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

Submission date
02/10/2021

Recruitment status
No longer recruiting

Registration date
20/10/2021

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
MCRI

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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
02/06/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

Total final enrolment
35

Key exclusion criteria
Those with unsuitable physical or mental health conditions, including visual impairment or pre-existing 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
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Sponsor information

Organisation
Chinese University of Hong Kong

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Chinese University of Hong Kong

Alternative Name(s)
The Chinese University of Hong Kong, , CUHK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. This is a pilot study. The study protocol of the full trial will be published later.

Intention to publish date
31/12/2023

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