kckecrec@ha.org.hk; +852-35066307), Ref: KC/KE-18-01064/ER-4
3. Approved 01/01/2019, Hong Kong East Clinical Research Ethics Committee (3 Lok Man Road, Chai Wan, Hong Kong; CRER-Portal@ha.org.hk; +852-2595-6111), Ref: HKEC-2018-0100

Study design
Single-blinded randomized controlled trial with a mixed-method design

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Primary gynaecological cancer (uterine, ovarian or cervical cancers)

Interventions
A total of four sessions of individual or couple-based counselling were conducted by a nurse, who had received training in sexual rehabilitation, motivational interviewing skills and cognitive-behavioural therapy, at the recruitment day, 1, 2, and 6months after the completion of the treatment. The PLISSIT model of counselling will be used as a framework for sexuality assessment and education. Participants will be provided with the opportunity to discuss sexual health. Limited information on the effects of treatment on sexuality, with specific suggestions on how to cope with sexual problems, will be provided. The study instruments will be conducted on the first day of recruitment, 1, 6 and 12 months after the completion of the treatment. The study instruments to be used are: Chinese versions of the Sexual Function-Vaginal Changes Questionnaire, Female Sexual Distress Scale-Revised and ENRICH Marital Satisfaction Scale.

The attention control group will only receive attention from the research nurse on the four occasions in the same period as the intervention group. The nurse will not provide any kind of

intervention, but only meet them to invite them to join the study and collect baseline data on recruitment. At one, two and six months post-treatment, the nurse will call them to deliver general greetings with general advice being given over the phone.

Subject allocation will be done by using stratified block randomisation with a block size of 10 and an allocation ratio of 1:1 to maintain a good balance of participants between the two groups throughout the recruitment period in each study site. A random sequence of grouping identifiers (I or C) for each site, based on computer-generated random numbers, will be prepared in advance by an independent statistician.

Intervention Type
Behavioural

Primary outcome(s)
Sexual functioning is measured by the Chinese version of Sexual Function-Vaginal Changes Questionnaire (SVQ) at baseline (T0), one month after the completion of cancer treatment (T1), on the completion of the intervention (T2) and 12 months after cancer treatment (T3).

Key secondary outcome(s))
1. Marital satisfaction is measured by the Chinese version of ENRICH Marital Satisfaction Scale (EMS) at baseline (T0), one month after the completion of cancer treatment (T1), on the completion of the intervention (T2) and 12 months after cancer treatment (T3).
2. Sexual distress is measured by the Chinese version of Female Sexual Distress Scale-Revised (FSDS-R) at baseline (T0), one month after the completion of cancer treatment (T1), on the completion of the intervention (T2) and 12 months after cancer treatment (T3).

Completion date
31/05/2022

Eligibility

Key inclusion criteria
1. Women newly diagnosed with primary GC (uterine, ovarian or cervical cancers) over the past three months
2. Not in the terminal stage of the disease
3. With a regular sexual partner
4. Over 18
5. Able to understand spoken Cantonese and to read Chinese
6. Consenting to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

Total final enrolment
150

Key exclusion criteria
Those with unsuitable physical or mental health conditions, or a known pre-existing psychotic illness

Date of first enrolment
11/07/2019

Date of final enrolment
10/07/2021

Locations

Countries of recruitment
Hong Kong

Study participating centre
Prince of Wales Hospital
30-32 Ngan Shing Street
Sha Tin
New Territories
Hong Kong
Hong Kong
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Study participating centre
Queen Elizabeth Hospital
30 Gascoigne Road
Yau Ma Tei
Hong Kong
Hong Kong
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Study participating centre
Pamela Youde Nethersole Eastern Hospital
3 Lok Man Road
Chai Wan
Hong Kong

Hong Kong
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Sponsor information

Organisation
The 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
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 is sensitive and all the results will be disseminated in publication.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/03/2022	05/05/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes