ISRCTN88199566 https://doi.org/10.1186/ISRCTN88199566

Feasibility study for an group online body image intervention for women who have received treatment for breast cancer

Submission date
21/06/2024

Recruitment status
No longer recruiting

Registration date
27/06/2024

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Mental and Behavioural Disorders

[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 in women in the UK. Many women feel unhappy with how their body looks and feels following treatment for breast cancer. 'Accepting your Body after Cancer' (ABC) is a group-based programme that has been tested in a small study and found to help women. More women could use ABC if it was delivered online, and we want to do a large study to see if ABC works online. Before the large study, we need to do a small 'feasibility' study to help us understand if it is feasible to carry out a larger study, and if so, how would we do this?

Who can participate?
We are looking for women (over 18 years old) who have had breast cancer and are struggling with how their body looks (e.g., due to scarring, weight changes, hair loss) or feels and functions (e.g., due to difficulties having sex, loss of sensation, fatigue). We can include women who:
• Have finished active treatment but are awaiting further cosmetic treatment (e.g., awaiting breast reconstruction) if this is not planned to take place during the study.
• Are still on hormone therapy.
• Have metastatic breast cancer and are only on endocrine therapy.
The study is not suitable for women who may have an eating disorder, are still having active treatment, have reconstructive surgery planned during the study period, are having explorations for cancer recurrence, or who have had prophylactic treatment for a gene mutation.

What does the study involve?
People who join the study will be randomly allocated to one of two groups: ABC or standard care. At the moment, there is no formally recommended therapy for women experiencing body distress following treatment for breast cancer. The standard care group will therefore receive a publicly available information booklet developed by Macmillan Cancer Support. The booklet aims to support people who are distressed by treatment-related changes to their body. The ABC group will receive the Macmillan booklet and the ABC course. ABC is a 7-session group-based therapy delivered online by a psychologist and cancer support specialist over 7 weeks, with 8-10 women in each group. There is pre-session reading, and activities during and in-between sessions.

All participants will be in the study for 8 months and will complete a number of questionnaires on 4 occasions (at the beginning of the study, and at 2, 5, and 8 months). These questionnaires will explore participant's thoughts and feelings relating to their body, as well as their mood, sexual wellbeing, and quality of life. It will take around 15-30 minutes to complete these questionnaires on each occasion, and they can be completed either online or in paper format. Some participants will also be asked if they would like to take part in an optional interview. The interview will ask about their experience of being in the study. For participants who had the ABC the interview will also ask about their experience of the course.

What are the possible benefits and risks of participating?
Women in the ABC group will hopefully find the course helpful and feel more comfortable in their body. Although women in the standard care group will not receive the ABC course but will have access to the Macmillan booklet that should provide some help to them.
As ABC will be delivered via a video conferencing platform, participants may experience technical issues. Participants will have guidance on how to use the platform prior to the first session and the course facilitators and study team will aim to help with any in-the-moment issues as quickly as possible. As ABC explores a sensitive issue, participants may find sessions upsetting. The experienced facilitators will be able to provide support within the sessions. Completing questionnaires about body image and sexual wellbeing may cause distress. If this happens, participants can skip any questions, take a pause, or stop completing the questionnaires entirely. Participants will also be signposted to other sources of support.

Where is the study run from?
The study is being run by researchers at the Centre for Appearance Research at the University of the West of England in Bristol (UWE Bristol) (UK)

When is the study starting and how long is it expected to run for?
November 2023 to June 2025

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
The head of the study is Dr Helena Lewis-Smith, Associate Professor of Psychology at UWE Bristol (email: helena.lewis-smith@uwe.ac.uk)
The study manager is Dr Abbie Jones, Research Fellow at UWE Bristol (abbie4.jones@uwe.ac.uk)

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Helena Lewis-Smith

ORCID ID
https://orcid.org/0000-0001-9000-8142

Contact details
Centre for Appearance Research (CAR), College of Health, Science, and Society, University of the West of England, Frenchay Campus

Bristol
United Kingdom
BS16 1QY
+44 11732 81895
helena.lewis-smith@uwe.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327507

ClinicalTrials.gov number
NCT06412341

Secondary identifying numbers
IRAS 327507, CPMS 55828

Study information

Scientific Title
A feasibility study to inform a Randomised Controlled Trial to evaluate ‘Accepting your Body after Cancer’ (ABC), an online-delivered group-based cognitive behavioural therapy (CBT) body image intervention, for women who have received treatment for breast cancer

Acronym
ABC

Study objectives
This is a feasibility study to establish the design of a definitive randomised controlled trial. Therefore, there are no hypotheses.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/06/2024, Newcastle North Tyneside 2 (NHS REC) (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8086; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: REC reference: 24/NE/0092

Study design
Two-arm randomized feasibility study with an embedded qualitative component to further assess feasibility and acceptability

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Charity/Voluntary sector, Community, Home, Internet/virtual, University/medical school/dental school

Study type(s)
Other, Quality of life

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

Health condition(s) or problem(s) studied
Addressing body image distress in patients who have been treated for breast cancer

Interventions
Once participants have provided informed consent, and completed baseline data collection (Week 1), they will be randomised to either the intervention or control arm using Sealed Envelope, a web-based randomisation system. Randomisation (at the individual level) will be independent and concealed, using permuted block randomisation.

Participants will be randomised to either the intervention or control arm. The control arm will receive the Macmillan Cancer Support psychoeducational body image booklet (freely available and currently the only body-image support available). The intervention arm will receive the Macmillan booklet and the ABC (Accepting your Body after Cancer) programme, a 7-session, CBT group-based programme delivered online.

ABC comprises seven 2-hour group sessions (with approximately 8 women per group) delivered online via Microsoft Teams and across 7 consecutive weeks. The intervention aims to improve body image among women treated for BC. Rooted in CBT, ABC uses strategies to alter unhelpful thoughts, reduce anxiety, and promote non-avoidant behaviours. Other topics are also explored, including sociocultural pressures for women, intimacy, physical activity, self-care, mindfulness, and relaxation. The sessions will be guided using PowerPoint slides, which will include text, images, and videos. Each session will include individual and group-based activities, and participants will be asked to complete between-session readings and activities.

ABC Content
Session 1:
• Introduction to body image
• Personal reflection upon the impact of body image concerns
• Exploration of personal goals
Session 2:
• Introduction to the CBT approach
• Physiological symptoms of anxiety
• Exploration of body image and self-esteem
• Relaxation training
Session 3:
• Stopping negative body-related self-talk
• Developing alternative, balanced thoughts
• Planning a self-care activity schedule

• Relationship between body function and movement
Session 4:
• Sociocultural pressures for women in midlife
• Internalisation of the youthful-thin ideal
• Body comparisons – experimental activity
• Body nurture with accepting self-talk
Session 5:
• Exploration of relationships and intimacy
• Managing people's reactions
• Cognitive restructuring process
• Physical activity and movement
Session 6:
• Identifying core beliefs
• Modifying mistaken beliefs
• Engaging the senses – mindful eating
• Relaxation exercise
Session 7:
• Positive body affirmations
• Reducing the chances of a setback
• Dealing with a setback
• Future plans

Macmillan's freely available psychoeducational body image booklet will be provided to both arms. This thorough 77-page booklet provides a substantial amount of support and guidance relating to managing body image concerns. It explains the effects of cancer on body image, and provides practical guidance (e.g., make-up) and psychoeducational guidance (e.g., managing others' reactions), in addition to some CBT strategies. Further, given that there is no current 'treatment-as-usual' in relation to body image support for women treated for breast cancer, this booklet may constitute the first time that these women have received support specifically relating to body image, and may even reduce distress.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment measured using total number of participants consented at the end of the study
2. Retention measured using percentage of consented participants completing data collection at baseline, post-intervention, 3-month follow up, 6-month follow up.
3. Data completion rates measured using percentage of missing data at baseline, post-intervention, 3-month follow up, 6-month follow up.
4. Participant feedback on the research process measured using qualitative interviews at baseline, post-intervention, 3-month follow up, 6-month follow up.

