A randomised clinical feasibility trial of a breast immobilisation device: The SuPPORT 4 All (S4A) Project.

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A randomised clinical feasibility trial of a breast immobilisation device: The SuPPORT 4 All (S4A) Project.

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Purpose:

The primary purpose of this trial was to test the feasibility of using the S4A bra for women undergoing breast irradiation (following a wide local excision) and to determine acceptability of the pathway to patients and clinicians. Feasibility and efficacy endpoints were measured to inform the design of a future larger randomised controlled trial and to confirm safety of the device.

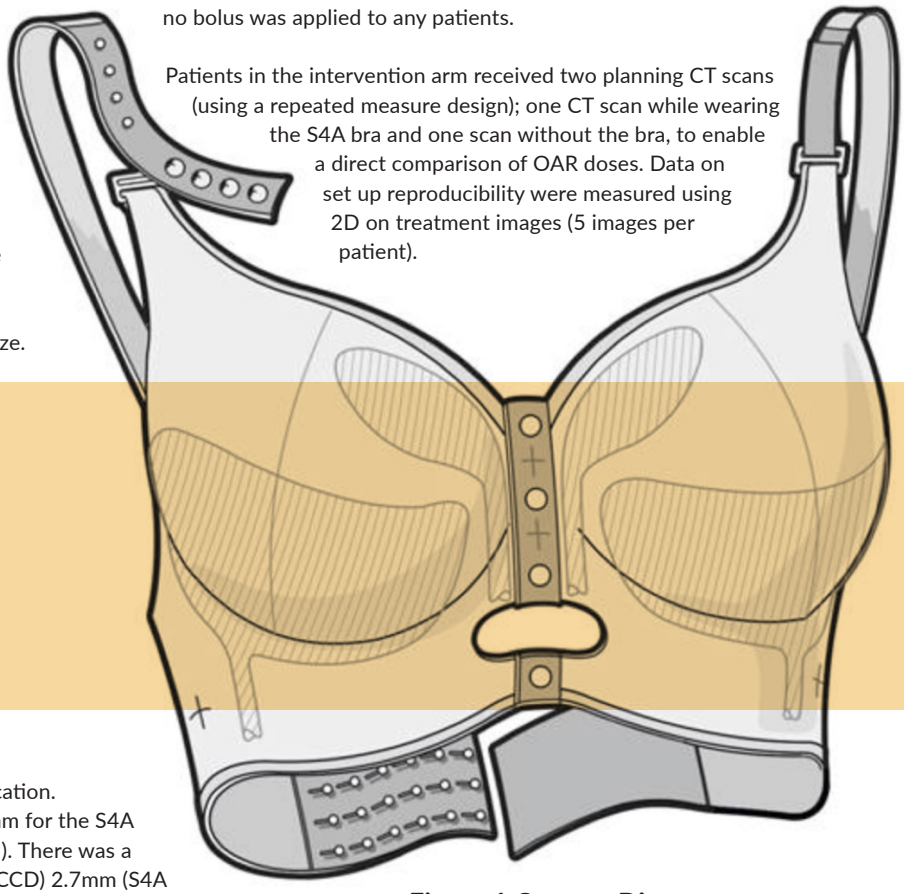
Background:

Improvements in cancer specific and overall survival for women with early breast cancer have led to more focus on the long-term toxicities of treatment. Whole breast radiotherapy has been shown to increase the risk of developing ischaemic heart disease(1), symptomatic pulmonary fibrosis or a second primary cancer of the lung (2, 3). Hence it is important to investigate methods to reduce radiation doses to these critical OAR. We have developed a novel support bra (S4A bra) to lift the breast away from the chest wall, particularly suited for women with larger breast size.

Method:

This was a single centre randomised feasibility trial. Eligible patients were assigned to either the S4A bra (group A) or standard positioning without immobilisation (group B) via a computer-generated randomisation process that was remote to the clinical and S4A project team; randomisation was stratified by breast size. All patients received 40Gy in 15 fractions over 3 weeks without a boost and without regional nodal irradiation; no bolus was applied to any patients.

