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A multimodal cancer rehabilitation programme for women treated for gynaecological cancer

Submission date
31/10/2023

Recruitment status
No longer recruiting

Registration date
02/11/2023

Overall study status
Completed

Last Edited
02/07/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Women treated for gynaecological cancers are challenged to cope with a wide variety of stressful events after treatment, which may lead to impaired health-related quality of life as well as an increased risk of developing other long-term conditions. National evidence-based guidelines consistently recommend that follow-up care for people treated for cancer should include components of lifestyle and psychosocial counselling. While the needs of this vulnerable group are well-recognised in Hong Kong, there is currently a lack of structured rehabilitation and supportive programmes. This study aims to examine the effects of a 12-week multimodal cancer rehabilitation intervention (MCRI) on the sense of coherence, cancer-specific distress, health-promoting behaviours and health-related quality of life. The cost-effectiveness of the MCRI will also be examined to inform healthcare policy.

Who can participate?
Chinese women aged 18 old and above who have completed intensive treatments for gynaecological cancers (uterine, ovarian or cervical cancers) within 3 months

What does the study involve?
Participants will be recruited at two public hospitals in Hong Kong. They will be allocated randomly to either the intervention or control group. The intervention group will receive the MCRI for 12 weeks (a self-guided online health education programme and three individual virtual counselling sessions with a research nurse) while the control group will receive attention from the research nurse. Participants will be assessed at the start of the study, at the end of the intervention, and after 12 weeks of intervention for outcomes including a sense of coherence, cancer-specific distress and health-related quality of life. Thereafter, health-related quality of life will be assessed every three months until 12 months after the intervention. The intervention group will be interviewed after the end of the intervention to explore their experiences and perceptions of about the intervention.

What are the possible benefits and risks of participating?
The potential benefits of participating in the study include improvements in sense of coherence,

cancer-related distress and health-related quality of life among women treated for gynaecological cancers. The interventions are not expected to cause any pain, discomfort, or harm to participants.

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

When is the study starting and how long is it expected to run for?
May 2021 to October 2025

Who is funding the study?
The study is funded by the 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?
Prof. Ka Ming Chow, kmchow@cuhk.edu.hk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A multimodal cancer rehabilitation programme promoting sense of coherence for women treated for gynaecological cancer: A randomised controlled trial

Study objectives

The intervention group will have 1) a better sense of coherence, 2) reduced cancer-specific distress, 3) more positive lifestyle changes and 4) better health-related quality of life after completion of the intervention than those in the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 02/06/2021, The 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, 000, Hong Kong; +852 3505 3935; crec@cuhk.edu.hk), ref: 2021.276-T

2. approved 17/01/2023, Research Ethics Committee (Kowloon Central / Kowloon East) (Room 414, Nurses Quarters, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon, 000, Hong Kong; +85235066307; kckecrec@ha.org.hk), ref: KC/KE-22-0224/ER-1

Study design
Parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Women treated for gynaecological cancer

Interventions
Each participant will be randomly assigned to either an intervention group or a control group in a 1:1 ratio using block randomisation. Participants in the intervention group will receive a 12-week multimodal cancer rehabilitation intervention (MCRI), in which they will be granted access to an enhanced version of the Women's Wellness After Cancer Programme (WWACPHK) developed by our research team via a mobile-enabled platform and three virtual counselling sessions. The 12-week programme will cover topics such as healthy diet, exercise, menopause-related symptoms and management, sleep, sexuality, body image, pelvic floor exercises, stress management, chronic disease prevention and cancer screening. For the WWACPHK app, new information and evidence will be posted on the app every day in the first three weeks, and then weekly for the following nine weeks. A research nurse will monitor the number of modules accessed and conduct reminder telephone calls when an account is inactive for a week or more to enhance adherence. Furthermore, three individual virtual counselling sessions with the research nurse will be scheduled at weeks 1, 6 and 12 to (i) empower the participants by providing guidance on the use of the digital platform and the needed health information; and (ii) engage the participants to reflect on their belief, assumptions, knowledge and goals.

Participants in the control group will receive brief information on the follow-up schedule during baseline data collection. To control for the attention effect, participants will receive attention from the research nurse on three occasions in the same period of time as the intervention group. The nurse will make telephone calls to them at weeks 1, 6 and 12 to deliver general greetings and will not provide any kind of intervention. After the completion of the study, the programme eBook will be sent to the participants.

Intervention Type
Behavioural

Primary outcome(s)
Sense of coherence measured using the Chinese version of the Sense of Coherence 13-item Scale (CSOC-13) at baseline, completion of the intervention, and 12 weeks after completion

Key secondary outcome(s))
1. Cancer-specific distress measured using the Chinese version of the Impact of Events-Revised scale (CIES-R) at baseline, completion of the intervention, and 12 weeks after completion
2. Dietary and physical activity practices measured using the Chinese version of Health Promotion Lifestyle Profile II (HPLP-II) at baseline, completion of the intervention, and 12 weeks after completion
3. Health-related quality of life measured using the Chinese version of the Medical Outcomes Study (MOS) 36-item Short Form (SF-36) Health Survey at baseline, completion of the intervention, and 12 weeks after completion
4. Health-related quality of life measured using the Hong Kong version of the five-level EuroQol-5 Dimension (EQ-5D-5L) every three months from baseline to 12-month post-intervention
5. Participants' experiences, perceptions and opinions explored by semi-structured interviews upon completion of the intervention

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Women with a primary diagnosis of gynaecological cancers (uterine, ovarian or cervical cancers)
2. Within 3 months of completion of intensive cancer treatments (e.g. surgery, radiotherapy, and /or chemotherapy)
3. Over 18 years old
4. Able to understand spoken Cantonese and to read Chinese
5. Having smartphones with iOS or Android operating systems
6. Consenting to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
Those with unsuitable physical or mental health conditions, including visual impairment or preexisting psychosis, will be excluded as their ability to comprehend information and answer questionnaires would be affected.

Date of first enrolment
01/12/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Hong Kong

Study participating centre
The Chinese University of Hong Kong
The Nethersole School of Nursing
Faculty of Medicine
Shatin
Hong Kong
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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
The anonymous datasets generated during and/or analysed during the study will be available upon reasonable request from Dr Ka Ming Chow (kmchow@cuhk.edu.hk) after the study results are published.

Anonymised demographic characteristics and summary scores of the outcomes will be shared. Consent from participants was required and obtained. There are no ethical or legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/06/2025	02/07/2025	Yes	No