Secondary outcome measures
1. Acceptability of ABC programme to participants and facilitators measured using qualitative interviews at post-intervention
2. Establishing the appropriate primary outcome for a full-scale clinical trial:
Candidate primary outcome measures for a full-scale RCT measured at baseline, post-intervention, 3-month follow up, 6-month follow up:
2.1. Kessler Psychological Distress Scale (K10)
2.2. Body Appreciation Scale-2 (BAS-2)

2.3. Functional Assessment of Cancer Therapy – Breast (FACT-B Version 4): Breast Cancer Subscale
2.4. Hopwood Body Image Scale
2.5. BREAST-Q: Sexual Well-Being Scale
Health economic outcome measures
2.6. Modified version of the Adult Service Use Schedule (AD-SUS) measured at baseline, 3-month follow up, 6-month follow up.
2.7. EQ-5D-5L measured at baseline, post-intervention, 3-month follow up, 6-month follow up.
2.8. Recovering Quality of Life-Utility Index (ReQoL-10) measured at baseline, post-intervention, 3-month follow up, 6-month follow up.
2.9. Work and Social Adjustment Scale (WSAS) measured at baseline, post-intervention, 3-month follow up, 6-month follow up.

Overall study start date
01/11/2023

Completion date
02/06/2025

Eligibility

Key inclusion criteria
1. Identify as a woman.
2. 18+ years old.
3. Finished active treatment for breast cancer (including chemotherapy, radiotherapy, targeted and immunotherapy) for breast cancer. There is no time limit on when they finished this treatment. Women on endocrine therapy are eligible to take part. Women with metastatic disease are eligible to take part if on endocrine therapy only.
4. Completed primary oncological breast cancer surgery with breast conserving surgery or mastectomy with or without immediate definitive breast reconstruction. Women awaiting delayed breast reconstruction, revision or contralateral symmetrisation surgery are eligible to take part provided this surgery is not planned within the duration of the study.
5. Recognises that they are experiencing BID as a result of treatment (regarding how the body looks and/or feels).
6. Has the capacity to provide informed consent or supported informed consent (e.g., with a family member/friend).
7. Has sufficient understanding of English (as the intervention content and measures are currently only available in English).

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Target number of participants
120

Total final enrolment
120

Key exclusion criteria
1. Still undergoing active treatment for breast cancer (e.g., oncological breast surgery including those awaiting the second stage of planned expander/implant reconstruction, chemotherapy, targeted therapies, radiotherapy).
2. Undergoing exploration for cancer recurrence.
3. Has not received a diagnosis of breast cancer e.g., has had prophylactic treatment for a gene mutation (such as risk-reducing mastectomy).
4. Has an eating disorder.
5. Unable to provide informed consent.

Date of first enrolment
10/07/2024

Date of final enrolment
17/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of the West of England, Bristol
Frenchay Campus
Coldharbour Lane
Bristol
United Kingdom
BS16 1QY

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym

Bristol
United Kingdom
BS10 5NB

Study participating centre
Manchester University NHS Foundation Trust - Comcov3 Covid19 Trials
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation

University of the West of England

Sponsor details
University of the West of England
Frenchay Campus
Bristol
England
United Kingdom
BS16 1QY
+44 11732 81670
olena.doran@uwe.ac.uk

Sponsor type
University/education

Website
http://www.uwe.ac.uk/

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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

Publication and dissemination plan

The study protocol and study findings will be published in peer-reviewed journals. Dissemination will target academic, healthcare, and third sector organisation settings, via accessible reports and presentations, knowledge exchange events, social media, conference presentations, and publications.

Intention to publish date
31/03/2026

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?
Protocol file	version 2	23/05/2024	26/06/2024	No	No
Protocol article		22/01/2025	29/01/2025	Yes	No