ISRCTN14016157 https://doi.org/10.1186/ISRCTN14016157

Promoting wellbeing, equality, and support in breast cancer survivorship

Submission date 26/03/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/04/2014	**Overall study status** Completed	
Last Edited 06/06/2018	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-support-programme-for-women-after-breast-cancer-treatment-prowess

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PROWESS protocol v1

Study information

Scientific Title
A feasibility study of delivering a culturally adapted group-based breast cancer self-management intervention in a community setting, designed to enhance confidence to self-

manage following treatment for primary breast cancer and promote peer support, among women from different ethnic and socio-economic backgrounds

Acronym
PROWESS

Study objectives
The overall aims of this study are to develop a culturally adapted self-management intervention for primary breast cancer patients from diverse ethnic and socio-economic backgrounds to be delivered in a community setting; and to assess the cultural appropriateness and acceptability of the content, mode of delivery, and outcome measures in a feasibility trial. The main research question is: "Can a self-management intervention for primary breast cancer patients be designed and delivered to be culturally relevant and engaging for patients in a community setting?" This research is based on the overarching hypothesis that culturally appropriate self-management interventions will improve patient acceptability and be more effective in increasing self-efficacy than standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Essex, 13/10/2014, ref: 14/EE/0124 - approval pending

Primary study design
Interventional

Study design
Open two-armed (1:1) multicentre randomised controlled trial with a process evaluation

Study type(s)
Quality of life

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

Interventions
Intervention arm: Participants in the intervention arm with be invited to attend the PROWESS intervention. This is a culturally appropriate group based self-management intervention in a community setting for women from different ethnic and socio-economic backgrounds, who are within 12 months of completing active treatment. This course aims to provide expert advice in addition to increasing peer support by allowing them to share their experiences with other survivors in a culturally appropriate environment. The PROWESS study intervention is currently in the process of being developed using a co-design approach involving patients and stakeholders. The length of the intervention has not been established yet, but we currently envisage one weekly 3 to 4 hour long sessions per week for 3 to 5 weeks each, resulting in a minimum of 9 to a maximum of 20 hours in total. The intervention will take place at one of four community settings, two of which will be faith based, e.g. a church hall, and two of which non-faith based, e.g. a library. Participants will be given the choice between faith and non-faith based settings, but it will be made clear that it might not be possible to match their preference if numbers at one venue are too low.

Control arm: Participants in the control arm will receive standard care. To ensure that every patient participating in this study will receive the care and support they need, a waitlist control will be used. Patients in the control will be invited to attend the PROWESS survivorship course, one month after study completion, which will be around 8 months after randomisation.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility and acceptability of the culturally adapted self-management intervention for primary breast cancer patients from diverse ethnic and social backgrounds, which will be assessed using both quantitative and qualitative measures.

Key secondary outcome(s)
1. Self efficacy will be measured using the Self-Efficacy for Managing Chronic Disease 6item Measure. In the feasibility study this will be used to inform sample size calculations for the randomised controlled trial and to assess the feasibility/acceptability of obtaining this measure.
2. The acceptability and feasibility of obtaining the following measures will also be assessed to determine their use as secondary outcome measures in the subsequent randomised controlled trial:
2.1. Exercise behaviour
2.2. Diet awareness and readiness to change (adopted from the California Department of Public Health Nutrition Risk Screening Questionnaire)
2.3. Breast cancer knowledge
2.4. The Brief Illness Perception Questionnaire (BIPQ)
2.5. Quality of life (FACTB)
2.6. Hospital Anxiety and Depressions Scale (HADS)
2.7. The Friendship Scale

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1.Patients diagnosed with primary invasive breast cancer
2. Completed active hospital based treatment in the last twelve months (likely to have included surgery, chemotherapy, radiotherapy)
3. Either continuing treatment on hormone therapies and monoclonal antibodies or Herceptin
4. Able to provide informed consent
5. English speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Patients with primary invasive breast cancer but who:
1. have completed hospital treatment MORE than 12 months ago
2. are receiving chemotherapy or radiotherapy treatment
3. are non English speaking
4. are not able to give written informed consent
5. have previously attended a cancer self-management/ survivorship course including Breast Cancer Care's Moving Forward course

Date of first enrolment
01/05/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

Study participating centre
Breast Cancer Care
London
United Kingdom
SE1 ONS

Sponsor information

Organisation
Breast Cancer Care (UK)

ROR
https://ror.org/00w85kx21

Funder(s)

Funder type
Charity

Funder Name
Big Lottery Fund (UK) ref. RGT/1/010334410

Alternative Name(s)
BIG

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration