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North of England women's diet and activity after breast cancer randomised controlled trial

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
03/02/2020

Overall study status
Completed

Last Edited
08/08/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Being overweight after hormone-positive breast cancer treatment increases the chance of cancer returning: extra weight (mainly fat) leads to higher levels of oestrogen/harmful substances in the blood. There is a lack of lifestyle support for overweight women after breast cancer. This study has designed a practical way to provide individually tailored lifestyle support to help them lose weight. This overall project has three phases, the first phase of which has already been completed, working with patients and clinicians to develop an intervention. The second and third phases are to complete the internal pilot of this intervention to test the feasibility of the study before going into the full trial.

Who can participate?
Overweight and obese women diagnosed with early-stage, oestrogen-positive breast cancer and are at least 8 weeks from any final chemotherapy and less than 3 years since primary treatment was completed. Women are required to be under the care of one of the four participating NHS Trusts.

What does the study involve?
Participants are randomly allocated to either the control or the intervention group. Participants allocated to the control group are asked to attend the initial assessment session and follow-up assessment sessions after 6 and 12 months. They continue to receive usual care from their healthcare provider and on completion of the 12-month assessment session, receive all the intervention materials that are given to participants in the intervention group.
Participants allocated to the intervention group attend an initial support session and attend support sessions over 12 months. These workshops offer healthy lifestyle (dietary and physical activity) education; support for the different ways to can engage in physical activity; provide an opportunity for discussion and resolving personal challenges; and help through the weight loss journey. After the first 3 months in the support group, the lifestyle advisor contacts the participant at regular intervals either by telephone or email (participant choice) to provide individual ongoing support.
All participants complete baseline, 6 and 12 months testing carried out by members of the research team who are blinded to group allocation. These sessions collect all outcome measures. Participants are also contacted by a researcher at 3, 6, 9 and 12 months to ask about their

healthcare resource use.
A process evaluation is ongoing throughout the study. This evaluation includes interviewing lifestyle advisors leading the group sessions, interviewing participants at different timepoints and observing group sessions.

What are the possible benefits and risks of participating?
Women allocated to the intervention group receive information and support regarding diet and physical activity to achieve and maintain weight loss and improve general level of fitness. This programme of support for lifestyle behaviour change has been specifically designed for breast cancer patients. The intervention will also inform the participants of the latest evidence-based guidance on dealing with possible side-effects that they might be experiencing. By decreasing weight and becoming more physically active, current scientific evidence suggests that improvements in the quality of cancer survivorship experience, as well as decreasing risk of future health conditions, including breast cancer recurrence, diabetes and cardiovascular problems. Intervention groups involve a physical activity component, which could lead to some muscle soreness or risk of injury. These sessions will be progressive and be taken by a qualified cancer-rehabilitation exercise instructor to ensure these risks are minimal. All participants complete up to three Dual Energy X-ray (DXA) scans. All of these will be extra to those that they would receive if they did not take part. These scans provide clinical information. The x-ray procedures use ionising radiation to form images of the body. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chance of this happening as a consequence of taking part in this study is extremely small.

Where is the study run from?
1. Northumbria University (UK)
2. Sheffield Hallam University (UK)
3. Sheffield Teaching Hospitals NHS Foundation Trust (UK)
4. The Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)
5. Gateshead Health NHS Foundation Trust (UK)
6. Northumbria Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2020 to September 2021(updated 16/10/2020, previously: October 2020)

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Prof. John Saxton
john.saxton@northumbria.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof John Saxton

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Additional identifiers

Integrated Research Application System (IRAS)
253794

Central Portfolio Management System (CPMS)
44178

Study information

Scientific Title
North of England Women's Diet and ActivitY After Breast Cancer: randomised controlled trial (NEW DAY-ABC)

