# A multimodal cancer rehabilitation programme for women treated for female reproductive cancers: a pilot study

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
02/10/2021		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/10/2021	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
09/07/2024	Cancer			

#### Plain English summary of protocol

Background and study aims

Women treated for reproductive 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 programme. This study aims to (1) assess the feasibility of a 12-week multimodal cancer rehabilitation programme for women treated for reproductive cancers; (2) test the early effects of the programme on sense of coherence, cancer-specific distress and health-related quality of life; and (3) collect views and comments on the programme.

#### Who can participate?

Chinese women aged 18 or above who have completed intensive treatments for reproductive cancers (breast, 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 a multimodal cancer rehabilitation programme for 12 weeks 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 sense of coherence, cancer-specific distress and health-related quality of life. The intervention group will be interviewed after the end of the intervention to assess its feasibility and acceptability.

#### 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 female reproductive cancers. The interventions are not expected to cause any pain, discomfort, or harm to participants.

Where is the study run from? Chinese University of Hong Kong (Hong Kong)

When is the study starting and how long is it expected to run for? June 2021 to May 2022

Who is funding the study? Chinese University of Hong Kong (Hong Kong)

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

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Ka Ming Chow

#### Contact details

The Nethersole School of Nursing Esther Lee Building Chinese University of Hong Kong Shatin Hong Kong 000 +852 (0)39434431 kmchow@cuhk.edu.hk

# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# Study information

#### Scientific Title

A multimodal cancer rehabilitation programme promoting a sense of coherence for women treated for female reproductive cancers: a pilot study

#### **Acronym**

#### **Study objectives**

This study aims to:

- 1. Assess the feasibility of the trial design
- 2. Test the preliminary effects of the programme on sense of coherence, cancer-specific distress and health-related quality of life
- 3. Collect views and comments on the programme

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

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, Hong Kong; +852 (0)3505 3935; crec@cuhk.edu.hk), ref: 2021.276-T

#### Study design

Parallel-group randomised controlled pilot trial

#### Primary study design

Interventional

#### Study type(s)

Quality of life

#### Health condition(s) or problem(s) studied

Women treated for female reproductive cancers (breast, uterine, ovarian or cervical cancers)

#### **Interventions**

Each participant will be randomly assigned either to an intervention group or a control group in 1:1 ratio using block randomisation.

Participants in the intervention group will receive a 12-week multimodal cancer rehabilitation intervention, in which they will be granted access to a culturally adapted version of WWACP (WWACPHK) developed by our research team via a web or mobile-enabled platform. 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; new information and evidence will be posted on the website/app every day in the first three weeks, and then weekly for the following nine weeks. A research nurse will monitor participants' page views and 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) engaging 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 Impact of Events-Revised scale (CIES-R) ) at baseline, completion of the intervention, and 12 weeks after completion
- 2. Health-related quality of life measured using the Chinese version of the MOS 36-item Short Form (SF-36) Health Survey at baseline, completion of the intervention, and 12 weeks after completion
- 3. Participants' experiences, perceptions and opinions explored by semi-structured interviews upon completion of the intervention

#### Completion date

31/05/2022

# Eligibility

#### Key inclusion criteria

- 1. Women with a primary diagnosis of female reproductive cancers (breast, uterine, ovarian or cervical cancers)
- 2. Within 3 months of completion of intensive cancer treatments (e.g. surgery, radiotherapy, and /or chemotherapy) but can be on maintenance therapies such as tamoxifen, trastuzumab and bisphosphonates
- 3. Over 18 years old
- 4. Able to understand spoken Cantonese and to read Chinese
- 5. Have internet-connected computing devices or smartphones

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Female

#### Total final enrolment

#### 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

26/10/2021

#### Date of final enrolment

31/12/2021

# **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

# Sponsor information

#### Organisation

Chinese University of Hong Kong

#### **ROR**

https://ror.org/00t33hh48

# Funder(s)

#### Funder type

University/education

#### **Funder Name**

Chinese University of Hong Kong

#### Alternative Name(s)

The Chinese University of Hong Kong, , , Heunggóng Jüngmahn Daaihhohk, CUHK,

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Universities (academic only)

#### 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 is published.

#### IPD sharing plan summary

Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/07/2024	09/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes