ISRCTN15196866 https://doi.org/10.1186/ISRCTN15196866

Community education and navigation to improve breast cancer screening uptake in Malaysia

Submission date
08/08/2022

Recruitment status
No longer recruiting

Registration date
10/08/2022

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Breast cancer screening uptake in Malaysia is low and a high number of cases present at a late stage. Community navigation and mobile health (mHealth) may increase screening attendance, particularly by women from rural communities. This randomized controlled study evaluated an intervention that used mHealth and community health workers to educate women about breast cancer screening (i.e. clinical breast examination - CBE) and navigate them to CBE services in the context of the COVID-19 pandemic.

Who can participate?
The target population comprised residents from Sungai Segamat and Jabi who were recorded in the South East Asia Community Observatory (SEACO) database, completed the SEACO health survey in 2018, and, previously, gave consent to be contacted about participating in research studies. Thus, we contacted women aged 40-74 years who had registered their phone number with SEACO. Only women who had a mobile phone number via which they could be contacted were able to participate in the study. BC patients and survivors, and women who reported to the research team at the time of the interview that they were experiencing BC symptoms were excluded from the research and encouraged to seek help from their local doctor as soon as possible.

What does the study involve?
Women from the two sub-districts in the SEACO database were randomized to the intervention group (IG) or comparator group (CG) with a 1:1 allocation prior to being contacted. Women who were randomized to the IG received an intervention consisting of mHealth education and community navigation by community health workers (CHWs). CHWs called the women to whom they had been assigned during the same week that the baseline assessment interview had been completed to discuss breast cancer symptoms and breast self-examination, address barriers to screening, and ask them if they were interested in attending a CBE at the LPPKN clinic in Segamat. CBE appointments were arranged to occur the following week at a time that suited interested participants. CHWs discussed with participants who did not want to avail of the offer of screening their concerns and fears, but respected the decision of women who reiterated that

they did not want to attend the CBE. Women with normal CBE results were asked by LPPKN nurses to attend screening biannually, either at the LPPKN or at a health clinic, as recommended in the clinical practice guidelines. A doctor at the LPPKN clinic met with women who received an abnormal CBE finding and referred them for a mammogram at the hospital as soon as possible after their CBE, free of charge.

The SEACO-trained data collectors contacted (via phone) women who were randomised to the CG - during this call, they informed women who agreed to participate that BC is the most common cancer amongst women in Malaysia and about the importance of early detection. Women in the CG did not receive the intervention (described above) but they could avail of 'usual' screening via their local clinic – however, elective procedures were stopped at the local government clinics to facilitate COVID-19 vaccinations and patients. In addition, CG participants were offered a scheduled free CBE at the LPPKN clinic after the follow-up data collection phase had been completed.

Information about gender, age, ethnicity, household income, marital status, education, occupation and study sub-district were extracted from the most recent health survey (2018) recorded in the SEACO database in order to present a profile of study participants. Participants were asked questions about mobile phone ownership/usage and internet usage during a baseline telephone survey. baseline and follow-up survey interviews were completed over the phone. Trained SEACO data collectors conducted telephone interviews with participants from the IG and CG that took approximately 15-20 minutes. The follow-up survey took between 20-25 min for the IG and 15-20 min for the CG. The survey interview comprised a number of previously adapted and validated questionnaires. LPPKN nurses were asked to record CBE attendance in a spreadsheet that was shared with SEACO on a weekly basis.

What are the possible benefits and risks of participating?
There were no immediate and direct benefits to participants; but the collected information will help to identify factors that may affect public awareness of breast cancer. Discussing and recollecting unpleasant feelings, fears, or worries about a sensitive topic such as breast cancer may have caused discomfort and distress. If participants felt upset at any stages of the study and wanted to talk about their concerns, we provided them with contact details of the Chief Investigator or encouraged them to call the National Cancer Society Malaysia hotline at 1800-88-1000. We do not expect any long-term risks associated with participating in a clinical breast examination.

Where is the study run from?
Queen's University Belfast (UK)
Monash Univerisity (Malaysia)

When is the study starting and how long is it expected to run for?
January 2021 to March 2022

Who is funding the study?
Newton Fund Impact Scheme which involved MRC from the UK and MIGHT from Malaysia.
Medical Research Council (UK) (Ref: 537084059) funded Prof Michael Donnelly as Principal Investigator on this project.
Malaysian Industry-Government Group for High Technology (MIGHT) (Ref: 2500235-122-00) funded Prof Tin Tin Su as Principal Investigator on this project.

Who is the main contact?
Prof. Michael Donnelly, michael.donnelly@qub.ac.uk
Prof. Tin Tin Su, TinTin.Su@monash.edu

Contact information

Type(s)
Principal investigator

Contact name
Prof Michael Donnelly

ORCID ID
https://orcid.org/0000-0001-8380-7413

Contact details
Centre for Public Health
Institute of Clinical Sciences
Block B, Royal Victory Hospital
Grosvenor Road
Belfast
United Kingdom
BT12 6BA
+44 2890978993
michael.donnelly@qub.ac.uk

Type(s)
Principal investigator

Contact name
Prof Tin Tin Su

ORCID ID
https://orcid.org/0000-0003-0387-6406

Contact details
Monash University Malaysia
Jeffrey Cheah School of Medicine & Health Sciences
Jalan Lagoon Selatan
Bandar Sunway
Subang Jaya
Malaysia
47500
+603-5514 4472
tintin.su@monash.edu

Additional identifiers

Protocol serial number

537084059

Study information

Scientific Title
Improving early detection of breast cancer in Malaysia during the COVID-19 pandemic - the use of mHealth to improve community education and navigation: a study protocol

Acronym
CENP

Study objectives
Our main aim was to design, implement and evaluate an intervention to improve uptake of Clinical Breast Examination (CBE) screening in Malaysia and breast cancer symptom recognition in the context of the COVID-19 pandemic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2021, Monash University Human Research Ethics Committee (Monash University, Malaysia; muhrec@monash.edu; +61 3 990 52052), ref: 29682

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Clinical Breast Examination (CBE) screening for breast cancer early detection

Interventions
This study was a randomised controlled trial and participants were randomised to either an intervention group (IG) or a control group (CG). Participant enrolment was conducted by trained data collectors. All women who were randomised to the IG or CG were invited to participate by trained data collectors over the phone. The resources for this study did not permit separation of enrollment and data collection procedures and, so, data collectors were aware of the group to which women were assigned. Participants and data collectors were not blinded during the enrollment and surveys.

The IG received a multi-component mHealth intervention i.e. information about breast cancer was provided through an educational website, and telephone calls and text messages from community health workers (CHWs) raised breast cancer awareness and offered to navigate women to CBE services. The usual free opportunistic screening service was available for CG participants. It was not possible to ‘blind’ participants, data collectors and CHWs.

Intervention Type
Behavioural

Primary outcome(s)
Clinical breast examination (CBE) screening uptake measured using records from the LPPKN clinic at follow-up as well as self-reported data at baseline and follow-up.

Key secondary outcome(s)
1. Breast cancer symptom recognition measured using the Breast Cancer Awareness Measure for Malaysia (B-CAM-M) at baseline and follow-up.
2. Intention to attend a CBE measured using the question 'I intend to have a Clinical Breast Examination to check for breast cancer in the near future' and a 5-point Likert scale for participants to rate their response at baseline and follow-up.
3. Beliefs and barriers regarding breast cancer and breast cancer screening measured using the Breast Cancer Awareness Measure for Malaysia (B-CAM-M) at baseline and follow-up.
4. Practice of breast self-examination measured using the Breast Cancer Awareness Measure for Malaysia (B-CAM-M) at baseline and follow-up.
5. Mammogram screening attendance (for CBE-positive women) measured using LPPKN clinic records at follow-up.

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Residents from Sungai Segamat and Jabi (Malaysia) who were recorded in the South East Asia Community Observatory (SEACO) database, completed the 2018 SEACO health survey and have previously given consent to be contacted about participating in other research studies.
2. Women aged 40 - 74 years
3. Registered a phone number with SEACO. Only women who were able to provide a mobile phone number when contacted were able to participate in the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
483

Key exclusion criteria
1. Breast cancer patients and survivors.
2. Women who reported to the researchers at the time of the interview that they are experiencing breast cancer symptoms were excluded from the research and encouraged to seek help from their local doctor as soon as possible.

Date of first enrolment
02/09/2021

Date of final enrolment
14/11/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
South East Asia Community Observatory
125, Jalan Sia Her Yam
Kampung Abdullah
Segamat District, Johor
Malaysia
85000

Study participating centre
Klinik LPPKN Segamat
Kawasan Hospital Segamat
Jalan Muar
Segamat District, Johor
Malaysia
85000

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Malaysian Industry-Government Group for High Technology (MIGHT)

Funder Name
Newton Fund

Alternative Name(s)
The Newton Fund, NF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from (South East Asia Community Observatory; mum.seaco@monash.edu; quantitative data; available from 01/01/2023 until 01/01/2028; information on how to request data can be found here: https://www.monash.edu.my/seaco/research-and-training/how-to-collaborate-with-seaco; participants consented for their data to be analysed anonymously for research purposes, identifying information will kept strictly confidential by only using SEACO ID numbers).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/10/2023	08/11/2023	Yes	No
Protocol (other)		18/01/2022	09/08/2022	No	No