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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public

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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
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Sponsor information

Organisation
University of Stirling

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