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# Promoting wellbeing, equality, and support in breast cancer survivorship

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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

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

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Quality of life

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### 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 measure
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.

## Secondary outcome measures
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

## Overall study start date
01/05/2014

## 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

### Age group
Adult

### Sex
Female

### Target number of participants
60

### 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
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# Sponsor information

**Organisation**
Breast Cancer Care (UK)

**Sponsor details**
5 - 13 Great Suffolk Street
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**Sponsor type**
Charity

**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

**Publication and dissemination plan**
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration