This design research led by Reed focused on the development of a brassiere to improve the treatment accuracy, and dignity for women undergoing radiotherapy for breast cancer.

In the UK, every year, around 55k woman who have undergone a lumpectomy (the removal of cancerous tissues) will require a course of radiotherapy. The therapy involves a series of separate breast irradiation treatment sessions. Many techniques for breast irradiation are used and vary in procedure across NHS clinics. However, all require the patient to undress from the waist upwards while up to 4 staff (including men) adjust their position in preparation for treatment. Positioning of the breast is important to avoid radiation doses to organs at risk (OAR) and to increase reproducibility to accurately target the cancerous cells.

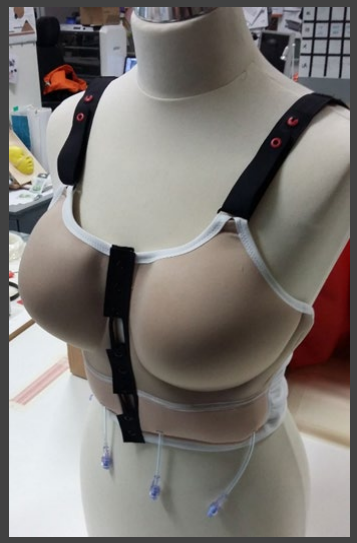
Reed explored patient and staff experiences and requirements for a support garment that balanced accurate positioning of the breast that was acceptable to patients and helped to maintain modesty. Initial designs were developed in response to findings from this phase of the study.

Working concurrently with radiologists, industry, patients and health-care professionals, these were refined using an iterative design research cycle. The final outcome of the research was a support bra which was the focus of a Clinical Feasibility Trial in compliance and approved by the Medicines & Healthcare products Regulatory Agency (MHRA). The study showed significant benefits in reducing negative effects to OAR and improved modesty and dignity.

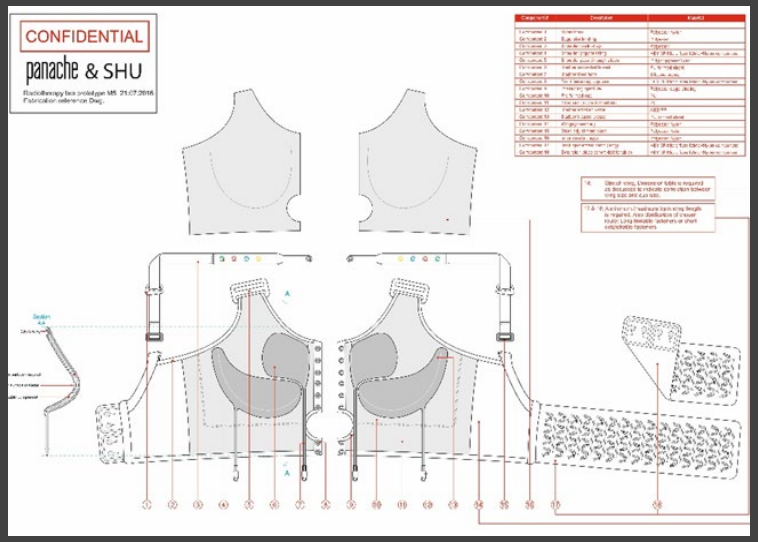
The outcome of the research has achieved patent and commercial licensing in negotiation. This research was selected as one of the Top 100 University Breakthroughs.

The study further sought to quantify if new interventions are capable of streamlining therapy processes across clinics, and provide self-monitoring materials through the use and adoption of Support4All Bra. This research was funded by the NIHR i4i.

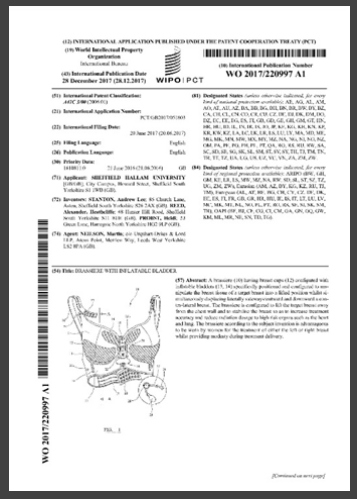
Above: Setting up the custom designed CT scan mannequin during pre-patient use/prototype bra testing



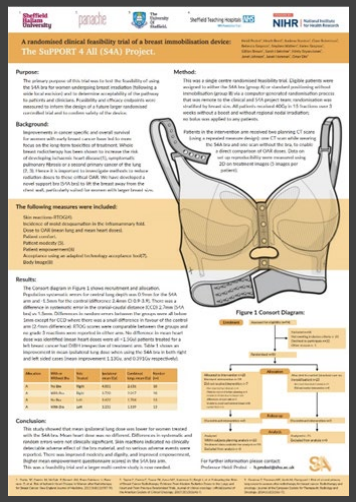
Prototype design used in the 50 patient Clinical Feasibility Trial.



Production manufacturing drawings and device specifications.



Granted international patent.



Published Clinical Feasibility Trial outcomes reporting reduced negative effects to OAR.

Research selected as one of the Top 100 University Breakthroughs.

This programme of research involved:

- Establishing insight of experiences of woman undergoing post-operative breast cancer.

- An iterative cycle of design development and testing.

- Development of custom phantom technologies enabling clinical evaluation, and enhancement of concept designs.

- Understanding product service and supporting system intelligence
- Consideration for manufacture and production.

A key aspect of this research was to establish a level of scientific, logistical and end user (patient and health care practitioner) knowledge within the design team, so as to develop and propose appropriate product and system solutions.

Aspects of this method of ‘introspective new knowledge’ building, leading to ‘new to world’ knowledge are reported in Dissemination ‘New to me, New to world’, presented at the Senses and Sensibilities Conference, ‘Lost in [G]Localization’ (S&S, Lisbon, Portugal, 2019) (http://senses2019.unidcom-iade.pt/).

Heath Reed presenting abstract ‘New to me, New to world’ at S&S 2019.

Establishing user insight and bra development

Having identified an unmet need for a stabilising and positioning garment for use during post-operative breast cancer radiotherapy, and a desire to improve dignity for women undergoing these treatments, a number of early-stage concept designs were generated based upon clinical requirements as defined by radiotherapist, HCPs and by end users through stakeholder workshops.

This included eight NHS radiotherapy staff and ten former patients in seven workshops.

Several concept designs were visualised and presented at the stakeholder workshop sessions to co-create several concept iterations. A physical design emerged that incorporated the provision of a product with capabilities to be personally modified for fit, within a potentially standardised bra garment range. This was to ensure both a customised fit with the wearer and facilitate reconfiguration to allow breast tissue repositioning appropriate for tailored radiotherapy treatment to ensure minimisation of radiation doses to organs at risk (heart, lung). Further development considered integration within the bra garment of inflatable air pockets (air being a medium that minimally attenuates radiotherapy dose), such that breast tissue may be repeatably, correctly positioned for repeat treatments.

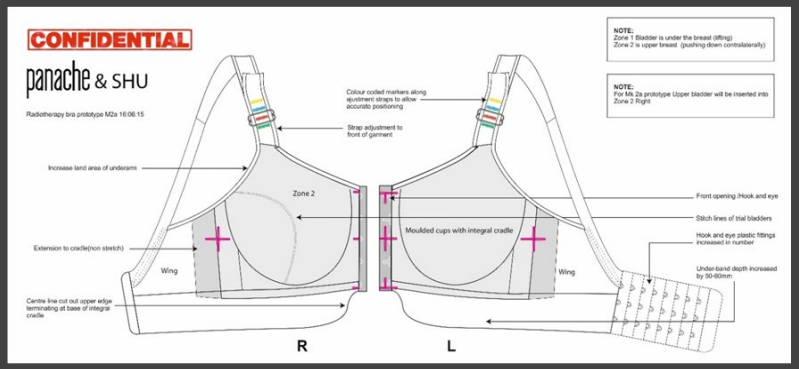
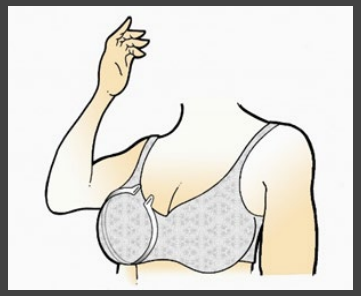


Illustration of proposed solution, after several iterations incorporating key performance specifications.

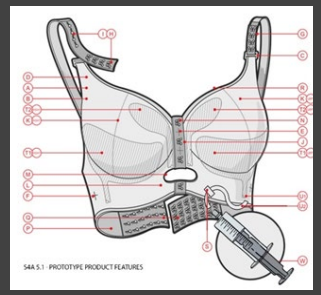

Early-stage tissue manipulation and positioning concept based on working group discussion and presented to them for feedback.


Bench testing a production method for a standard bra insert to evaluate performance, positionality and repeatability.


Trailing early-stage bra insert design on the first iteration bra and 'phantom'.


Alternative concept informing requirement for bra 'lift' and 'push' integration.


Mark 3 of bra design showing prototype inflation insert



Several iterations of the physical design considering use pathway, dignity issues, technical/clinical performance and manufacture capability. Led to the Mark 5.1 bra design.

Development of custom phantom to inform design development and enable clinical evaluation

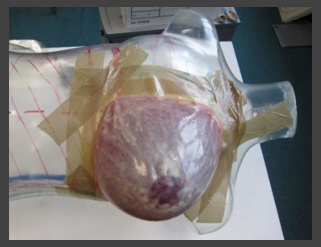
New products of this type require clinical approval for use; data validating the safety, efficacy, and technical performance in support of certification and CFT application. Often, where an entirely new product, procedure and treatment pathway is proposed, established validation methods do not exist.

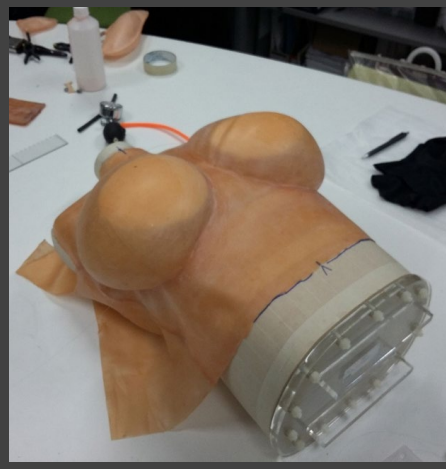
Further, in the early stages of development of a new product or device for treatment, it is not possible to test on living persons, where there is the potential for physical or psychological harm and risks to health. To mitigate this a series of tools or custom 'phantom mannequins' were created to which proposed bra designs were attached to simulate tissue manipulation.

The effect of prototype bras on mimicked tissue were recorded using spiral computed tomography ('CT') scanning, to help understand the impact on breast forms, simulate radiotherapy CT planning using a bra, validate proposed design function and use pathway, prior to actual human CFT project phases.

Internal organ mannequins exist ('phantoms'), they are constructed from ridged materials exhibiting varying degrees of radio translucency (for imaging internal organs) but do not reflect the mobility of human tissue. A requirement was therefore identified for a lifelike mannequin representative of tissue mobility volumes and internal organ forms of the human breast.

Research involved augmenting an existing male phantom mannequin with female anatomy that exhibited physical characteristics of mobile breast tissue. This was be used to investigate various parameters concerning the viability of concepts, including attenuation, treatment beam in relation to OAR, set up repeatability, the pathway of use, technical and clinical effectiveness. 'Proving the proof of Concept'; developing new methods and knowledge to evaluate products supporting cancer therapy', is documented and disseminated in the Design for Health Journal, 2017.

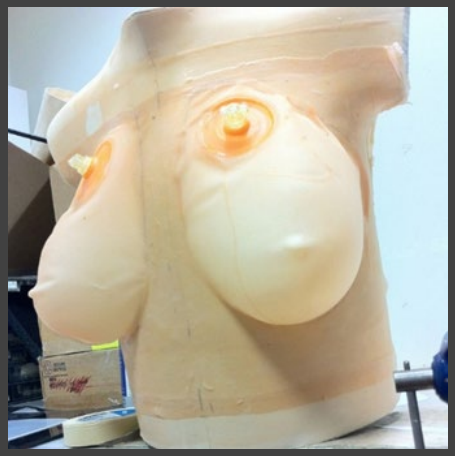


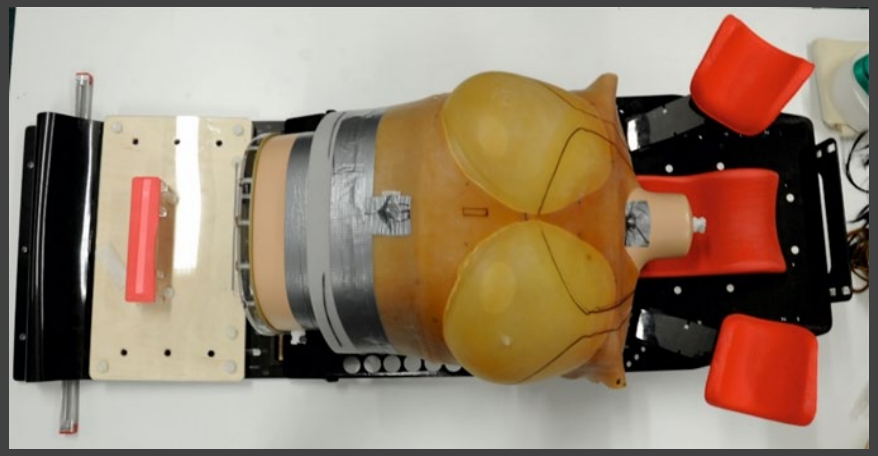


Images: Early-stage experimentation using latex skin, 'paste' filled breast form envelopes, representing mobile breast structures and located over a ridged shell, figures 018, 019.

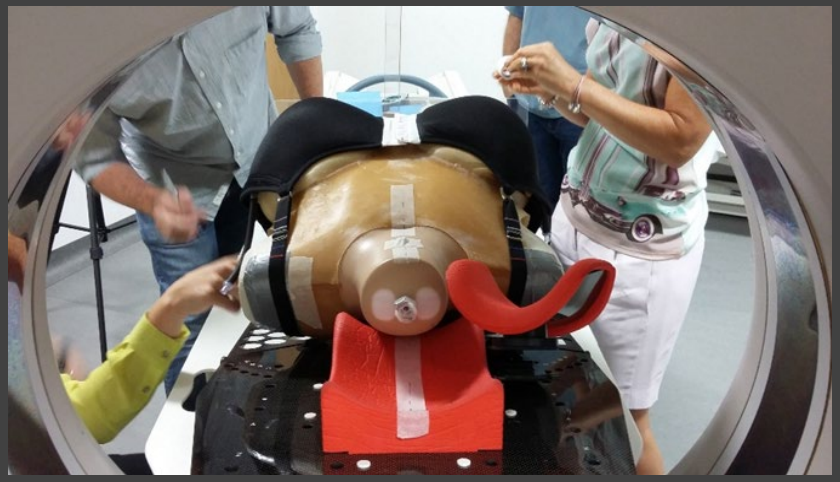
Selected mobile, custom phantom construction materials and methods, in conjunction with existing ridged phantom molding

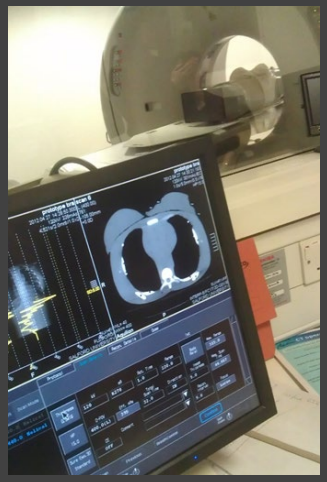
Development of custom phantom to inform design development and enable clinical evaluation.

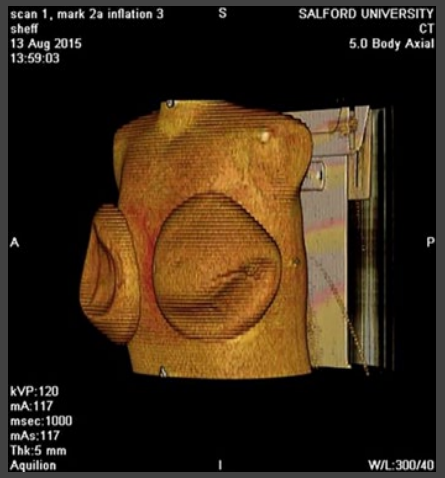




The simulated phantom, assembled with CT scan bed







The research team preparing the phantom for device performance tests.

The effects of a prototype bra design on the augmented phantom, visualised using CT scanner, showing positional relationship with ridged phantoms internal organs.

Composite model/image of multiple CT data/imaging slices, creating three-dimensional representation. Example showing evidence of desired breast lift (left breast) and 'push' (right breast).

Product and service support system requirements

The development of the bra and supporting service level materials were informed through a series of health care practitioner and end-user (surviving breast cancer patient) workshops.

Workshops were facilitated jointly between Design and Radiotherapy specialists and included, visualisations of the anticipated processes during a radiotherapy session. Images were used to promote conversations, as memory prompting devices and use pathway definition tools, drawing on the experience of end-users of their therapy in practice.

Latterly, as the design and intended use pathway developed, more detailed user scenarios were developed to further define use pathways, guide discussions and additionally formed of key part of the ethics approval process approved by the Medicines & Healthcare products Regulatory Agency (MHRA). Workshops using these methods and materials were audio recorded, anonymised, transcribed and reviewed by the research team. Issues and recommendations that emerged were considered and integrated into physical designs and supporting materials.

Example illustration of current practice pathway step used as workshop conversation prompt used in the early-stage insight building.

Examples of the refined user pathway illustrations used to elicit insight about existing and proposed use scenarios.

Manufacture and production

Based on feedback from all stakeholders the preferred design and systems technical configuration included curved air pocket features. This reason for this was firstly; to conform to the organic, compound (bending in at least two directions simultaneously) nature of human tissue forms (breast shapes), to allow integration with pre-formed bra cups.

In addition to minimize the extent of undulation effect of inflated air pockets, about their periphery, where undulation folds and bends may; (a) cause discomfort and poor fit and (b) where undulation of material surfaces may induce abnormalities in tissue shape (and dose distribution/dosimetry) during radiotherapy.

An extensive review of manufacturing processes for products with similar capability determined that compound curve inflation pocket manufacturing techniques were not currently available.

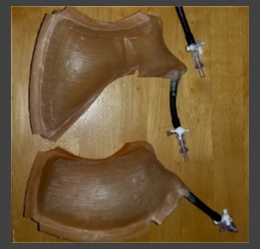
Current physical designs and enabling manufacturing technologies of similar air pockets involve the use of at least two layers of flat sheet material, bonded, welded, or otherwise affixed together to form an airtight enclosure. The resulting air pockets, made from sheet materials in this way, are therefore 'flat' (broadly speaking two dimensional), pre inflation.

Changes to the shape and form of air pockets occur once inflated. These result in the undulation of the air pocket surfaces/material layers, particularly around the periphery (weld seam), as the material is being forced to stretch in different regions once inflated. The research concluded that new methods, techniques and processes were required to be developed to achieve desired compound curve inflatable air pocket sub-assemblies.

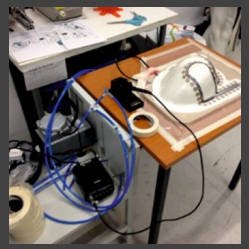
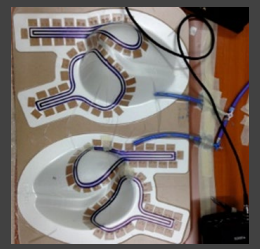
A number of production techniques, materials and processes have been researched, developed and tested to achieve non-flat air pockets, and described in the following, representative images.

Physical tests (images top right) evidenced the most cost-effective approach in very high-volume production scenarios. However, based on anticipated production volumes (UK 40K units PA) fabricated methods (images bottom right) were deemed the most cost effective for production, depending upon the production capabilities of the right to manufacture/ IP licensers.

This particular aspect of the research is subject to intellectual property disclosure and has therefore not been publicly disseminated to date.

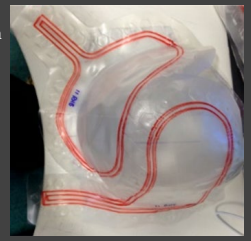

Nitrile dip. A machined form/tool is CNC cut representing the desired air pocket form. Tools are dipped in liquid rubber solutions (Latex/Nitrile) and cured. Air pockets are attached to air tubes and incorporated with completed garment assembly.


TPU heat weld. Two-stage process using TPU (thermoplastic polyure-thane sheet) vacuumed formed over a pattern/former or tool. Two matching compound curved sheet forms are located over/on a heat welding registration tool. Tools tested include CNC cut wooden patterns, 3D printed polymer and plaster. Heat is applied to secure about periphery. Excess material removed, air pockets attached to air tubes, and valves incorporated.

TPU USW. Two sheets of TPU material vacuumed formed over tool. Compound curved sheet forms registered on an ultra-sonic welding (USW) tool. Welds applied to secure the formed sheets together to form a continuous weld about the periphery.


Tool Integration. TPU sheet formed over an integrated vacuum form and ultrasonic weld tool. Two sheets of material formed and USW simultaneously to form a continuous weld about the compound curved air pocket periphery. Tests conducted with 3D printed, sintered deposition tools proven.

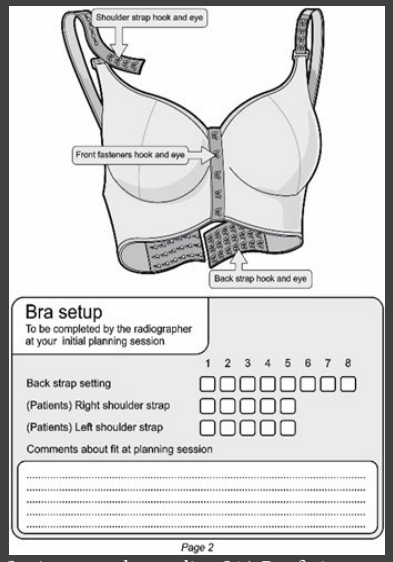


Materials for the human Clinical Feasibility Trial

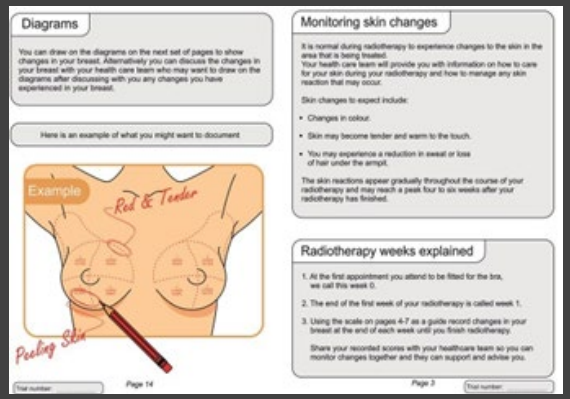
Alongside the production of garments used in the Clinical Feasibility Trial (CFT) further materials were developed to enable production, quality control, information and instructions for use (patient and HCP), documentation allowing self-monitoring and reporting of skin condition during therapy course , and post study survey materials to evaluate intended use pathways.

These materials formed components of the MHRA approved Clinical Feasibility Trial study protocol. The CFT involved a randomised human trial comprising 50 human participants currently undergoing post lumpectomy radiotherapy, 18 wearing the bra as part of their cancer treatment pathway. A fuller account of the clinical results of the study can be found in the dissemination section.

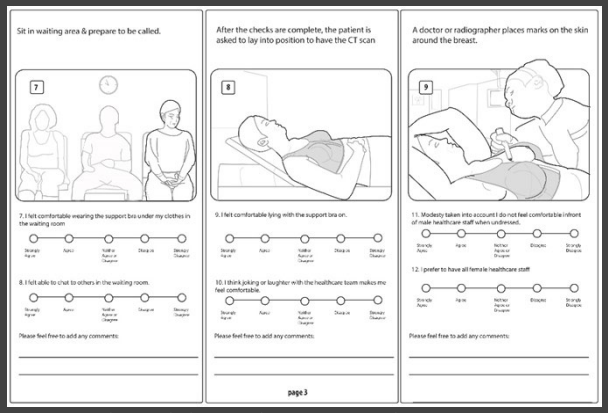
The research and development of the S4A bra included methods enabling its production, of systems enabling clinical testing and validation, and R&D in support of the proposed product service level designs. Each of these strands of activity ultimately fed into the S4A bra design being eligible for clinical feasibility-testing with human participants using the Medical Research Council framework for developing and evaluating complex interventions.



Setting up and recording S4A Bra fitting instructions

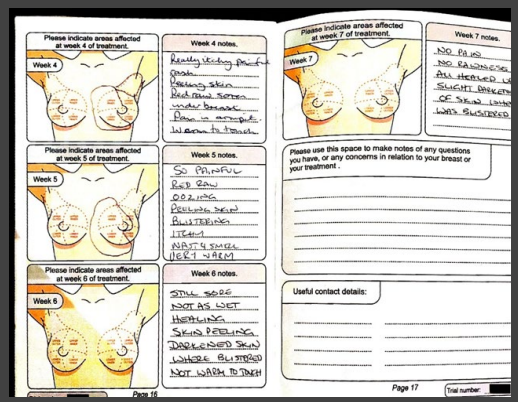


Instructions on how to monitor skin condition.



Existing and intended use pathways presented as CFT participant feedback and scoring. Use pathway illustrations and garment subjected to MHRA study protocol approval.

The batch produced version of the S4A Bra used in CFT and its associated quality control documention design.



Example of returned skin condition self-monitoring booklet showing areas affected by radiotherapy.

NARRATIVE

OUTPUT

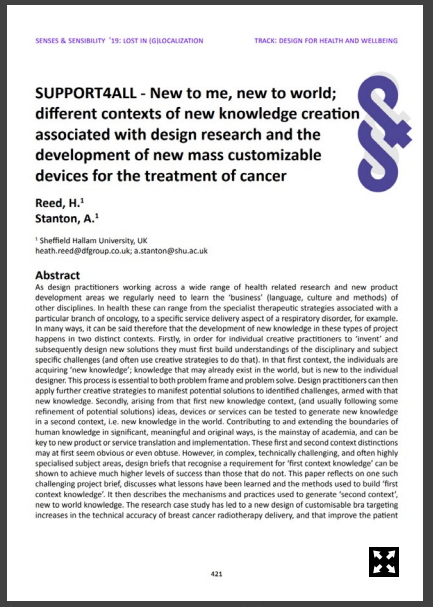
METHODS

DISSEMINATION 1/2

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

A mix of peer reviewed design, user-centred, clinical and scientific research has been dissemination alongside press, media, industry, and pedagogical publications.

A Granted patent 'BRASSIERE WITH INFLATABLE BLADDER' (WO2017220997A1 B, priority dated June 2016) was followed by a PCT and EP regional patent granted with national validations in Austria, Belgium, Germany, Denmark, Spain, France, GB, Ireland, Italy, Lithuania, The Netherlands, Switzerland and Sweden, US patent is pending.


SENSES & SENSIBILITY '19: LOST IN (G)LOCALIZATION TRACK: DESIGN FOR HEALTH AND WELLBEING

SUPPORT4ALL - New to me, new to world; different contexts of new knowledge creation associated with design research and the development of new mass customizable devices for the treatment of cancer

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heath.reed@dfgroup.co.uk; a.stanton@shu.ac.uk

Abstract

As design practitioners working across a wide range of health related research and new product development areas we regularly need to learn the 'business' (language, culture and methods) of other disciplines. In health these can range from the specialist therapeutic strategies associated with a particular branch of oncology, to a specific service delivery aspect of a respiratory disorder, for example. In many ways, it can be said therefore that the development of new knowledge in these types of project happens in two distinct contexts. Firstly, in order for individual creative practitioners to 'invent' and subsequently design new solutions they must first build understandings of the disciplinary and subject specific challenges (and often use creative strategies to do that). In that first context, the individuals are acquiring 'new knowledge'; knowledge that may already exist in the world, but is new to the individual designer. This process is essential to both problem frame and problem solve. Design practitioners can then apply further creative strategies to manifest potential solutions to identified challenges, armed with that new knowledge. Secondly, arising from that first new knowledge context, (and usually following some refinement of potential solutions) ideas, devices or services can be tested to generate new knowledge in a second context, i.e. new knowledge in the world. Contributing to and extending the boundaries of human knowledge in significant, meaningful and original ways, is the mainstay of academia, and can be key to new product or service translation and implementation. These first and second context distinctions may at first seem obvious or even obtuse. However, in complex, technically challenging, and often highly specialised subject areas, design briefs that recognise a requirement for 'first context knowledge' can be shown to achieve much higher levels of success than those that do not. This paper reflects on one such challenging project brief, discusses what lessons have been learned and the methods used to build 'first context knowledge'. It then describes the mechanisms and practices used to generate 'second context', new to world knowledge. The research case study has led to a new design of customisable bra targeting increases in the technical accuracy of breast cancer radiotherapy delivery, and that improve the patient

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'New to me, new to the world'. Sense & Sensibility conference. Porto, Portugal 2019.


Taylor & Francis Online

Design for Health
Volume 1, 2017 - Issue 1

Case Study

Proving the proof of concept; developing new methods and knowledge to evaluate products supporting cancer therapy

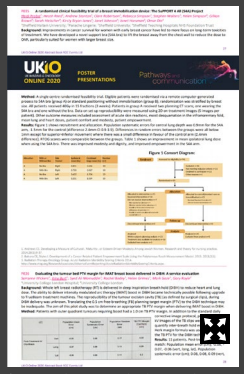
Heath Reed

ABSTRACT

This article illuminates through a case study, SuPPORT 4 All (Support, Positioning and Organ stabilisation during breast cancer radiation therapy/S4A). It describes how three-dimensional design research assesses, assimilates and is applied to define product requirements in a cross-disciplinary research team, activity occurring concurrently, yet also informing the act of designing the eventual products themselves. The study describes how a multidisciplinary research and development team, more specifically the design researchers within it, developed a range of holistic knowledge sets to establish critical criteria to validate physical outcomes. The study illustrates the methods used and developed to elicit the scale of the challenge and discusses the validity of these methods and technologies when wide-ranging design specifications may not exist at project outset.

KEYWORDS: Research design, new knowledge, innovation, applied research, cross-disciplinary, prototyping

'Proving the proof of concept'. Design for Health Journal (2017).

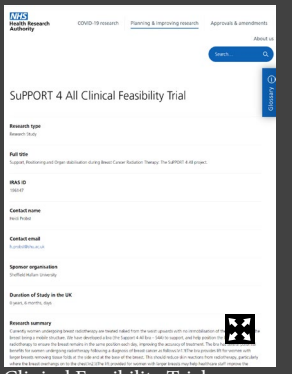

UKIO ONLINE 2020 FOSTER PRESENTATIONS

'A randomised clinical feasibility trial of a breast immobilisation device'. UK Imaging & Oncology 2020.


Radiography

The patient experience of radiotherapy for breast cancer: A qualitative investigation as part of the SuPPORT 4 All study

'The patient experience of radiotherapy for breast cancer'. Radiography Journal (2020).

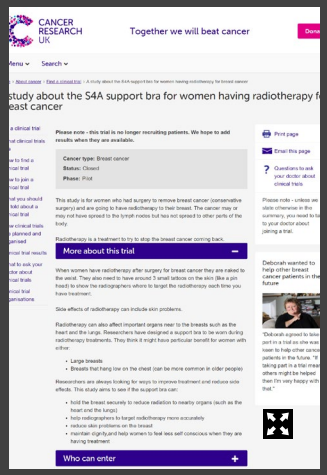

SuPPORT 4 All Clinical Feasibility Trial

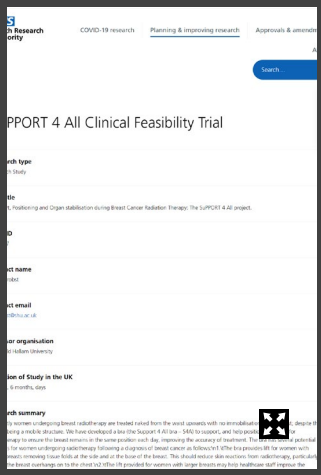
Clinical Feasibility Trial.

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

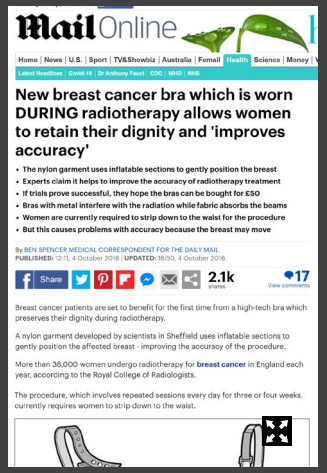
'The patient experience of radiotherapy for breast cancer:' PubMed.gov (2020)

'The development of a device to immobilise the breast during radiotherapy'. Radiotherapy and Oncology Journal (2018)

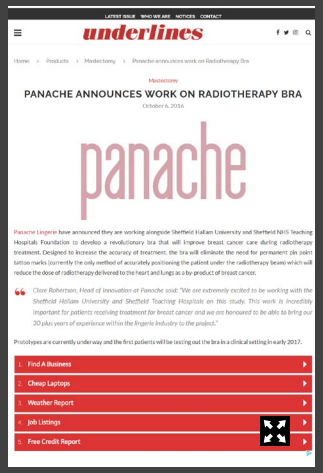




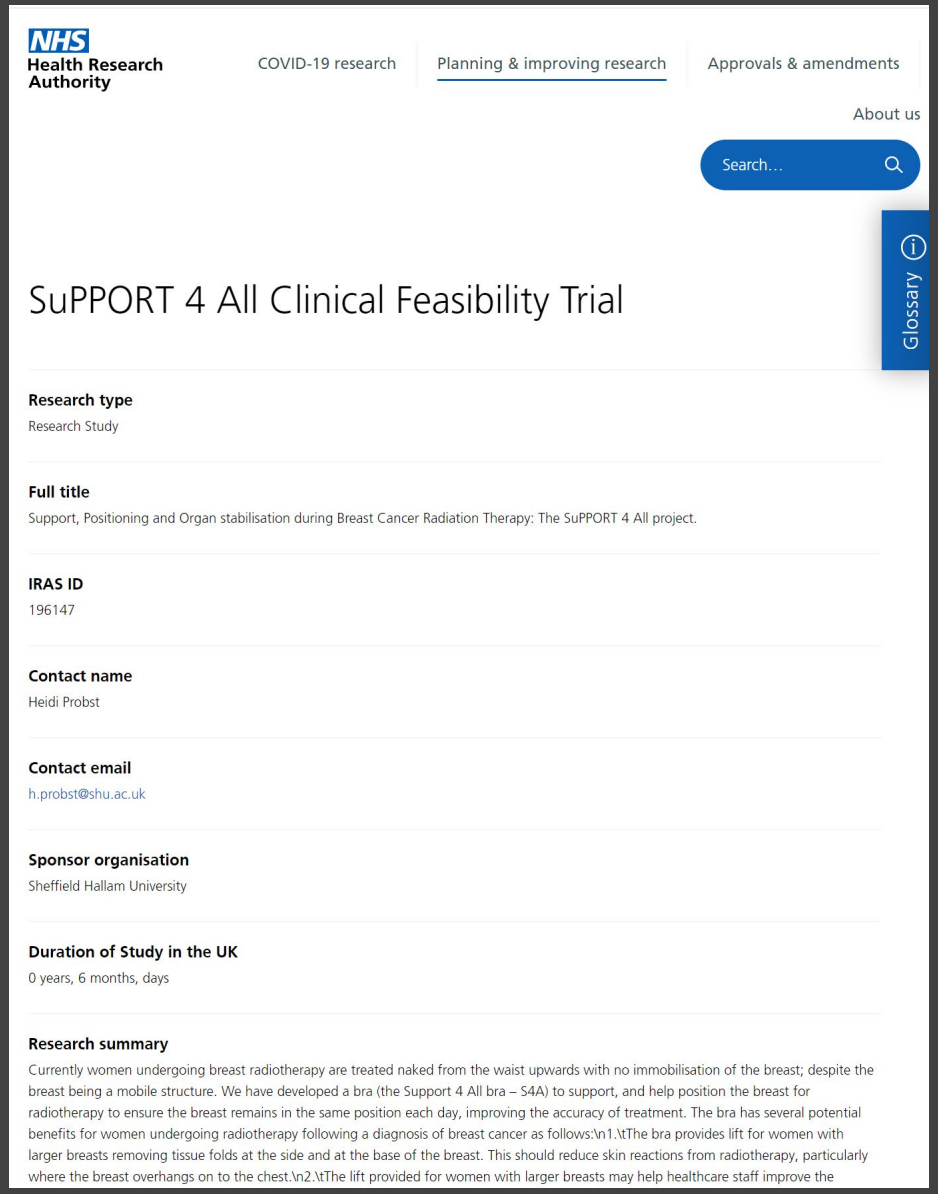
A national campaign to recruit participants was launched with Cancer Research UK, locally through the NHS Trust and approved by the NHS Health Research Authority.



Mail online (2016)



The project engaged Panache Lingerie and gained exposure through Garment industry news.



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Glossary

SuPPORT 4 All Clinical Feasibility Trial

Research type
Research Study

Full title
Support, Positioning and Organ stabilisation during Breast Cancer Radiation Therapy: The SuPPORT 4 All project.

IRAS ID
196147

Contact name
Heidi Probst

Contact email
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Sponsor organisation
Sheffield Hallam University

Duration of Study in the UK
0 years, 6 months, days

Research summary
Currently women undergoing breast radiotherapy are treated naked from the waist upwards with no immobilisation of the breast; despite the breast being a mobile structure. We have developed a bra (the Support 4 All bra – S4A) to support, and help position the breast for radiotherapy to ensure the breast remains in the same position each day, improving the accuracy of treatment. The bra has several potential benefits for women undergoing radiotherapy following a diagnosis of breast cancer as follows:\n1.\tThe bra provides lift for women with larger breasts removing tissue folds at the side and at the base of the breast. This should reduce skin reactions from radiotherapy, particularly where the breast overhangs on to the chest.\n2.\tThe lift provided for women with larger breasts may help healthcare staff improve the

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The patient experience of radiotherapy for breast cancer: A qualitative investigation as part of the SuPPORT 4 All study

H. Probst*, K. Rosbottom, H. Crank, A. Stanton, H. Reed

Sheffield Hallam University, UK

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ABSTRACT

Introduction: Breast cancer is a global health problem with 2.09 million cases of breast cancer diagnosed worldwide in 2018. With an increase in breast cancer survival attention has now focussed on the impact treatment side effects can have on the quality of life for women during survivorship. The aim of the SuPPORT 4 All project is to develop a support bra for use during radiotherapy, that can reduce normal tissue toxicity (for women with larger breasts) and provide accuracy, dignity and modesty for all women. The first stage of the project involved a co-design process to understand the current patient experience where no support bra or modesty device is used.

Method: A participatory co-design methodology was adopted. Workshops were held with patient representatives (n = 9) to seek understanding of experience during radiotherapy; a total of three workshops over 4 h. The workshops were audio recorded and framework analysis was adopted to identify key patient experiences.

Results: Twelve categories and twenty-six sub categories were identified specific to patient experience. Patient concerns focussed on information provision, Healthcare Practitioner (HCP) knowledge of breast lymphoedema, lack of choice, experiences of being naked, and feelings of disempowerment.

Conclusions: A number of areas were identified that had negative effects on overall patient experience.

Implications for practice: Practitioners should consider patient dignity when configuring services to support patient needs regarding undressing, outside or inside the linear accelerator room. Additionally, practitioners should have an understanding of the impact permanent tattoos may have on some patients' wellbeing and the impact that breast lymphoedema has on patient quality of life. Practitioners should also consider methods to encourage patient empowerment during radiotherapy; supporting patient self-monitoring of side-effects may be one way to facilitate this.

Introduction

Breast cancer is a global health problem with 2.09 million cases of breast cancer diagnosed worldwide in 2018,[1] accounting for 11.6% of all cancer incidence. Survival from breast cancer has improved in many countries, with over 1 million women surviving the disease in 2012.[2] Hence as more women survive, attention has now focussed on the impact treatment related side effects and treatment experiences can have on the quality of life for women and their ability to cope during survivorship.

There has been significant research in the field of breast irradiation techniques over recent years to reduce treatment related sequela.[3,4] The experience of involvement in clinical trials such as HeartSpare (I and II)[5,6] and the IMPORT trials[7] means many radiotherapy departments are moving to more complex radiotherapy techniques including Intensity Modulated Radiotherapy (IMRT), and the use of breath hold techniques, or implementing simultaneous integrated boost techniques; some of these techniques enable greater lung and heart sparing.

However, there has been less research investigating patients' experiences of the delivery of radiotherapy. There is a range of research that focusses on patient's lived experiences of a breast cancer diagnosis, perceptions of treatment and experiences of survivorship or assessments of symptoms from radiotherapy.[8–13] However, the research tends to focus primarily on information needs, or frequency or experience of side effects. There is little focus on the experience of attending for breast irradiation itself.

Schnur et al. (2009) reported on the assessment of patient diary reflections written during a course of breast irradiation (14) (n = 15 women). The key themes identified in this qualitative study

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https://doi.org/10.1016/j.radi.2020.09.011
1078-8174/

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P035 **A randomised clinical feasibility trial of a breast immobilisation device: The SuPPORT 4 All (S4A) Project**

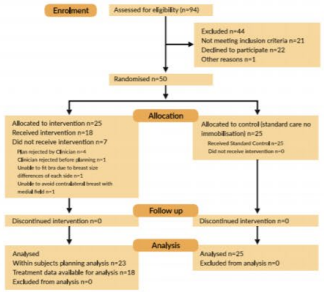
Heidi Probst[1]; Heath Reed[1]; Andrew Stanton[1]; Clare Robertson[2]; Rebecca Simpson[3]; Stephen Walters[3]; Helen Simpson[4]; Gillian Brown[4]; Sarah Hielscher[4]; Kirsty Bryan-Jones[4]; Janet Johnson[4]; Janet Horsman[3]; Omar Din[4]
[1]Sheffield Hallam University; [2]Panache Lingerie; [3]Sheffield University; [4]Sheffield Teaching Hospitals NHS Foundation Trust

Background: Improvements in cancer survival for women with early breast cancer have led to more focus on long-term toxicities of treatment. We have developed a novel support bra (S4A bra) to lift the breast away from the chest wall to reduce the dose to OAR, particularly suited for women with larger breast size.

Method: A single centre randomised feasibility trial. Eligible patients were randomised via a remote computer-generated process to S4A bra (group A) or standard positioning without immobilisation (group B); randomisation was stratified by breast size. All patients received 40Gy in 15 fractions (3 weeks). Patients in group A received two planning CT scans; one wearing the S4A bra and one without the bra. Data on set up reproducibility were measured using 2D on treatment images (5 images per patient). Other outcome measures included assessment of acute skin reactions, moist desquamation in the inframammary fold, mean lung and heart doses, patient comfort and modesty, patient empowerment.
Results: Figure 1 shows recruitment and allocation. Population systematic errors for central lung depth was 0.9mm for the S4A arm, -1.5mm for the control (difference 2.4mm CI 0.9-3.9). Differences in random errors between the groups were all below 1mm except for superior-inferior movement where there was a small difference in favour of the control arm (2.4mm difference). RTOG scores were comparable between the groups. Table 1 shows an improvement in mean ipsilateral lung dose when using the S4A bra. There was improved modesty and dignity, and improved empowerment in the S4A arm.

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:



1. Andrews CS. Developing a Measure of Cultural-, Maturity-, or Esteem-Driven Modesty Among Jewish Women. Research and theory for nursing practice. 2014;28(1):9-37.
2. Bulsara CE, Styles I. Development of a Cancer Related Patient Empowerment Scale Using the Polytomous Rasch Measurement Model. 2013. 2013;2(1).
3. Radiation Therapy Oncology Group. Acute Radiation Morbidity Scoring Criteria 2014. http://www.rtog.org/ResearchAssociates/AdverseEventReporting/AcuteRadiationMorbidityScoringCriteria.aspx.

P036 **Evaluating the tumour bed PTV margin for IMAT breast boost delivered in DIBH: A service evaluation**

Sairanne Wickers[1]; Amy Burt[1]; Syed Ali Moinuddin[1]; Rachel Bodey[1]; Helen Grimes[1]; Mark Gaze[1]; Gary Royle[2]
[1]University College London Hospital; [2]University College London

Background: Whole left breast radiotherapy (RT) is delivered in deep inspiration breath hold (DIBH) to reduce heart and lung dose. The ability to deliver intensity modulated arc therapy (IMAT) boost in DIBH became technically possible following upgrade to TrueBeam treatment machines. The reproducibility of the tumour excision cavity [TB] (as defined by surgical clips), during DIBH delivery was unknown. Translating the 0.5 cm free-breathing (FB) planning target margin (PTV) to the DIBH technique may be inadequate. The aim of this pilot study was to determine an appropriate TB PTV margin when delivering IMAT boost in DIBH.
Method: Patients with outer quadrant tumours requiring boost had a 1.0 cm TB PTV margin. In addition to the standard daily corrective image protocol, post-treatment kV images of the TB clips were acquired to quantify inter-breath hold error. The Van Herk margin formula was used to confirm the TB PTV for the DIBH technique.

n11		Population mean Error (cm)	Population Systematic Error (cm)	Population Random Error (cm)	TB PTV Margin (VanHerk) (cm)
Post-Treatment kV Clip-Match	Vert	-0.06	0.08	0.17	0.32
	Long	-0.07	0.08	0.13	0.29
	Lat	-0.06	0.09	0.11	0.3

