# Exercise referral to fitness centre or cardiac rehabilitation among breast cancer survivors

[X] Prospectively registered Submission date Recruitment status 16/09/2015 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 04/02/2016 Completed [X] Results Individual participant data **Last Edited** Condition category 11/06/2018 Cancer

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

### Type(s)

Public

#### Contact name

Dr Gill Hubbard

#### Contact details

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### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2014NovSP422

### Study information

#### Scientific Title

Exercise referral to fitness centre or cardiac rehabilitation among breast cancer survivors: Pilot single-arm trial with embedded process evaluation

### Acronym

**EFFECT** 

### **Study objectives**

This study aims to evaluate the feasibility and acceptability of providing BCS with a choice of attending one of the following existing structured PA interventions - NHS cardiac rehabilitation and fitness/leisure centres for the general public.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

North of Scotland Ethics Committee (1), 08/05/2015, ref: 15/NS/0036

### Study design

Single-arm pilot feasibility trial

### Primary study design

Interventional

### Secondary study design

Non randomised study

### Study setting(s)

Other

### Study type(s)

Other

### Participant information sheet

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

### Health condition(s) or problem(s) studied

Breast cancer

#### **Interventions**

Participants will be offered a choice of the two interventions:

#### Cardiac Rehabilitation

Phase III cardiac rehabilitation is usually a 10 to 12 week exercise programme delivered to patients within a traditional cardiac rehabilitation setting [31]. In the particular site where this study is being conducted, this will be a 10 week course, with a 60 minute exercise class once a week. The programme will be delivered by a cardiac physiotherapist, and is supported by a

cardiac nurse co-ordinator, and a physiotherapy assistant. Exercise will be tailored to the individual during an initial assessment with the physiotherapist. Participants will be given individual activity goals, and appropriate intensities for activities. Exercise will take place in a group setting, and will include both cancer and cardiac patients. Lower intensity classes will be available, if required. Educational components will form part of the programme, and include general health advice (e.g. diet, exercise, relaxation), alongside cardiac specific sessions (e.g. medications). Attendance will be recorded.

#### Fitness centre

Participants will be referred to an instructor who is qualified to Register of Exercise Professionals (REPs) Level 4, in Cancer and Exercise. Exercise will take place in a gym setting, or in a class setting (if appropriate), alongside members of the general public. An individual exercise programme will be set up between the participant and the specialist instructor during a one-to-one appointment. For the purpose of the study, participants will be provided with a 3-month free membership card, giving them free access to a range of fitness classes, gym and swimming pool. Advice will be offered on an individual basis on the safety of use for each participant. Participants will be able to visit the facility as often as they wish during the 3 month period. Attendance will be recorded.

Follow up: Participants will complete repeated measures on completion of the intervention of their choice. This will involve completion of the questionnaire (as done at baseline), and a semi-structured interview.

### Intervention Type

Behavioural

### Primary outcome measure

Physical Activity and sedentary behaviour is measured using an accelerometer, the Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ), a physical activity self-efficacy self-report questionnaire and analysing an activity diary at baseline and the end of the intervention.

### Secondary outcome measures

- 1. Quality of life is measured using the EQ-5D questionnaire and the Functional Assessment of Cancer Therapy for Breast cancer (FACT-B) questionnaire at baseline and the end of the intervention
- 2. Fatigue is measured using an additional questions in the FACT-B questionnaire at baseline and the end of the intervention
- 3. Functional strength is measured using the five repetition sit to stand test at baseline and the end of the intervention
- 4. Confounding/mediating factors are determined using patient records at baseline and the end of the intervention

### Overall study start date

01/06/2015

### Completion date

30/04/2017

### **Eligibility**

Key inclusion criteria

- 1. Are aged 16 years of age or over
- 2. Diagnosed with breast cancer (any stage) or Ductal Carcinoma In-Situ (DCIS) having surgery, axillary surgery, or undergoing risk-reducing mastectomy
- 2. Post-surgery and may (or may not) be having adjuvant therapy (chemotherapy and/or radiotherapy) and may have had neoadjuvant therapy before surgery

No longer appliable as of 25/07/2016:

3. Live within a 35-mile radius of cardiac rehabilitation/fitness centre

### Participant type(s)

Patient

### Age group

Adult

#### Sex

Both

### Target number of participants

12

### Key exclusion criteria

- 1. A clinician (e.g. consultant or clinical nurse specialist) decides that they are unsuitable for inclusion
- 2. A clinician decides that the BCS has a cognitive impairment and thereby cannot give informed consent
- 3. Scheduled to have further surgery in the next 12 weeks

### Date of first enrolment

01/09/2016

### Date of final enrolment

30/11/2016

### Locations

### Countries of recruitment

Scotland

United Kingdom

### Study participating centre Raigmore Hospital

NHS Highland
Old Perth Rd
Inverness
United Kingdom
IV2 3UJ

### **Sponsor information**

### Organisation

University of Stirling

### Sponsor details

Research and Enterprise Office 3B1 Cottrell Building University of Stirling FK9 4LA Stirling United Kingdom FK9 4LA

### Sponsor type

Charity

#### **ROR**

https://ror.org/045wgfr59

### Funder(s)

### Funder type

Charity

#### **Funder Name**

**Breast Cancer Now** 

### **Results and Publications**

### Publication and dissemination plan

Plan to publish the study protocol in a peer reviewed journal. Findings will also be shared with the Breast Cancer charity who fund the study (Breast Cancer Now), and the wider breast cancer community. Study findings will also be submitted for review and publication in a suitable peer reviewed journal and possibly at Local and National conferences.

### Intention to publish date

01/12/2015

Individual participant data (IPD) sharing plan

## **IPD sharing plan summary** Other

### Study outputs

Output type	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2018		Yes	No
HRA research summary			28/06/2023	No	No