Acronym
NEW DAY-ABC

Study objectives
Being overweight after hormone-positive breast cancer treatment increases the chance of cancer returning: extra weight (mainly fat) leads to higher levels of oestrogen/harmful substances in the blood. There is a lack of lifestyle support for overweight women after breast cancer. This study has designed a practical way to provide individually tailored lifestyle support to help them lose weight. This overall project has three phases, the first phase of which has already been completed and was a qualitative co-design process, working with patients and clinicians to develop an intervention. The second and third phases are to complete the internal pilot of this intervention to test the feasibility of the study before going into the full trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2020, North East – Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, UK; Tel: +44 (0) 207 104 8084; Email: nrescommittee.northeast-tyneandwearsouth@nhs.net), ref: 19/NE/0358

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Dietary, Psychological & Behavioural, Physical, Rehabilitation

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Participants will be recruited via breast care teams (including research nurses, breast care nurses, other healthcare professionals and consultants) in each of the associated NHS Trusts through face to face recruitment at bi-weekly outpatient breast cancer clinics and by use of existing databases of patients in follow up to enable them to be contacted by post. Potential participants will be pre-screened for any obvious exclusions with those that are potentially eligible contacted by either a healthcare professional or a research nurse to discuss the study and provided with an information pack. This pack will include a covering letter, a participant information sheet, screening height and weight questionnaire, consent form, expression of interest form to confirm they wish to be involved in the study and a reply-paid envelope. This contact will be either in person, via telephone or via a letter. Patients will be directed to the NEW DAY research team if they have additional questions regarding the study that the clinical team are unable to answer. The study will also be advertised via posters displayed in outpatient departments, local cancer support centres and GP practices. In addition, targeted adverts will be placed on local, relevant social media pages (e.g. local breast cancer support Facebook pages) and advertised via YCR on their social media outlets. These adverts will contain contact details for the research team. Women will have the opportunity to ask further questions regarding the study and for those that are interested will be sent a participant information pack. Women will be re-contacted after two weeks if they have not returned the form to ensure that they received the pack or to get confirmation if they do not wish to be involved.

After participants have agreed to be involved in the trial, they will be contacted by a study researcher or a member of the clinical research team at the site to arrange a visit confirm eligibility and take informed consent. If information has been given at a clinic visit, the women can choose to proceed directly to eligibility screening and consent. Informed consent will either be taken by the clinician or a research nurse at the outpatient breast cancer clinic at the site or by a member of the NEW DAY research team, who has completed the NIHR informed consent training, at the start of the assessment session. Participant consent will include allowing the research team access to their medical records, randomisation into the study and completion of all outcome measures. In addition, participants will be asked to consent for their GP and hospital clinical team (if they have accessed the study independently) to be informed of their involvement in the study. The researcher will have the time to ensure the participant is fully versed in the study and process involved. Eligibility will be confirmed by asking patients to complete a trial-specific clinical research screening form and height, weight and waist circumference will be measured. Written Informed Consent will then be obtained.

The baseline assessment will then be completed as detailed below in the data collection section. Only once these assessments are complete and information about the patient's treatment has been obtained (whether they had chemotherapy and whether treatment was with tamoxifen, aromatase inhibitors, or no hormone therapy will the participant be randomised. Randomisation will be done using a purpose-built, web-based data capture system with integrated randomisation provided and maintained by the Hull Health Trials Unit (HHTU).

Intervention: An initial 60-minute small-group (N=3-4) face-to-face lifestyle counselling session using behaviour modification techniques will explore current physical activity and dietary behaviours, social support structures, and perceived barriers/facilitators to health behaviour change. Goals will be set for physical activity, diet and body weight, based on baseline assessments (through discussion) and by suggesting practical changes to current behaviours. Following the initial counselling session, intervention participants will receive a 15 min individual follow-up telephone call or 2-way email correspondence prior to the first Support and Skills Workshop session (whichever is preferred), providing an opportunity to discuss individual concerns, their preferred healthy eating and physical activity plan, and other motivational factors for that individual.

Support & Skills Workshops: The intervention will be delivered to groups of ≤10 women at a community location and will be split into three progressive modules, covering key themes identified in phase 1 of our research. Modules 1 and 2 of the intervention will focus on delivering educational sessions focusing on nutrition (Eat Well) and physical activity (Move Well) for weight loss and cancer rehabilitation whilst introducing participants to evidence-based behaviour change techniques shown to be effective in assisting with diet and physical activity supported weight loss. Eat Well will educate participants about healthy food choices through a progressive series of modular-based workshops based on practical government guidance for healthful nutrition. This will include portion control, healthy snacks and drinks, healthful eating out and on the move, and understanding food labels. The Move Well physical activity sessions are based on the national physical activity guidelines and will support participants to gradually increase their physical activity levels. Move Well will follow on from the Eat Well sessions each meeting meaning that each intervention session will comprise of both nutritional support and practical physical activity. Module 3 will progress the behaviour change techniques used to Modules 1 and 2 to empower participants to better self-manage weight loss and weight loss maintenance through the core principles of the Eat Well and Move Well sessions, post-intervention support. These sessions will occur fortnightly for the first 3 months and monthly thereafter (15 sessions in total). Telephone and Email support: The programme of Support and Skills Workshops will be complemented by individual telephone and/or email support, according to personal preference. Participants will receive a minimum of 10 contacts with their Lifestyle Advisor during the 12-month study intervention, with telephone calls lasting approximately 15 min. Each telephone /Email contact will be tailored to individual needs. Conversations will focus on progress updates, relapse prevention, refocusing of goals (if necessary) and, if relapse occurs, and any further support that is needed. Participants will have access to a purpose-built website to support the teachings of Eat Well and Move Well.

Data collection: All participants will attend assessment sessions at baseline, 6 and 12 most post-randomisation at either Northumbria University or Sheffield Hallam University. During these sessions, a trained member of the research team will collect height, weight, waist and hip circumference measurements and blood pressure. In addition, a blood sample will be taken and participants will complete a supervised submaximal incremental treadmill test. Participants will undergo a DXA scan either during the session at Northumbria University or Sheffield Hallam University or on a separate visit to Western Park Hospital, part of the Sheffield Teaching Hospitals NHS Foundation Trust, where it will be conducted by a member of the Trust. Participants will be given an accelerometer to wear for 7 days and a time diary to complete for the same duration. Participants will be provided with a reply paid envelope to return the accelerometers to the university. Prior to these sessions, participants will be sent a questionnaire to complete prior to this visit and will be asked to bring it with them on the day. This will be in paper (with a pre-paid envelope to return it if they do not attend the follow-up visit) or electronic format depending on the women’s preference. If a patient declines to attend

a follow-up visit and the questionnaire has not been returned after two weeks, a reminder letter will be sent.

At 3, 6, 9 and 12 months post-randomisation, participants will receive a telephone call from a member of the research team asking them to report any healthcare resource use during the previous 3 months. These calls will last approximately 15 minutes in duration.

Participants randomised into the control group will complete all outcome assessments as the intervention group, however, will have no other contact with members of the data collection section of the research team during the intervention period. After completion of the 12-month assessment visit, participants in the control group will be provided with all intervention materials received by the intervention group.

As part of a process evaluation, the researchers will be looking at how participants feel about the intervention. This will involve looking at how many of the sessions they have attended, which sessions have been attended, how the participants found those sessions and the follow-up support emails and telephone calls. This will allow the researchers to understand if any changes to the intervention are required to improve it for future participants. The process evaluation will also look at how the lifestyle advisors delivering the intervention feel it has gone, how confident and comfortable they were in delivering the sessions, if they feel they require more training, and how receptive they feel the participants were to the intervention topics. To assess whether the intervention was delivered in the same way at each research site the data from the process evaluation at each site will be compared. This will help to assess reasons for any differences in the outcome data at each site. This evaluation will consist of telephone interviews with breast cancer nurse specialists at each Trust (approximately 60 minutes in duration) and face-to-face or telephone participant interviews (30-60 minutes in duration).

Intervention Type
Other

Primary outcome(s)
1. Body weight (kg) measured using standard techniques at baseline, 6 and 12 months post-randomisation
2. Health-related quality of life measured using the EORTC – QLQ-c30 and breast specific module (BR23) at baseline, 6 and 12 months post randomisation

Key secondary outcome(s)
1. Anthropometric measures (height, BMI, hip and waist circumference) measured using standard techniques at baseline, 6 and 12 months post-randomisation
2. Blood pressure measured via sphygmomanometer at baseline, 6 and 12 months post-randomisation
3. Body composition (skeletal muscle and fat mass) measured via DXA at baseline, 6 and 12 months post-randomisation
4. Fatigue measured via the Functional Assessment of Chronic Illness Therapy – Fatigue Scale (FACIT-Fatigue) at baseline, 6 and 12 months post-randomisation
5. Fear of cancer recurrence measured using the 7-point Fear of Cancer Recurrence Scale at baseline, 6 and 12 months post-randomisation
6. Body image measured with the Body Image Scale at baseline, 6 and 12 months post-randomisation
7. Self-report physical activity measured via the modified Godin Leisure Time Physical Activity Questionnaire at baseline, 6 and 12 months post-randomisation

8. Participant eating behaviours, including fruit and vegetable intake, assessed using a bespoke questionnaire based on the Scottish Health Survey at baseline, 6 and 12 months post randomisation
9. Alcohol consumption measured via the AUDIT-C questionnaire at baseline, 6 and 12 months post-randomisation
10. Participant fitness measured via a submaximal incremental treadmill test using the BRUCE protocol at baseline, 6 and 12 months post-randomisation
11. Objective physical activity and sedentary behaviour measured by ActivPAL accelerometers at baseline, 6 and 12 months post-randomisation
12. Inflammatory markers, adipokines, indices of insulin/IGF metabolism and biomarkers for breast cancer recurrence measured via blood samples at baseline, 6 and 12 months post-randomisation
13. Health economics measured using healthcare resource use measured at 3, 6, 9 and 12 months post-randomisation and health-related quality of life using the EuroQol EQ-5D-5L at baseline, 6 and 12 months post randomisation

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Pre-/post-menopausal breast cancer patients who completed surgery, radiotherapy and/or chemotherapy for early stage disease (I-III) ≤36 months previously and ≥8weeks after final chemotherapy cycle
2. Women with ER+ and HER2- tumour diagnoses; overweight/obese (BMI ≥25 or >30kg/m2) and /or waist circumference >88 cm
3. Willing and able to attend group lifestyle counselling/Support & Skills Workshops

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Metastatic/inoperable or active loco-regional disease; BMI < 25kg/m2
2. Following alternative/complementary diet or taking high dose antioxidants for >= 3 months
3. Severe physical/psychiatric or comorbid impairment (e.g. arthritis/multiple sclerosis)
4. Uncontrolled T2DM and CVD or severe osteoporosis
5. No telephone contact
6. Unable to consent
7. Enrolled on another weight loss/lifestyle behaviour change trial

8. Already engaged in > 150 min.week-1 of moderate-intensity PA
9. Expecting to have surgery during the study that would affect adherence to the study
10. Unable to speak/read English

Date of first enrolment
01/01/2021

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northumbria University
Department of Sport, Exercise and Rehabilitation
Northumberland Building City
Newcastle
United Kingdom
NE1 8ST

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre

Gateshead Health NHS Foundation Trust
Queen Elizabeth Hospital
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Sheffield Hallam University
Advanced Wellbeing Research Centre
Collegiate Cresent
Sheffield
United Kingdom
S10 2LX

Sponsor information

Organisation
Northumbria University

ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research; Grant Codes: NOR416

Alternative Name(s)
YCR

Funding Body Type
Government organisation

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

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/08/2025	08/08/2025	Yes	No
HRA research summary			28/06/2023	No	No