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A support bra to improve accuracy of radiation therapy for women having treatment to the breast

Submission date 24/04/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/04/2017	**Overall study status** Completed	
Last Edited 10/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-about-the-s4a-support-bra-for-women-having-radiotherapy-for-breast-cancer

Study website
www.support4all.org.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34420

Study information

Scientific Title
Support, Positioning and Organ stabilisation during Breast Cancer Radiation Therapy: The SuPPORT 4 All project

Acronym
SuPPORT 4 All

Study objectives
The aim of this study is to test how practical it is for women to wear the S4A bra during radiotherapy, and how easy it is for the radiographers to use the bra to help them position the patient underneath the radiotherapy machine each day.

Ethics approval required
Old ethics approval format

Ethics approval(s)
17/NW/0236

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Specialty: Cancer, Primary sub-specialty: Breast Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasm of breast

Interventions
Patients will be randomised 1:1 to one of two groups. Randomisation will be through block randomisation (with blocks an integer multiple of four); stratified by breast/bra cup size (S4A bra size 3-7 vs. S4A bra size 8-12). The trial statistician will generate a randomisation schedule using existing software. This will be held remotely by the study-co-ordinator (who will not be directly involved in recruiting patients to the study).

Intervention group: Participants receive breast radiotherapy with S4A bra with one tattoo. This involves standard radiotherapy to the breast with patients planned and treated in the S4A bra with a single anterior permanent tattoo placed on the midline according to normal practice for breast irradiation. Patients will receive a standard radiotherapy dose of 40Gy in 15 fractions (daily over three weeks).

Control group: Participants receive their existing radiotherapy with standard set-up with no immobilisation with tattoos. This involves patients being planned for breast irradiation and treated as per standard practice with three permanent tattoos place on the torso one anteriorly on the midline and one either side of the thorax. Patients in the control group will be treated to the standard radiotherapy dose of 40Gy in 15 fractions (daily over three weeks).

Follow up involves completion of a postal questionnaire at 7 weeks (body image questionnaire, skin and breast changes self assessment, and patient empowerment questionnaire) and a final postal questionnaire at 3 months to assess body image. (details of other outcomes measured during treatment are listed in the outcome section).

Intervention Type
Other

Primary outcome measure
Feasibility of recruitment to main trial is defined as recruitment of 50 participants recruited in a six-month recruitment window at one centre.

Secondary outcome measures
Secondary feasibility outcomes
1. Recruitment and attrition rates (CONSORT data): number of patients assessed for eligibility; reasons for exclusion, numbers discontinuing intervention (with reasons), numbers analysed and excluded from the analysis
2. Number of missing values/incomplete cases is measured by reviewing study data at endline
3. Intervention adherence: Defined objectively as the number of radiotherapy fractions where the bra is used (for the intervention group) divided by the number of fractions prescribed
4. Intervention fidelity: During the study period site observations will be undertaken of treatment set-up for patients in both the control and intervention arms to ensure the support bra is used and positioned correctly and technique protocols are used in a standard manner across intervention and control groups
5. Technology acceptance from both healthcare practitioners and patients using an adapted Technology Acceptance Tool (based on the Technology Acceptance Model) at baseline
6. Feasibility of recruiting future participating centres: target sites for the main study will be screened for suitability, by interviewing potential principal investigators

The following outcome measures will be assessed for suitability to be used in the main trial:
1. Skin reactions using the Radiation Therapy and Oncology Group skin scoring assessment (RTOG) both staff scored and patient self –reported using a new lay reporting skin assessment tool. Measured at baseline and weekly while on treatment then at four weeks post treatment.
2. Dose to organs at risk, including mean ipsilateral lung dose, and mean heart dose (for those treated for a left breast cancer) measured from the radiotherapy treatment plan
3. Incidence of moist desquamation in the inframammary fold at week 3 of radiotherapy
4. Patient comfort measured by a comfort questionnaire developed from interviews with healthy volunteers that have tried the support bra and adaptations of the Kolcaba patient comfort questionnaire for radiotherapy patients, measured at baseline (at the time of fitting during radiotherapy planning) and weeks 1, 2 and 3 of treatment
5. Patient modesty measured by the patient modesty scale and a newly developed story board of the radiotherapy journey to measure patient experiences of physical exposure at weeks 1, and 3 of treatment
6. Patient empowerment using the 28-item patient empowerment scale for cancer patients, measured at baseline and weeks 1, 2, 3 and 7 of radiotherapy
7. • Body Image using the 10-item body image scale, measured at baseline and at 3 weeks, week 7 (one month post treatment) and 3 months

Overall study start date
02/01/2016

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Have undergone conservative surgery leaving an intact breast.
3. Invasive carcinoma of the breast
4. pT1-3, pN0-1, M0 disease
5. Referred for whole breast radiotherapy only
6. Able to give written informed consent.
7. A bra cup size that fits in the S4A bra size 3 and above (i.e. 28F/30E/32DD/34D/36C and above)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Previous ipsilateral or contralateral breast cancer (including DCIS).
2. Concurrent cytotoxic chemotherapy, (sequential adjuvant chemotherapy is allowed).
3. Radiotherapy to regional lymph nodes.
4. Requires a radiotherapy boost to the site of the primary tumour bed.

Date of first enrolment
22/05/2017

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S10 2SJ

Sponsor information

Organisation
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Sponsor type
University/education

ROR

https://ror.org/019wt1929

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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
1. Conference presentation -ESTRO European Society for Radiation Oncology
2. Publication of the clinical test outcomes in either International Journal of Radiation Oncology Biology Physics or Radiotherapy and Oncology or Clinical Oncology journal
3. Dissemination of outcomes via established networks including patient groups Breast Cancer Care, Breast Radiotherapy Interest Group, UK Radiotherapy Managers group, College of Radiographers Research network and CTRad (radiotherapy research network supported by the NCRI)
4. Study outcomes as open educational resources shared via established radiotherapy networks
5. Presentation at the national radiotherapy managers group
6. Press release on project outcomes

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The current 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?
Basic results		04/05/2021	05/05/2021	No	No
Plain English results		20/10/2021	20/10/2021	No	Yes
Protocol file	version 4	01/08/2018	10/10/2022	No	No
HRA research summary			28/06/2023	No	No