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Reducing fatigue in women undergoing radiotherapy for breast cancer

Submission date
24/08/2017

Recruitment status
No longer recruiting

Registration date
11/09/2017

Overall study status
Completed

Last Edited
27/07/2021

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
About four-in-ten of the 1,700 women in Wales who undergo radiotherapy for curable breast cancer every year experience extreme tiredness. Patients who experience cancer-related fatigue describe great difficulty in doing their usual activities and distressing changes in how they think and feel. As fatigue at the end of radiotherapy predicts reduced quality of life, it is vital that the symptom is managed effectively. Research shows that psychological and educational support is effective at reducing cancer-related fatigue. The patient can use this support to motivate targeted behaviours that are useful for minimising fatigue. What remains unclear is the best way to deliver this support, the active ingredients of interventions aimed at changing behaviour and an understanding of why they only work for some. This study aims to test an existing behaviour change intervention that has been adapted to help women receiving radiotherapy for breast cancer self-manage their fatigue.

Who can participate?
Woman aged 16 and older who are diagnosed with breast cancer and who have cancer related fatigue.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the behavioural programme about how to motivate helpful behaviour. Those in the second group receive the Macmillan Cancer Support booklet called ‘Coping with Fatigue’. Participants are assessed to see if their symptoms have improved.

What are the possible benefits and risks of participating?
We cannot promise taking part will help participants, but the information we get from this study could help improve the recovery of future patients who have had treatment for breast cancer. The behaviours that people develop through the self-help intervention may help some women stay active and feel more in control of their lives. We do not expect there are any disadvantages or risks from participating. To minimise the potential for mixed therapeutic messages, the local psychology team will contact trial participants who have accessed psychological support or similar services outside of the study to discuss the priority of interventions. Any additional travel costs incurred from study related visits will be reimbursed.

Where is the study run from?
Velindre Cancer Centre (UK)

When is the study starting and how long is it expected to run for?
July 2016 to April 2018

Who is funding the study?
Tenovus (UK)

Who is the main contact?
1. Ms Sarah Gaze (Public)
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2. Dr Nick Courtier (Scientific)
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Contact information

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Public

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Additional identifiers

Protocol serial number

31419

Study information

Scientific Title
ACTIVE: A randomised feasibility trial of a behavioural intervention versus information alone to reduce fatigue in women undergoing radiotherapy for early breast cancer

Acronym
ACTIVE

Study objectives
Feasibility trial to evaluate processes and test the acceptability of a behavioural intervention to reduce fatigue in women prescribed radical radiotherapy for early breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 3, 30/08/2016, ref: 16/WA/0205

Study design
Pragmatic non-blinded parallel-group single-centre randomised feasibility trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Fatigue related to radiotherapy treatment for early breast cancer and the primary disease

Interventions
A prediction of the risk of fatigue will be made at baseline to allocate participants into a high or low risk group. The high risk group will be eligible for the feasibility trial. Randomised allocation within the trial and retention of randomisation codes will be via a central online database (www.sealedenvelope.com). Allocation to a behavioral intervention arm will be in the ratio 2:1 using a permuted block protocol. Participant age (≤57 years and >57 years) will be a stratification variable.

20 participants will be allocated to the behavioural intervention. This comprises three 60-minute sessions per participant. The sessions will be delivered face-to-face during the first, second and third weeks of treatment. The function of the behavioural intervention is to motivate helpful behaviour change. It is informed by a CBT model of symptom management with elements of motivational interviewing (MI) incorporated. The intervention is built on four main components: education; motivation to change; goal setting and monitoring; emotional support.

Participants allocated to the control (‘education alone’) arm will be given the Macmillan Cancer Support booklet called 'Coping with Fatigue'.

Approximately 45 participants who are predicted to be at a low risk of fatigue will be eligible to be included in a fatigue risk score validation sub study group. These participants will not enter the trial part of the study, but will complete the Functional Assessment of Chronic Illness Therapy fatigue subscale (FACIT-F) on the last day of their treatment and 10 days after their radiotherapy finishes. This will be used to enable an assessment of the accuracy of the fatigue risk score prediction tool.

Intervention Type
Behavioural

Primary outcome(s)
Fatigue, measured by the FACIT-F 10 days after the completion of radiotherapy

Key secondary outcome(s))
1. Anxiety, measured using the hospital anxiety and depression scale (HADS) anxiety scale at baseline and 10 days after radiotherapy
2. Physical activity, measured by the Fitbit Alta activity tracker (minutes active and asleep, daily steps taken, distance covered, calories burned if required) during radiotherapy
3. Physical functioning, measured using the European organization for research and treatment of cancer quality of life physical functioning subscale (EORTC-QLQc30 version 3.0) at baseline, end of radiotherapy and 10 days after completion of radiotherapy
4. Self-efficacy, measured using Amy Hoffman's measure of self-efficacy for fatigue self-management, at baseline, end of radiotherapy and 10 days after completion of radiotherapy

Completion date
04/12/2017

Eligibility

Key inclusion criteria
1. Females > 16 years
2. Diagnosis of Stage 0–IIIA breast carcinoma
3. Standard 4000cGy in 15 fractions over three weeks ± nodal irradiation, ± boost
4. Able to complete outcome measures
5. Patients will be eligible if they are receiving monoclonal antibodies or endocrine treatment as maintenance therapy
6. A score of ≥ 5 on the fatigue risk score tool to enter the trial study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
86

Key exclusion criteria
1. Not prescribed radical radiotherapy
2. Psychiatric illness requiring secondary care intervention
3. Serious comorbidity causing chronic fatigue
4. Too ill to engage with the intervention in the opinion of the clinical care team

Date of first enrolment
03/11/2016

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
United Kingdom
CF14 2TL

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Tenovus

Alternative Name(s)
Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon consideration by the TMG. Contact Dr Nick Courtier(courtierN@cardiff.ac.uk). The data will contain no personal identifiable information and will not be available until after publication of the main findings in a high-quality journal. Individual consent from participants was not required as confirmed by the HRA REC approval.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/07/2021	27/07/2021	Yes	No
Protocol article	protocol	11/06/2018		Yes	No
HRA research summary			28/06/2023	No	No