Improving comfort for cancer patients receiving radiotherapy

A thesis submitted in partial fulfilment of the requirements of the University of the West of England, Bristol for the degree of Doctor of Philosophy

Simon D. Goldsworthy

College of Health, Science and Society, University of the West of England, Bristol

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Abstract

Radiotherapy involves ionising radiation targeted at malignant tissue, benign conditions, or tumour beds over a course of 3 to 35 days; it is an effective treatment for cancer resulting in 40% of patients being cured. Patients are positioned to restrict motion and therapeutic radiographers aim to replicate this position during treatment ensuring reproducibility, accuracy and minimising the acute and long-term side effects of radiotherapy treatment. Positioning and immobilisation for radiotherapy can be uncomfortable for patients, especially with extended treatment times, and may be a crucial factor influencing accurate positioning. There was a need to develop comfort interventions to ensure that cancer patients can comply with potentially lifesaving radiotherapy.

The PhD programme started with a systematic literature review (SLR) which identified comfort interventions which may be suitable for radiotherapy. The SLR identified some clinically significant candidate comfort intervention categories in healthcare that may be adapted to improve patient comfort during radiotherapy. Many comfort interventions were also statistically significant with large effect sizes worthy of further investigation.

The experience of patient comfort is relatively unexplored in radiotherapy being limited to a few studies. Therefore, the next study was conducted to explore the phenomenon of comfort from the perspective of patients and therapeutic radiographers. Interviews with 25 patients' and 25 therapeutic radiographers explored patient comfort during radiotherapy and how it could be best managed, analysed using thematic analysis. Through thematic analysis, four shared comfort experience themes and three common comfort solution themes were identified.

The comfort categories of the SLR and the comfort solutions arising from interviews were synthesised to form a draft comfort intervention component list. Finally, an online nominal group technique consensus study with seven patients and three therapeutic radiographers prioritised comfort intervention components and discussed feasibility in radiotherapy. Overall, eleven comfort intervention components were recommended. Directed content analysis of narratives justified the practical rationale for the intervention recommendation. The next step (beyond the PhD) will be to develop the comfort intervention package and investigate effectiveness in radiotherapy.

Copyright statement

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Dedication

This thesis is dedicated to my parents for their endless love, support, and encouragement and to my wife Winifred.

In loving memory of my dear Mum, Margaret Goldsworthy, who passed away during the final write up phase. Her love strengthened me through the high and low times, and even when end-of-life, her stoic words of support strengthened me to succeed. Her tireless attention to me 'nerding out' when I felt like I had made a breakthrough with the thesis methods was unconditional. Mum, you would have loved to live this moment but your spirit lives with me forever in God's Kingdom.

Give him eternal rest, O Lord, and let eternal light shine upon him. Rest in peace.

Dad (David Goldsworthy), I thank you for the love and support you have given me to reach for the stars and chase my dreams. Life lessons of 'you can do it' and to always consider others even when our chips are down have been invaluable to me.

To my wife Dr Winifred Uche Goldsworthy, I am blessed to have your love, support, and encouragement to complete the PhD. You give me so much strength.

I am eternally grateful to you all.

"A little hope, some hard work, and new shoots of knowledge may grow from precarious foundations" Simon Goldsworthy 2023

Acknowledgements

A doctoral thesis is often described as a solitary endeavour; however, the long list that follows proves the opposite.

First and foremost, I am deeply grateful for the continuous support, insight and patience of my supervisors, Associate Professor Mary Cramp, Professor Shea Palmer, Professor Jos Latour and Professor Helen McNair: without their constant trust and, sometimes, gentle prodding, this thesis would not have been completed to such a high standard. I must also thank Dr Rachel Harris for mentorship, her constant encouragement that the doctorate is just the beginning, and words of absolute encouragement.

Secondly, a huge amount of gratitude goes to both patients and therapeutic radiographers' who gave their time to participate in the studies, and patient researcher partners Joyce Standring and John Attree ensuring patient centricity of the research at each step. I have learnt so much from you and will always be grateful. A big thank you goes to all my colleagues in radiotherapy at Somerset NHS Foundation Trust especially Stuart McGrail who never faltered in his support and listened to many doctoral quandaries. Thank you to the NHS supporting this endeavour to improve patient outcomes, and specifically to the library service (my second home) and staff always there to retrieve an obscure paper.

I am indebted to the Society and College of Radiographers Doctoral fellowship, for their generous funding, which removed financial concerns from my decision to embark on this journey. A big thank you also goes to the Macmillan Cancer Support Fund, the Anne Colley charity, Somerset NHS Foundation Trust and the University of the West of England who kindly provided further funding during the doctoral fellowship.

Last, but not least, my family had to accept my separation from them and still gave me nothing but support, day after day, both emotionally and practically: my love and gratitude for them can hardly be expressed in words. To my wife Winifred, who I first met during the COVID-19 pandemic, you have been a never-ending source of love, encouragement, and motivation. You have been a shining light in my life especially your kind words such as 'I will paint the town red when you complete this PhD'. To my children Esmée, Tochwuku, Okechi and Sol you mean the world to me and hope this accomplishment inspires you to chase your dreams. To my brother Mark thank you for always being there to support in anyway especially with the graphic work.

"It takes an entire village to raise a PhD" Simon Goldsworthy 2023

Author's declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral supervisory team.

Work submitted for this research degree at the University of the Werst of England has not formed part of any other degree either at the University of West of England or at another establishment.

The COMFORT study in radiotherapy was financed with a Society and College of Radiographers Doctoral Fellowship, Macmillan Cancer Support, the Anne Cooley charity, Somerset NHS Foundation Trust and University of West of England.

A programme of advanced study was undertaken, which included post graduate research modules at the University of the West of England: UZVSMM-15-M: QUALITATIVE HEALTH RESEARCH; USSJLK-30-M: RESEARCH IN CONTEMPORARY CONTEXT; UZWR1P-15-M: INDEPENDENT STUDY (Developing complex interventions). Further researcher training such as short courses was undertaken at the University of the West of England, South-West NIHR and some online courses for lone working for interviews; details given in the awards and grants section.

Word count of main body of thesis: 56,291

(Maximum is 80,000 with extra 10,000 for research output)

Signed

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Date: 03/01/2025

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PhD research outputs

Awards

2021 – Radiography journal Editors' Choice Award for: Goldsworthy.S, et al: A systematic review of interventions administered to improve patient comfort, assist with completion of a clinical procedure and reduce patient distress or anxiety applicable to radiotherapy: an evaluation of effectiveness. Radiography Journal. 2020. Vol 26. Issue 4, Pp 314-324

2019 – Best Poster award (3rd place) at University of the West of England HAS Postgraduate Research Conference

Grants

2022 – Anne Colley charity	£5,000
2022 – University of the West of England secondment	£6,167
2021 – MacMillan Cancer Support	£13,500
2017 – Somerset NHS Foundation Trust	1-2 days per week
2017 – Society and College of Radiographers doctoral fellowship	£25,000
2014 – Health Education Southwest Clinical Academic Training Prog	ramme
(Pre-doctoral)	£10,000

Training undertaken during course of PhD

2020 – Principal Investigator Essentials training for new and existing PI's, National Institute of Health Research Southwest

2019 – Introduction to NVivo (practical workshop), University of the West of England, Bristol, United Kingdom (UK)

2019 – Independent study module - Reviewing approaches to develop complex interventions for patient's receiving radiotherapy (M level 15 credits)

2018 – Lone working awareness for community research such as interviews in participant homes

2017 - Perfect posters, University of the West of England, Bristol, UK

2017 - Preparing to teach, University of the West of England, Bristol, UK

2017 - Research in contemporary context module - portfolio (M level 30 credits)

2017 – Qualitative research module (M level 15 credits), University of the West of England, Bristol, UK

2016 - Emerging clinical leaders' course at the Kings Fund, London, UK

Dissemination list

Invited speaker

Goldsworthy.S. The Martine Jackson Memorial keynote Lecture. UK Imaging & Oncology conference, Liverpool, UK. June 2024

Goldsworthy.S. Doctoral lecture on 'Patient comfort during radiotherapy'. UK Imaging & Oncology conference, Liverpool, UK. June 2023

Goldsworthy.S. Comfort management in radiotherapy: what patients and therapeutic radiographers say. Society and College of Radiographers annual radiotherapy conference, Brighton, UK. January 2020

Goldsworthy.S. Overview of PhD research. Society and College of Radiographers annual radiotherapy conference, Newcastle, UK January 2018

Goldsworthy.S. Overview of PhD for funders and HEI leads, London, UK February 2018

Poster presentation

2020 – Goldsworthy.S, Palmer.S, Latour.JM, McNair.H, Cramp.M. Interventions demonstrate potential to promote patient comfort during radiotherapy. Radiotherapy and Oncology. November 2020, Supplement 1, S1023-S1024

2020 – Goldsworthy.S, Palmer.S, Latour.JM, McNair.H, Cramp.M. A review of comfort interventions to promote patient comfort during radiotherapy. Radiography Journal. January 2020. Vol 26. Supplement 1, S17

2019 – Goldsworthy.S; A review of comfort interventions to promote patient comfort during clinical procedures greater than 10 minutes; University of the West of England HAS Postgraduate Research Conference, Bristol, UK.

Oral presentation

2021 – Goldsworthy.S, Palmer.S, Latour.JM, McNair.H, Cramp.M. Future solutions to improve comfort during radiotherapy: patient & radiation therapist interviews. Radiotherapy and Oncology. August 2021, 161: S222–23

Full-text published papers

2023 – Goldsworthy.S, Palmer.S, Latour.JM, McNair.H, Cramp.M. Identifying core components of a radiotherapy comfort intervention package using nominal group technique. Radiography. August 2023, 29 (5): 926-34

2023 – Goldsworthy.S, Palmer.S, Latour.JM, McNair.H, Cramp.M. A thematic exploration of patient and radiation therapist solutions to improve comfort during radiotherapy: A qualitative study. Journal of Medical Imaging and Radiation Sciences. December 2023, 54 (4): 603-10

2023 – Goldsworthy.S, Palmer.S, Latour.JM, McNair.H, Cramp.M. Patient and therapeutic radiographer perspectives of comfort during radiotherapy. Radiography. May 2023, 29: S24-S31

2020 – Goldsworthy.S, Palmer.S, Latour.JM, McNair.H, Cramp.M. A systematic review of effectiveness of interventions applicable to radiotherapy that are administered to improve patient comfort, increase patient compliance, and reduce patient distress or anxiety. Radiography. November 2020, 26(4):314–24

Podcasts

2023 – Julka-Anderson.N and McNamara.J (2023) RadChat [Audio podcast]. This episode Naman and Jo chat with Simon Goldsworthy about his PhD looking at comfort interventions in radiotherapy at the UK Imaging & Oncology conference: https://radchat.transistor.fm/episodes/ukio-2023-conference-simon-goldsworthy-comfort-interventions-in-radiotherapy

2021 – Reeve.R. (2021). Radiography Journal [Audio podcast]. This episode Ruth chats with Simon Goldsworthy about his paper: 'A systematic review of effectiveness of interventions applicable to radiotherapy that are administered to improve patient comfort, increase patient compliance, and reduce patient distress or anxiety.' <u>https://soundcloud.com/sorcor/radiography-journal-podcast-</u>002?utm_source=clipboard&utm_medium=text&utm_campaign=social_sharing

Newsletter

2021 – Simon awarded Radiography journal 'Editor's Choice', 12th July 2021, Somerset NH FT Spotlight; <u>https://www.somersetft.nhs.uk/?news=simon-awarded-radiography-journal-editors-</u>

<u>choice#:~:text=Simon%20Goldsworthy%2C%20our%20principal%20clinical,improve%2</u> <u>0patient%20comfort%2C%20increase%20patient</u>

National guidelines

2024 – UK Health Security Agency 'Advancing Safer Radiotherapy' guidelines chapter lead for patient comfort and working group member of patient engagement.

1. Chapter one: Introduction

1.1. Overview

This thesis explores the comfort experience of patients and views of therapeutic radiographers (TRs) about comfort and develops comprehensive recommendations for a comfort intervention package for radiotherapy. This chapter starts with a description of cancer and an outline of treatment options, introducing the context of radiotherapy. This is followed by an appraisal of patient comfort, positioning and immobilisation (P&I) in radiotherapy, the current state of the art in clinical practice to improve patient comfort and the need to develop knowledge and practice in this area. The chapter provides a glimpse of the future of comfort in radiotherapy and the research aim and objectives and then concludes with an outline of patient research partner (PRP) involvement in this research and the thesis structure.

1.2. Cancer and treatment options

Cancer is a large group of diseases in which some of the body's cells grow uncontrollably; it may start in any tissue or organ in the body – brain, head and neck, chest, pelvis or limbs – at any age (World Health Organization, 2023). The human body is made up of approximately 37.2 trillion cells (Bianconi *et al.*, 2013). In the normal healthy physiological paradigm, human cells undergo regulated proliferation and mitosis to generate new cellular entities in accordance with metabolic demands. Senescent or impaired cells undergo programmed cell death, or apoptosis, and are subsequently replaced by newly generated cells. However, instances may arise wherein this homeostatic equilibrium is disrupted, leading to the anomalous proliferation of defective cells beyond the requisite physiological confines. These cells may form tumours (lumps of tissue), which can be cancerous or noncancerous (benign). Cancerous tumours spread into, or invade, nearby tissues and can travel to distant places in the body to form new tumours, a process called metastasis (Halperin, Wazer and Perez, 2019). Cancerous tumours may also be called malignant tumours. Many cancers form solid tumours, but cancers of the blood, such as leukaemia, generally do not (Halperin, Wazer and Perez, 2019).

Cancer treatment involves the use of surgery, radiotherapy, medications and other therapies to cure/shrink a cancer or stop its progression. Many cancer treatments depend on the patient's clinical presentation; they may receive one treatment or receive a combination of treatments. This is generally based on the stage and grade of the cancer and tumour node metastasis classification (Rosen and Sapra, 2023).

In general, surgery and radiotherapy are used for localised tumours, while chemotherapy, endocrine therapy, immunotherapy and targeted therapies are systemic treatments.

Chemotherapy uses cytotoxic drugs to kill rapidly dividing cells as well as some normal cells, interfering with cell division at various stages and causing apoptosis. Endocrine therapy lowers or blocks hormones in the body to slow down or stop the growth of a hormone-sensitive cancer. Immunotherapy stimulates the body's immune system to identify and attack cancer cells. Targeted therapies specifically attack molecular structures associated with cancer growth (Debela *et al.*, 2021). Radiotherapy is often delivered for local control but can also exert a systemic effect of nonirradiated cancer cells, known as the abscopal effect, when delivered concurrently with immunotherapy. This effect can provoke further immune responses when combined with immunotherapies for cancer cell death (Zhang *et al.*, 2022).

The goal of cancer therapies is to achieve a cure, allowing patients to live a normal lifespan. If a cure is impossible, radiotherapy may be used to shrink or slow tumour growth to allow the patient to live symptom free for as long as possible and minimise the impact of the cancer. The goal of a primary treatment is to completely ablate the cancer cells. Many cancer treatments can be used in this sense, but the most common primary treatment is surgery (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021; Public Health England, 2020). The goal of adjuvant therapy is to ablate any cancer cells that may remain after primary treatment to reduce the likelihood of recurrence. Common adjuvant therapies include chemotherapy, radiotherapy and hormone therapy. Neoadjuvant therapy is similar; treatments are used before the primary treatment to make it easier or more effective, such as reducing a tumour to a smaller, more surgically operable size (Halperin, Wazer and Perez, 2019). Palliative treatments may help relieve the side effects of treatment or the signs and symptoms of the cancer itself. Surgery, radiotherapy, chemotherapy and hormone therapy can all be used to relieve symptoms. This thesis is concerned with radiotherapy as one of the key treatment options for cancer.

1.3. Context of radiotherapy

Radiotherapy uses high-energy radiation for cancer treatment. Over 320,000 patients are treated each year across 62 radiotherapy centres in the UK (NHS England, 2023; Royal College of Radiologists, 2017). Radiotherapy is an effective treatment that results in 40% of patients being cured (Royal College of Radiologists *et al.*, 2008). It is usually delivered in 10 minutes over the course of 1–35 days for an optimal therapeutic dose (Halperin, Wazer and Perez, 2019). Patients receiving radiotherapy first have a planning computed tomography (CT) scan. The acquired CT scan is transferred to a treatment planning computer to define the treatment parameters, such as the target area and position of radiotherapy beams. A radiation beam is focused to target the cancer over a set number

of days for the optimal therapeutic effect, which is to destroy the cancerous tissue while avoiding collateral damage to surrounding tissues and causing toxicity.

When the cells of the body are exposed to ionising radiation, the interaction of the radiation beam and the atoms of the cells occurs first, followed by possible biological damage to cell functions (Chapman and Nahum, 2015). In situations other than radiotherapy, the aim is to prevent cellular damage, but the intention of radiotherapy is to cause cellular damage to cancer cells. Cells in the human body are either dividing or not dividing. Dividing cells undergo four cycle phases: G1, S, G2 and M. During the interphase (G1 and G2), cells grow, accruing nutrients needed for mitosis (M), and deoxyribonucleic acid (DNA) and some organelles are replicated (S). This is important because the cell phase determines radiosensitivity, with cells being most sensitive in Phases G2 to M and least sensitive in G1 and S. During the M phase, the replicated chromosomes, organelles and cytoplasm split into new daughter cells. Direct ionising radiation is absorbed in biological material, and cell damage may occur in one of two ways: direct via interactions with critical targets in the cell or indirect via other molecules and atoms, such as water-producing free radicals (Chapman and Nahum, 2015).

The biological effects of radiation result mainly from damage to the DNA, which is the most critical target within the cell. However, there are also other cell sites that, when damaged, may lead to apoptosis (via single- or double-strand breaks in the DNA helix; Vignard, Mirey and Salles, 2013). Radiotherapy does not distinguish between cancerous and normal tissues; therefore, radiotherapy is optimised to target the radiation dose to the tumour and minimise damage to normal tissues – which may lead to toxicity near to the treatment site, causing potential acute and long-term side effects. The potential side effects are based on the anatomical location, beam energy and volume, dose fractionation and dose rate. The probable radiobiological effect is calculated prior to treatment, ensuring the target cancer is effectively treated and side effects are minimised using alpha-beta survival curves (van Leeuwen et al., 2018). However, during the precise planning of radiotherapy, there is inclusion of surrounding normal tissue to be irradiated to ensure the target cancer is fully covered; this, along with patient positional errors, may cause acute and long-term treatment side effects. The potential side effects are an important and serious consideration accompanying the rationale of radiotherapy to radically cure cancer, and depending on severity, they can have a huge impact on patients' quality of life (Bolderston, 2016).

Therefore, there is a need to localise the cancerous tissue using the planning CT scan, along with histological and diagnostic imaging for greater definition. The patient's overall performance status and mobility is taken into consideration when planning P&I for treatment (Barrett *et al.*, 2009). Positioning refers to the process of placing the patient in a

specific, reproducible posture that aligns the target area (such as a tumour) with the radiation beams. Once the patient is correctly positioned, immobilisation involves using devices or techniques to maintain that position consistently throughout each treatment session. This stability is crucial to prevent any movement that could lead to radiation being delivered to unintended areas. For patients with head and neck cancer undergoing radiotherapy, supine positioning on a hard couch, mask donning and a mouth bite or tongue suppressor are methods usually employed to ensure stability and precision to avoid toxicity. Patients with breast cancer are usually positioned supine on a hard couch, with both arms abducted for stable radiotherapy treatment. Patients may also be asked to hold their breath to avoid cardiac toxicity. Patients with pelvic cancer are usually positioned supine on a hard couch with head, knee and ankle supports for stability, and various protocols are employed to manage bladder filling and rectum status to limit toxicity. Further modifications may have to be made, such as the removal of cardiac devices, modifications to limb position and, if radiotherapy cannot be delivered safely, then halting treatment delivery (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). Recent advancements include upright radiotherapy systems where a patient is sitting upright positioned and immobilised on a chair (Boisbouvier et al., 2023). Upright radiotherapy holds potential as a novel approach to improve patient comfort, organ positioning and radiation targeting. However, its implementation is currently limited by technical challenges, a lack of comprehensive clinical data and the need for specialised equipment. Further research is needed to evaluate its effectiveness and determine which patient populations would benefit the most (Boisbouvier et al., 2023).

During treatment and verification scans, patients are positioned to restrict motion and ensure that normal tissues are avoided or moved from the path of potential radiation beams, ensuring the prescribed dose targets the cancer volumes (van der Merwe *et al.*, 2017; International Atomic Energy Agency, 2016; Dobbs *et al.*, 2009; Ausili-Cèfaro and Marmiroli, 1998). It is essential that the daily treatment position replicates the patient position and tumour delineation or the tumour bed on the planning CT scan to ensure the reproducibility and accuracy of radiotherapy and minimise the acute, late and long-term side effects of treatment (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021; Bolderston, 2016; Beadle *et al.*, 2014; Dobbs *et al.*, 2009).

Daily reproducibility of treatment delivery starts with TRs using indexing points on the immobilisation device to manually position the patient for accurate radiotherapy delivery (Goldsworthy and McGrail, 2014). Indexing refers to the process of precisely aligning and positioning a patient in the treatment machine to ensure accurate delivery of radiation to the targeted area. The goal is to reproduce the same setup consistently during each

treatment session to maximise the effectiveness of the therapy and minimise the impact on surrounding healthy tissues. The indexing process involves using various techniques and tools to verify and adjust the patient's position (Barrett *et al.*, 2009). Precise patient positioning is achieved using tattoos typically placed in areas that are easily visible and reproducible, ensuring that the radiation is delivered to the targeted area with high precision. The process of tattooing is usually quick and relatively painless. It is important to note that these tattoos are specific to the radiotherapy planning and treatment process and are different from decorative tattoos (Dobbs *et al.*, 2009). Advancements in radiotherapy technology, such as surface-guided radiotherapy, reduce the reliance on tattoos, as they allow for more precise and real-time adjustments based infrared optical cameras (González-Sanchis *et al.*, 2021).

The setup procedure performed by TRs is completed daily with specific measurements to verify the patient's position prior to acquiring a position verification X-ray image or CT scan at treatment delivery (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). After aligning the patient's anatomy, a two-, three- or four-dimensional X-ray image or infrared optical surface scan is used to verify the location of the internal or external target anatomy and make further adjustments needed to ensure $\leq 3-5$ mm geometric accuracy (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021; Gaisberger et al., 2013; van Herk, 2004). The X-ray image or CT scan at treatment delivery is compared to the original planning CT scan and registered, and the difference in position (displacement) is recorded. If this measurement is within acceptable clinical limits, treatment commences. Furthermore, novel types of Xray imaging and infrared optical surface scans can be acquired intrafraction (during radiotherapy delivery), adding an extra level of accuracy to radiotherapy treatment (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). There are other measurements made prior to treatment delivery, and each one also has a clinical threshold tolerance (Kron and Ferguson, 2000). These measurements can include the distance between the patient's external contour and the radiotherapy machine, the observation of light imitating the radiation beam area on the patient's skin and the alignment of the patient to a specific position on the bed or immobilisation device (Kron and Ferguson, 2000). This whole process is known as 'patient setup'.

A challenge for TRs is that practice across different radiotherapy clinics varies, which could impact patient treatment and care. The units and methods of measurement for evaluation of patient setup vary between centres, and this can be observed in several studies in the literature (Goldsworthy and McGrail, 2014; Kron and Ferguson, 2000). The beginning of this disparity is the manufacturing of radiotherapy equipment, where a

positive axis orientated right on one machine can be a negative axis on other equipment using different software within the same clinic (van der Merwe *et al.*, 2017). This is compounded by the documented and verbal description of the orientated direction of measurement or movement by TRs. They may describe the location of the target relative to the patient or the location of the patient relative to the target when making adjustments to a patient setup position. These differences in practice may impact patient experience and supports the need for ongoing refresher training on setup techniques (Goldsworthy and McGrail, 2014).

Patient-reported outcomes are being emphasised more in the efficacy of treatment, as such are an important facet of radiotherapy. Patient-reported outcomes are recommended for monitoring a range of side effects, from radiation-induced skin reaction to gastrointestinal toxicity. The intention is to manage and ameliorate these side effects to enable patients to continue treatment (Society and College of Radiographers, 2020). Other experiences, such as comfort, should also be measured to improve P&I management during radiotherapy and ensure treatment completion (Goldsworthy, Tuke and Latour, 2016). Presently, TRs assess comfort on an ad hoc basis by asking the patient if they are comfortable without any fixed guidance (Arino *et al.*, 2014). It can be suggested that comfort has been overlooked in the face of technological advancement. Patient comfort has been noted as important for treatment success, especially for P&I (Arino *et al.*, 2014; Schnur *et al.*, 2009). Fundamentally, a comfortable position may lead to greater reproducibility and, therefore, accuracy of radiotherapy treatment. However, there is limited evidence utilising patient comfort in positioning and minimising motion during radiotherapy treatment.

1.4. P&I in radiotherapy

Patient P&I in radiotherapy is crucial to the accurate delivery of radiotherapy, ensuring the cancer is targeted and collateral damage averted. The absence of carefully considered P&I would risk missing the cancer target while leading to unwanted toxicities for the patient. The primary objective of P&I is to limit motion and reduce positional errors. Presently, there are several patient positions and methods of immobilisation that may be used in radiotherapy to limit geometric errors, depending on the treatment site. For example, positioning may include whether a patient is supine, prone, lateral decubitus, or upright undertaking a breath hold or is using a rectal obturator (stabilising the prostate bed). Immobilisation may include a thermoplastic mould for head and neck fixation, breast and thoracic boards (stabilising the thorax and displacing bilateral arms from unwanted irradiation) and pelvic boards, including knee rest and foot stocks (ensuring pelvic stability and limiting pitch, roll and yaw; Boisbouvier *et al.*, 2023; Royal College of Radiologists,

Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021).

There are many geometric (spatial) uncertainties in radiotherapy; this may include the radiotherapy machinery (such as a linear accelerator), the patient's position or internal physiology, which have to be accounted for in the radiotherapy plan (van der Merwe et al., 2017). Although further research is required to enhance P&I, van der Merwe et al. (2017) reported the spatial uncertainty of patient repositioning ranged from 1-2 mm for intracranial radiotherapy, 3–15 mm for prostate radiotherapy and 2.5 mm for lung stereotactic ablative body radiotherapy (SABR). Their report outlined thresholds to which P&I can be evaluated and possibly improved towards, the lowest threshold being 1 mm for intracranial radiotherapy. These uncertainties can be evaluated to assess P&I or new setup techniques. There is a common formula used to evaluate uncertainty of P&I reproducibility. Systematic and random errors are analysed with respect to the average geometric displacement, with a standard deviation (SD) calculated per patient, between the planning CT scan and the CT scan on radiotherapy treatment. The individual patient error (Σ_{ind}) or mean (M) displacement is the mean average of each patient's geometric displacements; and the random error (σ_{ind}) is the SD of each patient's geometric displacements. Population systematic error (Σ_{pop}) is the SD of the patient group's systematic errors, and the population random error (σ_{pop}) is the root mean square of the group's random error (van Herk, 2004).

Spatial uncertainties or evaluation of the reproducibility of P&I has been undertaken in many studies seeking to improve radiotherapy treatment accuracy. For patients with head and neck cancers, it is common to use a thermoplastic mask. Mangesius et al. (2019) investigated intrafraction motion, finding notable random errors in six degrees of freedom. Most notably, they found that mean three-dimensional or vector deviation increased from 0.21 mm (SD = 0.26 mm) in the first two minutes to a maximum of 0.53 mm (SD = 0.31mm) 10 minutes after treatment commenced. The authors concluded that reducing treatment times below six minutes may improve treatment accuracy. Mangesius et al. (2019) did not have a powered sample size with a limited number of participants, meaning that it is difficult to make inferences about increased time raising positional deviation. A study of patients with breast cancer immobilised on a breast board found that abducting bilateral arms during radiotherapy reduced systematic and random errors in the superiorinferior direction (from $\Sigma_{pop} = 3.6 \text{ mm}/\sigma_{pop} = 2.4 \text{ mm}$ to $\Sigma_{pop} = 2.2 \text{ mm}/\sigma_{pop} = 2.6 \text{ mm}$; Goldsworthy et al., 2011). Goldsworthy et al. (2011) presented findings demonstrating a modest improvement in immobilisation with bilateral arms abducted, which may not be clinically significant. Pang et al. (2017) investigated the Clarity[™] immobilisation system (Elekta, Stockholm, AB, Sweden) in patients with prostate cancer – finding statistically significant differences in the superior-inferior direction, with a mean displacement of 0 mm

using the system compared to standard practice with a mean displacement of 1.1 mm (p = 0.003). They found no statistically significant difference in comfort between the two groups. A further study investigated a lower limb device – finding reduced setup errors that were statistically significant (p = 0.002), although setup error data were not reported (Lu *et al.*, 2018). These four studies indicate that improvements can be made to enhance accuracy, although improving comfort was not their main objective.

Patient comfort in radiotherapy has been explored only in a small number of studies. These studies have explored the potential link between comfort and accuracy in radiotherapy that supports further consideration. When a customised immobilisation device was compared to standard immobilisation in prostate cancer treatment, no difference in treatment accuracy was found along the translational axis (customised immobilisation device and standard immobilisation mean displacements reported in three degrees of freedom were not statistically significant). However, they found statistically significant reductions in craniocaudal (yaw) and anteroposterior (pitch) rotational (rot) errors using the customised immobilisation device (mean displacement craniocaudal rot = -0.1° , p = 0.03; anteroposterior rot = -0.4° , p = 0.04). Radiographers reported that patients found the customised immobilisation device more comfortable than the standard immobilisation (p < 0.001; Nutting *et al.*, 2000). Moreover, Cox and Davison (2005) proposed comfort may be determined by treatment position (prone or supine) in patients receiving treatment for prostate cancer. However, they found that patients treated prone or supine reported similar levels of comfort using a visual analogue scale (VAS) of comfortable to uncomfortable (p = 0.96); the authors did not evaluate positional stability and accuracy of radiotherapy. Bartlett et al. (2013) investigated a cardiac-sparing technique in patients undergoing radiotherapy for breast cancer in a series of studies. Notably, they compared a supine breath-holding technique to a prone technique where the ipsilateral breast hung below the patient (Bartlett et al., 2015). The principal intention of this study was to investigate heart-sparing radiotherapy techniques reducing the risk of cardiac damage. Coincidently, patients found the supine breath-holding technique more comfortable (p = 0.013), when reported using a 4-item Likert scale Radiotherapy Comfort Questionnaire validated by Nutting et al. (2000). Improved patient comfort incidentally coincided with a statistically significant (mean = 0, Σ = 1.8mm, σ = 3.5mm, p = 0.04) improvement in accuracy in the ventro-dorsal direction (Bartlett et al., 2015).

Both national and international radiotherapy guidance are gradually elucidating best practice according to emerging evidence. However, most guidelines fall short by lightly advising that healthcare professionals make sure patients are comfortable without providing any details or evidence of how (Mast *et al.*, 2023; Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021; Leech *et al.*, 2017).

1.5. Conceptualising patient comfort

Comfort is an elementary human need. However, Pineau (1982) suggested that in a modern society where the physiological needs of food, water and shelter have been met, the context of comfort is more complex and concerns the style of the environment to which a person must adapt. Pineau (1982) conducted a psychological study on the meaning of comfort which yielded four main themes: personalisation, freedom of choice, space and warmth. Personalisation was about customising the lived environment. Freedom of choice was the ability to choose a calming and silent environment. Space was about having adequate room, and warmth represented well-being. Furthermore, Pineau (1982) suggests that comfort is about the lived experience of the person, and his work provided the foundations of the holistic conceptualisation of comfort.

Professor Catherine Kolcaba (1994) developed a middle-range theory of comfort for nursing practice. A middle-range theory is a term initially described by the sociologist Robert K. Merton in the 1940s to adjoin high-level social theories to empirically observable practice (Merton, 1968). Through the 1990s, Kolcaba developed the concept, construct and taxonomic structure of patient comfort; this led to a conceptual framework of comfort in nursing care – the theory of comfort (Kolcaba, 1994, 1992, 1991; Kolcaba and Kolcaba, 1991). While the conceptual framework was developed with a focus on nursing care and practice, the emphasis is specific to the experience of patient comfort. Therefore, it was appropriate to consider the conceptual framework of comfort in nursing care for application in all health setting procedures, such as radiotherapy.

Kolcaba and Kolcaba (1991) suggested that the word 'comfort' has been phrased as a desirable outcome since the time of Florence Nightingale, but while its use is widespread, the meaning is unclear. Many nursing guidelines stipulate that nurses should provide comfort without any details of the construct or evaluators to determine if this standard is met. Comfort in ordinary language can be used to describe or indicate the relief of discomfort, ease or contentment or describe something that makes life easy and pleasurable. For example, when a patient takes medicine for a headache and the symptom eases, the person feels relief, which is a form of comfort. Comfort could also be a soft, warm blanket on a cold day, a good meal or even just having enough money. Comfort is also understood as a sense of being at peace or feeling at ease. It is that calm, relaxed feeling that is felt when a person is not worried, anxious or in pain. Finally, the etymological origins of the word include strengthening, encouraging, inciting, aiding, support, physical refreshment, and invigorating influence (Kolcaba and Kolcaba, 1991). The word 'comfort' comes from the Latin word *confortare*, which means to strengthen or console. It is made up of two parts: 'con' is a prefix meaning together or with, and 'fortis' means strong. In old French, the word 'comforter' meant to comfort, console or

strengthen. Then in Old and Middle English, the word 'comforten' retained the meaning to console and strengthen and later meant relief or ease (Bułat Silva, 2020). Comfort is an antonym of discomfort and a noun which describes the concept of a desirable outcome for nursing care. It has evolved to encompass physical and emotional relief, the state of ease, contentment and pleasure (Kolcaba and Kolcaba, 1991).

Kolcaba and Kolcaba (1991) conceptualised comfort and described three classes of comfort needs and three technical senses of comfort. The first need is to be in a comfortable state, the second is the relief from discomfort and the third is for education, motivation and inspiration. The three technical senses were developed from the meanings of comfort: the first is the state sense of comfort, which may be described as a person's baseline level of comfort. This is suggested to be a passive state in which comfort or discomfort may be experienced. The second is the relief sense in which a person is able to experience relief from discomfort. The third is the renewal sense, where the state level of comfort can be modified through a programme, such as physical therapy or other interventions. The first comfort need may be aligned to an enduring sense of ease and peaceful contentment. The second comfort need is relief from conditions that interfere with comfort and may be aligned to the relief from the sense of discomfort. The third comfort need is personal growth that may be aligned to the sense of renewal, being strengthened and invigorated. Kolcaba defined comfort as the state when a patient is relieved, eased or transcends the discomfort (Kolcaba and Kolcaba, 1991). However, as postulated by many, comfort is complex and therefore requires a rich explanation to contextualise in healthcare, especially in radiotherapy.

Further to their conceptualisation, Kolcaba and Kolcaba (1991) developed instruments to measure the three senses, organised into three technical subscales. Kolcaba (1991) addressed this ambition by developing a taxonomic structure for comfort, which would support its assessment. Kolcaba (1991) proposed contexts in which comfort may exist, including physical, sociocultural, psychospiritual and environmental. The physical pertains to bodily sensations, including physiology. Psychospiritual is about the self, identity, esteem, sexuality and relationship with a higher order or being (such as faith). Sociocultural is about one's personal life, societal relationships and family and cultural family traditions, religious practices and rituals. Finally, environmental comfort is the peripheral human experience, including aesthetics such as the furniture, odour, colour, temperature light and sound. The concepts and taxonomic structure of patient comfort led to Kolcaba (1992) theorising an operational construct of holistic comfort. Kolcaba (1992) asserted that comfort is a higher-order construct that is challenging to operationalise compared to lower-order constructs such as hope, certainty, function and contentment (Credé and Harms, 2015). She operationalised this construct by developing a taxonomic structure that organised patient needs, nursing interventions and measurable outcomes,

making comfort a holistic and central focus of nursing care (Kolcaba, 1992). Kolcaba's (1994) conceptual framework of patient comfort in nursing care was developed systematically from the concept of comfort (relief, ease and transcendence; Kolcaba and Kolcaba, 1991), which was further expanded into a construct with measurable attributes across four domains (physical, psychospiritual, environmental and sociocultural; Kolcaba, 1991).

Based on Murray's theory of human press developed in the 1930s, Kolcaba's (1994) conceptual framework of patient comfort in nursing care (Figure 1.1) is based on the needs of the environment, the whole person, their environment, effectiveness, and perceived subsequent outcomes. Murray's theory emphasises the interaction between an individual's internal needs and the external environment (human press) in shaping behaviour. This interactionist approach suggests that behaviour cannot be fully understood without considering both the person and the environment in which they operate. Murray's theory focuses on understanding human personality through the dynamic interplay of needs (internal factors/behaviours) and press (external factors/behaviours; Randheer, Almotairi and Naeem, 2014). Kolcaba (1994) used Murray's theory, which states that a part of a person cannot be dissected physically from another so they must be considered concurrently. A stimulus situation, as defined by the human press, lies within the total environment to which a person attends and reacts during a life event. Positive or negative human development evolves from ongoing impressions of the individual's success or failure within a given stimulus situation, such as a healthcare setting. Stimulus situations consist of alpha press and beta press. The alpha press is the negative force that may obstruct positive forces that facilitate interactional forces. Beta press is the total effect of forces within the alpha press.

In nursing or radiotherapy practice, the obstructing forces are the side effects, anxiety and the threatening or stressful environment. The facilitating forces are the interventions used to support or meet a persons' needs after their reserves have been depleted by obstructing forces. Events are understood as interacting forces that influence the outcomes of all of a person's experiences. These include past experiences, age, emotional state, attitude, familial support systems and their present experiences. A unitary trend is explained as coordinated behaviour towards an activity to achieve the desired effect. For example, a nurse promotes health through health-seeking behaviours. Internal behaviours are how someone may cope and accept discomfort, while external behaviour concerns seeking support or distraction from discomfort. The relation between the human press and nursing concepts can be observed in Figure 1.1. This implies that comfort can be the summation of entities in this model that contribute to comfort experienced in the three states (ease, relief and transcendence) and in the four domains (physical, psychospiritual, environmental and sociocultural). A comfort intervention may therefore be

developed based on patient needs to ease, relieve or transcend the patient in one or more of the domains, and this can be via an internal or external behaviour.



Figure 1.1. The conceptual framework for a theory of comfort (Kolcaba, 1994) (Agreement to reuse between Simon Goldsworthy and John Wiley and Sons:

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Kolcaba's (1994) conceptual framework of patient comfort in nursing care seeks to cover the complexity of the conceptualisation, together with constructs, of patient comfort. According to Lindqvist, Sendén and Renström (2021), the main consideration with this framework is that it focuses on the contexts of comfort during clinical procedures prior to developing interventions. The concept of comfort can be considered complex, as defined by Kolcaba (1994), so the paradoxical position is to suggest that individual patients may simply express themselves as feeling comfortable or uncomfortable without acknowledging these complexities. Indeed, when a person says they are comfortable or uncomfortable, they are verbalising the sum of all their experiences and interactional forces described in Kolcaba's conceptual framework. Therefore, caution should be addressed to the real-world meaning, ensuring reason and commonsense. A counterargument to this is that Kolcaba's conceptual framework is a middle-range theory that attempts to adjoin a high-level social theory to empirically observable practice, which could be suggested to be just commonsense (Merton, 1968). Nilsen (2015) viewed this pragmatically, stating that while theory cannot replace commonsense in the implementation of theory, developing theory enables the scrutiny of commonsense. Nilsen (2015) concluded that theory is open to examination, whereas commonsense is based on assumption, a way of thinking and beliefs that are difficult to challenge.

Another comfort theory was developed more recently to address the challenges of defining comfort and the lack of theory of comfort related to patients' perspectives (Wensley *et al.*, 2017). Wensley *et al.* (2017) developed the comfort always matters (CALM) framework as a more practice-based, less abstract construction. CALM was developed from the synthesis of 14 theoretical and 48 qualitative papers undertaken by a team of four researchers. This culminated in a framework consisting of 10 areas of influence within four interconnected levels including: patient self-comforting strategies, family presence, staff actions, behaviours and environmental factors (see Figure 1.2; Wensley *et al.*, 2017). The CALM framework has real-world applicability through describing the 10 areas of influence in clinical terms in an easy-to-digest visual format. Wensley *et al.* (2017) suggested that the simplicity and applicability is because the CALM framework was built on patients' perspectives; in contrast, Kolcaba's conceptual framework of patient comfort in nursing care was developed from theoretical perspectives.

However, comfort is a complex phenomenon; therefore, the concept, construct and framework are complex as well. It is unclear whether the CALM framework was influenced by Kolcaba's (1994) conceptual framework of patient comfort in nursing care. Kolcaba's conceptual framework delves deeper into the influences of patients' internal (a person's traits, abilities and physical characteristics) and external behaviours (environmental and social influences), which may include the environment and health professional interactions. CALM differs in delivering less detail of theory but an overarching clinical view. By providing that overarching view, the CALM framework could be used to situate a comfort intervention, but Kolcaba's conceptual framework may be considered more advanced, enabling a comprehensive development of interventions.

		STAFF		
		FAMILY		
		PATIENT		
	Self- comforting strategies	Culturally connected	Spiritually connected	
	Unio	que ability to	comfort	
Symptom Management	Holistic Care and Assistance	Engagement and Commitment	and	Perceived and Actual Competence

Figure 1.2. Comfort always matters framework (Wensley *et al.*, 2017) (Agreement to reuse between Simon Goldsworthy and Oxford University Press: terms and conditions provided by Oxford University Press and Copyright Clearance Center. License number 5972940582414).

Wensley *et al.* (2020) published a later study exploring the CALM framework and defined three further concepts that affect comfort, including influences, attributes and consequences. These new concepts relate further to the stimulus situation of Kolcaba's (1994) conceptual framework of patient comfort in nursing care. The CALM framework, although simpler, does not appear to improve upon the theory from Kolcaba's conceptual framework. Lin, Zhou and Chen (2023) stated that Kolcaba's conceptual framework still holds currency and is the most widely developed, used and advanced theory better suited to informing intervention development.

Furthermore, to make sense of how comfort interventions can be developed Wilson and Kolcaba (2004) proposed three intervention categories based on Kolcaba's (1994) conceptual framework of patient comfort in nursing care. The first category is standard comfort interventions delivered to maintain homeostasis. This has also been referred to as technical comfort intervention category (Wilson and Kolcaba (2004). These interventions concern easing pain, hypothermia, medications and repositioning (in radiotherapy) to

improve comfort. The second category is coaching, which can be delivered to ease anxiety and stress at a time that is appropriate for the patient if they choose. It involves listening and is culturally sensitive to the patient's needs, providing an optimistic plan when ready to receive new or positive thoughts. The third category is comfort food for the soul, which is about massage, music, warmth and empathetic touch. These comfort foods feed the soul and strengthen patients to transcend to more memorable connections with health professionals (Wilson and Kolcaba, 2004). These interventions may fortify patients to continue to get through treatments such as radiotherapy.

A further consideration outlined by Kolcaba in her conceptual framework of patient comfort in nursing care is health-seeking behaviours. Internal health-seeking behaviours refer to a person's thoughts, emotions and attitudes, and can significantly influence their sense of comfort or discomfort. Internal behaviours play a crucial role in how patients undergoing radiotherapy experience comfort. Radiotherapy can be physically taxing and emotionally challenging. Internal health-seeking behaviours, such as thoughts, attitudes and coping mechanisms, significantly influence a patient's comfort level across Kolcaba's conceptual framework. Understanding these behaviours can support comfort intervention development. During radiotherapy, patients may use cognitive strategies, such as visualisation, mindfulness and breathing exercises, to reduce their perception of physical or psychological discomfort. External health-seeking behaviours, which include actions, interactions with others and responses to the environment, play a crucial role in shaping comfort levels. Implementing these behaviours according to Kolcaba's conceptual framework can enhance overall patient well-being and promote a holistic sense of comfort throughout radiotherapy. In the real world, developing a standard intervention to comfort all patients may be impossible, so individually tailored perspectives need to be considered in the development of interventions.

Further work by Kolcaba (1992) outlined the importance of comfort as an outcome measure (OM). Kolcaba (1992) developed and validated an instrument to measure comfort to test the construct. The General Comfort Questionnaire (GCQ) was a generic instrument with 48 items developed using unpublished data based on the taxonomic structure of contexts and senses (Kolcaba, 1991). It was confirmed that all items of the questionnaire were measuring a single construct with a Cronbach's alpha of 0.88. Factor analysis was deployed using principal component analysis, a varimax rotation method which initially extracted 13 factors with eigen values above 1. After an original item pool of 48, 13 items were deleted after further factor analysis. Reliability was favourable on the remaining 35 items, finding an increased Cronbach's alpha of 0.90. Further testing found the GCQ statistically significant for sensitivity in several directions (Kolcaba, 1992). In summary, the construct of comfort is complex but can be measured. Kolcaba (1992) concluded that it is unknown how sensitive the GCQ would be in all clinical settings and

that although researchers may use the GCQ, the instrument may be invalid or unreliable. Furthermore, a bespoke radiotherapy instrument would be beneficial to measure the discreet differences in patients with cancer undergoing radiotherapy.

In summary, a level of pragmatism was needed when considering Kolcaba's (1994) conceptual framework of patient comfort in nursing care and how the concept, three comfort intervention categories, four contexts and health-seeking behaviours (Wilson and Kolcaba, 2004) apply to comfort experienced in radiotherapy and the potential interventions recommended for development in this PhD programme.

1.6. The importance of patient comfort during radiotherapy

Kolcaba's (1994, 1991) contexts of comfort may have applicability in radiotherapy. For example, as a patient enters the radiotherapy clinic, they arrive with their cultural beliefs and their supporting family or friends (sociocultural) impacted by external behaviours. They enter the physical environment – which may give feelings of ease or anxiety, depending on the simplicity of check-in or aesthetics. Physical comfort may be determined by the experience of being positioned for radiotherapy, and the patient's overarching psychology and spiritualism will contribute to their coping via internal behaviours. These interpretations of comfort are conceived to be transferable to radiotherapy to provide a patient-centred approach to a traditionally technical environment. In radiotherapy procedures, the role and purpose of comfort interventions are to make the procedure more accurate and tolerable to patients and ensure compliance, reducing discomfort, anxiety, distress and claustrophobia. The four contexts (physical, sociocultural, psychospiritual and environmental) were combined with the three senses of comfort (ease, relief and transcendence) to form a three-by-four taxonomic grid of 12 cells (Kolcaba, 1991). This taxonomic grid clarified the complexity of comfort, giving a clearer interpretation and conceptual road map that can be utilised by future researchers to analyse comfort. There was applicability to the conceptual stance within this PhD programme to develop recommendations for a comfort intervention package.

In a preliminary consultation that informed this thesis, the PhD researcher explored the issue of comfort in radiotherapy with a group of patients with head and neck cancers (Goldsworthy, Tuke and Latour, 2016). Comfort was important to them, and three major themes emerged: physical comfort, mental perception and passivity. Patients' descriptions were similar for each theme and are reflected in the following quotes. One patient described the use of a face mask for immobilisation as follows:

I imagine it's a bit like having your head in a polythene bag and you're breathing and it just sucks in and you feel as though I'm not gona breath here, and they say its gona take 10–15 minutes. (Goldsworthy, Tuke and Latour, 2016, pp. 147) A different patient described the whole experience of comfort as being 'a mental thing that you just have to overcome', while another felt like they were on a train, being 'taken for a ride' and passively stating that they will 'do it' (Goldsworthy, Tuke and Latour, 2016, pp. 147). These themes partially relate to Kolcaba's (1994) conceptual framework of patient comfort in nursing care, specifically the intervening variables: contexts of comfort behaviours of how comfort is achieved. Patient discussions of their experiences during head and neck radiotherapy indicated that TRs may not fully appreciate the level of patient discomfort and supported further focus on patient comfort during radiotherapy. Moreover, Nixon *et al.* (2018) explored the prevalence of mask anxiety in 100 patients receiving head and neck radiotherapy, finding that 26% of participants self-reported being anxious about the thermoplastic mask. In these 100 participants, the prevalence of mask anxiety scores was representative of two major themes arising from interviews with 20 patients: 'vulnerability' (claustrophobia and the psychological factor) and 'expectations' (not really prepared for it).

Kolcaba's (1994) conceptual framework of patient comfort in nursing care has been demonstrated to have relevancy for radiotherapy practice. Cheng and Wang (2014) studied the comfort level of patients undergoing curative head and neck radiotherapy. They used a validated Radiotherapy Comfort Questionnaire (based on Kolcaba's conceptual framework) that included Likert-type questions on physical, psychospiritual, environmental and sociocultural comfort (Kolcaba *et al.*, 2006; Kolcaba and Steiner, 2000). They also collected information about social support and medical coping methods using validated questionnaires. The results of this study indicated that physical and psychological experiences scored lowest of the four contexts, and the overall comfort level score was only slightly higher than previously reported in patients during late end-of-life care. The number of radiation sessions and coping modes influenced patient experience: an increased number of sessions and a resignation coping mode were negatively associated with comfort (Cheng and Wang, 2014).

The current literature suggests that it is important to consider the various contexts of comfort, particularly physical and psychological comfort, and develop appropriate interventions in radiotherapy practice. Nixon *et al.* (2019) found that patients relied on interventions from TRs and had their own self-taught coping strategies (such as music, visualisation and medications). Other methods to support patients coping have been pharmacological. For example, Nyárády *et al.* (2006) investigated a pharmacological approach using pilocarpine during and after radiotherapy to ease xerostomia by stimulating salivary glands. Medications can be used for treatment-induced distress, but the potential time to recover and not be able to drive means there is a probable impact on quality of life.

There is an interest in exploring nonpharmacological interventions for radiotherapy patients stemming from their ability to provide effective, holistic support that complements medical treatments. These interventions address physical, psychological and social needs; reduce the reliance on medications; and empower patients to take an active role in their care. By integrating these approaches, healthcare providers can enhance patient comfort, well-being and overall treatment outcomes during radiotherapy (O'Callaghan, Sexton and Wheeler, 2007). O'Callaghan, Sexton and Wheeler (2007) investigated music as a nonpharmacological anxiolytic for paediatric radiotherapy patients, providing the patient and the family with a means of communication, self-expression and creativity and finding a reduction in medications in a series of case studies. Bonett (2015) surveyed patients with head and neck (n = 42), breast/thorax and pelvic cancers attending radiotherapy sessions, seeking their responses to ceiling art. All respondents indicated that the ceiling art made them feel more comfortable (65% strongly agreed), and 98% indicated that it played a positive role during treatment (Bonett, 2015). Chao et al. (2014) explored coping in greater depth in patients with head and neck, thorax and pelvic cancers undergoing radiotherapy (n = 8). They used semi-structured interviews and explored, using grounded theory, how patients adapted to treatment. The overarching theme was a 'desire to survive'. Subcategories included facing unknown situations, pain and chances to extend life (Chao et al., 2014). Chao et al. (2014) suggested that healthcare professionals should better manage side effects of treatment, including providing psychological and spiritual support.

A more recent publication explored self-coping styles amongst patients with breast cancer undergoing radiotherapy, such as active (making plans), emotional (seeking support) and avoidance coping (denial of the problem; Roszkowska and Białczyk, 2023). They explored coping styles in relation to quality of life, using Spearman correlation. The authors found that maladaptive coping was strongly corelated to poor quality of life (r = -0.72, p = 0.001), and active coping correlated to limited improvement in quality of life (r = 0.39, p = 0.117). This study emphasised the need for multidimensional coping needs and the importance of considering psychosocial individually tailored interventions in cancer care. Research outputs are increasing in all patients with cancers receiving radiotherapy, demonstrating the importance of considering comfort in a wider group of patients with cancers of different anatomical regions.

1.7. The future of comfort in radiotherapy

Radiotherapy is advancing rapidly, and extended times are expected to be more commonplace (NHS England and NHS Improvement, Radiotherapy Trials Quality Assurance and National Institute for Health Research, 2020; SABR UK Consortium, 2019). With patients immobilised for longer, this has a foreseeable impact on patient comfort. It is vital that patient comfort is addressed and incorporated into the overall management of radiotherapy to maintain and improve the accuracy and safety of treatment. There is limited understanding of the patient experience of comfort, and this work was extended to consider the impact of longer treatment times. Conversely, developments in radiotherapy techniques may also reduce treatment times significantly in the next 5–10 years. On the horizon is a novel treatment method: ultra-high-dose rate radiotherapy (FLASH) – which is delivered in one fraction (session) in a very short time, promising a reduction in normal tissue damage (Wilson et al., 2020). This may be due to the oxygen depletion effect minimising free radical damage to the DNA helix of normal tissue while maintaining similar tumour response. Improving comfort is required at both ends of the spectrum: for extended treatment times and equally for single fractions, with reduced delivery times where there is a one-time opportunity to ensure precise treatment delivery. If a patient was uncomfortable and moved this could cause irreparable collateral damage and toxicity for the patient. Anecdotally, TRs are adapting practice to manage patients with extended treatment times; exploration of their views and practices is crucial to respond to the changes in practice. Patient comfort is an issue shared with other healthcare areas, and this provides an opportunity to identify and develop comfort interventions for radiotherapy based on the characteristics of effective interventions from other disciplines.

Recent advancements in radiotherapy, such as SABR, are improving cure rates and reducing side effects (Franks, Jain and Snee, 2015; Arcangeli, Scorsetti and Alongi, 2012) but are impacting on radiotherapy practice, particularly in relation to patient positioning and comfort. SABR is a high-dose treatment delivered over fewer day compared to conventional radiotherapy but requires a high level of precision via image guidance to ensure tumour targeting and the avoidance of organs at risk (Franks, Jain and Snee, 2015). This involves the addition of multiple scans during the radiotherapy session to ensure accurate targeting of radiation beams. A compromise of progress is that treatment times are extended, which may exacerbate patient discomfort. SABR has been commissioned across the UK for some of the following clinical indications (NHS England and NHS Improvement, Radiotherapy Trials Quality Assurance and National Institute for Health Research, 2020; SABR UK Consortium, 2019): lung cancer, which represents approximately 1,000 patients per year (National Cancer Intelligence Network and Cancer Research UK, 2015; NHS Commissioning Board, 2013), and metachronous oligometastatic cancer, estimated at 2,200 patients per year (NHS England, 2020). SABR use is anticipated to increase and become available for other cancers (Franks, Jain and Snee, 2015; Arcangeli, Scorsetti and Alongi, 2012), but the success of these advancements in radiotherapy may compromise patient comfort as treatment time increases from 10 to 30 minutes (Franks, Jain and Snee, 2015; National Cancer Intelligence Network and Cancer Research UK, 2015; Arcangeli, Scorsetti and Alongi,
2012). Fundamentally, as treatment times are extended, the experience of patient comfort is likely to be even more critical to the positional stability of patients and, therefore, accuracy of treatment during a radiotherapy session (International Atomic Energy Agency, 2016; Dawson and Balter, 2004). Dawson and Balter (2004) suggested that the main intervention for extended treatment times, which can lead to organ motion and involuntary patient movement, is to ensure patient comfort. There has been research on improving the therapeutic dose of radiation and how to measure toxicity. However, there has been a lack of scholarship into patient care and what it is like to actually experience radiotherapy (Bolderston, 2016). This is compounded by little guidance on how to best assess and manage patient comfort in radiotherapy practice (van der Merwe *et al.*, 2017; Goldsworthy, Tuke and Latour, 2016; International Atomic Energy Agency, 2016; Cheng and Wang, 2014; Cox and Davison, 2005).

In radiotherapy, psychological interventions, such as hypnosis, have improved patient comfort (Schnur *et al.*, 2009). In a study, Deng and Xie's (2013) demonstrated hypnosis stabilising respiration motion, which is ideal for patients undergoing radiotherapy for lung cancer. The findings of qualitative interviews with parents of children undergoing radiotherapy have provided multiple suggestions for comfort interventions (Ångström Brännström *et al.*, 2015). Some of these suggestions include repeated information, distraction and the provision of a child-friendly environment. Indications are that there are several preexisting interventions that may improve patient comfort during radiotherapy treatment. Some are suitable for use prior to radiotherapy treatment and some for use during radiotherapy treatment.

In summary, ensuring patient comfort is an integral part of the overall radiotherapy process. Tailoring the approach to each patient's needs can enhance the overall experience and contribute to treatment success. This PhD programme intends to identify potential comfort interventions, explore the multifaceted dimensions of patient comfort and how it can best be managed during radiotherapy and provide recommendations of comfort intervention components in consensus with patients and TRs.

1.8. Aim and objectives

1.8.1. Aim

The overarching aim of this PhD programme was to develop recommendations for a comfort intervention for patients receiving radiotherapy with extended treatment times. The PhD programme was split into three stages which are outlined in <u>Figure 1.3</u> and aligned to the objectives below.

1.8.2. Objectives

Stage 1: Systematic review of comfort interventions in health and social care practice

To identify comfort interventions used for clinical procedures that involve sustained inactivity (such as radiotherapy), record the characteristics of the comfort interventions for future practice and determine the effectiveness of the comfort interventions

Stage 2: Experiences of comfort during radiotherapy/comfort management during radiotherapy

- a) To explore patient experiences of comfort and how comfort is best managed (solutions) during radiotherapy through interviews with patients and TRs
- b) To explore TR views of managing patient comfort (solutions) during the delivery of radiotherapy through interviews with TRs

Stage 3: Recommendations for a radiotherapy comfort intervention package

To develop recommendations for a radiotherapy comfort intervention package via a consensus study with patients and TRs



Figure 1.3. PhD programme study schema. This figure is based on the Medical Research Council framework for developing and evaluating complex interventions (see <u>Figure 2.1</u>).

1.9. PRP involvement in the PhD programme

Bolderston (2016) described radiotherapy as lacking research into patient experiences, such as comfort. She asserted that partnering with patients and the public supports research aiming to improve experiences. The focus of the current thesis evolved from consultations with patients undergoing radiotherapy for head and neck and lung cancers. Patients highlighted the discomfort they experienced in preparation for, during and after their treatment but indicated that they may not report discomfort to TRs (Goldsworthy, Tuke and Latour, 2016). This was the initiator of the proposed development of

recommendations for a radiotherapy comfort intervention package, as well as the ongoing centricity of patient and public involvement (PPI), in this PhD programme. The PPI contributors to this PhD programme are given the name 'patient research partners', as they were key members of the research team. There is plenty of debate on PPI in research, particularly when researchers want to ensure impact on the planned research (Staley, 2015). PPI in radiotherapy research refers to actively involving patients and members of the public in the research process. This involvement has several benefits and adds significant value to the research endeavour. Patients and the public bring unique perspectives and insights into the research process. Involving them helps ensure that the research questions, outcomes and interventions are relevant and meaningful to those who will ultimately be affected by the findings (College of Radiographers, 2018; INVOLVE, 2012).

Gordon *et al.* (2017) appraised the value of PPI in radiotherapy research, first discussing PPI as a requirement and then addressing criticism by researchers as to it being a politically pleasing exercise. Gordon *et al.* (2017) suggested that PPI had sometimes been implemented with scepticism, paying lip service to funding bodies and steering committee but not influencing the research in any way. They suggested that carefully considered involvement is the solution, ensuring that the right groups of people are involved in the research. These people, qualified by their experiences as patients, want to altruistically contribute to improve treatment or care for future patients. In this way, PPI can contribute to the design of studies, making them more patient-friendly, feasible and deliverable. In the context of radiotherapy research, where the focus is on improving cancer treatment outcomes, PPI is particularly important. Patients undergoing radiotherapy can provide valuable insights into their experiences, preferences and needs, ultimately contributing as partners to the development of more effective and patient-centred radiotherapy interventions.

This PhD programme included two PRPs as active members of the study management group, which met twice per year. They were included in the group to ensure that patients' views and experiences remain central to ongoing research developments. PRPs reviewed materials for use by patients which were produced at various points during the programme. This included patient resources for ethics applications for two studies – qualitative interviews to explore patients' and TRs' experiences and views of comfort and how it is best managed – and a consensus study to develop recommendations for a radiotherapy comfort intervention package. PRPs were involved in the interpretation of the qualitative analysis in Stages 2 and 3 of this PhD research. This strengthened the process and provided counterbalance to the PhD researcher's professional background. Following this PhD, PRPs will also contribute to the development and design of resources. This will improve the appropriateness and accessibility of patient resources used in future studies.

1.10. Thesis structure

This doctoral thesis is organised in nine chapters.

<u>Chapter 1</u>: This chapter introduces the PhD programme research study by defining the topic, stating the aim and objectives, explaining the significance and the anticipated impact of the study and providing an overview of the thesis structure.

<u>Chapter 2</u>: This chapter critiques and justifies the philosophical, theoretical and methodological underpinnings of the research study.

<u>Chapter 3</u>: This chapter provides an overview of the methods of the research protocols for three studies.

<u>Chapter 4</u>: Here, a systematic literature review (SLR) identifies, characterises and synthesises the findings of studies (published in *Radiography*) investigating comfort interventions.

<u>Chapter 5</u>: This chapter presents a thematic exploration of comfort experiences and views regarding radiotherapy treatment via interviews with patients and TRs, published in the *Journal of Medical Imaging and Radiation Sciences*.

<u>Chapter 6</u>: This chapter presents a thematic exploration of how comfort can be best managed during radiotherapy via interviews with patients and TRs. The chapter suggests some comfort solutions and was published in the *Journal of Medical Imaging and Radiation Sciences*.

<u>Chapter 7</u>: This chapter presents a nominal group technique (NGT) consensus study (published in *Radiography*) that prioritised and explored the feasibility of comfort intervention components that could be recommended in the development of a radiotherapy comfort intervention package.

<u>Chapter 8</u>: This chapter presents a discussion of the main study findings, considering the existing clinical and theoretical literature.

<u>Chapter 9:</u> This is the conclusion of the thesis, addressing the research aims, explaining the implications and recommendations for clinical practice in radiotherapy, outlining future research directions and acknowledging the limitations of the research.

2. Chapter two: Methodology

2.1. Introduction

The overarching aim of this PhD programme was to develop recommendations for a comfort intervention for patients receiving radiotherapy with extended treatment times. To achieve this aim, the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Skivington *et al.*, 2021) was utilised as a frame to plan the three stages of work reported in this thesis. These stages involved a mix of qualitative and quantitative methods, as illustrated in Figure 1.1.

The methodology chapter presents the alignment of the PhD programme to the MRC framework for developing and evaluating complex interventions (Skivington *et al.*, 2021), philosophical assumptions of ontology and epistemology (Crotty, 1998), philosophical positionality (Fenge *et al.*, 2019), theoretical framework and method of inquiry applied to the PhD programme.

2.2. MRC framework for developing and evaluating complex interventions

It is acknowledged that there is a need for rigorously developed and evaluated clinical interventions, and several intervention development frameworks (IDFs) have been developed (Walker et al., 2017). These frameworks include the MRC guidance for developing and evaluating complex interventions (Skivington et al., 2021), intervention mapping (Bartholomew et al., 2016), the Criteria for Reporting the Development and Evaluation of Complex Interventions (Möhler, Köpke and Meyer, 2015) and the 6 Steps for Quality Intervention Development (Wight et al., 1979). All IDFs include various stages of development, starting at the conceptual stage through to the evaluation of implementation, so the decision to use the MRC framework was pragmatic. The MRC framework for developing and evaluating complex interventions is a widely recognised and respected approach used primarily in the field of healthcare and public health interventions research in the UK. The MRC guidance was first introduced in 2000 (Campbell et al., 2000) and has been updated twice: in 2006 (MRC, 2006) and, more recently, 2021 (Skivington et al., 2021). The updates have reflected the evolution of methodological practice, and more recently in 2021, the main evolution was to separate the development phase into two categories: to identify interventions and to develop interventions, which is pertinent to this PhD programme (Skivington et al., 2021).

This PhD programme first utilised the 2006 framework, but now, the update is even more applicable since this change to the two categories of development. The MRC framework provides a structured and systematic method for identify and developing, assessing the

feasibility of, evaluating and implementing complex interventions aimed at improving health and well-being (Skivington et al., 2021). The framework breaks down the process into distinct phases, making it easier to plan and execute research projects such as this PhD programme (Figure 2.1). The framework consists of four phases: development (identify and/or develop), feasibility and piloting, evaluation and implementation (Skivington et al., 2021). It emphasises the importance of clearly defining the purpose and objectives of the intervention during the development phase. This ensures that interventions are designed with a specific aim and that resources are appropriately allocated. The framework encourages the incorporation of theoretical foundations for intervention development, including the meaning of comfort highlighted in Section 1.6. It was critical to understand potential intervention components from the viewpoints of patients and TRs in the development process. Identifying interventions using the MRC framework ensures that potential interventions are contextually relevant and acceptable and address the needs of the target population. The focus of this PhD programme was to identify and recommend the development of comfort interventions in a future comfort intervention package in radiotherapy based on the 2021 MRC framework (Skivington et al., 2021).

The MRC framework has both proponents and critics. While it is praised for its structured approach, comprehensive evaluation of complexity and flexibility, it is also criticised for its perceived linearity, lack of methodological specificity and complexity in implementation. The updated MRC framework published in 2021 does not specifically define the methodology of implementing and testing of a complex intervention. However, the updated framework provides improved structure and approach for the development of a complex intervention (Skivington *et al.*, 2021). This suggesting that a comprehensive approach to developing complex interventions is required to enhance methodological specificity, ensuring success (Bleijenberg et al., 2018). Bleijenberg et al. (2018) recommended combining the framework with other models of intervention development to enhance the intervention design process. The MRC framework (2006) is criticised for lacking detail (Booth et al., 2019), but it possibly encourages flexibility to adapt the model to suit the needs of the project. Some have also argued that the framework is too complex, rigid and resource intensive and is unable to capture individual experiences when developing complex interventions (Lakshman et al., 2014). However, this stance seems to contradict the purpose of the framework, which is to encapsulate individual experiences.

This PhD programme used the MRC framework as an initial guide to build the three stages and their rationale rather than as a prescribed empirical method (Figure 2.1). All stages of the PhD were firmly within the identify and development part of the MRC framework. An SLR of comfort intervention components used in radiotherapy or similar

clinical procedures that require a comfortable position for stability and accuracy was planned as Stage 1 of the programme. The SLR utilised quantitative methods to analyse published studies (Goldsworthy, Palmer, *et al.*, 2020). Qualitative interviews with patients and TRs were used in Stage 2 was designed to explore comfort and how it is best managed in radiotherapy. The data from Stages 1 and 2 were triangulated and synthesised, providing an initial list of comfort intervention components, and aligned to the identify intervention phase of the MRC framework. Stage 3 was an NGT consensus study with patients and TRs to prioritise and rate comfort intervention components to recommend in a radiotherapy comfort intervention package and was aligned with the develop intervention phase of the MRC framework. This final study used quantitative and qualitative methods.





(Adapted to incorporate where the PhD programme was situated within the framework. Adaptation is in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license.)

2.3. Philosophical assumptions of ontology and epistemology

Ontology and epistemology are two branches of philosophy that deal with fundamental questions about the nature of reality and knowledge, respectively. Ontology is the branch

of philosophy concerned with the nature of being, existence or reality. It explores questions about what exists, what entities or things can be said to have real existence and how these entities relate to each other (Crotty, 1998). The key questions for ontology are as follows: What is the nature of reality? What kinds of entities exist? and How do these entities relate to each other? Epistemology is the branch of philosophy concerned with the nature, scope and limits of knowledge (Junjie and Yingxin, 2022). It investigates questions about how knowledge is acquired, the nature of truth and belief and the justification of beliefs. The key questions of epistemology are as follows: How do we know what we know? What is the nature of truth? and How can we justify our beliefs? (Junjie and Yingxin, 2022). These two branches of philosophy are closely related, as the understanding of reality influences knowledge, the epistemological stance affects how research is perceive and the nature of research interpreted (Marsh and Furlong, 2002). The aim of the PhD programme (<u>Section 1.8</u>) was based on an ontological perspective, while the objectives were built upon an epistemological perspective of how it will be known that the aim will be achieved.

This PhD programme focused on the exploration of patient comfort during radiotherapy and how it is best managed, followed by developing recommendations for a comfort intervention package for patients receiving radiotherapy to potentially improve accuracy. This means there could be various 'standing positions' when it comes to ontology and epistemology. For example, the scientific and technical field of radiotherapy lends itself to a positivist position. However, the exploration of patient comfort could take on a phenomenological or interpretivist position. This PhD programme was situated in radiotherapy, resulting in philosophical contemplation of epistemological and ontological fit for the PhD researcher.

Research philosophy is a framework that guides how research should be conducted based on ideas about reality and the nature of knowledge. There are two main philosophies: positivism and interpretivism (Junjie and Yingxin, 2022). These philosophies explain how sense is made of the world. In the positivist paradigm, reality is independent of the research and researcher, so reality is observed objectively. A researcher scientifically testing a hypothesis using statistical tests may sit within a positivist position. In the interpretivist paradigm, reality is observed subjectively and shaped by human perception of the researcher (Crotty, 1998). Interpretivism is related to many idealist philosophical positions – including feminism, critical inquiry, hermeneutics, phenomenology and social constructivism, which are all about the researcher observing the world (Junjie and Yingxin, 2022).

This PhD programme was underpinned by interpretivism with an idealist philosophical position. Idealism in this research priorities the role of the mind and consciousness in shaping researchers understanding of reality. Idealism encapsulates and provides

understanding to the lived experiences of patient comfort within the technically precise discipline of radiotherapy (Crull, 2018). This is a philosophy based on interpretivism that the physical reality of the world is a creation of the mind of the human observers rather than physical particles existing regardless of human observers (Allison, 2020; Allais, 2017). The idealist proposition that there are multiple interpretations and potentially multiple realities could sit nicely with the theory of fifth and sixth dimensions in the study of quantum physics, where there are multiple realities perpendicular or parallel to the origin (Junjie and Yingxin, 2022; Crull, 2018). This standpoint reflects the PhD researcher's professional background in caring for patients and his research focus of exploring the phenomenon of patient and TR comfort experiences and views to develop a radiotherapy comfort intervention. By approaching the research from an idealist perspective, researchers can gain a richer understanding of how individuals perceive and experience comfort in the context of radiotherapy.

2.4. Philosophical positionality

A quantitative SLR, qualitative interviews with patients and TRs and a modified NGT consensus study are consistent with an idealist approach. Positionality in research refers to the researcher's social, cultural, and personal background, which can influence their perspective and the research process (Fenge et al., 2019). In the context of a TR undertaking a PhD programme on the comfort of patients during radiotherapy, positionality is particularly important. As a TR, the PhD researcher's professional background brings valuable expertise to the research. The knowledge of radiotherapy processes, patient interactions and the healthcare system contributes to a nuanced understanding of comfort during radiotherapy. However, potential biases that may arise from this useful professional experience must be acknowledged. For example, a TR might have a certain perspective on what contributes to patient comfort based on their daily interactions in a clinical setting. The researcher may hold certain philosophical assumptions that guide their approach to the study. These assumptions provide the foundation for the research paradigm and shape the researcher's perspectives on knowledge, reality and the nature of the phenomenon being studied (Wilson, Janes and Williams, 2022). The professional and personal background of the researcher cannot be switched off but can be addressed through questioning assumptions and incorporating these assumptions into the research strategy.

However, there is a need to be transparent about the background of researchers set against the research methods and findings for credibility and trustworthiness (Anney, 2014). For this research, the professional background was viewed as most critical to impacting the qualitative research. The consideration of personal beliefs is important for the researcher to understand the effect on theories which inform the work. The PhD researcher is a White male in his 40s who is a registered TR. He assumes an idealist position, is Christian and harbours feminist views of equality, which may not be consistent with the beliefs of all the PhD programme study participants. However, his open and flexible view to reality means that he was open to all perspectives without judgement. A reflexive statement is that the PhD researcher may have planned to be open but still questioned the possibility of identifying inflexibility. Therefore, two PRPs, a peer researcher and four doctoral supervisors were included in the process of clinical study design through to analysis, questioning the PhD researcher's potential inflexible judgement (Davis, 2020).

The PhD researcher planned to be open and transparent to suggestions and making changes to the research process and interpretation of qualitative findings. Furthermore, the doctoral supervisors proposed that the research should 'talk for itself' without flamboyance or conflating the findings for credibility. The reflexive question was how that would be achieved in this PhD programme. The first step was to acknowledge the potential impact of the researcher's personal background and then to write a reflexive log in field notes. This log included how the PhD researcher felt, how the research was going, if there was rapport with the participants and if the objectives were being achieved. There are many ways to include reflexivity in PhD programme, and Peddle (2022) recommended six reflexive questions to answer through a PhD, covering values, beliefs and perceptions. These include consideration of the researcher's emotions, progress, thoughts about participants and data, and progress regarding outcomes, as well as three interesting things learnt. Peddle (2022) stated that although it can be used as an initial guide, this structured and intentional method may not be generalisable and suitable for the nuances of a PhD programme.

The PhD researcher felt like a phenomenological sociologist in a positivist TR's tunic. The researcher is a TR delivering clinical research between these core disciplines with oncology and medical physics. The researcher explored comfort in radiotherapy through an interpretivist ontological standing with idealist philosophical position (Allais, 2017; Marsh and Furlong, 2002)

The literature presents discussions on the epistemic norms, practical reasoning and categorisation of theoretical underpinnings (Fassio, 2017). Therefore, a flexible stance was taken so not to restrict the generation of new knowledge (and how we know what we know) to the strict confines of any paradigm in line with the PhD researcher's beliefs and perceptions (Peddle, 2022). The idealist standpoint is versatile and can evolve over time as the researcher achieves a greater understanding of patient comfort in radiotherapy. In this PhD programme, this means fluidity of thought at all stages of the work for the maximum generation of new knowledge from the exploratory interviews and consensus study. It grants the researcher an understanding of his realities, each shaped by the world

they live (Creswell and Poth, 2018). It allows for the generation of knowledge via the planned studies of the PhD programme based upon multiple realities of the idealist position. The philosophical assumptions of this PhD programme and position in the research are based on the personal experiences and views of leading researchers (Creswell, 2018).

2.5. Theoretical framework and method of inquiry

After generating a better understanding of potential interventions from the SLR (Stage 1) and the experience of comfort in the unique environment of radiotherapy from interviewing patients and TRs (Stage 2), a clinical synthesis of these findings was planned to develop an initial comfort intervention component list in keeping with an idealist philosophy, using Kolcaba's (1994) conceptual framework of patient comfort in nursing care as inspiration within the PhD programme. An NGT consensus study (Stage 3) refers to the initial comfort intervention component list as a theoretical framework to prioritise and vote on intervention choices, prioritisation, resources and training for patients and TRs.

2.6. Chapter summary

This chapter established and critiqued the philosophical and theoretical framework from which the PhD programme was designed. The study is rooted in an idealist philosophical perspective, which has informed the quantitative and qualitative methods embedded in the idealist paradigm. This philosophical assumption and framework, with a focus on a socially constructed multiple realities and the understanding of individual experiences, is the foundation of this PhD programme. Adopting an idealist philosophy (Allais, 2017) and Kolcaba's (1994) conceptual framework of patient comfort in nursing care means that a flexible methodology was sought to explore patients' and TRs' lived experiences of comfort and how it is best managed in radiotherapy.

3. Chapter three: Methods

This chapter sets out the research methods employed in the three stages of the PhD programme that are not covered in the published papers presented in chapters four to seven.

3.1. Outline

This thesis employed quantitative and qualitative methods to address the PhD programme objectives in three stages (Figure 1.3). The following topics will be discussed for each of the stages:

- Stage 1: The Cochrane Handbook for Systematic Reviews of Interventions, risk of bias (RoB) and data synthesis
- **Stage 2:** The rationale for choosing interviews, seeking commonality, sampling and sample frame, and ethics and governance.
- Stage 3: Shared decision-making and the panel member frame

The study procedures are outlined, and additional methods not found in Chapters 4–7 are supported by reflective commentaries, providing an insight into challenges and decisions for this PhD programme.

3.2. Stage 1: SLR of comfort interventions in health and social care practice

Stage 1 was an SLR of the effectiveness of interventions applicable to radiotherapy that were administered to improve patient comfort, increase patient compliance and reduce patient distress or anxiety. The intention was to search the literature for interventions that would support adult patients to undergo clinical procedures similar to radiotherapy, tabulate the details and evaluate the clinical significance of these interventions. This was a quantitative study that used the Template for Intervention Description and Replication (TIDieR) checklist to extract pertinent data about delivery of the interventions, followed by evaluation of interventions using descriptive statistics, confidence intervals, p-values and effect sizes. The RoB of the included studies was assessed. Clinical significance was determined using effect size and minimal clinically important difference (MCID). Full details are reported in <u>Chapter 4</u>.

3.2.1. Systematic Review Guidelines

There are many guidelines that can be accessed for conducting systematic reviews. However, two sources lead this area, providing checklists for a wide variety of reviews (Kolaski, Logan and Ioannidis, 2024). These are the *Cochrane Handbook for Systematic Reviews of Interventions* and the *JBI Manual for Evidence Synthesis*, with reviews ranging from qualitative, scoping and diagnostic to intervention categories. The Joanna Briggs Institute (JBI) manual provides the greatest range of review category guidance, while 96% of Cochrane reviews are categorised as intervention reviews (Kolaski, Logan and Ioannidis, 2024). The Cochrane and JBI guidelines have similar review items for intervention systematic reviews. The Cochrane guideline was followed with input from JBI in regard to the search strategy and the TIDieR guideline and checklist (Aromataris and Munn, 2021; Higgins *et al.*, 2019; Hoffmann *et al.*, 2014).

Before further discussion of the guidelines, it is worth noting the study selection criteria. This SLR followed the population, intervention, control, outcome and study (PICOS) criteria to frame the objectives to formulate clinical queries in a structured format. Huang, Lin and Demner-Fushman (2006) evaluated the criteria to investigate effectiveness across a range of clinical settings from diagnosis and therapy research. The authors concluded that PICOS is more suited to therapeutic research questions, giving relevance to the current review situated in radiotherapy. In accordance with the PICOS criteria, the following selection criteria were used.

3.2.1.1. Population

The population for this SLR was patients over 18 years undergoing a clinical procedure which requires alignment, stabilisation and immobilisation as well as sustaining, enduring or tolerating the procedure while conscious over a period greater than 10 minutes.

3.2.1.2. Interventions

Nonpharmacological interventions were sought in this SLR with the intention of increasing patient comfort during clinical procedures which require alignment, stabilisation or immobilisation as well as sustaining, enduring or tolerating while conscious over a period greater than 10 minutes.

3.2.1.3. Control

The standard care did not include any intervention with the aim of reducing discomfort.

3.2.1.4. Outcomes

The outcomes sought for the SLR were broad to include assessments of patient comfort, psychological well-being, patient satisfaction and/or quality of life outcomes. The intention

was to encapsulate the holistic experiences of patient comfort encapsulated in Kolcaba's (1994) theory of comfort.

3.2.1.5. Types of studies

Two types of studies were focused on: randomised controlled trials (RCTs), controlled before and after the trials, and non-RCTs. The Cochrane guidelines were specifically chosen for their emphasis on RCTs. They have a detailed protocol for conducting reviews of interventions (Higgins et al., 2019). The JBI manual has a broader range of guidelines to include an array of clinical study designs (Aromataris and Munn, 2021). The integration of the two guidelines was straightforward, but there were still decisions to make. The guidelines did not stipulate the exact process to undertake the specific SLR for this PhD programme, but the PhD researcher deduced that a bespoke process was required. The areas requiring a decision included the search strategy, selection of studies, critical appraisal/RoB and data synthesis. For the search strategy, a clinical and university librarian supported the database searches as recommended by Cochrane (Higgins et al., 2019). Conducting good-guality SLRs presents many dilemmas, which is why Lenart-Gansiniec (2022) recommended a prescribed process outlining a rigorous method. organisation and planning. The SLR protocol in this PhD programme was registered with PROSPERO for transparency and to avoid duplication (Moher, Booth and Stewart, 2014; Stewart, Moher and Shekelle, 2012). Future researchers could also assess this SLR for reporting bias, providing an extra level of rigour.

The PhD researcher (SG) and lead doctoral supervisor (MC) completed the initial search of titles and abstracts according to the inclusion criteria. This was completed independently with follow-up meetings to discuss the titles and abstracts recommended for inclusion. The PhD researcher reflected that an automated screening system could be more efficient and less subjective than researchers manually doing the initial search. However, the nuance of the topic and the potential time it could take for preparation may not be more efficient. Tsafnat *et al.* (2018) suggested that this could be a reality in the future as the automated screening tools are refined. After the initial reviewers selected the full text papers, a third reviewer adjudicated disagreements and had the final judgement on whether to include a paper in the SLR.

A limited search of two trial registries, clincialtrials.gov and the international trials registry platform was undertaken, and a literature search of databases was conducted for grey evidence, including unpublished studies (Montori, Smieja and Guyatt, 2000). For this SLR, only published studies which had been peer reviewed for methodological quality were included (Afonso *et al.*, 2024; Maier *et al.*, 2022). This is because unpublished studies would have caused an unknown impact on the final analysis of the SLR.

3.2.2. RoB

A key decision was how selected papers would be critically appraised or assessed for RoB and how this would be used. There are several critical appraisal and RoB tools which can be applied to different types of studies, whether they are randomised, nonrandomised or qualitative designs (Hancock, 2001). In 2004, Katrak et al. conducted a systematic review of the content of critical appraisal tools (CATs) and concluded that there was no gold standard or consensus. The authors also stated that there was an absence of anything specific to allied health, and only 49% of CATs included a numeric summary score for interpreting the strength of the evidence (Katrak et al., 2004). Further work is needed to comprehensively develop and then validate the use of CATs (Crowe, Sheppard, and Campbell, 2011). Pieper, Mathes and Eikermann (2014) found that there is also a degree of subjectivity and heterogeneity between reviewers using different CATs, including the assessment of multiple systematic reviews tool, Overview Quality Assessment Questionnaire, Guidelines for Assessing the Quality and Applicability of Systematic Reviews of the National Center for the Dissemination of Rehabilitation Research tools. Pieper, Mathes and Eikermann (2014) found that Cohen's kappa coefficient for CATs ranges from 0.47 to 0.76. However, it is advised that CATs should be used with caution, knowing the inherent weaknesses when an overall rating of quality or risk is required (Pieper, Mathes and Eikermann, 2014). RoB assessments can be executed with greater ease through tabulation and are less open to interpretation, but Hartling et al. (2009) opposed this suggestion. Hartling et al. (2009) evaluated internal validity of RCTs, interrater agreement and concurrent validity between the Cochrane RoB tool and two other CATs - the Jadad scale and the Schulz approach to allocation concealment. The interrater agreement varied across the Cochrane RoB domains, and poorer agreement was found where a greater judgement was needed (weighted kappa: 0.13-0.74). In summary, both CAT and RoB assessments are imperfect and require further development, especially for agreement between researchers. To improve the application of assessments, the process can be automated or semi-automated to reduce the effects of subjective judgement. Authors such as Marshall, Kuiper and Wallace (2016) developed automated processes for RoB assessment and aimed to reduce the effect of interrater differences using machine learning. They concluded that a hybrid computer-human system that can extract data while assessing RoB should reduce subjective assessment and interrater variability.

While tools such as the Jadad score or Schulz approach may include criteria related to concealment of allocation, the broader RoB assessment often considers multiple factors to provide a comprehensive evaluation of a study's methodological quality (Hartling *et al.*, 2009). Therefore, the Cochrane RoB tool was selected for RCTs and the Risk of Bias in Non-Randomised Studies of Interventions (ROBINS-I) for non-RCTs (Sterne *et al.*, 2016).

Finally, it was determined that the RoB criterion for random sequence generation and concealment should have an acceptable level of risk for included study data to be synthesised, and those studies that did not meet this criterion would not be synthesised.

The choice to use the Cochrane RoB tool in the SLR reported in this thesis was based on pragmatic reasons and the best available evidence at the time it was designed. The PhD researcher chose to use RobotReviewer[™] for RCTs (Marshall and Wallace, 2019; Marshall, Kuiper and Wallace, 2016). RobotReviewer is an artificially intelligent online tool that was used as 'Reviewer 1' to conduct the initial RoB assessment for all papers, apart from any non-RCTs. The process included importing PDF files of published papers into the online system, and in minutes the data and RoB assessment was completed by the robot. A second reviewer 'Reviewer 2 (the PhD researcher)' then checked through all the RoB assessments of RobotReviewer. ROBINS-I was used for non-RCTs in this SLR without any automated system of assessment (Sterne *et al.*, 2016). The Cochrane RoB Checklist (Version 5.1.0) was used to assess RoB in RCTs. Six areas of RoB were assessed (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective reporting), with each area denoted as a 'low', 'high' or 'unclear' RoB.

3.2.3. Data synthesis

For data synthesis it was conceived that criteria would be needed for the inclusion of study data. This would ensure the quality, reliability and credibility of inferences generated from the SLR. The first criteria were that validated OMs were used, the Cochrane RoB assessment was acceptable and that OMs were recorded before and after the clinical procedure. The next criterion was to determine a benchmark for clinical significance. Often, statistical significance is wrongly construed for inferring clinical significance. Ranganathan, Pramesh and Buyse (2015) suggested that researchers evaluating RCTs should consider clinical significance by taking an account of effect size rather than relying on the p-value alone. Bothe and Richardson (2011) discussed statistical, practical and clinical significance. Statistical significance infers a difference between two groups (e.g. pvalue), practical significance infers how much two groups differ (e.g. effect size) and clinical significance concerns inferring what the difference means (Bothe and Richardson, 2011). Furthermore, clinical significance can be defined as trying to understand whether an intervention has made a difference to patients. A further study recommended that clinical significance can be inferred by calculating the OM change before and after a clinical procedure (Ronk, Hooke and Page, 2016). For this SLR, published evidence about the MCIDs of suitable OMs representing patient comfort was used (Wright et al., 2012). The complexity of comfort given in the four domains by Kolcaba (1994) meant that a range of OMs were deemed appropriate in this PhD programme. For example, the

potential OMs included physical, psychospiritual, environmental and sociocultural assessment of comfort, such as the Radiotherapy Experience Questionnaire, State-Trait Anxiety Inventory (STAI) and Hospital Anxiety and Depression Scale (Olausson *et al.*, 2017; Leentjens *et al.*, 2011; Quek *et al.*, 2004).

Furthermore, only validated OMs were included in the data synthesis and were reported separately for intervention and comparator groups. A meta-analysis was considered as a method, but the included studies may have lacked homogeneity in clinical procedures and interventions. Therefore, the plan was to calculate the OM change from before to after clinical procedures as mean difference, percentage change, Cohen's d effect size (normalised distribution) or r effect size (nonnormalised distribution) with 95% confidence intervals. Studies were to be selected for the Cohen's d or r effect size analysis depending on whether the data followed a normal distribution (Jakobsen et al., 2014; Grissom and Kim, 2012), which was confirmed by the reported use of the Kolmogorov-Smirnov or Shapiro-Wilk test for normality or assumed based on the use of parametric tests (Grissom and Kim, 2012; Altman and Bland, 2011; Rice and Harris, 2005). Where means and SDs were not reported, an estimation from either interguartile range or p-value was calculated (Altman and Bland, 2011; Leech and Onwuegbuzie, 2002). However, the effect sizes do not determine clinical significance alone (Jakobsen et al., 2014; Bothe and Richardson, 2011). In this SLR, clinical significance was determined using the effect size and MCID. Effect sizes were interpreted using the following criteria: small (≤0.49), medium (≥0.5 to ≤0.79) or large effect (≥0.8; Rice and Harris, 2005). MCIDs of validated OMs were identified from the literature (Corsaletti et al., 2014; Leentjens et al., 2011). There were no agreed and validated criteria for clinical significance, so the research team defined and agreed on the clinical importance or impact on patients. A comfort intervention would be considered to demonstrate clinical significance when the effect size exceeded 0.49, mean differences were greater than the MCID and the RoB was acceptable.

3.3. Stage 2: Qualitative interviews with patients and TRs

Stage 2 was a qualitative study of patients' and TRs' perspectives and formed part of a programme of work to develop recommendations for a comfort intervention package for patients undergoing radiotherapy with extended treatment times. The study outlined in this protocol aimed to interview up to 25 patients and 25 TRs to explore their experiences and views of comfort and how it is best managed in radiotherapy. Details of the methods are presented in published papers in Chapters <u>5</u> and <u>6</u>. This section focuses on the rationale for the use of qualitative interviews, seeking commonality, sampling and sample frame.

3.3.1. Qualitative approach

The gualitative interviews required an inductive approach to openly explore the phenomena of comfort experiences and solutions. Several qualitative approaches were considered in this PhD programme with an idealist theoretical perspective (Creswell, 2018). Various methodologies commonly associated with qualitative research are widely discussed in the literature. These are phenomenology (Galvin and Holloway, 2015; Crotty, 1998; Parahoo, 1997), grounded theory (Corbin and Strauss, 2008; Crotty, 1998), ethnography and case studies (Willis, 2007). While these methodologies employ different methods, they share a common goal: understanding the world of lived experiences from the perspectives of those experiencing them. This involves 'interpreting' and 'reconstructing' subjective meanings (Hill Bailey, 1997; Schwandt, 2000). A further approach is pragmatically qualitative research (Barker and Pistrang, 2021). This approach prioritises the practical application and utility of qualitative methods to address real-world problems, focusing on outcomes rather than strict adherence to theoretical frameworks or methodological traditions. Rooted in the philosophy of pragmatism, this approach emphasises flexibility, problem-solving and the use of methods best suited to achieve the research objectives of this PhD programme (Barker and Pistrang, 2021). After considering alternative methodologies, a pragmatically gualitative approach was chosen as the most appropriate approach to meet the research objectives.

An initial comparison was made between phenomenology and grounded theory. While both approaches aim to describe and understand a phenomenon (Osborne, 1994), grounded theory seeks to develop a general abstract theory of a process or interaction grounded in participant views (Creswell, 2018). Grounded theory emphasises theoretical sampling, wherein participant selection evolves as the research progresses to support theory development (Chen *et al.*, 2012; Charmaz, 2006; Marshall, 1996). In contrast, phenomenology employs purposive sampling to select individuals whose experiences can illuminate the phenomenon of interest (Osborne, 1994). Although phenomenology seemed suitable, it was perceived as restricting when there was a need for flexibility.

Another comparison was drawn between phenomenology and ethnography. While both methodologies explore the meaning of experiences, phenomenology seeks to uncover the essential structures of individual meaning, whereas ethnography examines cultural patterns of thought and behaviour within a specific group or setting (Osborne, 1994). Ethnography often requires extensive fieldwork over long periods, focusing on cultural knowledge and interactions (Creswell, 2018; Cohen, Morrison and Manion, 2007). While ethnography excels in exploring cultural patterns, its focus on observable behaviours, reliance on prolonged fieldwork and limitations in addressing subjective experiences make it less suitable for studying comfort in radiotherapy.

Finally, a comparison was made between phenomenology and case studies. Case study research involves in-depth exploration of specific cases, events or processes within their natural contexts, using various data collection methods (Yin, 2015; Merriam, 2009). While a case study approach could have offered insights into individual experiences of comfort, it was deemed impractical for this research. Retrospectively identifying patients and the TRs who had treated them presented significant logistical challenges and would not have answered the PhD research objectives.

Ultimately, pragmatically qualitative research was selected as the most appropriate methodological approach. In summary, pragmatically qualitative research is an approach that values practical relevance and flexibility – ensuring that the methods and findings align closely with the specific needs of the problem and the context, such as developing recommendations for a comfort intervention in radiotherapy (Barker and Pistrang, 2021).

Each qualitative research approach has distinct strengths and limitations, making them suitable for different types of research questions and contexts. Grounded theory is ideal for theory development but can be time consuming and complex. Ethnography provides deep cultural insights but requires extensive fieldwork and is subject to researcher bias. Action research promotes practical change and collaboration but is limited in generalisability and can be biased by participant influence. Phenomenological research offers a rich understanding of lived experiences but is difficult to generalise and requires skilled interpretation. Narrative research captures personal stories and identity construction but is subjective and time intensive (Creswell, 2018).

Selecting the appropriate qualitative approach depends on the research goals, the nature of the phenomenon being studied and the research context (Creswell, 2018). Pragmatically qualitative research was deemed the most suitable approach for exploring the concept of comfort in patients undergoing radiotherapy because it prioritises the understanding of lived experiences of individuals in practice. This approach can reveal meaningful insights for patient-centred care or interventions, making it an ideal choice over other methodologies that focus on theory development or social interactions. The intention of this PhD programme was to identify patterns and define comfort or discomfort in rich detail.

3.3.2. Rationale for the use of qualitative interviews

The principal aim of this study was to gain greater understanding of patients' and radiographers' experiences and views of comfort to inform the development of a radiotherapy comfort intervention. The intention was to seek views about comfort experienced during radiotherapy, examples of good and bad practice, challenges to comfort management and the ideal comfort management solutions based on patients' and

TRs' views. Audio-recordings were transcribed verbatim and analysed thematically using the process indicated by Braun and Clarke (2006).

The challenge was seeking a method to explore patient comfort during radiotherapy that provides enough depth at an individual level to inform the development of recommendations for a comfort intervention package situated in the domain of the MRC framework (Skivington et al., 2021). Semi-structured interviews were chosen to explore comfort and how it is best managed after considering other approaches, such as focus groups and surveys (Gomez and Jones, 2010). Focus groups can be conducted with an open, semi-structured or structured interview guide, depending on the research specificity, and may suit exploring comfort in patients and TRs. A focus group was used for consultation with patients in predoctoral research (Goldsworthy, Tuke and Latour, 2016). Patients voiced that comfort was very important to them – providing a foundation to the PhD programme, which sought to capture individual experiences. The findings from the focus group also elucidated group dynamics such as hegemonic masculinity – which could have caused some group members not to be open, leading to comments suggesting a person is 'tougher' than the discomfort experienced (Goldsworthy, Tuke and Latour, 2016; Appleton et al., 2015). There are further group dynamics, such as those participants who may be more vocal than others. Focus groups provide an interchange between groups of people and are useful to hear debate around a topic and are a useful research method in some situations (Gomez and Jones, 2010). A deeper exploration was needed at an individual patient and TR level to tease out the lived experiences and views of comfort, rather than to debate or group experiences from focus groups.

Surveys are very good at collecting data from many self-reporting individuals and can be conducted in various formats, including paper questionnaires, in person and electronically by email or telephone. Surveys can successfully record population characteristics rapidly and may give a very good initial response about a topic, but they can be seen as a snapshot showing a very brief opinion at the moment for the respondent (Hutton *et al.*, 2023). The respondent may change their response half a day later, depending on the question. Surveys are generally analysed using descriptive statistics, although they may include free text questions which can provide data for qualitative analysis. Although the individual method of surveys was favourable to the PhD programme, the depth of qualitative exploration was considered more limited with surveys, although they can be effective as a supplement to interviews (Gomez and Jones, 2010). Therefore, a method with greater depth to explore patients' and TRs' experiences was necessary.

Individual interviews can be conducted as open, semi-structured or structured, similar to focus groups, and provide a suitable means of exploring individual experiences. The choice to utilise semi-structured interviews was based on the need of the PhD programme: to openly explore patients' and TRs' experiences and, at the same time, have

a structured focus on comfort during radiotherapy treatment. However, the use of semistructured interviews is not without criticism. Person-to-person interviews imply that rapport needs to be developed; if not, the interview may be brief and without substance. The dynamic of the PhD researcher as a TR interviewing a patient or a professional colleague could have caused greater or lesser openness to the interview (Garrels, Skåland and Schmid, 2022). Equally, the PhD researcher being male could have impacted the interview dynamic. The plan was to ensure that the interview guide contained open questions so as not to lead participants and were specific to explore comfort during radiotherapy. The PhD researcher conducted pilot interviews and received feedback to develop an open and listening approach to the interviews. One further consideration was whether interviews would be online, face to face or over the telephone, knowing that each has merit. There is much debate about the potential pitfalls of not conducting interviews face to face – one being that one may miss something, although the evidence suggests in person and by telephone provide comparable quality data (Oltmann, 2016). It was decided for pragmatic reasons that patients would be interviewed either in the hospital or in their homes due to the proximity of the PhD researcher, and TRs were interviewed over the telephone due to their physical locations being spread across the UK. Similar instrumentation, such as interview guides and recording devices, were used whether in person or over the telephone.

3.3.3. Sampling and sample frame

Twenty-five patients (Figure 3.2) and 25 TRs (Figure 3.3) were recruited based on the aim of achieving data saturation (Creswell and Poth, 2018). Data saturation is a concept in qualitative research that ensures that the data collected are adequate and sufficient to support comprehensive and meaningful findings (Thorne, 2020). By reaching saturation, the PhD researcher can feel confident he captured the phenomenon under study, making robust and reliable conclusions. It could be considered a throwaway term required to appease a PhD supervisory team, succeed in funding application or get a paper published. However, there is an ongoing debate on what saturation truly means because it seemingly reflects the belief that data saturation was somehow met at a spurious point when no more data could provide new information (Thorne, 2020). Some have regarded data saturation as nebulous and lacking systemisation (Bowen, 2008). Hence, authors such as Sebele-Mpofu (2020) have recommended being clear by narrowing the scope of saturation and to contextualise it within research. For this study, saturation was defined as no new information about comfort or how it is managed, arising from the interviews and concurrent transcribing for each group to a maximum limit of 25. The PhD researcher conducted the interviews, transcribed and thematically analysed the data and determined that data saturation was met at 25 participants when no new data arose (Thorne, 2020).

Purposive sampling was used for both patients and TRs to select specific participant characteristics, such as patients who have cancer and are treated using extended radiotherapy treatment times and by TRs The rationale was to capture the experiences and views of patient comfort and how it is best managed during a radiotherapy treatment session exceeding 10 minutes from the perspectives of patients and TRs. The basis for focusing on treatment sessions exceeding 10 minutes was that discomfort may be exacerbated with prolonged duration laying in the same position. It is also assumed from clinical practice that discomfort may be discreetly different for treatments of different regions of the body (e.g. a patient with head and neck cancer compared to one with prostate cancer; Fletcher, 2007). Therefore, the plan was to recruit participants with cancer at one of the three main anatomical sites (head and neck, breast/lung and pelvis) to ensure heterogeneity of views across the different cancer diagnoses to eventually develop an adaptable comfort intervention package. With a sample size of 25, depending on data saturation, this equated to eight to nine patients recruited for each anatomical cancer region. Additionally, no more than two TRs from the same radiotherapy department were to be recruited. This was to ensure heterogeneity of views and experiences across radiotherapy departments in the UK who will have variations in practice. Patients were recruited from oncology clinics or multidisciplinary team meetings, were given a participant invitation sheet, consented at Day 5 of radiotherapy and were interviewed halfway through radiotherapy treatment, as per Figure 3.2. TRs were recruited via professional forums and conferences, given information by telephone and provide the participant invitation sheet/consent by email and interviewed at a time of their choosing, as per Figure 3.3.



Figure 3.1. Patient study flow chart



Figure 3.2. Therapeutic radiographer study flow chart

Key to figures 3.1 & 3.2: Multidisciplinary team (MDT), Chief investigator (CI), and Health Care and Professions Council (HCPC).

3.3.4. Ethics and governance

The PhD researcher acting as the chief investigator (CI), and the research team applied the principles of safety and well-being in considering participants (MRC, 2012). The PhD researcher carefully considered issues regarding mental and physical harm and informed consent, ensuring that support to patient participants was in place with guidance from the PRPs.

While interviews can be low risk, there could be psychological risks to consider for participants. An interview could trigger an emotion causing potential psychological risk to the patients or TRs being interviewed. While the focus is primarily on the participants, the researcher also needs to ensure to prevent harm both physically and psychologically (Sanjari *et al.*, 2014). The consideration of participant distress has often been overlooked in the planning of research, and then researchers may over- or underreact when presented with a situation (Whitney and Evered, 2022). Therefore, in this PhD programme study, a distress protocol was prepared to protect the safety and well-being of participants and the PhD researcher.

3.3.5. Seeking commonality

The principle of seeking commonality was to ensure that the lived experiences and views of both patients and TRs retained their individual meaning when combined (Allison, 2020; Allais, 2017). There are many publications of how triangulation may be achieved but little on the process of generating commonality (Noyes et al., 2019; Åkerlind, 2012). The PhD researcher sought a well-defined process, a step-by-step guide, but there was a dearth of literature on this topic. The guidance found tended to lean towards advising the researcher to position themselves (Åkerlind, 2012). Åkerlind (2012) suggested the researcher must have an open mind- minimising any predetermined cues that would automatically prompt the researcher to conclude, for example, 'that is a discomfort code' for both patients and TRs. A code is a systematic way to categorise qualitative data leading to the development of themes and patterns. Conversely, the researcher may want to stretch the meaning of a code from the professional experience, and Åkerlind (2012) guided the researcher to have restraint. Åkerlind (2012) suggested flexibility to return to the data to recode or categorise if required. Maintaining focus on the transcripts and emerging categories rather than individual transcripts enabled a view of the groups for their collective experience (Åkerlind, 2012). Remaining open as suggested, the PhD researcher used inspiration from triangulation by Farmer et al. (2006) to create the following steps to achieve commonality:

- Subthemes from patients and TRs were sorted into similarly categorised segments that address the research area of interest to determine areas of content overlap and divergence.
- 2. The essence of the meaning and prominence and coverage of subthemes was explored, seeking similar subthemes in both groups.
- 3. The coverage and specific examples were provided in relation to subthemes, categories and the number of codes noted.
- 4. A commonality assessment was undertaken by viewing complete and partial commonality for each subtheme category which was narratively reviewed, and the number of codes noted. In some cases, it was necessary to review codes or categories against noncorresponding subthemes where there did or did not seem to be a link.
- 5. An overall commonality code was applied to a commonality subtheme. Steps 1–5 were repeated for each subtheme.
- 6. The research team conducted a final review for clarification.

The process defined above could be viewed as borderline idealist, although the principle of understanding the multiple views and realities of participants is situated within an interpretivist reality.

3.4. Stage 3: Recommendations for a radiotherapy comfort intervention package

Stage 3 was an online consensus study of patients' and TRs' perspectives that was the final part of a programme of work to develop recommendations for a comfort intervention package for patients undergoing radiotherapy with extended treatment times. The study aimed to attain consensus with 10 panel members (seven patients and three TRs) to consider the inclusion of and rank the comfort interventions components synthesised from Stages 1 and 2 of this PhD programme. Recruitment was weighted unevenly towards patients to enhance their voice. Details of the methods are presented in published paper presented on Chapter 7. This section focuses on the panel member frame and on ensuring an effective shared decision-making consensus study design.

3.4.1. Panel member frame

The patient and TR participants are known as panel members in the consensus study due to the shared decision-making process. In this section it is important to highlight the necessity of ensuring the panel members represented the stakeholders to which a developed comfort intervention package was applicable.

3.4.1.1. Patient panel members

As stated in <u>Stage 2 (Chapter 2)</u>, it was assumed from clinical practice that discomfort may be discreetly different between, for example, a patient with head and neck cancer and one with prostate cancer. Therefore, the aim was to recruit patients who have had cancer in one of three main anatomical cancer sites (head and neck, breast/lung and pelvis) to ensure heterogeneity of views across the different cancer diagnoses. A potential sample size of seven equates to approximately two patients recruited from each anatomical site. Perez *et al.* (2022) highlighted the challenges to panel member recruitment, specifically the lack of guidance of how to overcome problems. The authors suggested that the challenges can be multifaceted, highlighting that potential patient recruits may consider qualitative research to be time consuming and that reliving past experiences (such as their cancer diagnosis and treatment) may be distressing. It was understood that it would be a challenge in this PhD programme to recruit eligible panel members based on these common challenges.

Furthermore, Daykin *et al.* (2018) argued that the recruitment and retention of participants are likely to be heavily influenced by the researchers undertaking the recruitment, their behaviours and adherence to targets. The PhD researcher and doctoral supervisory team were aware of these challenges; therefore, two practices of the consensus event were conducted with feedback at every stage, including recruitment, consent and conduct of the study. The PhD researcher, with feedback, modified his approach in the mock consensus study to a more casual and approachable form. Although the practice consensus events could be considered a false simulation, the doctoral supervisor feedback was sensible in knowing that panel members may be more open to discussion in a less formal environment.

The PhD researcher was committed to overcoming these potential recruitment challenges by dedicating time to recruit each panel member, giving a balance of information and facilitating an informed decision on whether to participate. Potential patient panel members were given flexible times for consent and pre-consensus training and asked their preference on the consensus study date and time. They were also offered pastoral support before and during the consensus meeting from PRPs and informed they could leave the study at any time if they felt distressed.

3.4.1.2. TR panel members

Issues detailed in the previous section about patients were also applicable to TRs (Daykin *et al.*, 2018). The added complexity for the PhD researcher was that the TRs may know him, meaning that they could have preconceived ideas about him and the topic. Therefore, participants may not even have considered participation in the consensus study. Perez *et al.* (2022) also highlighted that health professionals have their own

resistance to participation, such as the added workload, a lack of interest in the topic and uncertainty about research. The PhD researcher considered the time burden for TRs and therefore requested consent and provided pre-consensus training on a suitable date and time as well as options for the date and time of the consensus study.

A further concern was to ensure heterogeneity of views from TRs and not to recruit from just one radiotherapy department. Therefore, to gain a broad perspective from clinical practice in radiotherapy, the intention was to recruit only one TR per radiotherapy service and not from the PhD researcher's department. Recruiting across the UK with these limits provided a challenge, and as per patient recruitment, plenty of time was front loaded to ensure participation was the right decision. It was also assumed that a sample of three would be straightforward to recruit.

3.4.2. Ensuring an effective shared decision-making consensus study design

Ensuring shared decisions in research consensus meetings is crucial for the generation of meaningful outcomes and avoiding unilateral decisions. The priority for the planned consensus study was to ensure all panels member voices were heard, their decisions counted and they made a difference. A few different types of consensus study were considered to ensure alignment to the ethos of the PhD programme to ensure every voice counted towards shared decision-making.

In a consensus development conference (CDC), all delegates are free to voice their opinion at any time (O'Hara *et al.*, 2017). O'Hara *et al.* (2017) utilised a CDC approach to develop care delivery in young adults with type 1 diabetes in a three-day conference with 18 expert panellists and 110 stakeholders. On Day 1, two surveys were issued to stakeholders with discussion to reach consensus on interventions, modelled on the Delphi technique (DT). On the second day, four keynote speakers presented key topics, and the discussion was qualitatively analysed. On the third day, the expert panel discussed methods to improve the research topic. Finally, four novel approaches were pitched to the expert panel, who chose the winner. In all these steps outlined by O'Hara *et al.* (2017), the group discussion is a useful attribute – although this may lead to the loudest voice being heard and the outcomes based on that unilateral view, which would jeopardise the ethos of the PhD programme. Furthermore, the CDC is not widely published and lacks details on how consensus is met, which precluded it from being used in this PhD programme.

Coproduction meetings were also considered due to the involvement of panel members (Vennik *et al.*, 2016; Voorberg, Bekkers and Tummers, 2015). The ethos of coproduction is to bring professionals and care receivers together to work on important health issues. Although there is support for coproduction, there are criticisms too (Grindell *et al.*, 2022).

A systematic review of coproduction methods discovered many good features in published studies but found that the findings of coproduction were based on the authors' opinions, supplemented with limited supporting evidence (Grindell *et al.*, 2022). These authors stated there is a need for better reporting and more robust methods of evaluation which are transparent and published so readers can ascertain the quality and suitability to their own research (Grindell *et al.*, 2022). A further criticism could be that only the loudest voice is heard similar to the CDC (O'Hara *et al.*, 2017). Coproduction lacks the structure and published details required to consider potentially important interventions to improve comfort and was precluded from this PhD programme.

A DT consensus study uses a series of surveys which are not face to face but are useful to generate ideas and views on an issue. Many respondents are asked to rate specific topics over repeated rounds (Barrett and Heale, 2020). Pitfalls of DT include that different series of surveys tend to be months apart, leading to potential participant attrition, and it lacks the ability to enable discussions of nuances of comfort interventions. The attributes of the DT were deemed potentially useful to the PhD programme, but the lack of discussion meant that DT was precluded as the consensus study design alone.

NGT is a highly structured consensus approach with four rounds to reach consensus on a topic (Mason *et al.*, 2021). This starts with silent generation of ideas. Then a round robin discussion is conducted, and ideas are clarified, followed by voting and ranking with 5–12 panels members in two to three rounds. The NGT seems to have a well-planned formation for consensus but is lacking in details of how voting and ranking methods should be calculated.

The RAND/UCLA Appropriateness Method (RAM) is a hybrid of NGT and DT and is recommended for 7–15 panel members (Fitch *et al.*, 2001). It starts with a foundation of theory from the literature to create an initial list. Panel members then rate the appropriateness, followed by discussion, rerating and then the calculation of a median of ratings (Arakawa and Bader, 2022). This method is extremely systematic and was considered a useful tool to pool the complexity of research data and conclude with comfort intervention components. The PhD researcher aimed for a methodical approach for individual ranking with some open discussion of ranking intervention components; therefore, a modified NGT with RAM was used in this PhD programme based on the following requirements:

- a) To utilise prior work from the early stages of the PhD programme, the SLR and interviews, which is planned to create an initial comfort intervention component list
- b) To hear the voices of patients and TRs in sharing decisions on which interventions proceed using a structured method
- c) For patients and TRs to individually rate and rank potential comfort interventions

d) To be face to face or online as might be required, depending on circumstances

3.4.3. Chapter summary

This chapter described issues associated with the quantitative and qualitative methods of the PhD programme to supplement the information provided in Chapters 4–7. The rationale for specific choices at each stage were presented. A rigorous method was developed for each section – with flexibility to adapt to participant and panel members, considering their well-being and safety, and to meet the objectives of each stage of the PhD programme.

4. Chapter four: SLR of comfort interventions in health and social care practice

4.1. Introduction

The principal aim of this study was to identify comfort interventions that are used for clinical procedures that involve sustained inactivity (e.g. radiotherapy), record the characteristics of the interventions for future practice and determine the effectiveness of the interventions. An SLR followed a rigorous approach of searching and synthesising the retrieved data from comfort interventions used in various clinical procedures similar to radiotherapy. The findings of the review contribute to the current knowledge of what is known about potential comfort interventions that can be used in radiotherapy.

The findings of the systematic review were submitted for publication in *Radiography* and published online on the 31st of March 2020. The PhD researcher was the lead reviewer and worked closely with supervisors and two PRPs to plan, deliver and report this research. This paper is presented as the main body of this chapter, using the last Word version accepted by the journal.

4.2. Published paper: A Systematic Review of Effectiveness of Interventions Applicable to Radiotherapy That Are Administered to Improve Patient Comfort, Increase Patient Compliance, and Reduce Patient Distress or Anxiety

Journal: Radiography

Goldsworthy, S., Palmer, S., Latour, J.M., McNair, H. and Cramp, M. (2020) A systematic review of effectiveness of interventions applicable to radiotherapy that are administered to improve patient comfort, increase patient compliance, and reduce patient distress or anxiety. *Radiography* [online]. 26 (4), pp. 314–324. Available from: <u>https://doi.org/10.1016/j.radi.2020.03.002</u>.

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4.3. Abstract

4.3.1. Objectives

The aim of this review was to search existing literature to identify comfort interventions that can be used to assist an adult patient to undergo complex radiotherapy requiring positional stability for a period greater than 10 minutes. The objectives of this review were to 1) identify comfort interventions used for clinical procedures that involve sustained inactivity similar to radiotherapy, 2) define characteristics of comfort interventions for future practice and 3) determine the effectiveness of the identified comfort interventions. The preferred reporting items for systematic reviews and meta-analyses statement and the TIDieR guide were used.

4.3.2. Key findings

The literature search was performed using the population, intervention, comparison, outcome and studies (PICOS) criteria on five databases (AMED, CINAHL, EMBASE, MEDLINE and PsycINFO), identifying 5,269 titles. After screening, 46 RCTs met the inclusion criteria. Thirteen interventions were reported and grouped into four categories: audiovisual, psychological, physical and other interventions (education/information and aromatherapy). Most aromatherapy, one audiovisual and one educational intervention were judged to be clinically significant for improving patient comfort based on anxiety OMs (effect size \geq 0.4, mean change greater than the minimal importance difference [MID] and low RoB). Medium-to-large effect sizes were reported in many interventions where differences did not exceed the MID for the measure. These interventions were deemed worthy of further investigation.

4.3.3. Conclusion

Several interventions were identified that may improve comfort during radiotherapy, assisting patients to sustain and endure the same position over time. This is crucial for the continual growth of complex radiotherapy requiring comfort to ensure stability for targeted treatment.

4.3.4. Implications for practice

Further investigation of comfort interventions is warranted, including tailoring interventions to patient choice and determining if multiple interventions can be used concurrently to improve effectiveness.

Keywords: Comfort interventions; Radiotherapy; Randomised controlled trial; Systematic review; Clinical significance

4.4. Main text of the paper

4.4.1. Introduction

Patient P&I is crucial for reproducible and accurate delivery of radiotherapy in both radical and palliative settings to ensure tumour control while avoiding healthy tissue toxicity (Folkert and Timmerman, 2017; Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2008). Recent studies have demonstrated that comfort in patients receiving radiotherapy for prostate cancer can be determined by treatment position, and a strong association has been observed between comfortable patient positioning and improved treatment accuracy in patients receiving radiotherapy for breast cancer (Bartlett et al., 2015; Boda-Heggemann et al., 2006). As more complex treatment techniques (such as SABR) become standard and treatment times are extended above 10 minutes, patients' comfort is an important consideration (Goldsworthy, Tuke and Latour, 2016; Bayley et al., 2004). It has also been hypothesised that there is an association between patient comfort and radiotherapy treatment time, and a limitation to technical radiotherapy advancements is managing the patients' tolerability of immobilisation to complete the procedure while achieving comfort (Osztavics and Kirchheiner, 2017; Dawson and Balter, 2004). Hypothetically, not providing a comfort intervention might increase the treatment time in radiotherapy.

To assist with identification and development of suitable comfort interventions, there is a need to consider what patient comfort is and means. Patient comfort is defined holistically as a state of having met the basic human needs for ease, relief and transcendence in four contexts (Kolcaba, 1994, 1992; Kolcaba and Fox, 1991). In radiotherapy procedures the role and purpose of holistic comfort interventions are to make the procedure more tolerable for patients and to ensure compliance, reducing discomfort, anxiety, distress and claustrophobia. Comfort has been explored in a few studies, including a focus group of patients with head and neck cancers receiving radiotherapy (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2008). Their experiences reflected the definition of holistic comfort and indicated that TRs may not fully appreciate their level of discomfort (Kolcaba, 1994, 1992; Kolcaba and Fox, 1991). A survey of 100 patients with head and neck cancers who had received radiotherapy found that a quarter were anxious and that interventions were required, including better patient preparation/education (Nixon et al., 2018). In UK and European guidelines, recommendations on how to manage patient comfort during radiotherapy are limited (Leech et al., 2017; Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2008; Malinowski and Stamler, 2002). Greater evidence of comfort intervention effectiveness is required to inform national radiotherapy practice and guidelines.

Interventions such as communication with professionals and music were reported to reduce distress in up to 86% of patients receiving radiotherapy for head and neck cancers (Nixon *et al.*, 2019). A previous systematic review explored the efficacy of holistic comfort interventions during invasive paediatric nursing procedures, such as venepuncture, port access and intramuscular injection (Bice and Wyatt, 2017). The review grouped comfort interventions into four categories – music, amusement and entertainment, caregiver facilitation and a multifaceted approach – and supported the use of various distraction methods to reduce anxiety, distress, fear and pain during procedures (Rudin *et al.*, 2007). Further studies have investigated interventions ranging from music to self-hypnosis and deep breathing exercises (Hudson and Ogden, 2016; Rudin *et al.*, 2007). Thus, there are promising procedural comfort interventions that may be applicable to radiotherapy. A limited number of interventions have been investigated to manage patient comfort during radiotherapy (Griffiths *et al.*, 2018; Dahele *et al.*, 2012).

The aim of this review was to search existing literature to identify comfort interventions that can be used to support an adult patient to undergo clinical procedures that require a patient to sustain the same position over a period greater than 10 minutes. The current estimated time cutoff set at 10 minutes was used to capture procedures that would replicate the radiotherapy phase after positioning when patients must remain still during pretreatment verification and delivery of treatments such as SABR or palliative radiotherapy. The focus above 10 minutes was set to ensure a breadth of clinical procedures were included that would be more representative of radiotherapy. The objectives of this review were to 1) identify comfort interventions that are used for clinical procedures that involve sustained inactivity similar to radiotherapy, 2) record the characteristics of the comfort interventions for future practice and 3) determine the effectiveness of the comfort interventions.

4.4.2. Methods

4.4.2.1. Protocol and registration

A review protocol was developed and prospectively published in PROSPERO (CRD42017059688) in line with the Centre of Reviews and Dissemination's (2009) guide (<u>Appendix A</u>).

4.4.2.2. Information sources

The review was structured and reported according to the preferred reporting items for systematic reviews and meta-analyses statement and the TIDieR guide (Hoffmann *et al.*, 2014; Liberati *et al.*, 2009).

4.4.2.3. Search

Five databases – AMED, CINAHL, EMBASE, MEDLINE and PsycINFO – were searched to identify relevant text in titles, abstracts and keywords to develop search terms. The literature search used the same databases and refined terms (<u>Appendix B</u>). The search was restricted to title and abstract fields to avoid retrieving nonrelated papers from the subject headings.

Selection criteria for eligible primary research was defined according to the PICOS framework (Huang, Lin and Demner-Fushman, 2006):

(P) Adult patients (≥18 years) undergoing a clinical procedure that required alignment, stabilisation and immobilisation and having to sustain, endure or tolerate the procedure while conscious over a period greater than 10 minutes. Clinical procedures included those where patients must remain stable and unwanted movement is critical. In the surgical and radiotherapy setting, unwanted movement could result in collateral damage – such as the laceration or irradiation of surrounding normal tissue, respectively, and potentially poorer outcomes for patients.

(I) Interventions to aid comfort for, ease, relieve, relax, calm, distract or transcend a patient/service user or alleviate/reduce distress/anxiety immediately before or within a clinical procedure which requires alignment, stabilisation or immobilisation and the patient has to sustain, endure or tolerate the procedure while conscious.

(C) Usual standard of care or comparator (another intervention).

(O) Assessments of patient comfort, psychological well-being, patient satisfaction and quality of life outcomes.

(S) RCTs and controlled clinical trials (CCTs).

Studies published in English between 2000 and January 2019 were included to focus on contemporaneous practice. The searches were initially performed in August 2017 and updated in January 2019. Following the removal of duplicates, two researchers independently reviewed the titles and abstracts initially and then full texts to identify papers that met the eligibility criteria. A consensus meeting was held, and concordance was achieved on 95% of the full texts. A third reviewer arbitrated on inclusion of the remaining 5% (n = 4) of full texts.

4.4.2.4. Data extraction

Data were extracted from each paper by one researcher using a data extraction form based on the TIDieR checklist and guidelines and reviewed by a second researcher

(Hoffmann *et al.*, 2014). The data extraction form included authors, year of publication, study design, setting, participants, clinical procedures, OMs, main outcomes (measured before and after clinical procedure delivery or as a mean change) and delivery characteristics of the comfort interventions.

4.4.2.5. RoB

The Cochrane RoB Checklist (Version 5.1.0) was used to assess the RoB in RCTs (Higgins and Green, 2011). of RoB areas were assessed: random sequence generation, allocation concealment, the blinding of participants and personnel, the blinding of outcome assessment, incomplete outcome data and selective reporting, with each area denoted as a 'low', 'high' or 'unclear' RoB (Higgins and Green, 2011). To reduce the effect of human factors in assessing the RoB, an online software – RoBotReviewer[™], which aims to semiautomate evidence synthesis using machine learning - was used in the review (Marshall et al., 2018; Mathes, Klaßen and Pieper, 2017; Marshall, Kuiper and Wallace, 2016; Armijo-Olivo et al., 2014). International clinical trial registers were accessed to determine selective reporting bias; if not registered, then studies were judged unclear for RoB. For CCTs, the RoB was assessed using ROBINS-I. For this SLR, studies were judged unacceptable if there was a high RoB for random sequence generation and allocation concealment. This is because randomisation is a crucial attribute of well-designed RCTs. Studies judged to have a high risk in one area of selection bias or another RoB component were deemed acceptable but treated with caution and not included in the data synthesis.

4.4.2.6. Data synthesis

Only validated OMs were included in the synthesis and were reported separately for intervention and comparator groups. Where available, the change in OMs from before to after clinical procedures was calculated as mean difference, percentage change, Cohen's D effect size (normalised distribution) or r effect size (nonnormalised distribution) with 95% confidence intervals (Wright *et al.*, 2012; Bothe and Richardson, 2011). Studies were selected for the Cohen's D or r effect size analysis – dependent on whether the data followed a normal distribution, which was confirmed by the reported use of the Kolmogorov–Smirnov or Shapiro–Wilk test for normality or assumed based on the use of parametric tests (Jakobsen *et al.*, 2014; Grissom and Kim, 2012; Altman and Bland, 2011; Rice and Harris, 2005). Where means and SDs were not reported, an estimation from either interquartile range or p-value was calculated (Luo *et al.*, 2018; Wan *et al.*, 2014; Altman and Bland, 2011; Leech and Onwuegbuzie, 2002). A meta-analysis was not conducted because of the clinical heterogeneity in the study populations, healthcare settings, interventions and comparator types.
To determine whether comfort interventions make an important difference to patients, the clinical significance of studies was assessed to supplement statistical significance (Jakobsen *et al.*, 2014; Wright *et al.*, 2012; Bothe and Richardson, 2011). In this review, clinical significance was determined using effect size and the MID. Effect sizes were interpreted using the following criteria: small (≤ 0.4), medium ($\geq 0.5 \leq 0.7$) or large effect (≥ 0.8 ; Rice and Harris, 2005). The MIDs of validated OMs were identified from the literature (Taghizadeh *et al.*, 2019; Corsaletti *et al.*, 2014; Facco *et al.*, 2013; Leentjens *et al.*, 2011). A comfort intervention was considered to demonstrate clinical significance when the effect size exceeded 0.4, mean differences was greater than the MID and RoB was acceptable.

4.4.3. Results

4.4.3.1. Study selection

Database searches initially identified 5,269 titles (Figure 4.1). After removing duplicates (n = 191), 5,078 titles and abstracts were screened, and 4,994 papers were removed, leaving 84 papers for the full review. Of these, 38 papers were excluded for reasons listed in Figure 4.1. One CCT was excluded because it used a parallel crossover design with potential for cross-contamination between intervention and comparator groups. In total 46 papers were included in the review (Ahlander et al., 2018; Eslami et al., 2018; McSherry et al., 2018; Navidian et al., 2018; Packiam et al., 2018; Uğraş et al., 2018; Heidari et al., 2017; Hozumi et al., 2017; Lee et al., 2017; Padam et al., 2017; Shahsavari, Abad and Yekaninejad, 2017; Trambert et al., 2017; Choi et al., 2016; Fang et al., 2016; Ng et al., 2016; Hizli et al., 2015; Hudson, Ogden and Whiteley, 2015; Sobana, Sundar and Dixit, 2015; Xiaolian, Xiaolin and Lan, 2015; Angioli et al., 2014; Kekecs et al., 2014; Walker et al., 2014; Ripley et al., 2014; Wu et al., 2014; Björkman et al., 2013; Jiménez-Jiménez et al., 2013; Rosen et al., 2013; Kola et al., 2013; Shenefelt, 2013; Nilsson, 2012; Snow et al., 2012; Weeks and Nilsson, 2011; Hu et al., 2010; Shabanloei et al., 2010; Nilsson et al., 2009; Drahota et al., 2008; Frank et al., 2007; Argstatter, Haberbosch and Bolay, 2006; Buffum et al., 2006; Schupp et al., 2005; Simmons et al., 2004; Diette et al., 2000; Lang et al., 2000).



Figure 4.1. Flow diagram of the strategy search

4.4.3.2. Study characteristics

The studies included consist of 46 RCTs, with a total of 5,782 patients. The age of participants ranged between 18 and 80 years. The study design of the RCTs included were two-arm parallel, multiple-arm parallel and mixed factorial multiple-/parallel-arm study designs (Ahlander *et al.*, 2018; Eslami *et al.*, 2018; McSherry *et al.*, 2018; Navidian *et al.*, 2018; Packiam *et al.*, 2018; Uğraş *et al.*, 2018; Heidari *et al.*, 2017; Hozumi *et al.*, 2017; Lee *et al.*, 2017; Padam *et al.*, 2017; Shahsavari, Abad and Yekaninejad, 2017; Trambert *et al.*, 2017; Choi *et al.*, 2016; Fang *et al.*, 2016; Ng *et al.*, 2016; Hızlı *et al.*, 2015; Hudson, Ogden and Whiteley, 2015; Sobana, Sundar and Dixit, 2015; Xiaolian, Xiaolin and Lan, 2015; Angioli *et al.*, 2014; Kekecs *et al.*, 2014; Walker *et al.*, 2014; Ripley *et al.*, 2013; Kola *et al.*, 2013; Shenefelt, 2013; Nilsson, 2012; Snow *et al.*, 2012; Weeks and Nilsson, 2011; Hu *et al.*, 2000; Shabanloei *et al.*, 2010; Nilsson *et al.*, 2009; Drahota *et al.*, 2005; Simmons *et al.*, 2004; Diette *et al.*, 2003; Hayes *et al.*, 2003; Chlan *et al.*, 2000; Lang *et al.*, 2000; Appendices C and D).

4.4.3.3. Clinical procedures

Nineteen different clinical procedures were identified. The two most common clinical procedures were observational investigations (n = 14), such as bronchoscopy/hysteroscopy, and interventional radiology (n = 13; <u>Appendix E</u>).

4.4.3.4. OMs

Most studies reported an anxiety OM (n = 44), and 29 studies used the STAI, aligning to psychological well-being. The STAI examines feelings 'at the present moment' and gives a score between 20 and 80, with a higher score indicating greater anxiety levels (Spielberger, 1983). One study used a 6-item short STAI which is stated to be more sensitive to fluctuations in anxiety (Marteau and Bekker, 1992). One study used the Visual Analogue Scale for Anxiety (VAS-A; Facco *et al.*, 2013; Leentjens *et al.*, 2011), and another study used the Beck Anxiety Inventory (BAI) and Hamilton Anxiety Scale (HAS) and nonvalidated numeric rating scales for comfort, satisfaction, willingness to repeat and experience of the environment (Ulusoy, Sahin and Erkmen, 1998). Only validated anxiety measures, including the STAI, VAS-A, BAI and HAS, reported before and after clinical procedures were included in the data synthesis. For the STAI, the MID was set at 10 (Taghizadeh *et al.*, 2019; Corsaletti *et al.*, 2014). The MID was set at 46 for the VAS-A (Facco *et al.*, 2013), 8.8 for the BAI and 8.2 for the HAS (Leentjens *et al.*, 2011).

4.4.3.5. Comfort interventions

Fifteen comfort interventions were identified (<u>Appendix F</u>) and grouped into the four categories (<u>Table 4.1</u>): audiovisual, psychological, physical and other interventions (education/information and aromatherapy). Comfort interventions were delivered before the clinical procedure in 10 studies, during the clinical procedure in 19 studies and both before and during the clinical procedure in 17 studies (<u>Appendix C</u>).

- Audiovisual technology interventions include audio only (n = 20; Ahlander *et al.*, • 2018; Packiam et al., 2018; Uğraş et al., 2018; Lee et al., 2017; Padam et al., 2017; Ng et al., 2016; Hudson, Ogden and Whiteley, 2015; Sobana, Sundar and Dixit, 2015; Angioli et al., 2014; Ripley et al., 2014; Björkman et al., 2013; Jiménez-Jiménez et al., 2013; Nilsson, 2012; Weeks and Nilsson, 2011; Shabanloei et al., 2010; Nilsson et al., 2009; Argstatter, Haberbosch and Bolay, 2006; Buffum et al., 2006; Hayes et al., 2003; Kwekkeboom, 2003; Chlan et al., 2000), audiovisual (n = 6; Navidian *et al.*, 2018; Fang *et al.*, 2016; Hudson, 2015; Xiaolian, Xiaolin and Lan, 2015; Drahota et al., 2008; Diette et al., 2003), virtual reality (n = 2; McSherry et al., 2018; Walker et al., 2014) and visual only (n = 1; Xiaolian, Xiaolin and Lan, 2015). The interventions were used for the purpose of improving (dis)comfort, reducing anxiety, distracting and improving well-being and relaxation. A wide range of music genres were used, ranging from classical to easy listening popular music, chants and nature sounds. The delivery features ranged from music or video players, loudspeakers or earphones to headsets and goggles for virtual reality. Interventions were delivered by professionals and/or self-administered by patients.
- Psychological interventions include breathing techniques (n = 1; Simmons *et al.*, 2004), cognitive behavioural therapy (n = 1; Shenefelt, 2013), distraction (n = 1; Kwekkeboom, 2003), empathetic attention (n = 4; Choi *et al.*, 2016; Hudson, Ogden and Whiteley, 2015; Schupp *et al.*, 2005; Lang *et al.*, 2000) and hypnosis (n = 4; Hızlı *et al.*, 2015; Snow *et al.*, 2012; Schupp *et al.*, 2005; Lang *et al.*, 2000). The interventions were used for the purpose of reducing discomfort, anxiety and pain or improving satisfaction and relaxation. The delivery features ranged from face to face to audio players. Interventions were delivered by therapists or self-administered by patients via audio players.
- Physical interventions include massage (n = 2; Rosen *et al.*, 2013; Simmons *et al.*, 2004), therapeutic touch (n = 1; Frank *et al.*, 2007), reflexology (n = 2; Heidari *et al.*, 2017; Shahsavari, Abad and Yekaninejad, 2017) and stress balls (n = 1; Hudson, Ogden and Whiteley, 2015). The interventions were used for the purpose of reducing discomfort, anxiety, distress and pain or improving satisfaction. The delivery was face to face with professionals.

 Other interventions include education/information (n = 4; Ahlander *et al.*, 2018; Kekecs *et al.*, 2014; Wu *et al.*, 2014; Kola *et al.*, 2013) and aromatherapy (n = 5; Eslami *et al.*, 2018; Hozumi *et al.*, 2017; Shahsavari, Abad and Yekaninejad, 2017; Trambert *et al.*, 2017; Hu *et al.*, 2010). The interventions were used for the purpose of improving experience and satisfaction or reducing anxiety and psychophysiological arousal/parameters. Interventions were delivered by a range of personnel and methods.

Some studies with multiple-arm parallel designs investigated interventions that crossed the above categories (n = 5; Padam *et al.*, 2017; J. Rosen *et al.*, 2013; Argstatter, Haberbosch and Bolay, 2006; Simmons *et al.*, 2004; Kwekkeboom, 2003).

Comfort intervention	Rationale	Materials	Delivery features	Delivered by
	AUDIOVI	SUAL TECHNOLOGY INTER	VENTIONS	
Audio →	 Reduce anxiety, ^{43–48, 55, 60, 64, 66, ^{71–73, 77, 84, 86, 88}, discomfort, ⁴⁸ stress, ⁶¹ pain, ^{42, 60, 64, 71–72, 77} heart rate⁶⁸ and analgesics/anxiolytics⁷¹} Improve satisfaction, ^{48, 60, 74} compliance, ^{48, 82, 92} relaxation, ^{42, 70, 71} comfort, ^{70, 71} well-being⁵⁹ and reactive hyperaemia index⁷⁴ 	 A range of music genres^{42,} 44–48, 55, 60, 61, 64, 68, 70–73, 77, 82 Vedic chants⁷³ Nature sounds Music therapy (meditative, relaxing)^{66, 68, 74, 86} 	 Music player (e.g. CD player/computer)^{44-48, 60, 61, 64, 68, 70-73, 77, 82, 86,} Loudspeaker^{70-72, 82} Earphones^{45-48, 60, 61, 64, 68, 73, 77} Cushion with speaker^{74, 86} Not specified^{42, 55, 68} Most at 50–80 bpm^{42, 44-48, 55, 60, 61, 64, 68, 70-73, 77, 82} 	 Technician⁴² Music therapist⁴⁵ Research nurse⁴⁴ Student nurses⁴⁶ Nurses^{46, 47, 55, 60, 70} Investigators^{48, 55} Physicians^{42, 46} CT technologists⁶⁸ Study personnel⁸⁶ Not specified^{50, 61, 64, 66, 68, 72–74, 77, 82, 84, 88}
Audiovisual →	 Reduce anxiety^{50-53, 60} Reduce pain^{50-52, 60} Improve experience^{52, 53} Improve satisfaction⁵² Tolerate the procedure⁶⁹ 	 Nature sounds, such as a waterfall^{50, 51, 88} Nature scene, such as a mountain stream, tropical beach, general landscape scenery or animation^{50, 51, 69, 88} Videos included documentaries and movies^{60, 88} Comedies, documentaries and panel-based quiz shows Iranian music⁶⁹ 	 Music player (e.g. CD player/computer)^{50, 51, 69} Loudspeaker Earphones^{50–52, 69} Wall or ceiling mounted murals of nature scenes with/without lighting^{50, 51, 53, 69, 80} Video goggles connected to DVD^{52, 53} Wall mounted monitor connected to DVD Projector connected to DVD⁶⁰ 	 Standard clinic staff⁵¹ Nurse^{52, 60} Not specified^{50, 52, 53, 69}
Visual →	Distraction from pain, anxiety, and tolerate procedure ⁸⁸	 Scenery, animation and film⁸⁸ 	 Monitor with DVD player (no sound)⁸⁸ 	Not specified ⁸⁸

Table 4.1. Intervention delivery characteristics

VR →	 Reduce pain⁸⁵ Reduce anxiety⁸⁵ Reduce opioid use⁶⁷ 	Throwing/shooting snowballs at objects by clicking a computer mouse button ^{67, 85}	 Headset goggles, earphones, DVD player and VR system⁶⁷ VR group donned a VR helmet and trackball hand controller⁸⁵ 	 Nurses⁶⁷ Not specified⁸⁵
	PS	SYCHOLOGICAL INTERVENTI	ONS	
Breathing techniques →	Reduce discomfort, pain and anxiety ⁸⁰	 Verbal coaching and slow breathing instructed⁸⁰ 	Face to face ⁸⁰	• Nurses ⁸⁰
Cognitive behavioural therapy →	Improve relaxation ⁷⁹	 Live guided imagery⁷⁹ Recorded guided imagery⁷⁹ 	 Face to face⁷⁹ CD player⁷⁹ 	Trained therapist ⁷⁹
Distraction \rightarrow	Reduce pain and anxiety ⁶⁴	Participant reads a book ⁶⁴	• Book ⁶⁴	Research nurses ⁶⁴
Empathic attention →	 Reduce pain^{60, 76} Reduce anxiety^{49, 60, 76} Improve satisfaction⁶⁰ Reduce discomfort⁶⁵ Reduce adverse effects⁶⁵ 	 Verbal empathy^{49, 65, 76} and touch⁴⁹ Nonverbal attention⁷⁶ Engage in conversation^{60, 76} Attentive listening, perception of control, emotionally neutral and avoidance of negative suggestions⁷⁶ 	 Face to face ^{49, 60, 65, 76} 	 Nurse⁶⁰ Medical student^{65, 76} Psychology graduate^{65, 76} Therapist⁴⁹
Hypnosis →	 Reduce pain^{76, 81} Reduce anxiety^{57, 76, 81} Reduce discomfort and adverse effects⁶⁵ 	Progressive relaxation, visualisation and deep trance ^{57, 65, 81}	 Face to face, 65, 81 Self-hypnosis^{57, 76} 	 Nurse^{65, 76} Medical student^{65, 76} Psychology graduate^{65, 76} Not specified⁵⁷

				Social worker ⁸¹
		PHYSICAL INTERVENTIONS	3	
Massage, therapeutic touch and reflexology→	 Reduce pain^{75,80} Reduce anxiety^{56, 75, 78} Reduce diststress⁵⁴ Reduce discomfort^{54, 80} 	 Massage^{75, 80} 'Energy repatterning' with hand movements over parts of the patient's anatomy (often the torso) where energy field abnormalities are detected⁵⁴ Three reflexology acupressure points for the pituitary gland, heart and solar plexus were stimulated by hand^{56, 78} 	 Face-to-face light finger⁸⁰ and 20-minute effleurage strokes across different parts of the body (massage)⁷⁵ Face-to-face Krieger and Kunz therapeutic touch massage⁵⁴ Face-to-face foot reflexology (both feet) for 10 minutes^{56,78} 	 Nurse⁸⁰ Four trained practitioners⁵⁴ Massage therapist⁷⁵ Reflexologist^{56,78}
Distraction →	Reduce pain and anxiety and improve patient satisfaction ⁶⁰	Stress balls ⁶⁰	Stress balls manipulated during the clinical procedure by the participant ⁶⁰	Self-directed by the patient ⁶⁰
		OTHER INTERVENTIONS		

Education/ information →	 Improve experience⁴³ Reduce anxiety^{62, 87} Reduce psychophysiological arousal⁶³ Increase satisfaction⁸⁷ 	 Participant watches live examination⁶³ Video education/information⁴³ Audio information about the procedure⁶² Instructional accessibility- enhanced multimedia informational education⁸⁷ 	 Monitor screen of examination⁶³ Monitor screen with DVD player^{43, 87} Music player and headphones⁶² Head-mounted display with headphones⁶³ 	 Radiographer⁴³ Research assistant⁶² Nurse^{63, 87}
Aromatherapy →	 Reduce anxiety^{52, 58, 59, 83} Reduce physiology parameters^{59, 78} 	 Lavandula angustifolia Miller and Citrus aurantium L. essences⁵² Lavender oil, grapefruit oil and Osmanthus fragrans + B7 oil for diffusion⁵⁸ Neroli essences were poured on gauze⁵⁹ Essential oils lavender/sandalwood on tab or orange/peppermint on tab⁸³ 	 Participants inhaled aroma from the tissue paper for 20 minutes from a 20 cm distance⁵² Diffuser used⁵⁸ Delivered via handhold nebuliser with oxygen mask which pneumatically pumps the oil into the mask; the oxygen masks were placed on the participants nose to smell for five minutes⁵⁹ Tabs placed on participant gown⁸³ 	 Study researchers⁵² Endoscopist⁵⁸ Nurse⁸³ Not specified^{59, 78}

Note. VR = virtual reality, CT = computed tomography. For the references, please see Goldsworthy, Palmer et al. (2020).

4.4.3.6. Cochrane RoB for included studies

Each of the included RCTs had areas where the RoB was high, low or unclear (Figure 4.2). About 38% of the RCTs had a low overall RoB. A low risk for random sequence generation and concealment was reported in 77% and 32% of studies, respectively. The blinding of professionals or participants to the allocated comfort intervention was reported in 6% of studies, whilst the blinding of outcome assessment was completed in 36%. About 81% of RCTs were judged unclear for selective reporting because the trials were not registered. Three RCTs were deemed unacceptable due to a high risk of selection bias and were not included in the data synthesis (McSherry *et al.*, 2018; Navidian *et al.*, 2018; Hu *et al.*, 2010).



Figure 4.2. Cochrane risk of bias summary of randomised controlled trials (n = 46)

4.4.3.7. Effectiveness of comfort interventions

Only anxiety outcomes were synthesised, as the OMs were validated and reported before and after the clinical procedure (<u>Table 4.2</u>). This result excluded another 17 RCTs (Packiam *et al.*, 2018; Uğraş *et al.*, 2018; Hozumi *et al.*, 2017; Shahsavari, Abad and Yekaninejad, 2017; Choi *et al.*, 2016; Kekecs *et al.*, 2014; Walker *et al.*, 2014; Ripley *et al.*, 2014; Björkman *et al.*, 2013; Jiménez-Jiménez *et al.*, 2013; Shenefelt, 2013; Weeks and Nilsson, 2011; Nilsson *et al.*, 2009; Frank *et al.*, 2007; Argstatter, Haberbosch and Bolay, 2006; Schupp *et al.*, 2005; Lang *et al.*, 2000). A total of 26 RCTs were included in the data synthesis.

Audiovisual technology interventions include studies of just audio (Lee *et al.*, 2017; Padam *et al.*, 2017; Ng *et al.*, 2016; Hudson, Ogden and Whiteley, 2015; Sobana, Sundar and Dixit, 2015; Xiaolian, Xiaolin and Lan, 2015; Angioli *et al.*, 2014; Nilsson, 2012; Buffum *et al.*, 2006; Diette *et al.*, 2003; Hayes *et al.*, 2003; Kwekkeboom, 2003; Chlan *et al.*, 2000), audiovisual (Fang *et al.*, 2016; Hudson, Ogden and Whiteley, 2015; Drahota *et* *al.*, 2008; Diette *et al.*, 2003) and just visual (Xiaolian, Xiaolin and Lan, 2015) interventions with data available for synthesis.

- Audio: Six out of 11 studies of audio interventions reported statistical significance favouring the intervention (p < 0.05; Padam *et al.*, 2017; Hudson, Ogden and Whiteley, 2015; Angioli *et al.*, 2014; Buffum *et al.*, 2006; Hayes *et al.*, 2003). The mean difference in anxiety exceeded the MID in one intervention and, with a medium effect size, was judged clinically significant (Nilsson, 2012). Medium-to-large effect sizes were observed in all 11 studies.
- Audiovisual: Three out of four audiovisual interventions studies reported statistically significance favouring the intervention (p < 0.05; Fang *et al.*, 2016; Hudson, Ogden and Whiteley, 2015; Drahota *et al.*, 2008). The mean difference in anxiety exceeded the MID in two studies (Drahota *et al.*, 2008; Diette *et al.*, 2003); one had a small effect size (Drahota *et al.*, 2008) and one favoured the comparator group (Diette *et al.*, 2003). Medium-to-large effect sizes were observed in all other studies (Fang *et al.*, 2016; Hudson, Ogden and Whiteley, 2015; Drahota *et al.*, 2008; Simmons *et al.*, 2004; Diette *et al.*, 2003).
- Visual: One visual intervention study favoured the intervention statistically (p < 0.05; Xiaolian, Xiaolin and Lan, 2015). The mean difference in anxiety did not exceed the MID but had a large effect size (Xiaolian, Xiaolin and Lan, 2015).

Only one study investigating music interventions was deemed clinically significant (Nilsson, 2012).

Psychological interventions with data available for synthesis included distraction (Kwekkeboom, 2003), empathetic attention (Hudson, Ogden and Whiteley, 2015) and hypnosis interventions (Hızlı *et al.*, 2015; Snow *et al.*, 2012).

- **Distraction:** One study did not show a statistically significant effect for distraction intervention (Kwekkeboom, 2003). The mean difference in anxiety did not exceed the MID, and the effect size favoured the comparator group.
- Empathetic attention: One study reported statistical significance favouring the intervention (p < 0.05; Hudson, Ogden and Whiteley, 2015). The mean difference in anxiety did not exceed the MID, and while it had a large effect size, it was deemed not clinically significant.
- **Hypnosis:** Two studies reported statistical significance favouring hypnosis interventions (p < 0.05; Hızlı *et al.*, 2015; Snow *et al.*, 2012). Both had large effect sizes, but the mean difference in anxiety did not exceed the MID in either study.

No intervention in this category was considered clinically significant.

Physical interventions were used in three studies with data available for synthesis and involved physical touch: reflexology (Rosen *et al.*, 2013), massage (Rosen *et al.*, 2013) and stress balls (Hudson, Ogden and Whiteley, 2015). Two out of three studies reported statistical significance favouring the intervention (p < 0.05; Heidari *et al.*, 2017; Hudson, Ogden and Whiteley, 2015). The mean difference in anxiety exceeded the MID in one study (Rosen *et al.*, 2013), with large effect sizes in the other two (Heidari *et al.*, 2017; Hudson, Ogden and Whiteley, 2015). None of the physical interventions were judged clinically significant (Heidari *et al.*, 2017; Hudson, Ogden and Whiteley, 2015). None of the physical interventions were judged clinically significant (Heidari *et al.*, 2017; Hudson, Ogden and Whiteley, 2015).

Other intervention studies with data available for synthesis involved education/information (Trambert *et al.*, 2017; Kola *et al.*, 2013) and aromatherapy (Eslami *et al.*, 2018; Trambert *et al.*, 2017) interventions.

- Education/information: Three studies evaluated the effects of education/information interventions (Ahlander *et al.*, 2018; Wu *et al.*, 2014; Kola *et al.*, 2013). After the clinical procedure, one study reported statistical significance favouring the intervention (p < 0.05; Kola *et al.*, 2013). The mean difference in anxiety did not exceed the MID in two studies (Ahlander *et al.*, 2018; Kola *et al.*, 2013), and small-to-large effects sizes favouring the comparator were observed. One study investigating a multimedia information and instruction intervention was deemed to be clinically significant (Wu *et al.*, 2014).
- Aromatherapy: Two studies evaluated the effects of essential oil interventions with different diffusion methods (Eslami *et al.*, 2018; Trambert *et al.*, 2017). One study reported statistical significance favouring the intervention (p < 0.05; Eslami *et al.*, 2018), and the other did not (Trambert *et al.*, 2017). The mean difference in anxiety exceeded the MID in both studies. Medium-to-large effect sizes were observed in both studies and deemed clinically significant. These two studies investigating *Lavandula angustifolia*, *Citrus aurantium* L., lavender-sandalwood and orange-peppermint aromatherapy were deemed clinically significant.

	Comfort	Outcon	ne measure	Mean dif Before-a procedu	fter clin			Mean - difference	% difference		Clinically
Source	intervention Category	Туре	MID	Intervent group Mean difference	t ion ≥MID	Comparat group Mean difference	or ≥MID	between groups	between groups	Effect size with CI (95%)	significant intervention
Angioli <i>et al.</i> (2014)		STAI	10	3.4	Х	1.1	Х	2.2	66%	4.2 (3.8 to 4.5)	No
Buffum <i>et al.</i> (2006)		STAI	10	3.4	х	1.1	Х	2.2	66%	4.1 (3.5 to 4.6)	No
Chlan <i>et al.</i> (2000)		STAI	10	2.4	х	-1.6	Х	4.0	167%	0.7 (0.2 to 1.2) *	No
Hayes <i>et al.</i> (2003)		STAI	10	4.4	х	1.5	Х	2.9	66%	1.2 (0.9 to 1.5)	No
Hudson <i>et al.</i> (2015) (music)	Audiovisual	STAI	10	0.0	х	-2.3	Х	2.3	102%	1.3 (1.0 to 17)	No
Kwekkeboom <i>et</i> <i>al.</i> (2003)	technology interventions	STAI	10	4.1	Х	7.0	Х	-2.9	-71%	-5.0 (-3.8 to -6.2)	No
Lee et al. (2017)		STAI	10	5.3	Х	-0.7	Х	5.9	88%	5.6 (4.6 to 6.6)	No
Ng <i>et al.</i> (2016)		STAI	10	2.0	Х	1.2	Х	0.8	41%	0.6 (0.3 to 0.9)	No
Nilsson <i>et al.</i> (2009)		Short STAI	10	14.7	\checkmark	14.3	\checkmark	0.4	2%	0.5 (0.5 to 0.5)*	Yes
Padam et al.	•••	STAI	10	1.9	_	1.4	Х	0.5	26%	0.4 (0.0 to 0.7)	No
(2017)		STAI	10	3.8	Х	1.4	Х	2.4	63%	2.6 (2.1 to 3.1)	No
Shabanloei <i>et al.</i> (2010)		STAI	10	9.7	х	5.8	Х	3.9	40%	3.6 (2.9 to 4.3)	No
Sobana <i>et al.</i> (2015)		Short STAI	10	6.1	Х	0.1	Х	6.1	99%	2.0 (2.6 to 1.3)	No

Table 4.2. Clinical significance of interventions before and after clinical procedures

	Comfort	Outcom	e measure	Mean dif Before-a procedur	fter clin			Mean difference	% difference		Clinically
Source	intervention Category	Туре	MID	Intervent group Mean difference	ion ≥MID	Comparate group Mean difference	or ≥MID	between groups	between groups	Effect size with CI (95%)	significant intervention
Diette <i>et al.</i> (2003)	_	STAI	10	13.5	\checkmark	12.0	\checkmark	1.5	11%	-1.8 (-1.3 to -2.4)	No
Drahota <i>et al.</i> (2008)	u	STAI	10	13.5	\checkmark	12.0	\checkmark	1.5	11%	0.2 (-0.3 to 0.6)*	No
Fang <i>et al.</i> (2016)		STAI	10	6.1	Х	0.1	Х	6.1	99%	2.0 (2.5 to 1.5)	No
Hudson <i>et al.</i> (2015) (DVD)		STAI	10	2.3	Х	-2.3	х	4.6	199%	3.3 (3.8 to 2.8)	No
Xiaolian <i>et al.</i>		STAI	10	5.0	Х	4.1	Х	0.8	17%	0.7 (0.3 to 1.0)	No
(2015)		STAI	10	2.5	Х	-2.3	Х	4.7	7%	3.3 (3.8 to 2.8)	No
$H_{\rm rel}$ at $a/(2015)$		BAI	8.8	3.0	Х	-1.9	Х	4.8	38%	0.9 (0.6 to 1.2)*	No
Hızlı <i>et al.</i> (2015)		HAS	8.2	4.6	Х	-2.8	Х	7.4	40%	0.9 (0.6 to 1.3)	No
Snow <i>et al.</i> (2012)	Psychological	VAS-A (0–100 mm)	46	22.0	X	13.0	x	9.0	41%	0.7 (1.2 to 0.3)	No
Kwekkeboom <i>et al.</i> (2003)	interventions	STAI	10	6.3	Х	7.0	Х	0.7	11%	-1.2 (-0.5 to -1.9)	No
Hudson <i>et al.</i> (2015)	·	STAI	10	2.5	Х	-2.3	Х	4.7	193%	3.3 (3.8 to 2.8)	No
Heidaria <i>et al.</i> (2017)	Physical	STAI	10	4.4	Х	1.5	Х	2.9	66%	1.0 (0.9 to 1.0)*	No
J. Rosen <i>et al.</i>	interventions	STAI	10	6.5	Х	8.6	Х	-2.1	-32%	-0.2 (0.5 to -0.9)	No
(2013)		STAI	10	12.1	\checkmark	9.5	Х	2.6	21%	0.2 (0.9 to -0.4)	No

	Comfort	Outcom	ne measure	Mean diff Before-at procedur	after clin			Mean – difference	% difference		Clinically
Source	intervention Category	Туре	MID	Intervent group Mean difference	i tion ≥MID	Comparate group Mean difference	t or ≥MID	between groups	between groups	Effect size with CI (95%)	significant intervention
Hudson <i>et al.</i> (2015)		STAI	10	3.0	х	-2.3	х	5.3	176%	2.4 (2.8 to 1.9)	No
Ahlander <i>et al.</i> (2018)		STAI	10	6.5	Х	1.1	Х	5.4	83%	-1.0 (-1.4 to -0.6)	No
			10	-4.0	Х	4.5	Х	-8.5	212%	1.0 (−1.2 to −0.7)*	No
Kola <i>et al.</i> (2013)	Other:	STAI	10	6.2	Х	3.5	Х	2.7	44%	0.4 (-0.3 to 1.1)*	No
	Education/		10	-6.2	Х	4.5	Х	-10.7	-173%	−1.0 (−1.3 to −0.5)*	No
	information		10	4.1	Х	3.9	Х	0.1	3%	0.0 (-0.3 to 0.4)*	No
Wu <i>et al.</i> (2014)		STAI	10	16.3	\checkmark	10.2	\checkmark	6.2	38%	0.9 (0.6 to 1.2)*	Yes
	<u> </u>			13.5	\checkmark	10.2	\checkmark	3.3	25%	0.5 (0.0 to 1.0)*	Yes
Eslami <i>et al.</i>		STAI	10	12.8	\checkmark	-1.0	Х	13.8	92%	5.9 (4.7 to 7.1)	Yes
(2018)		STAI	10	13.7	\checkmark	-1.0	Х	14.7	93%	9.0 (4.7 to 10.7)	Yes
Hu <i>et al.</i> (2010)	Other: Aromatherapy	STAI	10	11.0	\checkmark	7.1	Х	3.9	35%	0.3 (−2.6 to 2.1)*	No
Trambert <i>et al.</i>	Alonationapy	STAI	10	14.2	\checkmark	2.9	Х	11.3	79%	0.5 (-2.4 to 3.3)*	Yes
(2014)		STAI	10	6.5	Х	2.9	X	3.6	55%	0.2 (-2.8 to 3.1)*	No

Note. Confidence Interval (CI), Minimal important difference (MID), Stait trait anxiety index (STAI), Hamilton anxiety index (HAS), Beck anxiety index (BAI), Anxiety visual analogue scale (VAS -A).

4.4.4. Discussion

The aim of this review was to identify effective comfort interventions to support patients undergoing clinical procedures that require the patient to sustain the same position over a period greater than 10 minutes. Thirteen comfort interventions were identified, which ranged from aromatherapy to virtual reality delivered before and during 19 different clinical procedures in 46 studies. Anxiety outcomes were synthesised, as the OMs were validated and reported before and after clinical procedure in 26 studies.

The findings of the review indicate that many comfort interventions produced statistically significant improvement in anxiety outcomes but did not demonstrate clinical significance as defined for this study. Aromatherapy used in colonoscopy, interventional radiology and minor surgery demonstrated both statistical and clinical significance and could be used in radiotherapy with careful consideration (Eslami et al., 2018; Trambert et al., 2017; Hu et al., 2010). Aromatherapy using vaporising systems may be contraindicated because of the potential for skin irritation or allergies linked to radiation-induced skin toxicity or the risk of vapour damage to radiotherapy equipment. A clothing tab infused with aromatherapy oils found to be favourable in previous clinical trials (Atwal, Hayes and Nanalal, 2016) may be more appropriate in radiotherapy. Audio and audiovisual interventions demonstrated medium-to-large effect sizes, with several indicating clinical significance that warrant further investigation in radiotherapy (McSherry et al., 2018; Padam et al., 2017; Fang et al., 2016; Ng et al., 2016; Hudson, Ogden and Whiteley, 2015; Sobana, Sundar and Dixit, 2015; Xiaolian, Xiaolin and Lan, 2015; Angioli et al., 2014; Nilsson, 2012; Shabanloei et al., 2010; Drahota et al., 2008; Buffum et al., 2006; Hayes et al., 2003; Chlan et al., 2000). Several radiotherapy departments have audiovisual technology available to support their patients, and audio interventions have been successfully tested in radiotherapy. For example, Chlan et al. (2000) reported that music therapy reduced pre-radiotherapy anxiety only but did not focus on the effect during the clinical procedure and, hence, was not included in this review. Audio interventions may be contraindicated in radiotherapy at times where constant communication between radiographers and patients is required. such as verbal instructions to patients on performing deep inspiration breath hold or where an audio device (such as earphones or audio pillows) attenuates the radiation beam. Devices may be impractical due to an immobilisation mask. Visual interventions may not be so easily accommodated during some radiotherapy techniques, but some interventions (such as decorative wall colour or murals) may be a pragmatic option.

Three psychological and two physical interventions provided immediately before or during the clinical procedure demonstrated medium-to-large effect sizes (Hızlı *et al.*, 2015; Hudson, Ogden and Whiteley, 2015; Snow *et al.*, 2012). Psychological interventions provided as part of radiotherapy preparation have been studied, and cognitive behavioural

therapy and hypnosis have been indicated to significantly (p = 0.0035) improve the general experiences of patients with breast cancer (Schnur *et al.*, 2009) and likewise was not included in this review. Similarly, massage provided during a course of radiotherapy treatment reduced anger, anxiety and depression in patients with breast cancer receiving radiotherapy (p < 0.001; Darabpour, Kheirkhah and Ghasemi, 2016). This review focused on interventions that could be delivered within radiotherapy sessions. Psychological interventions could be readily adopted if self-administered using an audio player. Empathetic interventions encouraging social interaction could be challenging to deliver. However, Gibon *et al.* (2013) found that patient-orientated communication skills training for a radiotherapy multidisciplinary team resulted in significantly more empathetic interactions (p = 0.037).

Distraction using physical devices such as stress balls could be implemented with care taken not to disrupt the desired position for accurate radiotherapy. One intervention providing educational information via DVD demonstrated clinical significance and could be implemented in a radiotherapy department (Wu *et al.*, 2014). These interventions could also be applicable to clinical procedures – including brachytherapy, where there is a need to develop nonpharmacological interventions (Humphrey, Bennett and Cramp, 2018), and paediatric radiotherapy, where general anaesthesia could be reduced (O'Callaghan, Sexton and Wheeler, 2007).

One gap observed from the studies is the effect of combining interventions as a 'comfort package' to enhance effectiveness. Simmons *et al.* (2004) investigated four interventions to support patients undergoing cataract surgery, finding favourable results for combined interventions. Similarly, a systematic review by Bice and Wyatt (2017) found statistically significant differences favouring multifaceted (more than one intervention) interventions in most studies reviewed. Further research investigating a comfort intervention package (multiple interventions) may provide greater effectiveness for patients during radiotherapy treatment.

Some methodological aspects of the SLR and reviewed studies warrant further consideration. First, anxiety OMs may not be the most suitable measure of comfort. The current review included studies with interventions that aimed to comfort, alleviate or reduce the discomfort, anxiety and distress of clinical procedures. Comfort can be viewed holistically within physical, sociocultural, psychospiritual and environmental contexts that are not reflected in anxiety measures. There are limited comfort Oms; however, the recently validated Radiotherapy Experience Questionnaire could be considered for measuring comfort in radiotherapy (Olausson *et al.*, 2017). Going forward, the use of comfort OMs within all specialties is required for generating new evidence and confirming treatment effects of comfort interventions.

For the purposes of this review, the clinical significance of the anxiety measures was demonstrated with a medium or above effect size (\geq 0.4) and mean differences greater than the MID. However, the availability of information about MID specific to the OMs reported in this review was limited. The MID level of 10 for the STAI was based on a population of smokers; in a nonsmoking population, the MID may be higher or lower (Taghizadeh *et al.*, 2019). Similarly, the MIDs for the BAI and HAS were based on a sample of patients with Parkinson's (Leentjens *et al.*, 2011). Further work is required for MID development in appropriate populations to assist with determining clinically effective interventions.

The research quality of the reviewed studies was an issue, and a meta-analysis was not conducted due to this factor and because of the challenges of defining the nuances of comfort, clinical procedures and interventions. Eight RCTs were deemed unacceptable due to a high risk of selection bias and were not included in the data synthesis. Many studies were not registered in an international clinical trial register, which affected the assessment of selective reporting; these studies were therefore judged as having an unclear RoB. Although there were some methodological challenges, a rigorous review process was followed, and a semi-automated machine learning programme, RoBotReviewer[™] (Marshall *et al.*, 2018; Marshall, Kuiper and Wallace, 2016), was used for Cochrane RoB to increase the rigour of this review by reducing the impact of human factors during data extraction. Combining the use of semi-automated extraction with manual assessment was useful, and future reviews should consider using machine or deep learning systems to improve the rigour and quality of data extraction (Goswami *et al.*, 2019).

To our knowledge, this is the first systematic review that could support the further investigation of comfort interventions in radiotherapy. Given the limited recommendation of how to manage patient comfort during radiotherapy from national and European guidelines (Leech *et al.*, 2017; Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2008), the findings of this review and further investigation of comfort interventions will provide the evidence required for future guidelines. Given the perpetual increase in new effective treatment options and technology available in radiotherapy, it is essential that the radiotherapy community embraces and implements comfort interventions that ensure the best outcomes for patients.

4.4.5. Conclusion

Most aromatherapy interventions reviewed were clinically significant, but they can be potentially considered for radiotherapy that requires patients to sustain and endure the same position over time similar to these clinical procedures. There is limited evidence for other comfort interventions – although most effect sizes favour the interventions, suggesting important benefit to patients. Further investigation of these comfort interventions is warranted, including tailoring interventions to patient choice and determining if multiple interventions can be used concurrently to improve their effectiveness. This is crucial for complex radiotherapy that necessitates more demand and attention to patient comfort to ensure stability for targeted treatment.

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4.4.7. Funding

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4.4.8. Disclosures

The authors declare that there is no conflict of interest.

4.5. Chapter summary

In this chapter, the characteristics of comfort interventions applicable to radiotherapy are given, along with their effectiveness. Thirteen interventions were identified and grouped into four categories which have great potential to comfort patients during radiotherapy. Four interventions from two categories were considered clinically significant, although many were recommended for further investigation. Kolcaba's (1994) conceptual framework of patient comfort in nursing care was critical in developing a deeper understanding of the findings within Stage 1 of this PhD programme, especially the comfort intervention categories (Wilson and Kolcaba, 2004).

5. Chapter five: Experiences of comfort during radiotherapy

5.1. Introduction

The principal objectives of this study were to explore patient experiences of comfort and how comfort is best managed (solutions) during radiotherapy through interviews with patients and TRs. This qualitative study used semi-structured interviews and followed a rigorous approach to thematic analysis. It extends the current knowledge about the experiences of comfort and provides a foundation for improving comfort for patients with cancer receiving radiotherapy.

The findings of the experiences of patients and TRs were submitted for publication in *Radiography* and published on the 24th of February 2023. The PhD researcher was the CI, leading the design of the research and ethics and governance process, conducting the interviews and analysis and reporting the findings. He worked closely with supervisors and two PRPs. This paper is presented as the main body of this chapter by using the last Word version accepted by the journal.

5.2. Published paper: Patient and Therapeutic Radiographer Experiences of Comfort During the Radiotherapy Pathway: A Qualitative Study

Journal: Radiography

Goldsworthy, S., Latour, J.M., Palmer, S., McNair, H.A. and Cramp, M. (2023b) Patient and therapeutic radiographer experiences of comfort during the radiotherapy pathway: a qualitative study. *Radiography* [online]. 29, pp. S24–S31. Available from: https://doi.org/10.1016/j.radi.2023.02.011.

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5.3. Abstract

5.3.1. Introduction

There is little research regarding the experiences of patient comfort and how it is best managed in radiotherapy. The aim of this study was to explore the experiences of patients and TRs' views of comfort during radiotherapy.

5.3.2. Methods

This qualitative study involved semi-structured interviews with patients with cancer (n = 25) and TRs (n = 25) conducted between January and July 2019. Patients were recruited from one radiotherapy clinic and TRs were recruited from across the UK via specialist interest groups and social media. Interviews were audio recorded and transcribed verbatim. Thematic analysis was used to analyse the data separately between both groups and shared themes were identified.

5.3.3. Results

Four themes were identified, of which two themes were shared among both the patients and TRs. Emotional Health was a shared theme highlighting experiences such as stress, vulnerability and privacy. The second shared theme, P&I Experiences, concerned how patients' experience being physically positioned and immobilised for accurate radiotherapy. The theme Information and Communication Experience was derived from patients highlighting concerns over the sharing and provision of information and ways of communication. The last theme, Environmental Experience, emerged from the patient interviews and related to the first impressions of the radiotherapy environment such as reception or treatment rooms and how this effects the overall feelings of comfort.

5.3.4. Conclusion

This qualitative study has provided the shared voice of patients and TRs and their experiences of comfort during radiotherapy. These shared experiences emphasise the importance of considering comfort holistically and not just from a physical context. This information can be used by TRs to better understand their patients' experiences and needs to provide better comfort during radiotherapy to improve patient outcomes.

5.3.5. Implications for practice

The clinical implications of our study can encourage TRs to provide holistic care for their patients throughout the radiotherapy pathway and specifically to comfort patients while they are having treatment. In the short term, this could be via simple adaptions to practice,

while in the long term, research is needed to develop comfort interventions for patients receiving radiotherapy.

5.4. Main text of the paper

5.4.1. Introduction

Recent advances in radiotherapy delivery have led to greater treatment accuracy, with improved targeting and avoidance of toxicities (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). SABR, extreme hypofractionation, 4D approaches and online adaptive approaches have improved survival, quality of care and treatment availability (Wilson *et al.*, 2020). However, most of these advances have increased treatment times, which may have a negative impact on patient comfort and treatment accuracy because patients need to maintain a set position for longer (Hoogeman *et al.*, 2008). International radiotherapy guidelines specify that patients should be in a stable and reproducible position for a treatment course but provide limited details on patient experiences or guidance for practice (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021; De Ruysscher *et al.*, 2017; Solberg *et al.*, 2012; Benedict *et al.*, 2010). The evidence base for patient comfort during radiotherapy is increasing, but further research on a wider range of cancers is required to guide TRs in treating patients (Probst *et al.*, 2021; Nixon *et al.*, 2018; Goldsworthy, Tuke and Latour, 2016).

TRs have commonly used rigid P&I devices to hold patients in position for accurate radiotherapy treatment. Comfortable positioning might increase treatment accuracy (Hubie et al., 2017; Bartlett et al., 2015; Li et al., 2011; Wang et al., 2010; Grills et al., 2008; Bayley et al., 2004). To date, investigations have used nonvalidated patient-reported scales to assess comfort and evaluated treatment accuracy using geometric measurements of verification imaging. In a crossover study comparing a conventional treatment system to a customised pelvic immobilisation system and using 2D planar imaging to verify accuracy, the treatment accuracy was reported to be similar between groups (Nutting et al., 2000). Although the authors suggested that comfort had improved, the TRs believed patients were more comfortable using the pelvic immobilisation system rather than the conventional system. Bayley et al. (2004) randomised patients between supine and prone positioning for prostate cancer treatment and observed a better median patient comfort score for supine compared to prone. Later research by Bartlett et al. (2015) identified that an improvement in patient comfort using a supine position coincided with a significant improvement in treatment accuracy in patients undergoing breath-hold radiotherapy for breast cancer. These studies demonstrate there is a need to explore

patient comfort in radiotherapy to generate a better understanding prior to developing interventions to improve comfort.

The shift towards exploring comfortable positioning has led to studies of patient experiences using qualitative methodologies. Two qualitative studies explored the experiences in patients with head and neck cancers (Nixon et al., 2018; Goldsworthy, Tuke and Latour, 2016). A focus group study involving such patients identified that comfort was important for them. The three themes that emerged were the physical comfort of wearing a mask, passivity of doing what they were asked to do and mental perception of how comfort was perceived and felt differently (Goldsworthy, Tuke and Latour, 2016). An interview study performed by Nixon et al. (2018) identified two themes: 'vulnerability' of feeling exposed in radiotherapy and 'response to experience', which is either the psychological or physical response to the experience of wearing a mask. Although these studies focused on patients with head and neck cancers, it is possible that similar themes could feature in patients with cancers in other anatomical sites. A framework analysis from a workshop for patients with breast cancer receiving radiotherapy identified experiences such as misinformation, issues of modesty, the impact of side effects and emotional experiences (Probst et al., 2021). These studies demonstrate the relevance of further exploring comfort across different anatomical sites. Therefore, the aim of this study was to explore patient and TR experiences of comfort during radiotherapy.

5.4.2. Methods

A qualitative study using semi-structured interviews with patients and TRs was conducted. The research team consisted of five researchers (SG, JML, SP, HM and MC) and two PRPs. The PRPs contributed throughout the study, including reviewing study materials, piloting the interview schedules and discussing the findings to ensure that they reflected patient experiences.

Ethical approval was granted by the Berkshire B NHS Research Ethics Committee (Appendix G) in January 2019, and the protocol was prospectively registered (www.clinicaltrials.gov; NCT03984435]. Patients and TRs gave written informed consent, and interviews were conducted between January 2019 and July 2019. This study is reported in accordance with to the Consolidated Criteria for Reporting Qualitative research (COREQ) checklist (Tong, Sainsbury and Craig, 2007).

5.4.2.1. Patient participants

Participants were recruited via a radiotherapy department in the southwest of England. They were identified and screened for eligibility from a radiotherapy clinic list, and invitations to participate were sent to eligible patients. Participants had to be 18 years or older, have been diagnosed with cancer at one of the three major anatomical sites (head and neck, breast/lung or pelvis) and have received radiotherapy within the last three months, with a treatment time exceeding 10 minutes to encompass patients who need to hold position for a longer time. Purposive sampling was used to reach maximum variation across the three major anatomical sites to ensure heterogeneity of views across the different treatment experiences (Fletcher, 2007). The proposal was to recruit up to 25 patients, depending on data saturation, with eight to nine patients recruited from the three anatomical regions (Yin, 2015; Creswell, Creswell, 2014).

5.4.2.2. TR participants

Participants were recruited across the UK mainly via social media (Twitter and LinkedIn). A hand-out leaflet of the study was distributed at two conferences and electronic advertisement were distributed to specialist interest groups. Responding participants were sent invitations to participate and eligibility was assessed via an online form prior to electronic consent. Participants had to be practising TRs (Health and Care Professions Council [HCPC] Register check) and delivering radiotherapy techniques with times exceeding 10 minutes. No more than two TRs from the same radiotherapy clinic were recruited to ensure heterogeneity of views and practices. A sample size of 25 was set for TRs, depending on data saturation (Yin, 2015; Creswell, Creswell, 2014).

5.4.2.3. Procedure

Semi-structured interview guides for the patients and TRs (<u>Appendix H</u>) were developed using the existing literature. The interview guides were tested in two pilot interviews with two volunteer patients and two TRs. Minor textual changes for the probing questions were suggested and amended. The final interview guide was approved by the research team. The lead researcher (SG) conducted all the interviews and was unknown to patient participants. The lead researcher was known to some of the TR participants due to the specialised nature of the work.

Patients were interviewed at a place and time of their choosing, either in the hospital or in their homes. This was planned midway during radiotherapy or within three months of completing treatment to ensure patients were able to recall their experiences of comfort, aiming to limit the effect of patient recall bias (Sedgwick, 2014). TRs were interviewed via telephone at the time of their choosing. Interviews were audio recorded and transcribed verbatim by the lead researcher.

5.4.2.4. Data analysis

Thematic analysis was conducted using NVivo, focusing on the exploration of comfort experiences during radiotherapy from the experiences of patients and TRs. The six steps of thematic analysis were followed as described by Braun and Clarke (2006). The steps include familiarising with the data, generating initial codes, searching for themes, reviewing themes, defining the themes and executing the write-up.

Transcripts of patients and TRs were analysed separately initially and then synthesised. Themes and subthemes arising from patient and TR interviews underwent a process of synthesis to identify shared themes and subthemes (Farmer *et al.*, 2006). This was assessed by first reviewing and aggregating codes, subthemes and themes.

Trustworthiness and credibility were acquired through peer reviews and debriefings with an independent TR researcher and PRPs. The researchers aimed to establish the codes' similarities, differences and relevance to the phenomenon under study (comfort). Dependability was established by maintaining consistency in data collection and analysis process over the duration of the study (Graneheim and Lundman, 2004; Guba *et al.*, 1982).

5.4.3. Findings

5.4.3.1. Participant characteristics

In total, 34 patients were approached, with nine declining. Twenty-five patients provided written informed consent and were interviewed (Table 5.1). The age range of the patients was 33–84 years, with an even distribution of gender (female, n = 12; male, n = 13). Anatomical cancer site was evenly distributed: head and neck (32%), breast/lung (36%) and pelvis (32%). For TRs, 30 responded, and 25 agreed to participate and provided written informed consent (Table 5.2). The age range of the TRs was 23–50 years, with an uneven distribution of gender (female, n = 20; male, n = 5). Most were senior practitioners (n = 14).

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Table 5.1. Patients' characteristics

beam computed tomography started to treatment completion

Table 5.2. Therapeutic radiographers' characteristics

Attribute	Ν	Mean (SD)		
Age (all)	25	35 (9)		
Years of experience		11 (9)		
		Percentage (%)		
Female	20	80%		
Male	5	20%		
Role				
Lead practitioner	3	12%		
Advanced practitioner	5	20%		
Senior practitioner	14	56%		
Practitioner	3	12%		

5.4.3.2. Comfort experiences of patients

We purposefully report the experiences of the patient participants first, as the phenomenon of the study is directly related to the comfort of patients during radiotherapy. Following thematic analysis, four themes emerged (Figure 5.1): Emotional Health (3 subthemes), P&I Experiences (3 subthemes), Information and Communication Experiences (2 subthemes) and Environmental Experiences (2 subthemes). The full data set and thematic analysis, with related quotations, are available in <u>Appendix I</u>.

5.4.3.2.1. Emotional Health

The theme Emotional Health entails the negative experiences of radiotherapy for patients. Many patients reported emotional symptoms of stress, anxiety, distress and fright, as well as of being scared when receiving radiotherapy for a range of cancers. Additionally, some patients voiced feelings of vulnerability during radiotherapy. For patients receiving radiotherapy for head and neck cancers, the negative experiences included the immediate emotional sensation of being restrained in a thermoplastic mask, causing distress or claustrophobia. One patient voiced this emotional response as follows:

I was frightened. But it still is frightening. But when I had it made, I did not know what was going on in my head. It was not nice and then did not know what was going to happen. [P1]

Another patient with head and neck cancer described the feelings as 'I actually felt as though I was in a horror film' [P12], while a patient receiving radiotherapy for breast cancer mentioned feelings of vulnerability:

Although the people couldn't be in the room while it is going on, it is radiotherapy. So I do understand the whys and where for so, although the comfort level [physical] was as hard. Mentally, I wasn't prepared for the feeling of being quite so vulnerable. [P17]



Figure 5.1. Patients' comfort experience themes

5.4.3.2.2. P&I Experiences

The P&I Experiences theme concerns how patients experience being positioned for accurate radiotherapy, including the physical positioning of a patient's body with or without an immobilisation device to ensure treatment accuracy. Patients found holding position for a longer time a challenge, which for some was intensified by preexisting health conditions causing discomfort or pain (e.g. arthritis or previous injury). Patients expressed discomfort being positioned for radiotherapy as follows:

Well, it is not that comfortable having your arms up. They [the arms] felt really numb because they were up, and the blood was going downwards, I guess. [P15]

Another patient found being manoeuvred manually a challenge:

The hardest part is to relax into the table. The moment they touch you and you are tensing again. Then as soon as you relax, they move you again, [and] you tense up again. [P6]

The experiences of discomfort while being positioned could be worsened with prior conditions, as mentioned by a patient with a long-standing injury:

That was really caused by an accident that I had 50 odd years ago; I lost the muscles in my chest. You do not use those muscles very often until I came here really basically. So that was one thing that was slightly uncomfortable to start with. [P5]

5.4.3.2.3. Information and Communication Experiences

This theme describes the patients' experiences of receiving sufficient provision of information and communication before and during radiotherapy and refers to information received in a range of formats, including written or multimedia to support patients undergoing radiotherapy. The communication between patients and TRs was important to patients. Specifically, patients said they were concerned that they would not be able to inform TRs if they had a problem during radiotherapy, with one patient with breast cancer stating,

I was really worried that if I had a problem, how would they know. I guess I could have waved, and they would have stopped the radiotherapy. But I was not told it was safe to do this. [P3]

This quote demonstrates how important simple communication is to ease patients' worries and concerns. Furthermore, several patients from all anatomical sites voiced concern over the type and amount of information they received: 'Yes, I am overrun with booklets and other bits of paper telling me what to do' [P16].

The challenge with an overload of information is that there is potential that it will not be read, and rather, targeted information may be more appropriate. One patient expressed a need for tailored information when there were too many leaflets:

I would have liked to choose the type of information, such as a video explanation where I could click to different sections so I could look at my cancer [and] then how I would get treated by radiotherapy. Otherwise, I threw the leaflets away; it was too much. [P21]

5.4.3.2.4. Environmental Experiences

In addition to having to manage the experience of initial cancer diagnosis, patients also need to deal with the complexities of the radiotherapy environment. The first impressions of entering the reception to the high-tech environment and unfamiliar nature of radiotherapy played a major role in the patient experience. Several patients from all anatomical sites found the experience of attending radiotherapy efficient, voicing positive and negative comments about the ease of 'check-in': 'So I found the whole thing really efficient and really well put together' [P4]. A patient had an alternative view: 'Although check-in was easy, I found the automatic check-in very impersonal' [P7]. There was also an appreciation for a pleasant hospitality: 'The atmosphere was nice, and I didn't feel like a cancer patient. I felt like I had nothing wrong with me' [P12]. Another patient found the environment not so pleasant: 'The reception and waiting areas had that clinical feel and smell, and radiotherapy [treatment rooms] was something like I have never seen' [P9].

5.4.3.3. Comfort experiences of TRs

Following thematic analysis, two themes emerged which were similar to themes emerging in the patient analysis (Figure 5.2): Emotional Health (5 subthemes) and P&I Experiences (2 subthemes).

5.4.3.3.1. Emotional Health

The theme Emotional Health entails the negative patient experiences of radiotherapy as observed by TRs. The TRs perceived many different views of patients receiving radiotherapy, ranging from stress, anxiety and distress to being scared when confronted with being positioned or immobilised. The TRs remarked on the distress or claustrophobia of thermoplastic masks for patients receiving radiotherapy for head and neck cancer. They also felt that patients' privacy was compromised and that they suffered from negative experiences due to side effects, pain and expectations before and during radiotherapy (e.g. bladder preparation or the donning of a tight-fitting mask). The TRs had observed anxiety or distress in many patients, with one TR noting,

You know, you get some patients that say fine come in quietly, and then you get other patients that come in and they're very anxious. [R11]

Another TR furthered this view:

It's always frightening and scary, and they [all patients] have got no idea what to expect. Wham bam, thank you, ma'am. But they have got to take that for the next 10 weeks every day. [R1]

The TRs also had thoughts on how patients may experience issues with their privacy: 'Again, comfort comes in a different number of definitions. For breast [cancer] patients, comfort may be body perception' [R4].

Finally, patients suffer from the side effects of radiotherapy which impact emotional health:

Yeah, patients, they get a lot of swelling, changes that are often easy to monitor. And we are much better at treating things, even though their skin is getting sore, and they get difficult [*sic*] swallowing and breathing, which has an emotional strain for patients. [R24]

5.4.3.3.2. P&I Experiences

From the perspective of TRs, P&I in radiotherapy includes how patients experience having their bodies positioned 'externally' and 'internally' for accurate radiotherapy. 'Externally' includes the physical positioning of a patient's body with or without an immobilisation device, and 'internally' includes internal soft tissue positioning through methods of preparation, such as bladder or rectal filling for pelvic irradiation or a breath hold for breast irradiation to ensure treatment accuracy. The TRs reported that they have supported many patients going through the discomfort of P&I or experiencing generalised physical discomfort, such as cramping. For example, one TR said,

So it wasn't always the most comfortable position, especially for patients [referring to all patients]. So they would often feel cramping like some things; they would usually be able to tolerate without having to stop always. [R13]

Several TRs commented specifically about patients struggling to hold position during treatment: 'Some patients manage 10 minutes quite easily, whereas other patients struggle with 10 minutes, even less than that really' [R5].



Figure 5.2. Therapeutic radiographers' comfort experiences

5.4.3.4. Shared experiences of comfort between patients and TRs

The four main themes of the patient and TR analyses present the experiences of comfort in radiotherapy. The shared experiences between both groups are presented in the two themes Emotional Health and P&I Experiences. The themes Information and Communication Experiences and Environmental Experiences only emerged from the patient interviews (<u>Appendix I</u>).

The theme Emotional Health included three subthemes from the patient interviews and five subthemes from the TR interviews. The common subtheme 'stressed, anxious, distressed, frightened or scared' was a shared subtheme between patients and TRs. One subtheme emerged only from the patient interviews and was named 'vulnerability'. A further four subthemes were from the TRs only: 'consequence of pain', 'expectations' (of patients), 'privacy in care' and 'side effects'.

The theme P&I Experiences included a shared subtheme '(dis)comfort of position or preparation' arising from the interviews of patients and TRs. Another subtheme occurred among patients and TRs, which was 'challenges of holding position'. One subtheme was from patients only: 'preexisting health conditions'.

There were two main themes emerging from the patient interviews only: Information and Communication Experiences and Environment Experiences, which included

two subthemes ('efficiency of the service' and 'pleasant hospitality') with no shared experiences from the TRs (<u>Appendix I</u>).

5.4.4. Discussion

This study explored the comfort experiences of patients receiving radiotherapy treatment and TRs delivering radiotherapy. The main findings highlight aspects of comfort during radiotherapy treatment exceeding 10 minutes. The four main themes in our study can be aligned to the comfort theory described by Kolcaba et al. (2006). For example, the theme Emotional Health relates closely to Kolcaba's 'psychospiritual comfort' context in which comfort can occur. Our P&I Experiences fit well in the 'physical comfort' context, the Information and Communication Experiences theme can be linked to the 'sociocultural comfort' context and the Environmental Experiences theme has a close relationship with the 'environmental comfort' of Kolcaba's conceptual framework of patient comfort in nursing care. Overall, the patients do not experience comfort in isolated contexts or, like in this study, in themes. For example, the subtheme 'challenges of holding position' during radiotherapy relates to physical comfort, although patients experience discomfort (e.g. distress) in the psychospiritual context. This highlights that patient comfort is a complex phenomenon within radiotherapy. It can be suggested that comfort experience in radiotherapy is multidimensional and requires a complex approach to improve patient experiences and outcomes.

The multidimensional views of comfort can be observed in the findings of two previous studies exploring experiences of patients with head and neck cancers wearing thermoplastic masks (Keast et al., 2020; Nixon et al., 2018). Nixon et al. (2018) explored mask anxiety using quantitative measures and qualitative interviews. They used a validated distress thermometer midway between planning and the end of radiotherapy treatment and found that 26 of 100 patients reported being anxious during radiotherapy. This is consistent with our study, where several patients reported being stressed during radiotherapy. Nixon et al. (2018) identified themes linked to psychological and physiological experiences consistent with Kolcaba's (1992) psychospiritual and physical contexts of comfort. One such theme was 'vulnerability', which arose from claustrophobia of being isolated in a mask and having preexisting mental health problems. In our study, many patients having cancer across different anatomical sites expressed vulnerability of being in an unknown environment and of being isolated during treatment delivery. A recent qualitative study by Keast et al. (2020) identified a theme named 'trajectories of mask anxiety' that arose from the distress of mask fitting. In our study, there were many psychological and physiological experiences of discomfort voiced by patients and TRs (e.g. anxiety and distress as well as being scared) and physiological experiences such as suffering pain and side effects, similar findings reported in other studies (Keast et al.,

2020; Nixon *et al.*, 2018). It is possible that a greater number of patients with head and neck cancers will suffer distress wearing a thermoplastic mask. However, many patients in our study with cancer in other anatomical sites reported some form of anxiety, stress or distress. It has been reported that patients with breast cancer experience distress during radiotherapy as well (Probst *et al.*, 2021).. This study highlighted the 'experience of being naked', which arose from the need to remain undressed during treatment, and staying with permanent tattoos on the body which has similarities with the subtheme 'privacy in care', as identified by TRs.

In our study, patients expressed how communication can be reassuring, consistent with the literature (Probst *et al.*, 2021). Probst *et al.* (2021) found that patient experience was negatively impacted by the limited answers given by TRs to questions. This is relatable to our subtheme 'choice of information'. In a survey about the quantity of radiotherapy information, patients responded that they were overloaded with written information which they did not read. Mattarozzi *et al.* (2019) surveyed 91 patients with a range of cancers about communication with TRs using nonvalidated scales to measure attitude towards radiotherapy, pain and discomfort. The relationship with TRs and communication was significantly associated with radiotherapy-induced pain intensity and patient attitudes toward radiotherapy (Mattarozzi *et al.*, 2019). Overall, communicating effectively has the potential to improve comfort and support patients (Probst *et al.*, 2021).

The importance of the environment should not be overlooked as a contributing factor to the overall patient experience of comfort. As a person enters any new environment, they process a mixture of thoughts and feelings. Mullaney *et al.* (2016) found that adopting a person-centred approach to the design of the radiotherapy environment affects patient anxiety levels (Mullaney *et al.*, 2016). We discovered that individuals have a preference for personalisation of care, such as having automated check-in machines versus being greeted by a receptionist or TR. Therefore, the environment of a radiotherapy department remains an important factor for considering comfort experiences.

5.4.5. Study limitations

One researcher conducted all interviews and performed the transcriptions, which has the potential for bias. However, the analysis was conducted with the full research team to secure the credibility, rigour and trustworthiness of the findings, including the involvement of the PRPs. Another limitation is that patients were recruited and interviewed from only one radiotherapy centre. Therefore, the findings of the two patient-only themes may not be transferable to other centres. The third limitation is the recruitment strategy of TRs. The TRs were approached via social media, conferences and forums. This might have led to

capturing clinically excellent practice among 25 TRs, which may not represent the wider scope of practice among TRs.

5.4.6. Conclusion

This qualitative study has provided the voices of patients and TRs and their experiences and views of comfort during radiotherapy. Exploring patient comfort in radiotherapy has provided greater insight into patient experiences and how services may be able to tailor treatment and care to patients. The findings have enriched the shared experiences and understanding of comfort by patients and TRs. These shared experiences emphasise the importance of considering comfort holistically and not just from a physical context. The clinical implications of our study can encourage TRs to provide holistic care for their patients throughout the pathway and specifically to comfort patients while they are having treatment. In the short term, this could be via simple adaptions to practice, including how patients are greeted, effective communication and P&I procedures accommodating existing health conditions. In the long term, research is needed to develop comfort interventions for patients receiving radiotherapy coupled with testing in clinical trials. The study has highlighted some of the positive and negative experiences of comfort based on current UK practice, which may support changes to clinical practice.

5.5. Chapter summary

In this chapter, valuable descriptions of patient and TR experiences and views of comfort are given, along with the observed commonality. Participants voiced positive and negative aspects of comfort, from how patients cope to physical discomfort experienced. The heterogenous sample of patients with cancers of different anatomical sites and TRs across the UK has provided new knowledge needed to improve radiotherapy practice. The following chapter presents findings based on interviews with patients and TRs that explored solutions to better manage comfort in radiotherapy.

6. Chapter six: Comfort management during radiotherapy

6.1. Introduction

In this chapter, the findings of qualitative interviews providing a detailed exploration of solutions to better manage comfort during radiotherapy are presented. Comfort management was explored, alongside experiences of comfort during radiotherapy, in the qualitative interview study. The latter was analysed separately to focus on extending the knowledge of what is known about the potential solutions to improve comfort for patients with cancer receiving radiotherapy.

The findings of interviews exploring solutions to improve comfort management with patients and TRs was submitted for publication in the *Journal of Medical Imaging and Radiation Sciences* and published on the 19th of July 2023. The PhD researcher was the CI, who worked closely with a supervisory and two PRPs. This paper is presented as the main body of this chapter by using the last Word version accepted by the journal.

6.2. Published paper: A Thematic Exploration of Patient and Radiation Therapist Solutions to Improve Comfort During Radiotherapy: A Qualitative Study

Journal: Journal of Medical Imaging and Radiation Sciences

Goldsworthy, S., Latour, J.M., Palmer, S., McNair, H. and Cramp, M. (2023c) A thematic exploration of patient and radiation therapist solutions to improve comfort during radiotherapy: a qualitative study. *Journal of Medical Imaging and Radiation Sciences* [online]. 54 (4), pp. 603–610. Available from: <u>https://doi.org/10.1016/j.jmir.2023.07.008</u>

Citations as at 26th December 2024 = 2

Date accepted: 11th July 2023

Date of publication: 19th July 2023
6.3. Abstract

6.3.1. Purpose

Patients undergoing radiotherapy are positioned to restrict motion, ensuring treatment accuracy. Immobilisation can be uncomfortable, impacting treatment accuracy. TRs are responsible for managing patient comfort, yet there is little evidence to guide practice. The objective of this study was to explore patient and TR experiences of comfort management during radiotherapy and identify solutions for how comfort may be managed.

6.3.2. Materials and methods

Twenty-five adult patients were purposefully recruited from Somerset NHS Foundation Trust from those referred for, receiving or who had received radiotherapy within three months. Further criteria were that treatment delivery time on the couch exceeded 10 minutes (the time the patient was immobilised on the radiotherapy couch). Twenty-five practising TRs were recruited across the UK with experience of treatment delivery times exceeding 10 minutes. Semi-structured interviews were conducted by the researcher at Somerset NHS Foundation Trust or in patients' own homes and via telephone for TRs. Interviews were audio recorded and transcribed verbatim. Thematic analysis was performed by SG, and after familiarisation with the data and the generation of codes, the themes defined were reviewed by researchers and patient partners.

6.3.3. Findings

For patients, the three themes were Supported Coping, Modification to Position or Immobilisation and Information Communication and Preparation. For TRs, three main themes emerged: Supported Coping, Supporting and Adjusting Patients to Maintain Position and Preparational Approaches.

6.3.4. Conclusion

This qualitative paper provided a shared voice of how comfort can be best managed from the perspectives of patients and TRs. Patient and TR views of how comfort is best managed provided solutions that may be used during radiotherapy. This study highlights some of the positive and negative experiences of comfort solutions based on current UK practice. This information will be used to develop recommendations in a radiotherapy comfort intervention package.

6.4. Main text of the paper

6.4.1. Introduction

Patients must be immobilised in a stable and reproducible position for accurate radiotherapy (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). However, P&I may not be physically comfortable, and patients may experience anxiety and distress (Goldsworthy, Tuke and Latour, 2016). Evidence suggests that patient discomfort is associated with reduced accuracy of radiotherapy treatment (Bartlett *et al.*, 2015; Bayley *et al.*, 2004). The principle is that greater comfort may lead to greater stability, as patients are able to remain positioned for radiotherapy. Greater stability during radiotherapy is synonymous with improved accuracy (Bartlett *et al.*, 2015; Bayley *et al.*, 2004). Recent advancements in radiotherapy, such as extreme hypofractionation and 4D approaches, require a greater obligation for patients concerning P&I. These advanced treatments warrant a revisit of patient comfort interventions during radiotherapy (Goldsworthy, Palmer *et al.*, 2020).

Studies have investigated comfort interventions during radiotherapy within the last decade (Probst et al., 2021; Nixon et al., 2019). Nixon et al. (2019) surveyed 35 patients with head and neck cancers about strategies that reduced mask anxiety during treatment. Nonpharmacological interventions were found most helpful by patients, including discussions with TRs, meditation and music. Another study conducted workshops with nine women to explore their experiences of radiotherapy for breast cancer (Probst et al., 2021). Probst et al. (2021) confirmed the importance of meeting information needs and highlighted the need for patient empowerment during the treatment process. These studies have explored the possibilities of developing comfort interventions. Our previous research included an SLR identifying 46 RCTs testing comfort interventions used for healthcare procedures (Goldsworthy et al., 2020). These RCTs tested various comfort interventions, including music, movies, aromatherapy, education or information about the procedure, cognitive behavioural therapy and massage (Goldsworthy et al., 2020). While there is growing interest in developing and testing comfort interventions in radiotherapy, further exploration of potential candidate interventions is required. This may include physical to psychological interventions, such as cushions to areas of pain (arthritis) and audiovisual distraction.

A large interview study already reported patient and TR experiences of comfort during radiotherapy (Goldsworthy *et al.*, 2023b). An understanding of potential comfort solutions is required to fill the gap in the literature and enable the development of a comfort intervention package for patients receiving radiotherapy. This paper focuses on improvements in patient comfort during radiotherapy, as voiced by patients and TRs.

6.4.2. Methods

The methods of the interview study have been reported previously and are summarised below (Goldsworthy *et al.*, 2023b). The methodological paradigm is idealist, forming an arc between the technical, positivist demands of radiotherapy precision and the comfort experienced by patients and supported by TRs (Allais, 2017).

6.4.2.1. Design

The interview study used semi-structured interviews with patients and TRs (Creswell and Poth, 2018). Ethical approval was granted by Berkshire B NHS Research Ethics Committee (18/SC/0689; <u>Appendix G</u>) in January 2019, and the protocol was prospectively registered (<u>www.clinicaltrials.gov</u>; NCT03984435). Patients and TRs provided written informed consent, and interviews were conducted between January and July 2019. This study is reported in accordance with to the COREQ checklist (Tong, Sainsbury and Craig, 2007). Pragmatically, we chose a sample of 50: 25 patients and 25 TRs (Creswell, 2018).

6.4.2.2. Patient participants

Eligible participants were recruited from those attending a radiotherapy department in the southwest of England. Patient participants (n = 25) were adults over the age of 18 years, were diagnosed with malignancy in one of the three main anatomical sites (head and neck, breast/lung and pelvis) and received radiotherapy within the last three months (to remember their experience clearly) with a treatment time exceeding 10 minutes (to encompass patients who needed to hold position for a longer time. Participants had to read and understand English to participate in the study.

6.4.2.3. TR participants

Participants were recruited via social media and specialist interest groups of professional societies linked to radiotherapy. The TR participants (n = 25) were working clinically (HCPC Register check) and delivering radiotherapy with times exceeding 10 minutes.

6.4.2.4. Procedure

Interview guides for patients and TRs were developed using existing literature (Appendix H). The lead researcher (SG) performed all the interviews and was unknown to patient participants but known to some of the TR participants as a TR. The lead researcher holds a master of science in therapeutic radiography and is undertaking his PhD supported by an experienced supervisory team, who also acted as coresearchers. Patients were interviewed midway during radiotherapy at a place of their choosing (Sedgwick, 2014). The TRs were interviewed via telephone at a date and time of their choosing. Interviews were audio recorded and transcribed verbatim by the lead researcher. Interviews were conducted for a duration of up to one hour.

6.4.2.5. Data analysis

The six steps of thematic analysis as described by Braun and Clarke (2006) were applied, facilitated by NVivo software (v1.6.1). The thematic analysis performed in this paper specifically focused on the suggestions for improving patient comfort during radiotherapy from the perspectives of patients and TRs.

In summary, the first step of thematic analysis started with familiarising with the data. The next step was generating codes, followed by defining subthemes and themes. Afterwards, the themes were reviewed and redefined by the research team and two PRPs. The final step is the report described in this paper.

6.4.3. Findings

6.4.3.1. Participant characteristics

Of the 25 patient participants, 13 were male. The anatomical cancer site was almost evenly distributed (head and neck, n = 8; thorax, n = 9; and pelvis, n = 8), with treatment times ranging from 10 to 15 minutes. Most of the 25 TR participants were female (n = 20) and were predominantly in senior practitioner roles (qualified for 2 years or more; n = 14).

6.4.3.2. Comfort solutions proposed by patients

Three themes emerged from the thematic analysis of patient interviews (<u>Figure 6.1</u>): Supported Coping (5 subthemes), Modification to Position or Immobilisation (3 subthemes) and Information Communication and Preparation (2 subthemes). Findings were similar across all anatomical cancer sites for the reported themes (<u>Appendix J</u>).



Figure 6.1. Patient comfort solutions

6.4.3.2.1. Supported Coping

The theme Supported Coping included strategies to help patients get through radiotherapy with greater comfort. Patients discussed being supported by TRs to cope with radiotherapy using audiovisual distraction, empathetic support (hand holding & gentle words) and self-initiated distraction/coping. Patients appreciated the transcending effect of music – 'Once they had the greatest showman and I was singing along in my head, and I was gone' [P3] – and having their choice of music: 'Often, there's music on, and often, it's the music I'll ask for, which is great as well' [P4]. Patients also appreciated empathetic support, such as gentle words and handholding: 'They came to talk to me and held my hand. The mask felt very tight to start off with and obviously you are not used to such things' [P17].

Patients reported using various methods to cope with radiotherapy. Some patients reported using positive self-talk: 'Well ... the first time I panicked was day one, but after that, I was fine. So you get used to it, and yes, I thought to myself, You can do this, man up' [P14]. Others used distraction via counting or focusing on something: 'I listened to the machine; I listened to the noises that were going on, so I knew what's happening' [P18]. Others relied on their spiritual faith. For example, one patient said, 'Because of my Christian faith, there were some times when I was praying, and most of the time, I shut myself off' [P12]. Participants also reported benefiting from the radiotherapy service hospitality (greetings, check-ins and refreshments).

6.4.3.2.2. Modification to Position or Immobilisation

This theme reflected the daily P&I of patients for accurate radiotherapy treatment. The suggested comfort solutions included adjustments to P&I, prioritising comfort, soft comfort aids and accommodation of preexisting health concerns. Many patients reported adjustments to their position or immobilisation before or during treatment to alleviate discomfort, such as 'They would ask. Are you comfortable or whatever, and then move me down a bit [or ask me to] move up a bit' [P11].

Some patients found that TRs would ensure their comfort was prioritised: 'And they made sure that if I was uncomfortable, they would reposition me' [P22]. Other patients highlighted how these radiographers supported them, taking into consideration their existing healthcare conditions: 'As for comfort I was so pleased I had the flexi gel for my back. That stopped any pain that I was going to get' [P12].

6.4.3.2.3. Information Communication and Preparation

This theme emerged from the information provided before radiotherapy: Compassionate Communication and Preparational Approaches. Patients expressed the importance of good communication and tailored information provision. They wanted appropriate preparation before attending radiotherapy and preferred to be kept informed during treatment delivery:

I think it would have been a small improvement to have a session before coming for the actual thing. [P7]

Yes, they kept you informed of what was happening and exactly what you needed to do to stay still. [P5]

Although patients were content with verbal communication, many would have liked modifications to the amount and format of information received:

That's why I said I would like to say I didn't want to be informed of everything because I have a filter system on this and only want to know about stuff on a really need-to-know basis. [P17]

Some patients emphasised that greater preparation may have helped: 'Even video would be OK so you know what you are going into' [P2].

6.4.3.3. Comfort solutions proposed by TRs

The TR interviews revealed three themes (<u>Figure 6.2</u>): Supported Coping (7 subthemes), Supporting and Adjusting Patients to Maintain Position (8 subthemes) and Preparational Approaches (3 subthemes). Findings were similar across all anatomical cancer sites for the reported themes (<u>Appendix J</u>).



Figure 6.2. Therapeutic radiographer solutions

6.4.3.3.1. Supported Coping

The theme Supported Coping included strategies that TRs used to help patients get through radiotherapy more comfortably. TRs reported supporting patients using a multitude of methods, including physical, audiovisual distraction and psychological support and individualised care. Physical methods included handholding or the provision of a comforting blanket: 'Sometimes, the patients from time to time want us to hold their hand' [R5]. TRs mentioned the use of music or lighting: I think some people might like the lights down. It's like when you when you just assume the person would prefer the lights on and walk out and assume that. [R8]

Psychological support included information provision during treatment:

So they're on the bed for like 40 minutes, but we spend a lot of time talking to them, coaching them through microphones. [R6]

Pharmacological interventions were also highlighted:

I suppose head/neck patients or anybody in a shell [thermoplastic mask] – which is, you know, a whole different league in terms of comfort. Patients often talk about them digging into their neck and stuff, not everybody's neck is the same size and shape. People have daily lorazepam to get through treatment in a shell. [R2]

Some TRs also referred patients to external services to support coping:

Absolutely, you always offer complementary therapies to sort of try and go alongside. They always offer things like that. I really wish there was some way we could have a psychiatrist on hand because I think that it's a major problem. [R3]

TRs noted other forms of psychological distraction:

The patients sometimes use stress balls. [R11]

Others take themselves to somewhere in their minds, but that's on an individual patient basis. [R7]

Many patients have some form of spiritual faith, with a TR suggesting,

I mean, it was just one example. There could be someone from a religious background, and we would say to a Roman Catholic you can bring your rosary beads or, you know, often ask our Muslim patients if they would want the Koran played. [R9]

6.4.3.3.2. Supporting and Adjusting Patient Position or Immobilisation

This theme emerged from TRs reporting adjustments to positioning and immobilisation or making mask modifications before and during radiotherapy. TRs highlighted the challenge and judgement required to make changes once radiotherapy treatment had commenced:

Obviously, if on treatment the patient tells you it is not comfortable, maybe it would not be changed just because you wouldn't want to change your rotations too much. Obviously, you have a bit of leeway with some patients where the treatment area is further away. [R9] Some TRs gave examples of mask modifications:

If we have had patients in the past where we've been able to cut parts out of the mask in order so they can see a bit better maybe given that a little bit of comfort means a little bit less anxious about the mask and claustrophobic and things like that. We have had patients in the past that have post-traumatic stress disorder from things that happened previously in their lives. [R15]

TRs described using various approaches to support patients to maintain position: 'Well, the first thing that we do is question if the patient was actually capable of holding position' [R10].

Another TR highlighted that preparation may benefit patients too: 'Advise them that if they want to stretch out their arms and just have a little stretch or wriggle that's okay' [R1].

Then TR voiced their concern for patients with existing health conditions:

We have also had patients before in the past who haven't been able to lie flat due to things like scoliosis problems with the spine and things like that, and they actually ended up creating a device that the patient could have a leg up in the air completely so that he could like foster the treatment. And he was able to manage that position really well and ended up managing. [R15]

TRs expressed how they aimed to prioritise comfort:

So that's always been our aim from the very beginning: to make the patient as comfortable as possible so we don't always use what would seem to be the most restrictive immobilisation because it's not always all that comfortable. [R1]

Other TRs suggested holding something with a calming effect:

Yes, we suggest they may like to hold things of sentimental value like a toy from grandchild, or a piece of jewellery or something like it. [R13]

6.4.3.3.3. Preparational Approaches

This theme arose from TRs' perspectives that information and communication must be tailored to the needs of the patient and that they should be prepared. TRs reported that patients appreciated tailored information:

I try to make sure our patients think that they get what they need and that they know enough information prior to and during radiotherapy treatment. [R19]

TRs also found that patients benefited from personable communication:

In my previous trust there were advanced practitioners who probably meet the patients at the consent stage and get to know them at the personal level so that they would have better insight. Communicate with a treatment team and any of the special needs of the patient were noted. [R18]

TRs used different approaches to prepare patients for radiotherapy:

Oh yes, the open evening or coaching/education. So basically, some sort of session before they come in just to give them an overview [of radiotherapy]. [R11]

Other TRs suggested that providing information about the procedures might be beneficial to patients:

He did an animation of a couple of setups with the head and neck setup that actually showed them like an X-ray or the spine and showed them the position that we were putting them into and why we would do that. And that works to care for the head and neck, but the one that really worked quite well for was prostate patients. [R14]

6.4.3.4. Shared proposals for comfort solutions between patients and TRs

Two of the three themes of the patients and TRs demonstrated a shared vision of comfort solutions that could be used in radiotherapy (<u>Appendix J</u>). The theme Supported Coping emerged from patients and TRs, and it included five subthemes from the patient interviews and seven subthemes from the TR interviews. The common subthemes were Supported Distraction Techniques, Audiovisual Distraction, Hospitality/Hospitality and Aesthetics, Empathetic Support/Approaches and Self-Initiated/Perceived Coping. Two subthemes emerged only from the TR interviews and were named Pharmacological and Referral to External Services.

The patient theme Modification to Position or Immobilisation and the TR theme Supporting and Adjusting Patient Position or Immobilisation included the following shared subthemes: Accommodating Preexisting Health Conditions, Prioritising Patient Comfort with Soft Pads or Mattress, and Adjusting Position or Immobilisation/Adjusting Position Before or During Treatment.

6.4.4. Discussion

The objective of this paper was to explore patient and TR views of how comfort can be better managed to support patients undergoing radiotherapy. Similar comfort solutions were identified by patients and TRs, which suggests that comfort solutions may be used interchangeably to meet individual patient needs. The similarities of suggested comfort solutions indicate that interventions might be suitably developed for patients undergoing radiotherapy at a range of anatomical cancer sites. Moreover, our previous work exploring patient comfort demonstrated that patients may experience a combination of physical and psychological discomfort (Goldsworthy *et al.*, 2023b), which means a range of comfort solutions could be used concurrently to ameliorate discomfort. Based on the current explored themes, this may include a supportive coping strategy used in conjunction with support for a patient to maintain position, ensuring they can successfully complete their radiotherapy course. For example, a modesty gown to cover exposed breasts may help a patient to cope with potential embarrassment (Probst *et al.*, 2021), while a soft elbow restraint could help maintain arm position (Cox and Davison, 2005). This highlights the importance of holistically addressing patient comfort.

One of the shared themes, Supportive Coping, revealed several subthemes that can be translated into comfort interventions to support an array of discomfort experienced by patients during radiotherapy. These comfort interventions might align with the four contexts of comfort described by Kolcaba (1994), which are physical, psychospiritual, sociocultural and environmental. For example, a patient donning a thermoplastic mask may suffer the physical discomfort of restraint due to the tight-fitting mask and may also feel highly anxious, a psychospiritual discomfort. In this situation, an empathetic approach from TRs, together with a form of distraction (such as music or gentle words over the intercom), may help ease the discomfort. Therefore, multicomponent interventions might need to be developed and tested for effectiveness to improve patient comfort through radiotherapy.

The second shared theme to arise from patient interviews was Modification to Position or Immobilisation and from TR interviews was Supporting and Adjusting Patients to Maintain Position. These themes reflect common radiotherapy practice – the daily pursuit to position and immobilise patients for accurate radiotherapy (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). These themes include accommodating preexisting health conditions, prioritising comfort with soft pads or mattresses and adjusting position or immobilisation, including modifications to thermoplastic masks. A qualitative study of patients with pelvic cancers reported that they experienced discomfort with the hardness of the couch and bladder/rectal preparations (Cox and Davison, 2005). Patients described feeling 'rigour mortis' from holding still during prostate irradiation and requested a lateral extension for their elbow, which helped (Cox and Davison, 2005). Some participants in our study suggested that the hardness of the couch could be modified with soft pads under elbows or areas away from the target area that would not impact on the stability and accuracy of radiotherapy. Together with the lived experiences of comfort (Goldsworthy *et al.*, 2023b),

and the need to consider holistic comfort interventions, the physical aspect of comfort, such as modifications to immobilisation, must not be overlooked.

The final theme arising from patient interviews was Information Communication and Preparation. Many patients voiced the importance of communication and how information was delivered. In our study different formats, such as video or online applications, were suggested and could also be used to prepare patients for radiotherapy. A similar final theme arising from TR interviews was Preparational Approaches. Many TRs noted that preparation was key, including tailored information, proactive communication, preparation methods and tours of the radiotherapy department. Again, TRs suggested that video or online applications could support these comfort solutions.

These findings are supported by other studies in the UK and Europe which found patients were dissatisfied with the information received after cancer diagnosis (Thomas *et al.*, 2000). Thomas *et al.* (2020) identified that patients preferred video information before and during treatment, reducing the anxiety significantly compared to standard of care. For some patients, a greater understanding of the radiotherapy process improves the overall feeling of comfort. Therefore, information provision should be considered along with other solutions.

The presented comfort solutions in our study may be used to improve patient comfort during radiotherapy. Exploring solutions to provide comfort in radiotherapy has provided greater knowledge of how services may be able to tailor individual treatment and care to patients. The clinical implications of our findings suggest that TRs should consider using various comfort solutions for their patients. Several suggested comfort solutions in our study might be easy to adapt and implement in radiotherapy practice. However, the feasibility of implementing these solutions has not been explored in-depth in clinical practice. Therefore, TR clinicians and academics should focus on whether comfort solutions are feasible in practice and how they can be delivered as a care package.

6.4.4.1. Methodological considerations

It must be acknowledged that interviewing a greater number of participants may have increased the number of proposed comfort solutions arising from subthemes, although the final interviews did not reveal any new comfort solutions. However, the principle of generating new knowledge is a continuum, where this paper provides the foundation for generating more knowledge and improvements to comfort for future patients.

6.4.5. Conclusion

Patients and TRs proposed solutions to improve comfort management during radiotherapy. Three themes emerged – Supported Coping, Modification to Position or

Immobilisation and Information Communication and Preparation. Although the findings were similar across anatomical cancer sites, site-specific needs were identified, supporting individually tailored approaches. These results provide a basis for determining comfort interventions appropriate for use in practice. We recommend that future research includes investigations of the effectiveness of individually tailored packages of comfort solutions.

6.5. Chapter summary

In this chapter, the proposed solutions to improve or better manage comfort during radiotherapy were given by patients and TRs, relating well to L. Wilson and Kolcaba's (2004) three comfort intervention categories: technical, coaching and comfort food for the soul. The observed commonality of comfort solutions in patient and TR themes and subthemes ranged from physical to psychological. Participants voiced how they support or cope with discomfort experienced, providing valued suggestions. The heterogenous sample of patients with cancers of different anatomical cancer sites and TRs across the UK has provided new knowledge needed to improve radiotherapy practice. The following chapter describes a consensus study with patient and TRs which was convened to recommend comfort intervention components to be developed in a package.

7. Chapter seven: Recommendations for a radiotherapy comfort intervention package

7.1. Introduction

In this chapter, a modified NGT consensus study brought together patients and TRs to identify, rate and prioritise comfort intervention components for recommendations for a future comfort intervention package in radiotherapy. An online modified NGT followed a rigorous methodology extending knowledge through developing recommendations for the package. The NGT consensus study was online due to the COVID-19 pandemic.

The findings of the NGT consensus study of patients and TRs was submitted for publication in *Radiography* and published on the 25th of July 2023. The PhD researcher was the CI, who worked closely with the supervisory team and two PRPs. This paper is presented as the main body of this chapter by using the last Word version accepted by the journal.

7.2. Published paper: Identifying Core Components of a Radiotherapy Comfort Intervention Package Using Nominal Group Technique

Journal: Radiography

Goldsworthy, S., Latour, J.M., Palmer, S., McNair, H. and Cramp, M. (2023a) Identifying core components of a radiotherapy comfort intervention package using nominal group technique. *Radiography* [online]. 29 (5), pp. 926–934. Available from: https://doi.org/10.1016/j.radi.2023.07.006

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7.3. Abstract

7.3.1. Introduction

A comfortable treatment position in radiotherapy may promote patient stability and improve outcomes such as accuracy. The aim of this study was to identify, prioritise and determine the feasibility of delivery of intervention components as part of a radiotherapy comfort intervention package.

7.3.2. Methods

Prior research, consisting of a systematic review and qualitative interviews with patient and TRs, was triangulated and 15 intervention components developed. An online NGT consensus meeting was conducted, with seven patients who received radiotherapy exceeding 10 minutes for one of three anatomical cancer sites and 3 TRs participating. Four activities were undertaken – 1) discussion of comfort intervention components, 2) initial vote, 3) prioritisation of intervention components and 4) discussion of feasibility in radiotherapy – and analysed using established quantitative and qualitative methods.

7.3.3. Results

One intervention component was added from initial discussions to the 15 predetermined components being discussed. Eleven components were recommended as 'Included' (n = 5) or 'included with caution' (n = 6) to proceed to development. The highest scoring intervention components were 'compassionate and empathetic communication training for TRs' and 'tailored information (e.g. TRs provide the required information only as part of preparation for treatment)', followed closely by 'adjustments and supports provided for arms or legs during treatment by TRs'. One of the components 'included with caution' was 'soft pads/mattress under the body to alleviate body discomfort managed by TRs'. A qualitative analysis highlighted concerns over the radiation environment and emphasised the importance of resources such as equipment, training and time.

7.3.4. Conclusion

The recommended comfort interventions have potential to improve patient comfort during radiotherapy and should be considered to incorporate into P&I guidelines. However, specific intervention strategies to address these components will need to be developed and robustly evaluated.

7.3.5. Implications for practice

Comfort interventions might help patients relax and stay still during treatment, which could improve treatment accuracy and efficacy. Introducing these comfort interventions in practice have the potential to lead to a more positive patient experience and improved overall quality of care during radiotherapy.

7.4. Main text of the paper

7.4.1. Introduction

Patient comfort is increasingly considered a fundamental need to address stress, anxiety, pain and discomfort in healthcare (Pineau, 1982). Patient comfort is multidimensional and

recognised to have physical, psychospiritual, environmental and sociocultural aspects (Kolcaba, 1994). In radiotherapy, patient comfort can be affected by the need to adopt rigid and uncomfortable positions to achieve accurate and safe treatment (Cui *et al.*, 2021; Lateef, 2011; Purdy, 2011). Cancer treatment also affects psychological and social well-being (Mullaney *et al.*, 2016), yet there has been limited attention on improving comfort during radiotherapy and evaluating its impact on clinical outcomes (Bartlett *et al.*, 2015; Bayley *et al.*, 2004).

Five studies have explored patient comfort during radiotherapy (Holt *et al.*, 2021; Probst *et al.*, 2021; Nixon *et al.*, 2019; Engvall *et al.*, 2018; Ångström Brännström *et al.*, 2015), three of which were qualitative and provided useful insights into psychological interventions for paediatric patients (Holt *et al.*, 2021; Engvall *et al.*, 2018; Ångström Brännström *et al.*, 2015). Improvements such as concrete and repeated age-adjusted information, distractions (e.g. listening to a parent via earphones, video or augmented realities), well thought out procedures, routines, compassionate care, and a friendly environment were suggested (Holt *et al.*, 2021; Engvall *et al.*, 2018; Ångström Brännström *et al.*, 2015). The remaining studies investigated interventions to improve comfort in adult patients undergoing radiotherapy and reported similar suggestions, including distractions and compassionate care (such as dignity, Probst *et al.*, 2021; Nixon *et al.*, 2019).

