

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/06/2023	Condition category Cancer	<input type="checkbox"/> 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

Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

Esther Lee Building

Ma Liu Shui

Hong Kong

Hong Kong

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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, , , Hēunggóng Jūngmàhn Daaihohk, 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 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
Study website	Study website	11/11/2025	11/11/2025	No	Yes