Patients in the intervention arm received two planning CT scans (using a repeated measure design); one CT scan while wearing the S4A bra and one scan without the bra, to enable a direct comparison of OAR doses. Data on set up reproducibility were measured using 2D on treatment images (5 images per patient).



The following measures were included:

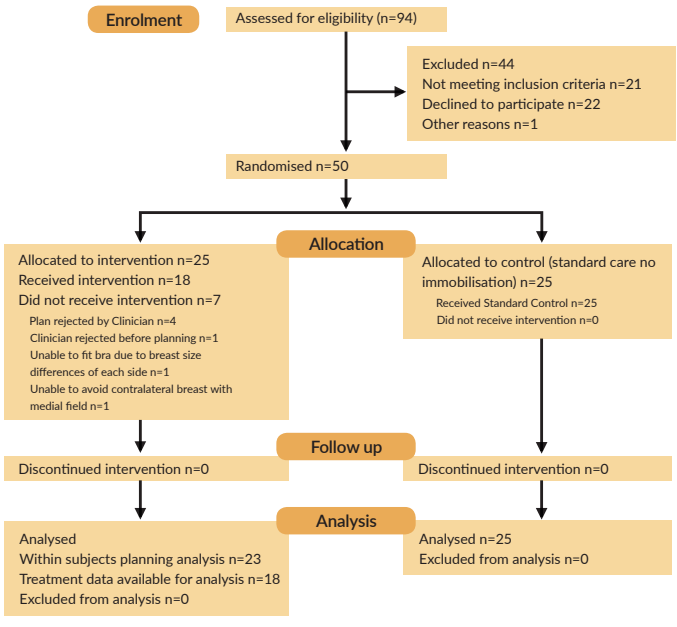
Skin reactions-RTOG(4).
Incidence of moist desquamation in the inframammary fold.
Dose to OAR (mean lung and mean heart doses).
Patient comfort.
Patient modesty (5).
Patient empowerment(6)
Acceptance using an adapted technology acceptance tool(7).
Body Image(8)

Results:

The Consort diagram in Figure 1 shows recruitment and allocation. Population systematic errors for central lung depth was 0.9mm for the S4A arm and -1.5mm for the control (difference 2.4mm CI 0.9-3.9). There was a difference in systematic error in the cranial-caudal distance (CCD) 2.7mm (S4A bra) vs 1.5mm. Differences in random errors between the groups were all below 1mm except for CCD where there was a small difference in favour of the control arm (2.4mm difference). RTOG scores were comparable between the groups and no grade 3 reactions were reported in either arm. No difference in mean heart dose was identified (mean heart doses were all <1.5Gy) patients treated for a left breast cancer had DIBH irrespective of treatment arm. Table 1 shows an improvement in mean ipsilateral lung dose when using the S4A bra in both right and left sided cases (mean improvement 1.13Gy, and 0.391Gy respectively).

Allocation	With or Without Bra	Side Treated	Ipsilateral mean (Gy)	Combined lungs mean (Gy)	Number (n=)
A	No Bra	Right	4.851	2.636	10
A	With Bra	Right	3.720	2.017	10
A	No Bra	Left	3.622	1.704	13
A	With Bra	Left	3.231	1.539	13

Figure 1 Consort Diagram:



Conclusion:

This study showed that mean ipsilateral lung dose was lower for women treated with the S4A bra. Mean heart dose was no different. Differences in systematic and random errors were not clinically significant. Skin reactions indicated no clinically detectable adverse effect of the bra material, and no serious adverse events were reported. There was improved modesty and dignity, and improved empowerment, (higher mean empowerment questionnaire scores) in the S4A bra arm.
This was a feasibility trial and a larger multi-centre study is now needed.

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