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A multimodal couple-coping intervention after treatment for premenopausal breast cancer

Submission date
04/05/2023

Recruitment status
No longer recruiting

Registration date
08/05/2023

Overall study status
Completed

Last Edited
18/03/2025

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
Breast cancer is a common cancer among women in Hong Kong. Even though medical technology has advanced and improved the survival rate, many women still experience negative effects from treatment. Specifically, many women, especially those who haven't gone through menopause, report changes in their sexuality, which can lead to difficulties in their intimate relationships and affect their quality of life.
Some evidence suggests that couple-based interventions can help promote sexual health for women with breast cancer and their partners, but such interventions are not commonly offered in Hong Kong, and it's unclear how effective they are.
This study aims to develop and test a new intervention called the multimodal couple-coping intervention (MCI) for premenopausal women with breast cancer and their partners. In phase I, researchers will gather input from women who have undergone breast cancer treatment, their partners, and experts in oncology to see if the MCI is acceptable and relevant in the Hong Kong context. In phase II, researchers will evaluate the effects of the MCI on sexual adjustment, relationship quality, and quality of life among the women and their partners.

Who can participate?
Phase I: Premenopausal women treated with breast cancer and their partners, oncology experts including academics and healthcare professionals.
Phase II: Premenopausal women treated with breast cancer in recent six months and their partners.

What does the study involve?
In Phase I of the study, researchers will use a qualitative approach to find out if the multimodal couple-coping intervention (MCI) is acceptable and relevant for premenopausal women with breast cancer and their partners in Hong Kong. Eligible participants will be invited to take part in an eight-week program consisting of five sessions that include individual and couples counseling, online reading, discussion forum, and telephone calls. The program covers topics like the impact of breast cancer on sex and intimacy, communication and problem-solving skills, coping, cognitive restructuring of sex and intimacy, intimacy-building activities, and maintaining intimacy. After completing the program, participants and their partners will be interviewed about their experiences with the program.

For the experts, the researchers will explain the MCI intervention components, content, and design and invite them to provide feedback on the intervention's implementation and sustainability.

In Phase II of the study, participants will be randomly assigned to either the intervention or attention control group. Those in the intervention group will receive the MCI program described above, while those in the attention control group will receive the same amount of contact without the intervention components. Both groups will complete questionnaires before and after the program to assess sexual adjustment, relationship quality, and quality of life. After completing the program, participants and their partners will be interviewed to explore their experiences and opinions about the intervention.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in their sexual adjustment, relationship quality and quality of life. There are no risks associated with participating in this study.

Where is the study run from?
Oncology units in Pamela Youde Nethersole Eastern Hospital, Prince of Wales Hospital and Princess Margaret Hospital.

When is the study starting and how long is it expected to run for?
September 2022 to December 2025

Who is funding the study?
General Research Fund of the Hong Kong Research Grants Council.

Who is the main contact?
Dr Ka Ming Chow
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Randomised controlled trial of a multimodal couple-coping intervention to enhance couples' sexual adjustment after treatment for premenopausal breast cancer

Study objectives
Participants in the intervention group will have better 1) sexual adjustment, 2) relationship quality, and 3) quality of life, after the completion of the intervention than those in the attention control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 09/09/2022, Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC; 8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; +852 (0)3505 3935; crec@cuhk.edu.hk), ref: 2022.416-T
2. Approved 03/11/2022, Hong Kong East Clinical Research Ethics Committee (3 Lok Man Road, Chai Wan, Hong Kong; +852-2595-6111; CRER-Portal@ha.org.hk), ref: HKECCREC-2022-061
3. Approved 02/02/2024, Hospital Authority Central Institutional Review Board (A503, 5/F, Block A, Centre for Health Protection, 147B, Argyle Street, Kowloon, Hong Kong), ref: CIRB-2023-185-1

Study design
Multicenter single-blinded prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Breast cancer

Interventions
This study consists of two phases:
Phase I of the study aims to explore the acceptability and relevance of the MCI from the

perspective of Hong Kong premenopausal women treated for breast cancer and their partners, a panel of experts including academics specialising in oncology research, and healthcare professionals working in oncology units;
Phase II of the study aims to evaluate the effects of the MCI on sexual adjustment among premenopausal women treated for breast cancer, and relationship quality and quality of life among the women and their partners.

In Phase I, 10 participants and their partners will be recruited to participate in the intervention while in Phase II, 160 participants will be recruited and assigned randomly to participate in the intervention or to an attention control group.

The eight-week intervention comprises five face-to-face and virtual individual couple counselling sessions combined with online reading, a discussion forum, and telephone calls. Each session will be delivered by a trained research nurse every two weeks (at Weeks 0, 2, 4, 6, and 8) covering topics on the impact of BRC on sex and intimacy, communication and problem-solving skills, dyadic positive coping, cognitive restructuring of sex and intimacy, intimacy-building activities, and maintaining intimacy.

The attention control group will only receive attention from the research nurse on the five occasions in the same period as the intervention group. At Week 0, the nurse will not provide any kind of intervention, but only meet them to invite them to join the study and collect baseline data on recruitment. At Week 2, 4, 6 and 8, the nurse will call them to deliver general greetings with general advice being given over the phone.

