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A multimedia method for genetic counselling in breast cancer patients

Submission date
27/09/2023

Recruitment status
Recruiting

Registration date
09/10/2023

Overall study status
Ongoing

Last Edited
13/12/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Mutations in the BRCA genes are associated with an 80% risk of breast cancer. However, women must know that they have a genetic mutation so that they can use this information to make treatment choices. The availability of genetic testing and counselling is important for women with breast cancer. In the traditional model, genetic counselling is facilitated over two appointments (pre-test and post-test) with a genetic counsellor. However, there is an established shortage of manpower in genetic counselors. In this pilot study, we aim to assess the feasibility of a novel genetic counselling method and evaluate preliminary outcomes compared to women who receive traditional genetic counselling.

Who can participate?
Breast cancer patients aged 18 years or older.

What does the study involve?
A cohort of 108 dyads will be recruited to the study. Each dyad includes a woman with breast cancer and a history of breast cancer and a female family member with or without breast cancer history. Dyads will be recruited from the breast cancer clinic of three acute hospitals (PYNEH, PWH, UCH) in Hong Kong. The inclusion criteria for recruitment are women who have not done any previous genetic testing; over 18 years old; Chinese in ethnicity; and consenting to participate in the study. Those who are currently pregnant or have given birth in the last 6 months will be excluded from this study due to emotional concerns.

What are the possible benefits and risks of participating?
Participants can opt for free genetic testing provided by our team. Pre- and post-test genetic counselling will be provided. No potential risk for the participants is expected.

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

When is the study starting and how long is it expected to run for?
August 2023 to August 2026

Who is funding the study?
The Nethersole School of Nursing at The Chinese University of Hong Kong

Who is the main contact?
Dr Judy Chan, judychanyw@cuhk.edu.hk

Contact information

Type(s)
Scientific

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 multimedia method for pre-test genetic counselling in breast cancer patients – A pilot feasibility study

Study objectives
Current study hypothesis as of 13/12/2023:
Hypothesis 1: The use of multi-media in genetic counselling will lead to higher rates of genetic testing uptake compared to traditional genetic counselling.
Hypothesis 2: Participants who receive multi-media genetic counselling will demonstrate a greater understanding of their personal breast cancer risk and the benefits/risks of genetic testing compared to those who receive traditional genetic counselling.
Hypothesis 3: Participants who receive multi-media genetic counselling will show higher levels of

perceived threat (severity and susceptibility) and perceived efficacy (response efficacy and self-efficacy) according to the Protection Motivation Theory, compared to those who receive traditional genetic counselling.
Hypothesis 4: Participants who receive multi-media genetic counselling will report higher satisfaction levels and find the genetic counselling process more engaging and less anxiety-provoking compared to those who receive traditional genetic counselling.
Hypothesis 5: The effect of the multi-media genetic counselling on genetic testing uptake after intervention is mediated by changes in women's perceived threat and perceived efficacy.

Previous study hypothesis:
The uptake of genetic testing, satisfaction with genetic counselling, the accuracy of recall of genetic knowledge as well as the quality of life will be higher or similar in women who receive non-face-to-face multimedia pre-test genetic counselling compared to women who receive traditional genetic referral and counselling.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/08/2023, The Joint CUHK-NTEC CREC (8/F, Lui Che Woo Clinical Sciences Building, PWH, Shatin, Hong Kong, -, Hong Kong; +852 35053935; crmo@cuhk.edu.hk), ref: 2023.359-T

Study design
Prospective randomized controlled study

Primary study design
Interventional

Study type(s)
Efficacy

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

Interventions
Current interventions as of 13/12/2023:
A total of 108 dyads including 108 breast cancer patients and 108 high-risk people (female family members) will be recruited to the study. Participants will be evenly randomly assigned to either an intervention group (n = 54), which will receive multi-media genetic counselling, or a control group (n = 54), which will receive standard face-to-face genetic counselling. After receiving pre-test genetic counseling and within 72 hours, the participants will determine if they want to uptake genetic testing provided by our team. Outcome measurements in quantitative and qualitative approaches will be done before and after the participants finish the pre-test genetic counselling.

Participants in the intervention group will receive a multimedia information package which includes a leaflet and a mobile application (app) user guide. The content of each item will be developed by our team as below:
1. Written and electronic leaflet
We will prepare an educational leaflet and send it to the participants by mail (hard copy), email, or WhatsApp Messenger (soft copy). The leaflet will illustrate the following elements of pre-test

genetic counselling.
a. Reasons why genetic testing is needed.
b. Gene variant(s) being tested, the risks associated with the gene variants and implications for health care.
c. Possible test outcomes: Positive (pathogenic variant was identified), negative (no pathogenic variant was found) or variant of uncertain significance (VUS) with unknown impact on disease risk.
d. Risks, benefits, and limitations of genetic testing (e.g., psychosocial impacts of test results, privacy, and data security).
e. Implications of genetic testing for family members (e.g., pattern of variant transmission and risks of inheritance in children and other family members.)
f. Possible uncertainties due to present lack of knowledge.
2. Mobile app
A mobile app for smartphones and tablets will be developed by our team. The features of the app will include:
a. Digital version of the educational leaflet in the format of slides.
b. An educational video conducted by genetic counselor to deliver a pre-test counselling in a clear, objective, and nondirective fashion, which allows participants sufficient time to understand information and make informed decisions regarding testing and further evaluation or treatment. Simple questions will be asked at the end of the video to assess the participants' understanding of genetic testing.
c. A discussion forum led by a genetic counselor to enhance the engagement of the participants by asking questions and sharing their experience.
d. A chat room that could allow the participants to communicate privately with the counselor.

Previous interventions:
60 breast cancer patients who will be randomly assigned (using Excel) to either, the face-to-face consultation group (30 subjects, Face arm, control group, traditional pre-test genetic counselling will be provided) or the multimedia non-face-to-face consultation group (30 subjects, non-Face arm, intervention group, multimedia information will be provided). After receiving pre-test genetic counseling, the participants will determine if they want to uptake a free genetic testing provided by our team. Outcome measurements including the uptake of genetic test, the satisfaction with genetic counselling, the quality of life, knowledge recall accuracy of genetic testing as well as cancer risk perception will be assessed in both groups within 72 hours (short-term) and 6 months post-test (long-term) after post-test genetic counselling.

Participants in the intervention group will receive a multimedia information package which includes a leaflet and a mobile application (app) user guide. The content of each item will be developed by our team as below:
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d. Risks, benefits, and limitations of genetic testing (e.g., psychosocial impacts of test results, privacy, and data security).
e. Implications of genetic testing for family members (e.g., pattern of variant transmission and

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Intervention Type
Behavioural

Primary outcome(s)
Uptake of genetic testing measured using patient records at 72 hours after pre-test genetic counselling.

Key secondary outcome(s))
1. Knowledge and understanding of genetic testing measured via follow-up surveys and personal interviews at enrollment, 72 h and 6 months after pre-test genetic counselling
2. Risk perception of breast cancer and satisfaction of genetic counselling measured via follow-up surveys and personal interviews at 72 h and 6 months after pre-test genetic counselling
3. Health-related quality of life measured using validated questionnaires administered before and after the intervention at enrollment, 72 h and 6 months after pre-test genetic counselling
4. Implementation of breast cancer prevention and management strategies measured using phone interviews after completion of quantitative measurements

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Women who have been diagnosed with breast cancer
2. Not done any previous genetic testing
3. Over 18 years old
4. Chinese ethnicity
5. Consenting to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Key exclusion criteria
Those who are currently pregnant or have given birth in the last 6 months

Date of first enrolment
01/10/2023

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
Hong Kong

Study participating centre
Prince of Wales Hospital
30-32 Ngan Shing Street
Shatin
New Territories
Hong Kong
Hong Kong
-

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

Study participating centre
United Christian Hospital
130 Hip Wo Street

Kwun Tong
Kowloon
Hong Kong
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, , , Hēunggóng Jūngmàhn 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 data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	In Mandarin version 1	29/06/2023	09/10/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes