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Managing anxiety after completing treatment for primary breast cancer

Submission date
08/07/2026

Recruitment status
Recruiting

Registration date
15/07/2026

Overall study status
Ongoing

Last Edited
05/08/2026

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
Many people continue to experience anxiety after completing treatment for primary breast cancer. Although treatments such as cognitive behavioural therapy (CBT) can help, they do not work for everyone. This study is comparing two evidence-based approaches to managing anxiety after breast cancer. One approach provides information and practical strategies for managing anxiety after breast cancer. The second is a newer therapy called Aligning Dimensions of Interoceptive Experience after Breast Cancer (ADIE-BC). ADIE-BC is a mind-body approach that aims to improve how accurately people detect internal bodily signals, such as their heartbeat, and to help them use this awareness to regulate their emotions, reduce worry about normal bodily sensations, rebuild trust in their body after cancer treatment, and develop more helpful beliefs about their body. The study will compare these two approaches to find out which is most effective for reducing anxiety after breast cancer.

Who can participate?
Adults aged 18 years or older who have previously been diagnosed with stage 0–III primary breast cancer, have completed hospital-based cancer treatment and have at least mild anxiety.

What does the study involve?
The research team will complete a screening assessment to check whether the study is suitable for each person, as additional eligibility criteria also apply. Participants will first complete screening to check whether they are eligible. Those who take part will attend a baseline assessment at King's College London before being randomly allocated to one of two groups. Participants allocated to the ADIE-BC group will attend six face-to-face therapy sessions over approximately six weeks. These sessions involve computer-based heartbeat awareness exercises using a heart rate sensor, together with a handbook and practical techniques to help manage anxiety. Participants allocated to the Enhanced Usual Care group will receive a handbook containing information and evidence-based strategies for managing anxiety after breast cancer, together with a clinical check-in during the study. All participants will complete questionnaires before treatment, during the study, at 8 weeks and at 18 weeks after randomisation. They will also complete heartbeat tasks and provide saliva and blood samples at baseline and 8 weeks. Up

to 80 participants may choose to take part in an optional MRI study involving two brain scans. Participants will also be invited to complete an optional questionnaire 12 months after randomisation.

What are the possible benefits and risks of participating?
Participants may or may not benefit directly from taking part. They may experience improvements in anxiety or gain a better understanding of their body and emotions. Information gained from this study may help develop better treatments for anxiety after breast cancer for future patients. The study is considered low risk. Some participants may experience temporary emotional discomfort when discussing anxiety or completing questionnaires and behavioural tasks. Blood sampling may cause temporary discomfort, bruising or light-headedness. MRI scans (for participants choosing the optional substudy) may feel noisy or confined but do not involve radiation. Participants can withdraw from the study at any time without affecting their medical care.

Where is the study run from?
The study is sponsored by King's College London. Recruitment takes place through Guy's and St Thomas' NHS Foundation Trust, The Royal Marsden NHS Foundation Trust, breast cancer charities and community organisations. Study assessments and therapy sessions take place at Guy's Hospital in London. Optional MRI scans take place at the Centre for Neuroimaging Sciences, King's College London.

When is the study starting and how long is it expected to run for?
July 2026 to December 2028.

Who is funding the study?
Wellcome Trust, UK.

Who is the main contact?
Dr Lauren Heathcote, Health Psychology Section, King's College London, UK.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
369405

Central Portfolio Management System (CPMS)
74472

Wellcome Trust Award number
309734/Z/24/Z

Study information

Scientific Title
Aligning Dimensions of Interoceptive Experience after Breast Cancer (the ADIE-BC trial)

Acronym
ADIE-BC

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/07/2026, London - Chelsea Research Ethics Committee (Skipton House 80 London Road, London, SE1 6LH, United Kingdom; +44 0207 104 8000; chelsea.rec@hra.nhs.uk), ref: 26/LO/0459

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose

Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Anxiety management in survivors of primary breast cancer.

Interventions
Participants will complete baseline assessments before being randomly allocated in a 1:1 ratio to either ADIE-BC or Enhanced Usual Care (EUC). Randomisation will use a secure web-based system with stratified block randomisation and varying block sizes. Stratification factors are recruitment source, time since completion of cancer treatment, and baseline anxiety severity.

Participants allocated to ADIE-BC will receive six individual face-to-face sessions of interoceptive training delivered over approximately six weeks. Sessions involve biofeedback-assisted heartbeat discrimination and heartbeat tracking exercises using real-time heart rate monitoring, together with confidence ratings, structured feedback, and supportive psychoeducational materials designed to encourage adaptive engagement with bodily sensations, emotion regulation and helpful body mindsets. Participants also receive an ADIE-BC handbook and reminder card to support application of the techniques in everyday life.

Participants allocated to Enhanced Usual Care will receive a psychoeducational handbook providing evidence-based information and strategies for managing anxiety following breast cancer, together with a reminder card and signposting to additional support resources. They will also receive brief clinical check-ins alongside study visits to discuss use of the handbook and anxiety management strategies.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety measured using the State-Trait Anxiety Inventory: Trait subscale at 8 weeks post-randomisation

Key secondary outcome(s)
1. Anxiety severity measured using State-Trait Anxiety Inventory – Trait Version (STAI-T) at 18 weeks post-randomisation

2. Generalised anxiety symptoms measured using Generalised Anxiety Disorder-7 (GAD-7) at 8 weeks, 18 weeks post-randomisation

3. Fear of cancer recurrence measured using Fear of Cancer Recurrence Inventory – Short Form (FCRI-SF) at 8 weeks, 18 weeks post-randomisation

4. Anxiety sensitivity measured using Anxiety Sensitivity Index (ASI) at 8 weeks, 18 weeks post-randomisation

5. Depressive symptoms measured using Patient Health Questionnaire-8 (PHQ-8) at 8 weeks, 18 weeks post-randomisation

6. Health-related quality of life measured using EQ-5D-5L at 8 weeks, 18 weeks post-randomisation

7. Fatigue measured using PROMIS Fatigue Short Form 7a at 8 weeks, 18 weeks post-randomisation

8. Pain intensity measured using PROMIS Pain Intensity 1a at 8 weeks, 18 weeks post-randomisation

9. Pain interference measured using PROMIS Pain Interference 6a at 8 weeks, 18 weeks post-randomisation

10. Menopause-related vasomotor symptom interference (hot flushes/night sweats) measured using MENQOL Vasomotor Domain at 8 weeks, 18 weeks post-randomisation

11. Work ability and employment status measured using Work Ability Score (WAS-1) plus study-specific work status items at 8 weeks, 18 weeks post-randomisation

12. Patient global impression of change measured using Patient Global Impression of Change (PGIC) at 8 weeks, 18 weeks post-randomisation

13. [Mechanistic secondary outcome] Interoceptive accuracy measured using Heartbeat Discrimination Task (HDT) and Heartbeat Tracking Task (HTT) at Midpoint, 8 weeks post-randomisation

14. [Mechanistic secondary outcome] Interoceptive sensibility measured using Multidimensional Assessment of Interoceptive Awareness-2 (MAIA-2), Bodily Threat Monitoring Scale (BTMS), and Body Mindset Inventory-2 (BMI-2) at MAIA-2: Midpoint, 8 weeks, 18 weeks; BTMS: 8 weeks, 18 weeks; BMI-2: Midpoint, 8 weeks, 18 weeks

15. [Mechanistic secondary outcome] Diurnal cortisol measured using Salivary cortisol (home saliva collection) at 8 weeks

16. [Mechanistic secondary outcome] Inflammatory biomarkers measured using Blood biomarkers (e.g. C-reactive protein and cytokines) at 8 weeks

17. [Mechanistic secondary outcome] Neural correlates of interoception measured using Task-based functional magnetic resonance imaging (fMRI) at 8 weeks (optional neuroimaging substudy)

18. [Acceptability, feasibility, and adverse event outcome] Intervention acceptability measured using Theoretical Framework of Acceptability questionnaire (TFA) at 8 weeks

19. [Acceptability, feasibility, and adverse event outcome] Participant recommendation of intervention measured using Net Promoter Score (NPS) at 8 weeks

20. [Acceptability, feasibility, and adverse event outcome] Intervention adherence measured using Session attendance and completion records at Throughout the intervention period

21. [Acceptability, feasibility, and adverse event outcome] Serious adverse events measured using Serious adverse event reporting at Continuously from randomisation until study completion

Completion date
30/12/2028

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Resident in the United Kingdom
3. Able and willing to attend weekly sessions in London for 8 consecutive weeks
4. Able to read, write, and follow instructions in English
5. Have previously received a diagnosis of primary breast cancer (stages 0-III)
6. Have completed hospital-based cancer treatment between 6 months and 10 years prior to enrolment (long-term adjuvant therapies are permitted)
7. Meet criteria for at least mild anxiety, defined using a pre-determined cut-off score GAD-2 (≥2) (GAD-2: Kroenke et al., 2007)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Key exclusion criteria:
Unable to provide informed consent

Cancer-related exclusions:
1. Diagnosis of Lobular Carcinoma in Situ (LCIS) only
2. Diagnosis of secondary or metastatic breast cancer

Other ADIE therapy contraindications:
1. Previous participation in any ADIE therapy trial
2. Presence of an implantable cardioverter defibrillator and/or pacemaker
3. Scheduled to begin Cognitive Behavioural Therapy (CBT) during the intervention period
4. Health anxiety specifically related to cardiac symptoms or cardiac events where it is considered to interfere with ADIE therapy
5. History of severe cardiac events (e.g., myocardial infarction, sudden cardiac arrest, stroke) within the past 12 months where it is considered to interfere with ADIE therapy

Other physical health exclusions:
1. Pregnancy
2. Current substance or alcohol dependence where it is considered to interfere with ADIE therapy
3. Neurological diagnoses, including epilepsy, dementia, or Parkinson’s disease where it is considered to interfere with ADIE therapy

Other mental health exclusions:
1. Current medium or high risk of suicide intention and plan, determined by item 9 of the Patient Health Questionnaire (PHQ-9) and accompanying risk assessment questions
2. Current severe depression determined by Patient Health Questionnaire (PHQ-8) (≥20)
3. Current diagnosis of obsessive-compulsive disorder (OCD), psychosis, or bipolar disorder where is considered to interfere with ADIE therapy

Date of first enrolment
15/07/2026

Date of final enrolment
01/01/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's Hospital
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
London
England
SE1 9RT

Study participating centre
The Royal Marsden Hospital
The Royal Marsden NHS Foundation Trust
Fulham Road
London
England
SW3 6JJ

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

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 are available from the corresponding author on reasonable request. We will make data available within 12 months of trial completion.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	26/06/2026	09/07/2026	No	No