Subject allocation will be done by using stratified block randomisation with a block size of 10 and an allocation ratio of 1:1 to maintain a good balance of participants between the two groups throughout the recruitment period in each study site. A random sequence of grouping identifiers (I or C) for each site, based on computer-generated random numbers, will be prepared in advance by an independent statistician.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 11/09/2024:

Sexual adjustment will be measured by the Chinese version of the Sexual Adjustment and Body Image Scale (SABIS) at baseline (T0), on completion of the intervention (T1), 3 months post-intervention (T2) and 6 months post-intervention (T3). [Phase II]

Previous primary outcome measure:

Sexual adjustment will be measured by the Chinese version of the Sexual Adjustment and Body Image Scale (SABIS) at baseline (T0), on completion of the intervention (T1) and 3 months post-intervention (T2). [Phase II]

Key secondary outcome(s))
Current secondary outcome measures as of 11/09/2024:

1. Relationship quality will be measured by the Chinese version of the ENRICH Marital Satisfaction Scale (EMS) at baseline (T0), on completion of the intervention (T1), 3 months post-intervention (T2) and 6 months post-intervention (T3). [Phase II]
2. Quality of life will be measured by the Chinese version of MOS 36-item Short Form version 2 (SF-36v2®) Health Survey at baseline (T0), on completion of the intervention (T1), 3 months post-intervention (T2) and 6 months post-intervention (T3). [Phase II]
3. Intervention participants and their' experiences, perceptions and opinions will be explored by semi-structured interviews upon completion of the intervention. [Phases I & II]
4. Expert's comments and suggestions on the intervention will be explored by semi-structured interviews. [Phase I]

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Previous secondary outcome measures:

1. Relationship quality will be measured by the Chinese version of the ENRICH Marital Satisfaction Scale (EMS) at baseline (T0), on completion of the intervention (T1) and 3 months post-intervention (T2). [Phase II]
2. Quality of life will be measured by the Chinese version of MOS 36-item Short Form version 2 (SF-36v2®) Health Survey at baseline (T0), on completion of the intervention (T1) and 3 months post-intervention (T2). [Phase II]
3. Intervention participants and their' experiences, perceptions and opinions will be explored by semi-structured interviews upon completion of the intervention. [Phases I & II]
4. Expert's comments and suggestions on the intervention will be explored by semi-structured interviews. [Phase I]

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/09/2024:

Phase I:
1. Patients: Women with a diagnosis of breast cancer; all active treatment completed but endocrine and/ or maintenance therapy allowed; with a regular sexual partner, either heterosexual or homosexual; over 18 years; in a premenopausal state when diagnosed with breast cancer; has a smartphone with internet connection;
able to understand spoken Cantonese and to read Chinese; consenting to participate.
2. Partners of the participating patients.
3. Academics: Academics who specialise in oncology research from the institute of the PI.
4. Healthcare professionals: Registered nurses and physicians working in the oncology unit of two participating hospitals, with at least two-year clinical experience in the specialty.

Phase II:
1. Patients: Women with a diagnosis of breast cancer; completed active treatment for breast cancer in recent six months but endocrine and/ or maintenance therapy allowed, and with no evidence of metastatic disease; with a regular sexual partner, either heterosexual or homosexual; over 18 years; in a premenopausal state when diagnosed with breast cancer; has a smartphone with internet connection; able to understand spoken Cantonese and to read

Chinese; consenting to participate.
2. Partners of the participating patients.

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Previous inclusion criteria:

Phase I:
1. Patients: Women with a diagnosis of breast cancer; all active treatment completed but endocrine and/ or maintenance therapy allowed; with a regular sexual partner, either heterosexual or homosexual; over 18 years; in a premenopausal state when diagnosed with breast cancer; has a smartphone with internet connection;
able to understand spoken Cantonese and to read Chinese; consenting to participate.
2. Partners of the participating patients.
3. Academics: Academics who specialise in oncology research from the institute of the PI.
4. Healthcare professionals: Registered nurses and physicians working in the oncology unit of two participating hospitals, with at least two-year clinical experience in the specialty.

Phase II:
1. Patients: Women with a diagnosis of breast cancer; completed active treatment for breast cancer in recent three months but endocrine and/ or maintenance therapy allowed, and with no evidence of metastatic disease; with a regular sexual partner, either heterosexual or homosexual; over 18 years; in a premenopausal state when diagnosed with breast cancer; has a smartphone with internet connection; able to understand spoken Cantonese and to read Chinese; consenting to participate.
2. Partners of the participating patients.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Phases I & II: Patients with a known pre-existing psychiatric illness will be excluded.

Date of first enrolment
01/06/2023

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Hong Kong

Study participating centre
Prince of Wales Hospital
30 Ngan Shing Street
Sha Tin
Hong Kong
Hong Kong
-

Study participating centre
Pamela Youde Nethersole Eastern Hospital
3 Lok Man Road
Chai Wan
Hong Kong
Hong Kong
-

Study participating centre
Princess Margaret Hospital
2-10 Princess Margaret Hospital Road
Kwai Chung
Hong Kong
Hong Kong
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Sponsor information

Organisation
The Chinese University of Hong Kong

Funder(s)

Funder type
Government

Funder Name
Research Grants Council, University Grants Committee

Alternative Name(s)
, , , ,

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan
Current participant level data sharing plan as of 11/09/2024:

The de-identified dataset will be deposited to a public depository after study completion and study findings have been published.

Previous participant level data sharing plan:

The datasets generated during and analysed during the study will be available upon request from Dr Ka Ming Chow at kmchow@cuhk.edu.hk.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/08/2024	23/08/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes