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Support for lifestyle behaviour change after breast cancer treatment

Submission date
02/07/2024

Recruitment status
No longer recruiting

Registration date
12/08/2024

Overall study status
Ongoing

Last Edited
11/03/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Breast cancer is the most common cancer. More than half of people who have breast cancer weigh more than a healthy weight. When people weigh more than a healthy weight, cancer treatments may not work as well, and breast cancer is more likely to return after treatment. It is recommended that patients with breast cancer do regular exercise and eat healthy foods. For those who have excess weight it is suggested that they try to lose between 5% and 10% of their body weight. Activities which help people lose weight can improve quality of life and mental health. Examples of these activities are eating healthily, exercising and accessing psychological (therapy) support. However, there is no clear way to help people with breast cancer do this, and different activities are provided in different places. We also need to know more about what people with breast cancer do if they are offered support.

This study aims to describe what lifestyle and behaviour change support is offered by the NHS to breast cancer survivors after their diagnosis or during their treatment, and to understand what helps or hinders health services offering support or patients taking up support.

Who can participate?
Breast care nurses and cancer navigators working in NHS Trusts across England, and breast cancer patients who have been diagnosed up to 12 months before the study at one of five participating NHS Trust study sites.

What does the study involve?
The study involves exploring what activities to lose weight and help with lifestyle change are offered to people with breast cancer by NHS services. We will also look at what activities they do. We will do this by sending surveys to breast care nurses working across England and people diagnosed with breast cancer within the last 12 months from five selected NHS Trusts across England. We will also carry out interviews with around 20 nurses and 20 people with breast cancer to talk about their experiences in more detail. At the end of the study, we will bring together the information from the surveys and interviews and have an event to discuss our results with people working in health services and patients, to learn what works well and what doe not work well for breast cancer patients and services.

What are the possible benefits and risks of participating?
There are no anticipated risks to taking part in this study. Participants who complete a survey will be offered a £20 voucher to thank them for their time. Those who go on to participate in a semi-structured interview will receive an additional £20 voucher to thank them for taking part.

Where is the study run from?
The University of Birmingham and Shrewsbury and Telford NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2024 to November 2025

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme (UK)

Who is the main contact?
Dr Sarah Damery; s.l.damery@bham.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Sarah Damery

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332207

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57719, NIHR206118, IRAS 332207

Study information

Scientific Title
Understanding the offer and uptake of support for lifestyle behaviour change following breast cancer treatment

Study objectives
Eating healthily, undertaking physical activity and accessing wellbeing support (together termed as lifestyle behaviour change support (LBCS)) may improve quality of life, response to treatment and mental health for people diagnosed with breast cancer. However, we do not know what support patients are offered by healthcare services, what activities patients do, and what the barriers and facilitators to the offer/uptake of LBCS are. These issues need to be explored with both healthcare staff and patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/08/2024, Wales Research Ethics Committee 5 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2071048197; Wales.REC5@wales.nhs.uk), ref: 24/WA/0201

Study design
Observational cross-sectional

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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

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

Interventions
This mixed methods study will combine three work packages.

1. Work package 1 will focus on collecting quantitative data via surveys of healthcare professionals (breast cancer nurses/cancer navigators) working in NHS Trusts across England. Any individuals who choose to complete the survey will be participants in the research for up to

20 minutes, which is the estimated completion time for the survey. WP1 will also include surveys of breast cancer patients who had been diagnosed 12 months previously. Patients at five participating NHS Trust research sites will be sent the survey for completion by the direct care team at the Trust. Those who choose to complete it will be participants in the research for up to 20 minutes, which is the estimated completion time for the survey.

2. Work package 2 will use semi-structured interviews (qualitative data collection) with breast cancer nurses/cancer navigators (up to 20 interviews). Interview participants will be drawn from the pool of respondents to the survey in WP1 and will be approached to participate in an interview if they had indicated on their survey return that they may be interested in being interviewed. Participants will be interviewed once, for up to 45 minutes. Work package 2 will also use semi-structured interviews with patients (up to 20 interviews). Interview participants will be purposively sampled from the pool of respondents to the survey from WP1 and will be approached to participate in an interview if they had indicated on their survey return that they may be interested in being interviewed. Participants
will be interviewed once, for up to 45 minutes. For healthcare professionals/patients who wish to participate in the survey only, their participation in the research will last for up to 20 minutes. For healthcare professionals/patients who participate in the survey and an interview, their participation in the research will last for up to 70 minutes in total (including time for taking consent at the start of any
interview).

3. Work package 3 will being together the data from WP1 and WP2 and there will be a stakeholder workshop to identify recommendations from the research about how lifestyle and behaviour change support for people with breast cancer could/should be offered.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Factors that explain the offer and/or uptake of lifestyle and behaviour change support activities by patients with breast cancer measured using semi-structured interviews at a single time point

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2024

Completion date
30/11/2025

Eligibility

Key inclusion criteria
Work package 1 (healthcare staff)
1.1. Breast cancer nurses/cancer navigators currently working in breast care services in the NHS across England

1.2. Breast cancer nurses/cancer navigators who have regular contact with breast cancer patients and who engage in treatment discussions
1.3. Aged 18+ years

Work package 1 (patients)
1.4. Aged 18+ years
1.5. Patients diagnosed with early or locally-advanced breast cancer within the previous 12 month period who will be between 6-12 months post-diagnosis at the time the survey is administered
1.6. Treated at any of five participating NHS Trust sites

Work package 2 (healthcare professionals)
2.1. Respondents to the WP1 survey who indicated they would be interested in being interviewed

Work package 2 (patients)
2.2. Respondents to the WP1 survey who indicated they would be interested in being interviewed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 670; UK Sample Size: 670

Key exclusion criteria
Work package 1 (healthcare staff)
1.1. Breast cancer nurses/cancer navigators who are not currently working in breast care services in the NHS across England
1.2. Breast cancer nurses/cancer navigators who do not have regular contact with breast cancer patients and do not engage in treatment discussions

Work package 1 (patients)
1.3. Unable to consent to take part, as determined by clinical review of patient lists at participating NHS sites before survey packs are sent
1.4. Unable to take part in a survey for any other reason (e.g. mental health issues), as determined by clinical review of patient lists at participating NHS sites before survey packs are sent

Date of first enrolment
01/09/2024

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
Macclesfield District General Hospital
Macclesfield District Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Shrewsbury and Telford Hospital NHS Trust

Sponsor details
Mytton Oak Road
Shrewsbury
England
United Kingdom
SY3 8XQ
+44 7703388049
joanne.sawyer1@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.sath.nhs.uk/

ROR
https://ror.org/047feaw16

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/11/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Sarah Damery, s.l.damery@bham.ac.uk once the study has completed in November 2025 for up to 3 years after study conclusion. Deanonymised survey data and

deanomymised qualitative interview transcripts will be made available to bona fide researchers for the purposes of quantitative or qualitative analysis as long as suitable permissions are obtained for data analysis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	01/08/2024	12/09/2024	No	No