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A culturally-adapted Women's Wellness after Cancer Program for Chinese women treated for gynecological cancer

Submission date
11/03/2021

Recruitment status
No longer recruiting

Registration date
25/03/2021

Overall study status
Completed

Last Edited
08/06/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Previous research indicates that nearly 90% of gynecological cancer survivors report a need for supportive care services. However, such services are limited in most countries, including Hong Kong. Psychological distress was also found to be significantly associated with unmet needs. Therefore, the incorporation of psychosocial care as an integral component in the care of survivorship is important to alleviate survivors' psychosocial health associated with previous cancer treatment and improve their health-related quality of life. Previously, a "Women's Wellness after Cancer Program (WWACP)" was developed to improve health-related quality of life and reduce chronic disease risk in Australian women previously treated for breast, gynecological and blood cancers. This trial aims to assess the feasibility and acceptability of a culturally adapted version of WWACP, known as WWACPHK.

Who can participate?
Chinese women aged 18 or older who have been previously treated for gynecological cancer.

What does the study involve?
Participants will be recruited at a public hospital in Hong Kong. Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). One group of participants will be given access to the culturally-adapted WWACP program materials for 12 weeks, while the other group of participants will receive standard care. Participants will be assessed before at the start of the study, after the WWACPHK programme, and after 12 weeks for health-related quality of life, psychological outcomes and perceived self-efficacy to adopt a healthy lifestyle. The participants who follow WWACPHK will be interviewed at the end of the programme to assess its acceptability.

What are the possible benefits and risks of participating?
The potential benefits of participating in the study are an improvement in the quality of patient care for gynaecological cancer survivors and improvement of patient psychological state and

health-related quality of life. Upon completion of the study, a cash allowance of HK$200 will be given to all participants to cover travel expenses and compensate for their time. The interventions are not expected to cause any pain, discomfort, or harm to participants.

Where is the study run from?
The Nethersole School of Nursing, The Chinese University of Hong Kong (Hong Kong)

When is the study starting and how long is it expected to run for?
From September 2017 to November 2018

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

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

Study website
https://wwacp.nur.cuhk.edu.hk/

Contact information

Type(s)
Public

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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 culturally-adapted Women's Wellness after Cancer Program for reducing psychological distress and improving health-related quality of life among Hong Kong women treated for gynecological cancer: a feasibility study

Acronym
WWACPHK

Study objectives
To assess the feasibility of the trial design, participant perceptions of the acceptability of the intervention, and the acceptability and feasibility of the outcome measures (health-related quality of life, anxiety, depression, and self-efficacy in engaging in healthy lifestyles) as methods to assess the value of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/02/2018, 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; +8523505 3935; crec@cuhk.edu.hk), ref: CREC 2017-692

Study design
Parallel-group randomized controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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 gynecological cancer

Interventions
The enrolled subjects were randomized in a 1:1 ratio into intervention group or control group after baseline data collection. Sealed envelopes were used to ensure allocation concealment. Group allocation was conducted by an independent statistician using computer-generated random numbers prepared in advance.

The WWACP (Women's Wellness after Cancer Program) is an evidence-based, multidisciplinary, whole-of-lifestyle intervention developed by Australian health researchers. The program provides informational and psychological support for female cancer survivors, by means of an eBook, a discussion board and virtual consultations over 12 weeks.

The intervention group received the WWACPHK (Women's Wellness after Cancer Program- Hong Kong), which was a culturally adapted version of WWACP. The eBook included topics on healthy diet, exercise, menopause-related symptoms and management, sleep, sexuality, body image, pelvic floor exercises, stress management, chronic disease prevention and health screening; new information was posted on the website every day in the first three weeks, and then weekly for the following nine weeks. Participants' click-through rates were monitored and follow-up telephone calls were conducted weekly for the first two weeks to reinforce adherence. Further phone calls or reminder emails were sent throughout the 12 weeks wherever needed. In addition, the participants were encouraged to post messages on the online discussion board at least once a week. The interactive discussion board was a semi-structured, asynchronous, anonymous discussion forum led by a nurse moderator. The forum was only accessible to participants and the research team during the 12 weeks of the programme. The nurse moderator was responsible for monitoring the discussion forum on a daily basis and responding to the participants to encourage further discussion. A 20-minute long questionnaire was administered at baseline, immediately post-intervention, 12 weeks post-intervention. Qualitative data were collected at immediately post-intervention through semi-structured interviews to collect participants' views and opinions about the program.

The control participants were provided with standard care, where they merely received health information in general from healthcare professionals on diet, physical activity and risks of increased alcohol consumption during clinic visits. Consistent with the intervention group, a 20-minute long questionnaire was administered at baseline, immediately post-intervention, 12 weeks post-intervention.

Intervention Type
Behavioural

Primary outcome measure
Health-related quality of life measured using the Traditional Chinese version of the Functional Assessment of Cancer Therapy-General Version 4 at baseline, immediately post-intervention, and 12 weeks

Secondary outcome measures
1. Depression and anxiety measured using the Chinese version of the Hospital Anxiety and Depression Scale at baseline, immediately post-intervention, and 12 weeks
2. Self-efficacy in adhering to a healthy diet measured using the Chinese version of Bandura's

Eating Habits Self-Efficacy scale at baseline, immediately post-intervention, and 12 weeks
3. Self-efficacy in adhering to an exercise routine measured using the Chinese version of Bandura's Exercise Self-Efficacy scale at baseline, immediately post-intervention, and 12 weeks

Overall study start date
01/09/2017

Completion date
27/11/2018

Eligibility

Key inclusion criteria
1. Chinese women diagnosed with cervical, ovarian, uterine, vaginal, or vulva cancer as a primary cancer and have completed treatment
2. Aged ≥18 years
3. Able to comprehend Chinese and communicate in Cantonese
4. In possession of a tablet computer or smartphone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

Total final enrolment
26

Key exclusion criteria
Unsuitable physical or mental health conditions, including visual impairment or pre-existing psychosis

Date of first enrolment
01/05/2018

Date of final enrolment
12/06/2018

Locations

Countries of recruitment

Hong Kong

Study participating centre
The Nethersole School of Nursing
The Chinese University of Hong Kong
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Sponsor information

Organisation
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Sponsor type
University/education

Website
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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, , 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.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Ka Ming CHOW at kmchow@cuhk.edu.hk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2023	08/06/2023	Yes	No