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Long-term follow-up of breast cancer survivors: A randomized controlled study

Submission date
27/08/2017

Recruitment status
No longer recruiting

Registration date
06/09/2017

Overall study status
Completed

Last Edited
11/04/2022

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
The number of cancer survivors is increasing rapidly in Taiwan with the aging population and the advancement in cancer therapy. Breast cancer survivors consists a large proportion of this population. Cancer survivors are traditionally followed by oncology (cancer) specialists after cancer treatment. However, cancer survivors have unique needs in treatment-related symptoms, psychosocial care, chronic disease management, and lifestyle interventions. As one of the major cancer centers in Taiwan, Koo Foundation Sun Yat-Sen Cancer Center (KF-SYSCC) is building an academic institution-based comprehensive long term follow up programme that consists of providing a primary care physician (PCP) coordinated multidisciplinary care delivery model, for cancer survivors. It is thought that this will be better places to meet the unique needs of breast cancer survivors and use health care resources better. The aim of this study is to examine the quality of care provided by PCP in the new care model for breast cancer survivors as compared to the traditional model by oncology specialist.

Who can participate?
Women aged 18 and older who have breast cancer and have undergone breast cancer surgery within nine months of the joining the study.

What does the study involve?
Participants are randomly allocated to receiving the early transfer or the late transfer of their care to the multidisciplinary team. Participants receive personalised comprehensive breast cancer survivorship care from an expert multidisciplinary team from either one year or two years onward after their breast cancer surgery. Participants fill out surveys every six months for 2.5 years to assess their quality of life, satisfaction, medication, cancer recurrence and health care utilization.

What are the possible benefits and risks of participating?
Participants may benefit from receiving holistic health care delivered by the survivorship programme, better awareness of cancer treatment related long term adverse effects by regularly filling out questionnaires, and more personalized attention and coordination from the study nurse. Potential risks include having to change primary physician at a fixed time, although participant could opt to stay with the treating physician for longer as medically indicated.

Where is the study run from?
Koo Foundation Sun Yat-Sen Cancer Center (Taiwan)

When is the study starting and how long is it expected to run for?
May 2014 to December 2023

Who is funding the study?
Koo Foundation Sun Yat-Sen Cancer Center (Taiwan)

Who is the main contact?
Dr Yong Wang

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20130710C

Study information

Scientific Title
A randomized controlled study for the long term follow-up of breast cancer survivors: Effect of primary care physician (PCP) coordinated care delivery model on patient-reported outcomes

Study objectives
PCP-coordinated care for breast cancer survivors results in better patient-reported quality of life measures compared to traditional oncologist-based care

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved by the Institutional Review Board Committee of Koo Foundation Sun Yat-Sen Cancer Center (Taipei, Taiwan), 07/07/2014, ref: FSYSCC-IRB No. 20130710C

Study design
Single-center randomised non-blinded controlled trial with staggered transfer of breast cancer survivors to PCP-coordinated care program, with the early-transfer arm (intervention group) transferring care at 12 months and the late-transfer arm (control group) transferring care at 24 months after breast cancer surgery.

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (available only in Chinese)

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

Interventions
The intervention of the study is the PCP-coordinated survivorship program which adopts a multidisciplinary team approach, consisting of physicians, advanced practice nurses (APNs), nurses, social workers, psychologists, dieticians, and activity coordinators.

Family physicians or general internists and APNs undergo training to familiarize themselves with late effects of breast cancer and cancer treatment, surveillance guidelines, and cancer recurrence patterns. Survivors in the program will be seen by a physician and/or an APN every 3-6 months. The office visits include proactive screening of symptoms, emphasizing psychosocial screening and intervention, patient education of survivorship issues, responsiveness to patient needs, chronic disease management, and preventive care. The multi-disciplinary team coordinates medical care of the cancer survivors, ensures smooth transition of care and rapid referral to the cancer treatment team and other specialists as necessary, and empowers patients to take control of their own lifestyle and engage in better self-care.

Three to nine months after surgery, enrolled stage 0-III breast cancer patients are randomly allocated to the early-transfer arm (intervention group) or late-transfer arm (control group) using a computer-generated sequence stratified by whether or not the patient received neoadjuvant chemotherapy. The early-transfer arm patients will transfer their care to the PCP-coordinated survivorship program at 12 months post-surgery while patients in the late-transfer

arm will remain under the care of surgical or medical oncologists until 24 months when their care will then be transferred to the PCP-coordinated program. This study design will eventually transition all breast cancer survivors to PCP-coordinated program. Surveys including measures in breast cancer treatment related symptom scales, anxiety/depression, quality-of-life, and patient satisfaction will be taken at baseline and every 6 months thereafter until 36 months post-surgery.

Intervention Type
Other

Primary outcome measure
Breast cancer survivor specific quality of life (physical health and mental health) are measured using the Breast Cancer Prevention Trial (BCPT) symptom scale, the Patient Health Questionnaire for depression PHQ9 and anxiety GAD7, and the SF-36 health survey at 6, 12, 18, 24, 30, 36 months after surgery.

Secondary outcome measures
1. Patient satisfaction is measured using a patient satisfaction survey developed for this study at 12, 18, 24, 30, 36 months after surgery
2. Medication adherence is measured using a patient survey developed for this study at 12, 18, 24, 30, 36 months after surgery
3. Cancer recurrence confirmation and serious clinical events are measured using patient survey and by reviewing medical records at 18, 24, 30, 36 months after surgery
4. Healthcare utilization is measured using claims data at the completion of the study
5. Preventive care is measured using patient survey and by reviewing medical records at 18, 24, 30, 36 months after surgery
6. Management of chronic disease is measured using patient survey and by reviewing medical records at 18, 24, 30, 36 months after surgery

Overall study start date
01/05/2014

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged from 18 to 100
2. Female
3. Stage 0,1,2,3 breast cancer
4. Underwent breast cancer surgery within 9 months from enrollment

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
1200

Total final enrolment
902

Key exclusion criteria
1. Other active cancer
2. Renal failure on dialysis
3. Heart failure NYHA class III or IV
4. Cirrhosis Child B or C
5. Severe COPD
6. Active tuberculosis
7. Moderate to severe cognitive dysfunction
8. Any condition resulting in the individual unable to receive breast cancer follow-up care at KF-SYSCC

Date of first enrolment
23/02/2015

Date of final enrolment
25/08/2021

Locations

Countries of recruitment
Taiwan

Study participating centre
Koo Foundation Sun Yat-Sen Cancer Center
125 Lih Der Road
Taipei
Taiwan
11259

Sponsor information

Organisation
Koo Foundation Sun Yat-Sen Cancer Center

Sponsor details
125 Lih Der Road
Taipei
Taiwan
11259

Sponsor type
Hospital/treatment centre

Website
http://www.kfsyscc.org/

ROR
https://ror.org/049zx1n75

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Koo Foundation Sun Yat-Sen Cancer Center

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The current 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