Results: 11 patients. Post-treatment kV clip match: Population mean error (cm); -0.06, -0.07, -0.06 (vert, long, lat). Population systematic error (cm); 0.08, 0.08, 0.09 (vert,

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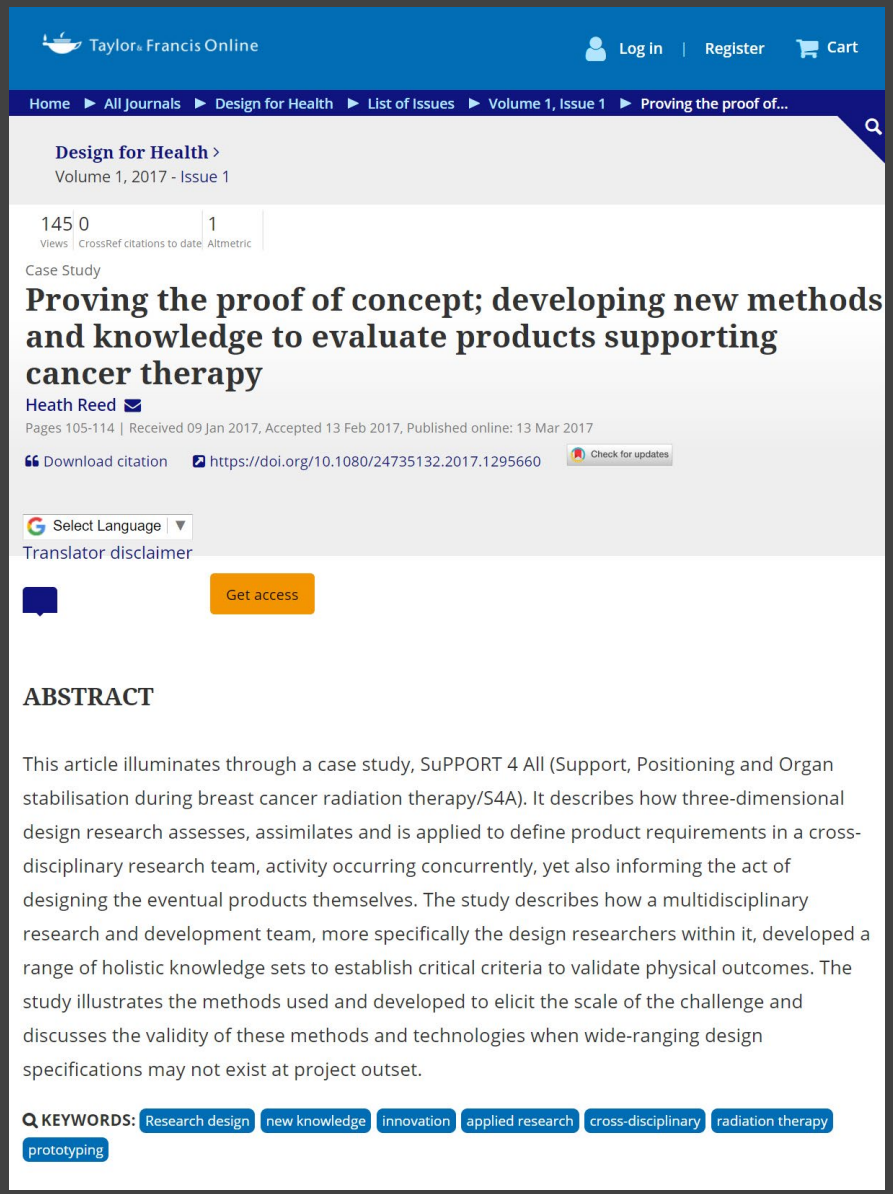

Design for Health ›
Volume 1, 2017 - Issue 1

Case Study

Proving the proof of concept; developing new methods and knowledge to evaluate products supporting cancer therapy

Heath Reed

Pages 105-114 | Received 09 Jan 2017, Accepted 13 Feb 2017, Published online: 13 Mar 2017

ABSTRACT

This article illuminates through a case study, SuPPORT 4 All (Support, Positioning and Organ stabilisation during breast cancer radiation therapy/S4A). It describes how three-dimensional design research assesses, assimilates and is applied to define product requirements in a cross-disciplinary research team, activity occurring concurrently, yet also informing the act of designing the eventual products themselves. The study describes how a multidisciplinary research and development team, more specifically the design researchers within it, developed a range of holistic knowledge sets to establish critical criteria to validate physical outcomes. The study illustrates the methods used and developed to elicit the scale of the challenge and discusses the validity of these methods and technologies when wide-ranging design specifications may not exist at project outset.

KEYWORDS: Research design | new knowledge | innovation | applied research | cross-disciplinary | radiation therapy | prototyping

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SUPPORT4ALL - New to me, new to world; different contexts of new knowledge creation associated with design research and the development of new mass customizable devices for the treatment of cancer

Reed, H.[1]
Stanton, A.[1]

[1] Sheffield Hallam University, UK
heath.reed@dfgroup.co.uk; a.stanton@shu.ac.uk

Abstract

As design practitioners working across a wide range of health related research and new product development areas we regularly need to learn the 'business' (language, culture and methods) of other disciplines. In health these can range from the specialist therapeutic strategies associated with a particular branch of oncology, to a specific service delivery aspect of a respiratory disorder, for example. In many ways, it can be said therefore that the development of new knowledge in these types of project happens in two distinct contexts. Firstly, in order for individual creative practitioners to 'invent' and subsequently design new solutions they must first build understandings of the disciplinary and subject specific challenges (and often use creative strategies to do that). In that first context, the individuals are acquiring 'new knowledge'; knowledge that may already exist in the world, but is new to the individual designer. This process is essential to both problem frame and problem solve. Design practitioners can then apply further creative strategies to manifest potential solutions to identified challenges, armed with that new knowledge. Secondly, arising from that first new knowledge context, (and usually following some refinement of potential solutions) ideas, devices or services can be tested to generate new knowledge in a second context, i.e. new knowledge in the world. Contributing to and extending the boundaries of human knowledge in significant, meaningful and original ways, is the mainstay of academia, and can be key to new product or service translation and implementation. These first and second context distinctions may at first seem obvious or even obtuse. However, in complex, technically challenging, and often highly specialised subject areas, design briefs that recognise a requirement for 'first context knowledge' can be shown to achieve much higher levels of success than those that do not. This paper reflects on one such challenging project brief, discusses what lessons have been learned and the methods used to build 'first context knowledge'. It then describes the mechanisms and practices used to generate 'second context', new to world knowledge. The research case study has led to a new design of customisable bra targeting increases in the technical accuracy of breast cancer radiotherapy delivery, and that improve the patient

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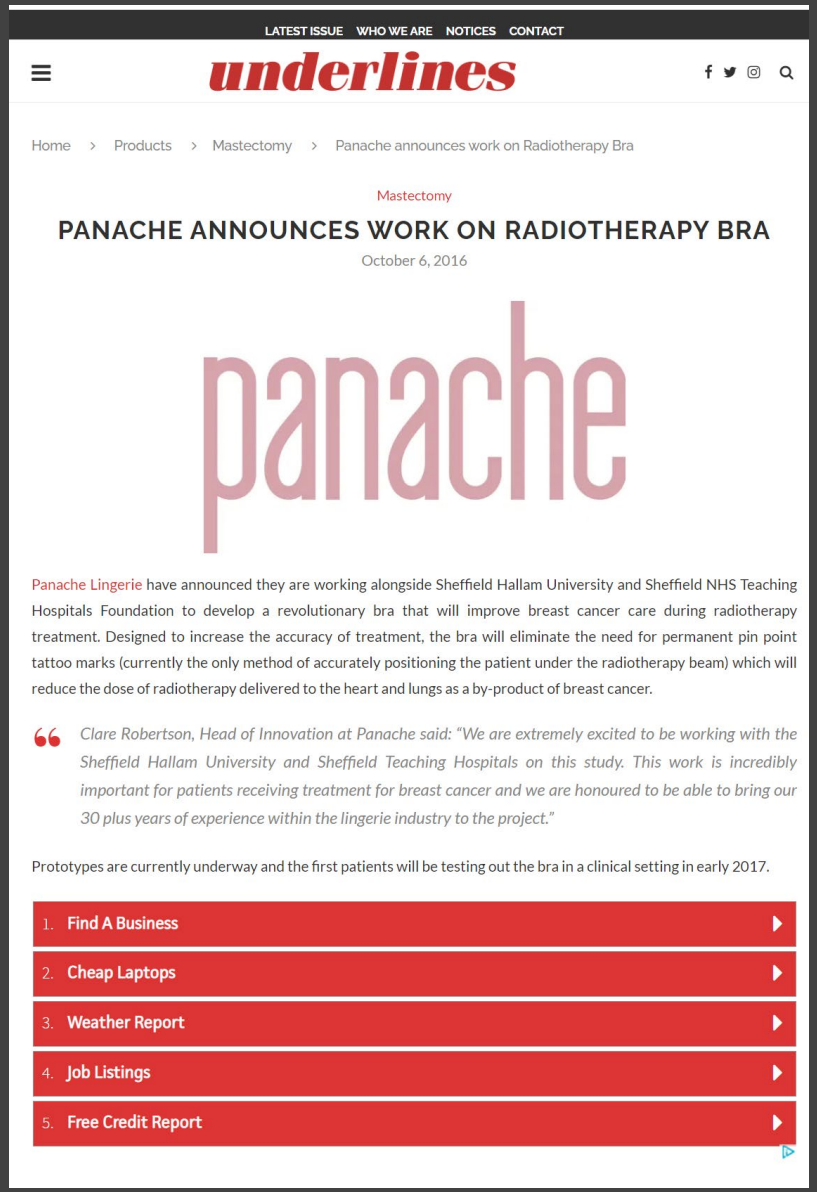

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Mastectomy

PANACHE ANNOUNCES WORK ON RADIOTHERAPY BRA

October 6, 2016

panache

Panache Lingerie have announced they are working alongside Sheffield Hallam University and Sheffield NHS Teaching Hospitals Foundation to develop a revolutionary bra that will improve breast cancer care during radiotherapy treatment. Designed to increase the accuracy of treatment, the bra will eliminate the need for permanent pin point tattoo marks (currently the only method of accurately positioning the patient under the radiotherapy beam) which will reduce the dose of radiotherapy delivered to the heart and lungs as a by-product of breast cancer.

> *Clare Robertson, Head of Innovation at Panache said: "We are extremely excited to be working with the Sheffield Hallam University and Sheffield Teaching Hospitals on this study. This work is incredibly important for patients receiving treatment for breast cancer and we are honoured to be able to bring our 30 plus years of experience within the lingerie industry to the project."*

Prototypes are currently underway and the first patients will be testing out the bra in a clinical setting in early 2017.

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Mail Online

New breast cancer bra which is worn DURING radiotherapy allows women to retain their dignity and 'improves accuracy'

- The nylon garment uses inflatable sections to gently position the breast
- Experts claim it helps to improve the accuracy of radiotherapy treatment
- If trials prove successful, they hope the bras can be bought for £50
- Bras with metal interfere with the radiation while fabric absorbs the beams
- Women are currently required to strip down to the waist for the procedure
- But this causes problems with accuracy because the breast may move

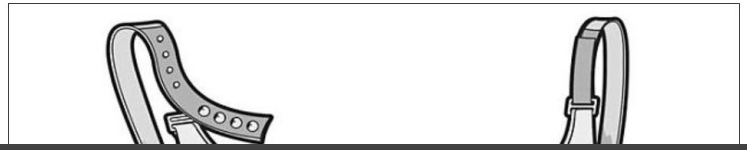
By BEN SPENCER MEDICAL CORRESPONDENT FOR THE DAILY MAIL
PUBLISHED: 12:11, 4 October 2016 | **UPDATED:** 16:50, 4 October 2016

Breast cancer patients are set to benefit for the first time from a high-tech bra which preserves their dignity during radiotherapy.

A nylon garment developed by scientists in Sheffield uses inflatable sections to gently position the affected breast - improving the accuracy of the procedure.

More than 38,000 women undergo radiotherapy for **breast cancer** in England each year, according to the Royal College of Radiologists.

The procedure, which involves repeated sessions every day for three or four weeks, currently requires women to strip down to the waist.



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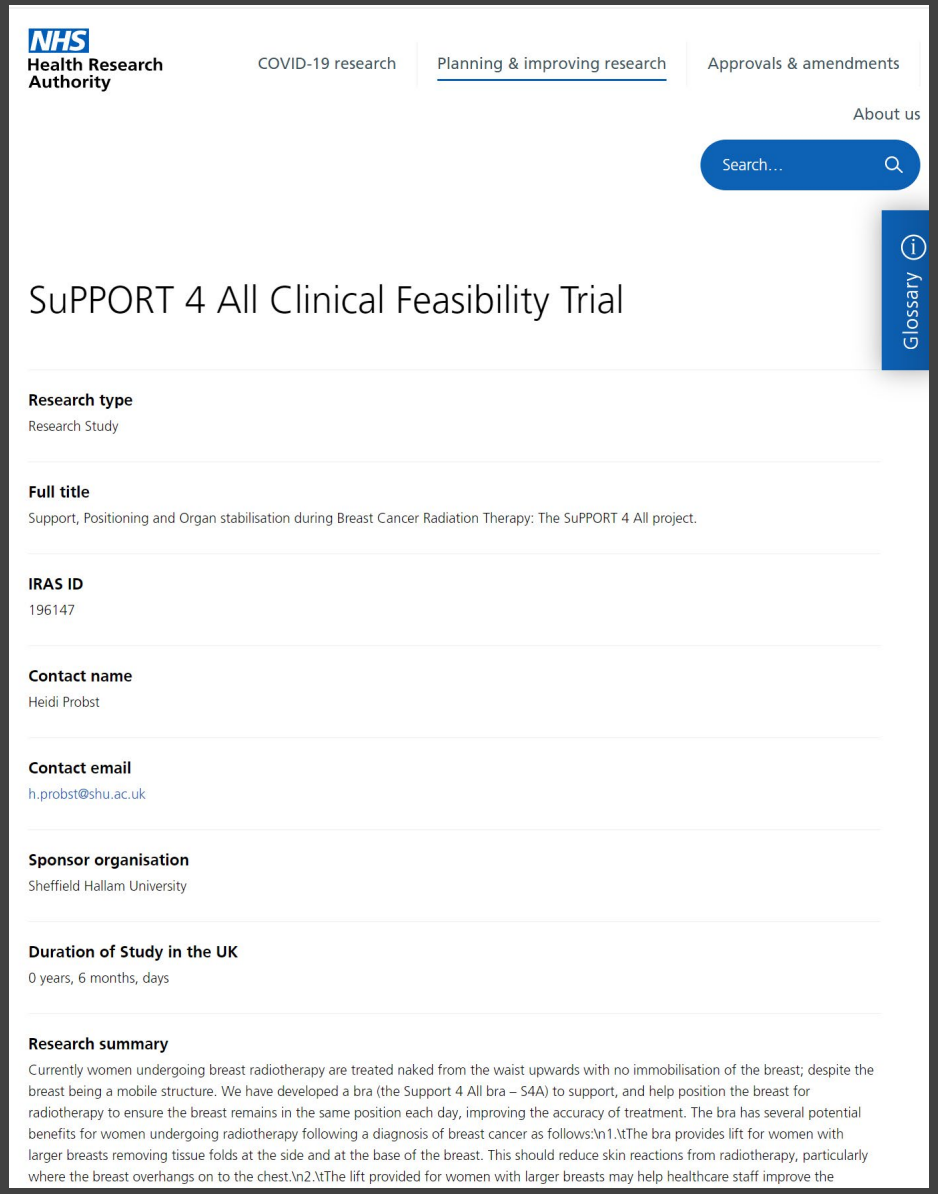

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Glossary

SuPPORT 4 All Clinical Feasibility Trial

Research type
Research Study

Full title
Support, Positioning and Organ stabilisation during Breast Cancer Radiation Therapy: The SuPPORT 4 All project.

IRAS ID
196147

Contact name
Heidi Probst

Contact email
h.probst@shu.ac.uk

Sponsor organisation
Sheffield Hallam University

Duration of Study in the UK
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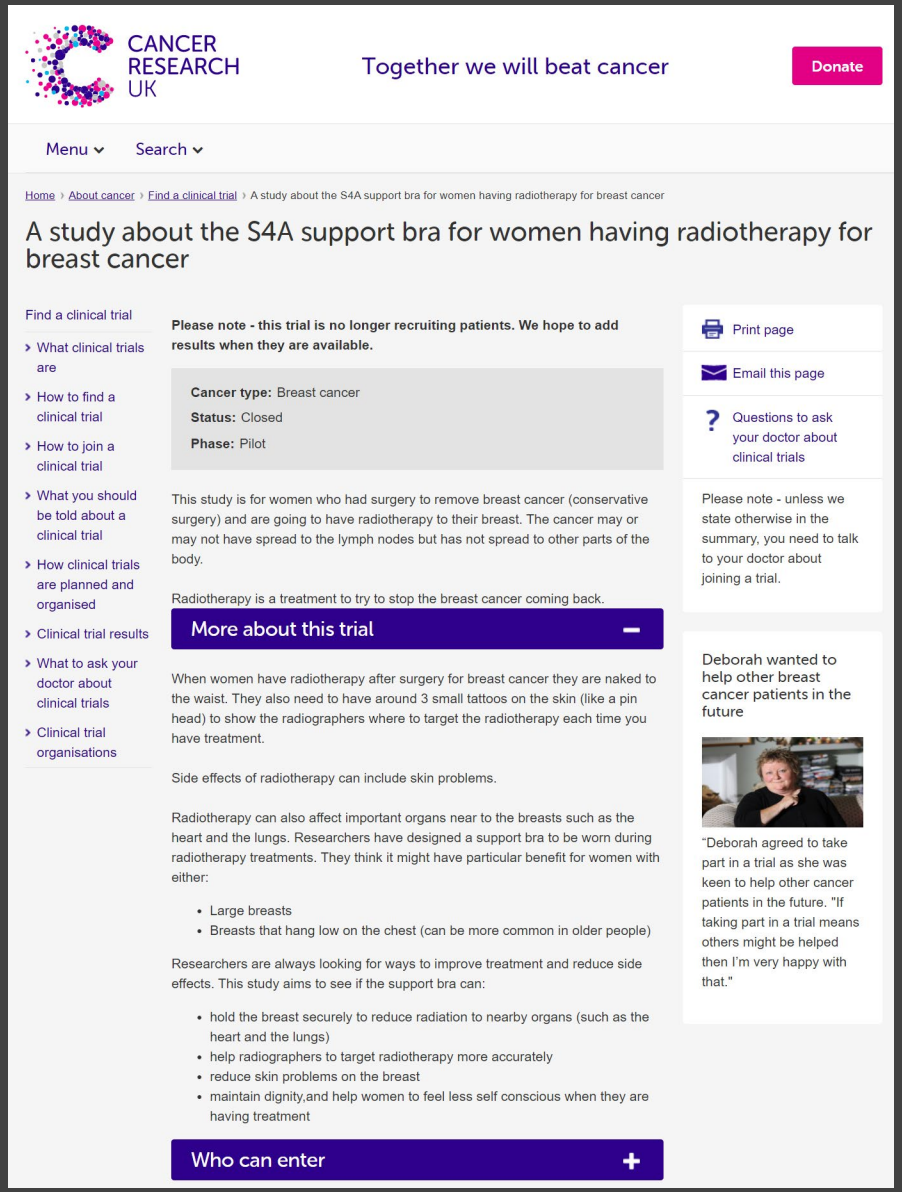

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Home › About cancer › Find a clinical trial › A study about the S4A support bra for women having radiotherapy for breast cancer

A study about the S4A support bra for women having radiotherapy for breast cancer

Find a clinical trial

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- How to find a clinical trial
- How to join a clinical trial
- What you should be told about a clinical trial
- How clinical trials are planned and organised
- Clinical trial results
- What to ask your doctor about clinical trials
- Clinical trial organisations

Please note - this trial is no longer recruiting patients. We hope to add results when they are available.

Cancer type: Breast cancer
Status: Closed
Phase: Pilot

This study is for women who had surgery to remove breast cancer (conservative surgery) and are going to have radiotherapy to their breast. The cancer may or may not have spread to the lymph nodes but has not spread to other parts of the body.

Radiotherapy is a treatment to try to stop the breast cancer coming back.

More about this trial −

When women have radiotherapy after surgery for breast cancer they are naked to the waist. They also need to have around 3 small tattoos on the skin (like a pin head) to show the radiographers where to target the radiotherapy each time you have treatment.

Side effects of radiotherapy can include skin problems.

Radiotherapy can also affect important organs near to the breasts such as the heart and the lungs. Researchers have designed a support bra to be worn during radiotherapy treatments. They think it might have particular benefit for women with either:

- Large breasts
- Breasts that hang low on the chest (can be more common in older people)

Researchers are always looking for ways to improve treatment and reduce side effects. This study aims to see if the support bra can:

- hold the breast securely to reduce radiation to nearby organs (such as the heart and the lungs)
- help radiographers to target radiotherapy more accurately
- reduce skin problems on the breast
- maintain dignity,and help women to feel less self conscious when they are having treatment

Who can enter +

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Questions to ask your doctor about clinical trials

Please note - unless we state otherwise in the summary, you need to talk to your doctor about joining a trial.

Deborah wanted to help other breast cancer patients in the future

"Deborah agreed to take part in a trial as she was keen to help other cancer patients in the future. "If taking part in a trial means others might be helped then I'm very happy with that."

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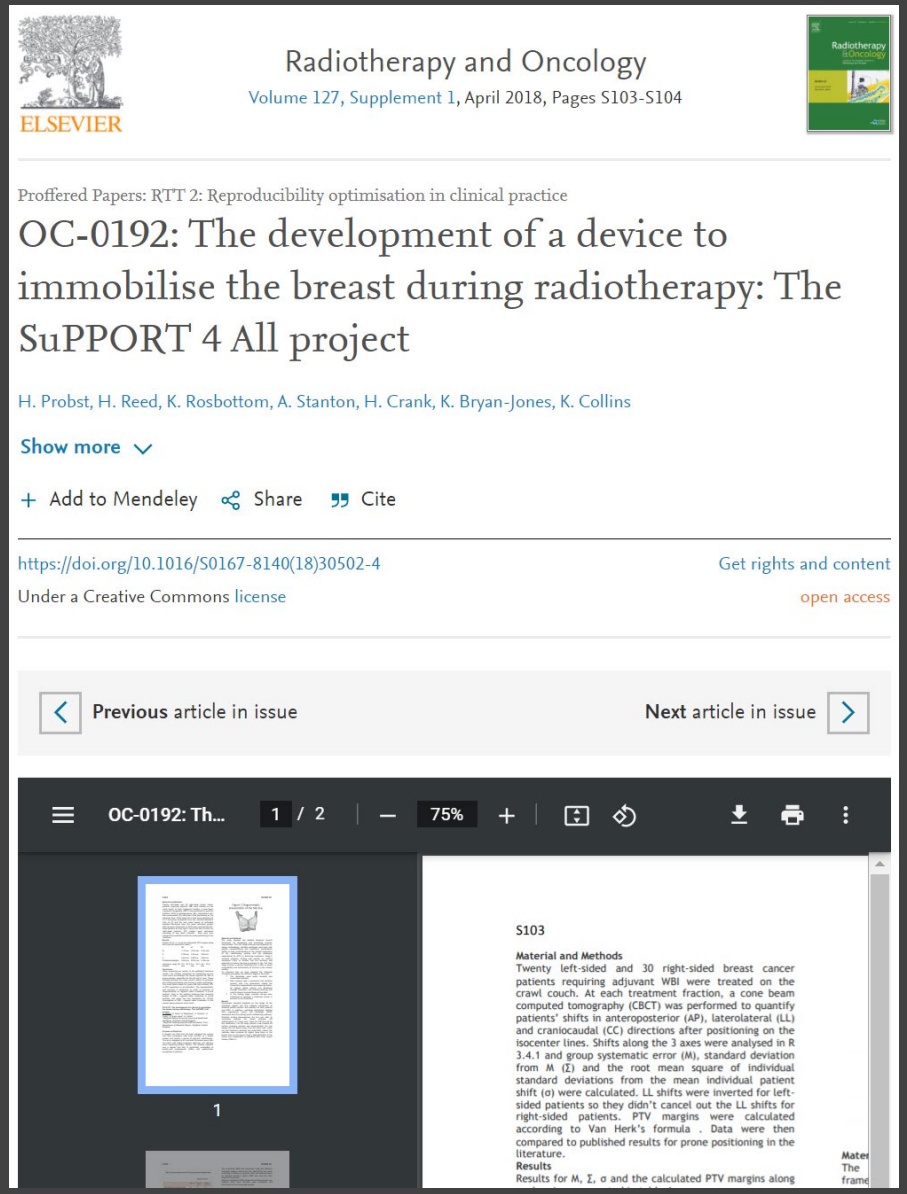

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Radiotherapy and Oncology

Volume 127, Supplement 1, April 2018, Pages S103-S104

Proffered Papers: RTT 2: Reproducibility optimisation in clinical practice

OC-0192: The development of a device to immobilise the breast during radiotherapy: The SuPPORT 4 All project

H. Probst, H. Reed, K. Rosbottom, A. Stanton, H. Crank, K. Bryan-Jones, K. Collins

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https://doi.org/10.1016/S0167-8140(18)30502-4

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OC-0192: Th... 1 / 2 75%

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S103

Material and Methods

Twenty left-sided and 30 right-sided breast cancer patients requiring adjuvant WBI were treated on the crawl couch. At each treatment fraction, a cone beam computed tomography (CBCT) was performed to quantify patients' shifts in anteroposterior (AP), laterolateral (LL) and craniocaudal (CC) directions after positioning on the isocenter lines. Shifts along the 3 axes were analysed in R 3.4.1 and group systematic error (M), standard deviation from M (Σ) and the root mean square of individual standard deviations from the mean individual patient shift (σ) were calculated. LL shifts were inverted for left-sided patients so they didn't cancel out the LL shifts for right-sided patients. PTV margins were calculated according to Van Herk's formula . Data were then compared to published results for prone positioning in the literature.

Results

Results for M, Σ, σ and the calculated PTV margins along

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Radiography (Lond). 2020 Oct 6;S1078-8174(20)30198-X. doi: 10.1016/j.radi.2020.09.011. Online ahead of print.

The patient experience of radiotherapy for breast cancer: A qualitative investigation as part of the SuPPORT 4 All study

H Probst [1], K Rosbottom [2], H Crank [2], A Stanton [2], H Reed [2]

Affiliations + expand

PMID: 33036914 DOI: 10.1016/j.radi.2020.09.011

Abstract

Introduction: Breast cancer is a global health problem with 2.09 million cases of breast cancer diagnosed worldwide in 2018. With an increase in breast cancer survival attention has now focussed on the impact treatment side effects can have on the quality of life for women during survivorship. The aim of the SuPPORT 4 All project is to develop a support bra for use during radiotherapy, that can reduce normal tissue toxicity (for women with larger breasts) and provide accuracy, dignity and modesty for all women. The first stage of the project involved a co-design process to understand the current patient experience where no support bra or modesty device is used.

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Conclusions: A number of areas were identified that had negative effects on overall patient experience.

Implications for practice: Practitioners should consider patient dignity when configuring services to support patient needs regarding undressing, outside or inside the linear accelerator room. Additionally, practitioners should have an understanding of the impact permanent tattoos may have

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