To inform the development of comfort interventions for adults undergoing radiotherapy, a programme of work was undertaken that included an SLR and qualitative investigation of comfort experiences and suggested solutions (Goldsworthy *et al.*, 2023b, 2023c; Goldsworthy, Palmer, *et al.*, 2020). The SLR identified comfort interventions reported for clinical procedures that involved sustained inactivity and stability over time, similar to radiotherapy (Goldsworthy, Palmer, *et al.*, 2020). Interventions were grouped into four categories: psychological, physical, audiovisual and other (aromatherapy and education/information). Medium-to-large effect sizes were reported in many intervention categories. Subsequently, 25 adult patients who had received radiotherapy for cancers in the head and neck, breast/lung and pelvis and 25 TRs were interviewed. Five themes emerged: 'Modification or Adjusting Patient Position', 'Support Patients to Maintain Position', 'Self- and Supported Coping Methods', 'Individually Tailored Information', 'Preparational Approaches', and 'Environmental Modifications' (Goldsworthy *et al.*, 2023c). The interventions from three studies were prioritised as part of the current study.

7.4.1.1. Generation of comfort intervention components

The findings of the SLR of comfort interventions applicable to radiotherapy (Goldsworthy, Palmer, *et al.*, 2020) were triangulated with the findings of qualitative interviews with patients and TRs of how comfort is best managed in radiotherapy (Goldsworthy *et al.*,

2023c). During triangulation (<u>Appendix K</u>), the data were combined for real-world meaning in radiotherapy (<u>Appendix L).</u>

A package of comfort interventions is likely to be required to address the complex and multidimensional needs of patients receiving radiotherapy. Therefore, the present study aimed to identify, prioritise and determine the feasibility of the delivery of intervention components as part of radiotherapy comfort.

7.4.2. Methods

A modified NGT consensus meeting with patients and TRs was used to identify and prioritise recommendations of components for a comfort intervention package in radiotherapy (Potter, Gordon and Hamer, 2004). An online NGT consensus meeting was chosen because patients and TRs did not have to attend in person – which provided safety during the COVID-19 pandemic, especially for immunocompromised patients. Moreover, participants have previously felt more open to speak up in an online environment (verbally or by text; McMillan, King and Tully, 2016; McMillan *et al.*, 2014; Harvey and Holmes, 2012). This technique has also been used successfully within a similar population group to develop interventions (Somers *et al.*, 2019). Ethical approval was granted by the Southwest – Frenchay Research Ethics Committee on October 2021 (Appendix M), and the protocol was prospectively registered (www.clinicaltrials.gov; NCT03984435). Patients and TRs gave written informed consent, and the consensus study was conducted on the 18th of January 2022. This study is reported in accordance with the COREQ checklist (Tong, Sainsbury and Craig, 2007).

7.4.2.1. Recruitment

Patient and TR panel members were initially identified if they had indicated agreement on the consent form as part of involvement in previous qualitative interviews (Goldsworthy *et al.*, 2023b, 2023c). Further patient participants were recruited via a radiotherapy department in the southwest of England.

Patients were included if they were deemed well via their electronic medical record, were 18 years or older, were diagnosed with cancer at one of three major anatomical sites (head and neck, breast/lung or pelvis) and received radiotherapy with delivery time exceeding 10 minutes. TR panel members were included if they were practising TRs (HCPC Register check) and delivering radiotherapy techniques with times exceeding 10 minutes. No TRs from the host radiotherapy clinic or more than two TRs from the same radiotherapy clinic were recruited to ensure heterogeneity of views and practices. Patients and TRs needed to be able to use a computer and perform the required tasks to participate in the study. A training session was provided to facilitate participation.

The proposal was to recruit up to 12 panel members: up to nine patients and three TRs. Recruitment was unevenly weighted towards patients to amplify their voice amongst potential vocal TRs and patients. Patients were purposively recruited to include at least two patients with cancer in the head and neck, breast/lung or pelvic regions.

7.4.2.2. NGT procedure

Following expression of interest, potential panel members were contacted by the CI, sent the Participant Information Sheet by email and subsequently issued a formal written confirmation letter, joining instructions and the schedule (<u>Appendix N</u>). The CI ensured panel members could access Microsoft Teams. After three to seven days, the CI provided a compulsory one-on-one training session. Potential panel members were guided through Microsoft Teams and asked to complete a couple of tasks required for the consensus study before giving electronic informed consent via Jotform[©] (<u>www.Jotform.com</u>).

The NGT consensus meeting consisted of a facilitator and session moderators. The NGT consensus meeting convened for 4.5 hours (<u>Appendix N</u>). The four activities of the modified NGT consensus meeting are outlined in <u>Figure 7.1</u>. Panel members having difficulties during any of the activities were placed in breakout rooms with a moderator to support them. Activities 2 and 3 were deployed in real time with Jotform[®] questionnaires. A summary was presented back to panel members after Activities 1–3.



Figure 7.1. Overview of nominal group technique consensus meeting

7.4.2.2.1. Activity 1: Idea generation and round robin (convened for 30 minutes)

In three breakout groups, panel members discussed the intervention component list and were asked by the researchers if any interventions were missing and needed inclusion.

7.4.2.2.2. Activity 2: Clarification of important intervention components (convened for 30 minutes)

Panel members were asked to choose which interventions they felt were important by answering 'Yes' or 'No' on an electronic questionnaire. After the activity, the results were shared and discussed.

7.4.2.2.3. Activity 3: Ranking of important intervention components (convened for 45 minutes)

Panel members were asked to rate intervention components on scale of 1–9, with 9 indicating a high priority, demonstrating that it is important to them or could be to others based on RAM (Fitch *et al.*, 2001). After the activity, the results were shared and discussed.

7.4.2.2.4. Activity 4: Feasibility intervention components (convened for 45 minutes)

Panel members had a group discussion of whether it is important and feasible to deliver the included intervention components based on RAM (Fitch *et al.*, 2001). The NGT consensus meeting exceeded the scheduled time by 30 minutes, so panel members were emailed post hoc, asking them to rate whether interventions were important and feasible by answering 'Yes' or 'No' and to provide comments. All panel members responded to the email.

The discussion about whether intervention components were important and feasible were audio recorded and transcribed verbatim. The data derived from Microsoft TEAM audio recordings and chat, field notes and comments sent by email to the facilitator and were collected for analysis.

7.4.2.3. Analysis

The purpose of the study NGT consensus meeting was to reach agreement over priorities for comfort intervention components through the application of an NGT technique. The consultation groups generated two forms of data: a ranked list of comfort intervention components and a qualitative narrative of panel members' discussions about the feasibility of interventions in practice. RAM (Fitch *et al.*, 2001) was used to evaluate the quantitative data arising from the NGT consensus meeting. This method is used to combine scientific evidence with the collective judgement of experts (e.g. patients and TRs) to achieve a consensus opinion from the group. Patients were considered experts in their experience of comfort while receiving radiotherapy and how comfort interventions may help them and others. TRs were considered experts in treating multiple patients with radiotherapy and comforting patients in their care. The analysis of activities was

conducted in real time at the online consensus meeting and downloaded using Jotform[©] (<u>www.Jotform.com</u>) and Microsoft Excel.

7.4.2.3.1. Activity 1: Idea generation and round robin

Intervention components, including those suggested by the group were added to Activity 2 after discussion and clarification with the research team.

7.4.2.3.2. Activity 2: Clarification of important intervention components

Intervention components with >50% votes continued to Activity 3.

7.4.2.3.3. Activity 3: Ranking of important intervention components

Median Likert scores were recorded for prioritisation of individual intervention components. The mean absolute deviation of the median was calculated for interrater agreement between panel members and rated as low (>1.41), moderate (1.08–1.41) or high (<1.08; Fitch *et al.*, 2001).

7.4.2.3.4. Activity 4: Feasibility intervention components

Intervention component feasibility scores \geq 75% were judged feasible in radiotherapy, scores \geq 50% were judged feasible with caution and <50% were judged not feasible in radiotherapy.

7.4.2.4. Recommendations for inclusion in a comfort intervention package

Intervention components with a median Likert priority score ≥ 6 , a 'moderate' to 'high' interrater agreement and judged as feasible by $\geq 75\%$ of participants were recommended as 'included' for development in a radiotherapy comfort intervention package. A median priority score >6, a 'low' interrater agreement and/or a feasibility percentage between 50% and 74% were recommended as 'included with caution', indicating further investigation is required. A median priority <6 with a low interrater agreement and a high or low feasibility score were 'excluded' from consideration for a comfort intervention package or further investigation.

7.4.2.5. Qualitative analysis of feasibility

Qualitative analysis of the transcripts was undertaken using NVivo software package (Woolf and Silver, 2017). Due to the structured format of the modified NGT groups, a deductive analysis approach was adopted (Assarroudi *et al.*, 2018; Hsieh and Shannon, 2005). That is, comfort intervention components rated as 'included' and those recommended 'included with caution' and 'excluded' were used as a predetermined framework for the thematic analysis. Key terms used by participants to describe

intervention components were coded according to the intervention component they described. This process identified themes and contextual considerations associated with the intervention component and helped identify interactions or themes across multiple intervention components. These themes were used to determine the salient categories for the feasible implementation of a radiotherapy comfort intervention package. For trustworthiness and rigour, two panel members (one patient and one TR) were asked to complete a member check of the NGT consensus meeting findings.

7.4.3. Findings

7.4.3.1. Patient characteristics

Seven patients consented to participate: five new patients and two from the previous interviews (Goldsworthy *et al.*, 2023b, 2023c). Panel members were aged 35–72 years, and five were male. Two patients had received radiotherapy for head and neck cancer, three for lung cancer and two for pelvic cancer.

7.4.3.2. TR characteristics

Three TRs consented to participate, all from the previous interviews (Goldsworthy *et al.*, 2023b, 2023c). All were female and in advanced practice roles (years of experience ranged from 8 to 28 years) and were aged 32–51 years.

7.4.3.3. Prioritisation and feasibility of comfort intervention components

Fifteen intervention components were considered by panel members in Activity 1 (Table 7.1; Appendix O) to suggest modifications or additions. After discussion by the panel members and consideration by the research team, one further intervention component 'Visible or audio countdown clock of treatment length' was included for sifting at Activity 2. During Activity 2, panel members therefore considered 16 intervention components for importance. The panel voted to exclude 'Aromatherapy provided at patient request' but voted favourably for the other 15 intervention components. During Activity 3, five intervention components were recommended as 'include', moderate-to-high priority and feasible for development in a radiotherapy comfort intervention package. Six intervention components were 'included with caution', indicating further investigation is required based on a moderate-to-high priority and/or low interrater agreement and a low feasibility percentage. Four intervention components were 'excluded' from consideration in a comfort intervention package or further investigation due to low priority scores. In total, 11 intervention components were recommended for inclusion in a comfort intervention package consisting of those recommended as 'included' and 'included with caution' (Table 7.2).

Table 7.1. Intervention component list

	Before consensus meeting	After consensus meeting
1	Adjustments & supports provided for arms or legs during treatment by Therapeutic radiographers	Adjustments & supports provided for arms or legs during treatment by TRs
2	Aromatherapy provided at patient request	
3	Compassionate & empathetic communication training for TRs	Compassionate & empathetic communication training for TRs
4	Customised immobilisation provided by TRs (e.g. head moulds, vacuum bags or mask modifications)	Customised immobilisation provided by TRs (e.g. head moulds, vacuum bags or mask modifications)
5	Human touch in person (hand holding) or having something to remind of human contact (e.g. holding a soft item, such as a blanket) provided at patient request	
6	Patient advice/training in meditation, including talking to self, faith readings, chants, counting down or visualising going on a holiday and focusing on machine lights/lasers or noise	
7	Patient practice run of treatment position with TR	Patient practice run of treatment position with TR
8	Referral to talking therapies (e.g. counselling, hypnosis or cognitive behavioural therapy) by TRs at patient request	
9	Soft pads/mattress under the body to alleviate body discomfort, managed by TRs	Soft pads/mattress under the body to alleviate body discomfort, managed by TRs
10	Sound and music interventions, such as nature sounds, music, audio books, relaxation, instructions and updates during treatment delivered at patient request	Sound and music interventions, such as nature sounds, music, audio books, relaxation, instructions and updates during treatment delivered at patient request
11	Stretching and exercises coaching before and after positioning for radiotherapy treatment	Stretching and exercises coaching before and after positioning for radiotherapy treatment
12	Tailored information – for example, TRs provide the required information only as part of preparation for treatment	Tailored information – for example, TRs provide the required information only as part of preparation for treatment

13	Tour of radiotherapy in person or video provided at patient request	Tour of radiotherapy in person or video provided at patient request
14	Visual interventions, such as pictures or projections of nature or similar on walls or screens delivered at patient request	Visual interventions, such as pictures or projections of nature or similar on walls or screens delivered at patient request
15	Workshop by TRs on what to expect (e.g. position, mask and bladder/bowel preparation)	Workshop by TRs on what to expect (e.g. position, mask and bladder/bowel preparation)

	-	Activit Prioritis	-		Activity 4 Feasibility		
After Activity 1	Is intervention	score	Mean absolute deviation from the median		Feasible & deliverable in radiotherapy (%Yes)	Recommendation for inclusion in a radiotherapy comfort intervention package: include*, include with caution [†] or exclude [‡]	Qualitative analysis of participant discussion leading to categories for feasible implementation (e.g. subthemes linking interventions to quotes) – a full analysis can be found in Appendix O.
Compassionate and empathetic communication training for TRs		9.0	0.7	High	90%	INCLUDE	Four categories emerged from the panel: 'Natural Compassion from Staff Appreciated', with one patient saying, <i>Personal interaction</i> ++++, <i>You can't</i> <i>beat personal interaction</i> [P1]. The second category was about retaining humanity: 'Don't Overmedicalise', with another patient stating, <i>Don't</i> <i>overmedicalise that bit of informality, that bit of humanity</i> [P2]. The third category was 'Education in Compassion & Empathy', embedded in TR comments such as <i>I think any advanced communication skills</i> [and/or clinical <i>supervision</i>] should be as available [R2]. The final category was about choice – 'Choosing from a Toolbox of Interventions', with a TR voicing their thoughts: <i>It's good because then you can just select from them. Depending on the</i> <i>patient's needs</i> [R2]. Patients agreed there should be a choice: Upon request <i>is vital</i> [P2].
Tailored information – for example, TRs provide the required information only as part of preparation for treatment	100%	9.0	0.8	High	80%	INCLUDE	Three categories emerged from the panel: Although priority and feasibility were high, there was concern voiced by participants represented in the category 'Time for TRs to Tailor Information', including this quote: <i>But time for therapeutic radiographers to do this is required</i> [R1]. Another category, 'Do Not Overload Patients', considered the information burden on patients demonstrated in this quote: <i>because it's quite hard to take everything in [amount of information] in one go</i> [P4]. The final category emphasised a focus on when to provide information 'Provide Information When Required During Radiotherapy (Not All#1)', with a patient suggesting, <i>It might be a good idea to have maybe have six or eight sessions and then for someone just to say,</i> ' <i>Right? You know we've been through some of it. Is there anything you're puzzled about? Or is there anything we can make clear'</i> [P4].

Table 7.2. Prioritisation and feasibility of comfort intervention components

Workshop by TRs on what to expect (e.g., position, mask and bladder/bowel preparation)	90%	7.5	0.9	Moderate	80%	INCLUDE	Here, there were three categories for feasible implementation: first, 'Choice & Format of Workshops', with patients voicing their view that choice is important (<i>I would like to attend a workshop upon request</i> [P2]) and a TR stating, <i>I think these could be online too</i> [R1]. The second category was 'Efficiency of Workshops', which was derived from quotes such as <i>If patients are grouped together, this is feasible</i> [R2]. The third category was 'Specificity of Workshops': <i>What is quite big because of discomfort can be having to maintain a full bladder, so a specific workshop would help</i> [R3].
Adjustments and supports provided for arms or legs during treatment by TRs	80%	8.5	1.2	Moderate	80%	INCLUDE	Two categories for feasible implementation were: 'Adjustment, Consideration & Risk', derived from quotes such as 'Yes, we want to make someone comfortable on the couch, but how far do we go?' [R1] and 'Assessment of Position for Individualisation', derived from the desire to assess a patient's ability to hold position: <i>Not just about exercising, but straight up assessing our movement beforehand if required</i> [P7].
Sound and music interventions, such as nature sounds, music, audio books, relaxation, instructions and updates during treatment delivered at patient request	100%	6.5	1.4	Moderate	80%	INCLUDE	Two categories were created: The first was 'Choice and Selection', voiced by a patient who indicated it was straightforward: <i>Easy enough to provide or</i> <i>have patient bring their own iPod/mobile phone</i> [P1]. The second category was about using this intervention component as a 'Distraction & Coping' solution, with a TR noting, <i>A distraction with music or sounds are beneficial</i> [R3], and a patient stating, <i>Broad agreement with this as a coping strategy</i> [P5].
Tour of radiotherapy in person or video provided at patient request	90%	8.0	0.6	High	70%	INCLUDE WITH CAUTION	The potential challenge of tours in person were highlighted with a preference by participants for virtual approaches as per the category 'Online or Video Tour or Information Is Time Efficient', which was voiced by participants: <i>Video</i> <i>definitely could be done. [It is] difficult to do in the working day in a busy</i> <i>department</i> [R3].
Soft pads/mattress under the body to alleviate body discomfort, managed by TRs	90%	7.5	1.3	Moderate	60%	INCLUDE WITH CAUTION	The concern over this component may be around ensuring reproducibility of treatment position. A TR highlighted the category 'Caution in Using Soft Pads Due to Reproducibility': <i>Providing a balance is struck – that is, a mattress which is too soft and thick may cause the patient to move more</i> [R1]. A second category suggested a focus is required 'Soft Wedges & Mattresses to Assist Position of Limbs', as voiced by one patient: <i>All I said really is that so long as you get the original position in right and if you could add a perhaps some of these soft pads elsewhere</i> [P4].

Visual interventions, such as pictures or projections of nature or similar on walls or screens delivered at patient request	, 90%	6.0	1.5	Low	50%	INCLUDE WITH CAUTION	Two categories emerged. There were concerns about cost implications. This was observed in the first category – 'Cost Implication of Visual Interventions', with a TR saying, <i>There is a cost implication of visual interventions</i> [R2]. However, visual interventions may not have to be complex, as illustrated by the second category: 'Simple & Calming Visualisation Possible', with a TR stating, <i>Simple visualisation techniques/counting etc is reasonable</i> [R3], and patients acknowledging potential benefits as well: <i>Calming images or videos would have allowed me to put myself elsewhere</i> [P7].
Stretching and exercises coaching before and after positioning for radiotherapy treatment	90%	7.5	1.5	Low	80%	INCLUDE WITH CAUTION	Three categories emerged: There was concern about the time indicated as 'TR Time & Training', with a TR stating, <i>Staff time is required to specifically</i> <i>discuss this. Training is required for staff</i> [R1]. However, in another category, 'Self-Direction (Video) in Stretching to Save Time', it was suggested that time could be saved by using a prerecorded video: <i>This could be covered fairly</i> <i>easily face to face and save time with video</i> [P5]. It was felt that specificity is required in the category 'Specific Anatomical Stretches', with a patient voicing, <i>I think it's a great idea, particularly for patients receiving treatment to the torso</i> <i>region</i> [P3]. A TR agreed, mentioning that TRs need to be up to date with most recent research/practice in exercise – for example, pelvic floor exercises [R1].
Patient practice run of treatment position with TRs	80%	8.5	1.6	Low	70%	INCLUDE WITH CAUTION	There was concern about the extra time and resources required. The category 'Time & Resources for Practice Run Through of Position' was expressed by a TR who highlighted key considerations for the service: <i>Time implications and</i> <i>machine availability implications</i> [R3]. Contrary to this concern, patients favoured the intervention component, believing that it could be accommodated: <i>This could happen during the planning appointment if not</i> <i>already achieved</i> [P1].
Customised immobilisation provided by TRs (e.g. head moulds, vacuum bags or mask modifications)	80%	7.5	1.5	Low	90%	INCLUDE WITH CAUTION	Two categories emerged. The potential lack of customisable immobilisation available in a radiotherapy department was a concern. The first category defines the challenge – 'Availability of Customisation Devices' – as per a TR quote: <i>Providing the centres has customisable immobilisation available</i> [R1]. A second category suggests 'Customisation to Aid Overall Position' should be attempted: <i>If this were expanded to include patients requiring help to remain in a position, then it is a very good idea</i> [P3].

Patient advice/training in meditation, including talking to self, faith readings, chants, counting down or visualising going on a holiday and focusing on machine lights/lasers or noise	60%	4.5	1.6	Low	30%	EXCLUDE	Three categories emerged. There was some concern that specific training would be required for TRs. The first category was 'Specialist Training Required', as per the following TR quote: <i>I don't think that I am able. It's in my skill-set to train people in meditation or chanting</i> [R2]. Similarly, a second category proposes that 'Not Everyone Can Meditate', and a patient said, <i>Uncertain about this not everyone goes on holiday?!</i> [P2]. However, in a third category, 'Do It Yourself', some patients find their own way without anything formal, with a patient stating, <i>And I think me and then you just find you just think. Well, it's 'I'm here now'. It's not going to be too long, and you find your own way through it, really</i> [P4].
Aromatherapy provided at patient request	40%	-	-	-		EXCLUDE	Two categories emerged. Although some panel members seemed positive about aromatherapy, they did state that smells are person dependent, leading to the first category 'Smells Are Person Dependent and Can Be Like "Marmite". A TR said, <i>I thought aromatherapy was a nice option, as some</i> <i>people find smells more comfortable than visual/audio. Aromatherapy, I think,</i> <i>is very person dependent? As X said, some smells may not be great for other</i> <i>people</i> [R1]. The second category was 'Smells Can Linger'. A patient stated, <i>Smells or aromas will linger, which may have made me feel sick</i> [P6].
Human touch in person (hand holding) or having something to remind of human contact (e.g. holding a soft item, such as a blanket) provided at patient request	60%	4.0	1.7	Low	30%	EXCLUDE	The exclusion of this intervention component caused some controversy, with three categories emerging: The first category was 'Human Touch Is Essential': <i>I'm just surprised that the human touch didn't make it through, given how technological and how clinical the whole system is and has to be</i> [P2]. The second category 'Holding Something May Help' suggests that touch may be feasible in other formats: <i>[It is] possibly feasible to hold a soft item, etc. should treatment allow, but human contact during treatment [is] infeasible</i> [P3]. Then on balance a TR stated why some forms of touch may not be possible: <i>And things that people can hold to remind them. For obvious reasons, handholding during treatment is impossible, but if someone wanted to hold an object of comfort, I don't see why not</i> [R2]. The last quote leads to the third category – 'Holding Something During Treatment Is Not Feasible'.
Referral to talking therapies (e.g. counselling, hypnosis or cognitive behavioural	70%	5.5	2.2	Low	70%	EXCLUDE	Four categories emerged. Panel members stated that some patients may have benefited from talking therapies and were surprised it was excluded with Category one, 'Some Would Benefit from Talking Therapies or Coping Strategies', and Category two 'Surprised That Talking Therapies Were Excluded'. A patient said that talking therapies <i>could be an extremely useful</i> <i>tool for worried patients</i> [P2], and a TR surprised of the exclusion noted,

therapy) by TRs at patient request							Yeah, I mean I'm a bit surprised about the referral to talking therapies as well? [R2]. However patients and TRs voiced that it should be standard, with the third category 'Should Be Standard Care Already' (<i>Do this anyway and should</i> <i>be standard practice</i> [P6]) and a fourth category 'Elsewhere in the Patient Pathway' (<i>That is a really relevant point that some of the interventions may be</i> <i>better at different times in the radiotherapy pathway, and in order to practically</i> <i>apply, these could be useful to think about</i> [R1])
Visible or audio countdown clock of treatment length	90%	4.0	2.3	Low	70%	EXCLUDE	One category emerged: 'Challenging Logistics of Having a Countdown Clock at Treatment Delivery'. Panel members suggested this is not really feasible, considering treatment times vary day to day. A TR noted, Our treatment delivery times change each day, so a countdown will be challenging. We can tell patients when halfway through [R3].
Total interventions included or included with caution							11

Note. TR: therapeutic radiographer

Based on the comfort interventions components, categories of feasible implementation emerged (<u>Table 7.2</u>) from panel member narratives (<u>Appendix O</u>). These categories arose from the consideration of TR time, resources, training, practicalities and online or video approaches to utilising a toolbox approach for patients to select from. An example of an excluded intervention component was 'Human touch in person (hand holding) or having something to remind of human contact (e.g. holding a soft item, such as a blanket) provided at patient request'. Panel members were divided over their views, some disappointed that human touch was excluded with a category 'Human Touch Is Essential': 'I'm just surprised that the human touch didn't make it through' [P2]. Others acknowledged that human touch was not practical during radiotherapy with the category 'Holding Something During Treatment Is Not Feasible':

For obvious reasons, handholding during treatment is impossible, but if someone wanted to hold an object of comfort, I don't see why not. [R2]

Although human touch is an important aspect of care, it is impossible during the delivery of radiotherapy, although touch can be facilitated using remote technology (Goldsworthy *et al.*, 2020b).

An example of an intervention component that was included with caution was 'Stretching and exercises coaching before and after positioning for radiotherapy treatment' with the category 'TR Time & Training'. Panel members felt that this component had the potential to be a time burden for TRs, stating,

Staff time is required to specifically discuss this. Training [is] required for staff so they are up to date with most recent research/practice in exercise – for example, pelvic floor exercises'. [R1]

Others suggested that there may be opportunities to make these interventions possible with the category 'Self-Direction (Video) in Stretching to Save Time'. Panel members suggested that time could be saved by using a prerecorded video, with a patient stating, 'This could be covered fairy easily face to face and save time with video' [P5].

An example of an 'included' intervention component was 'Compassionate & empathetic communication training for TR' with the category 'Natural Compassion from Staff Appreciated', with a patient noting, 'Personal interaction ++++. You can't beat personal interaction' [P1]. A second category– 'Don't Over Medicalise' – summed it all up, with another patient saying, 'Don't over medicalise that bit of informality, that bit of humanity' [P2].

'Resource Considerations' was an outlier and was deemed applicable to all interventions, including the following categories: 'Do We Actually Need an Intervention?', 'Financial

Considerations', 'Logistics, Staffing, Equipment, Training & Access', 'Online or Video' and 'Radiation Environment Considerations'. The following patient quote summarises this category:

It is a very good idea and would be fantastic in a perfect world, but I recognise this could be unworkable or severely restricted by departmental budgets, staffing levels, workloads and space. [P3]

7.4.4. Discussion

The objectives of this NGT consensus meeting were to identify and prioritise intervention components for inclusion in recommendations for a radiotherapy comfort intervention package and explore feasibility. Eleven intervention components were recommended for development in a radiotherapy comfort intervention package, and five components were excluded. Aromatherapy was the only intervention component 'excluded' at Activity 2. The panel considered aromas to be person dependent and that smells could linger impacting on patients who really do not want it. This is a serious concern because patients receiving cancer therapies can suffer hyperosmia, causing nausea (Bernhardson, Tishelman and Rutqvist, 2009). At Activity 3, four more intervention components were 'excluded' because the panel members felt that TRs were not skilled to coach patients in meditation and a countdown clock is logistically difficult, with fluctuating treatment delivery times. Intervention components 'accepted with caution' arose from panel members who considered there was potential for extra training, increased treatment session times, an effect on positional reproducibility, radiation attenuation, availability of devices in all departments and cost. Intervention components 'accepted' were considered feasible for practice; however, the panel had similar concerns to intervention components accepted with caution, although they highlighted some categories that enabled implementation. These included choosing intervention components and a format, providing information when required and in groups (for efficiency) and assessing position.

For many intervention components, there was concern about the impact on the efficiency of radiotherapy services. This led to the emergence of the overall implementation category 'Resources'. In the real world, this highlights, for example, that training, extra facilities, extra equipment and extra time during treatment or after the treatment session may be needed. However, how an intervention component is implemented and delivered will determine the overall impact on services. For example, if a thorough process of implementation is undertaken, where observation (Gemba walking – a walk through to refine the process) and refinements are made, then it is possible to create efficiencies and negate the concerns in this category (Cheuk *et al.*, 2015). Furthermore, some studies have found that taking steps to improve comfort during radiotherapy produces similar or

improved reproducibility and reduces patient setup times (Deseyne *et al.*, 2020; Bartlett *et al.*, 2013). Therefore, the recommended comfort intervention components should be carefully considered in practice.

Although there is a justified concern about resources, many of the intervention components exist within the current infrastructure of many radiotherapy services. The recommended list of intervention components has the potential to improve patient outcomes through improving comfort as radiotherapy treatment times increase with more advanced techniques (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). Supporting patients to complete their radiotherapy treatment using a comfort intervention package is likely to improve stability and the accuracy of radiotherapy. A previous work in this area, including an SLR of effective interventions, provides the required details to develop intervention package needs to be developed for patients with cancer receiving radiotherapy, and this package should be adaptable to age and deployed at the patient's choosing.

Given the limited recommendations of how to manage patient comfort during radiotherapy from national and European guidelines (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021; Leech *et al.*, 2017; Benedict *et al.*, 2010), we suggest that a comfort intervention package now needs to be developed and tested for fidelity in radiotherapy.

7.4.4.1. Methodological considerations

A limitation of the present study is there was only one NGT consensus meeting round. Furthermore, even after further recruitment initiatives, the panel was small, consisting of seven patients and three TRs. This may have been due to the COVID-19 pandemic. While including patients and TRs can be highlighted as one of the strengths of this NGT consensus meeting, different participants may have yielded different conclusions, and one vote in a small panel could exclude an intervention component which warrants further investigation. Regarding this methodological consideration, we utilised a pragmatic approach to recommending interventions using a modified NGT endorsing an 'included with caution' criteria. Even with this dispensation, this potential limitation must be acknowledged.

7.4.5. Conclusion

This study determined the important components to include in a radiotherapy comfort intervention package, based on consensus from a panel of patients and TRs. As

radiotherapy evolves to improve outcomes, interventions must also be developed to ensure patients can comfortably comply with the associated increased treatment times. Eleven components have been recommended for inclusion in a radiotherapy comfort intervention package. The clinical implications of our study are to encourage the incorporation such intervention components into the existing infrastructure of radiotherapy services. Future research is recommended to develop specific intervention strategies to address the recommended components. The resultant radiotherapy comfort intervention package can then be evaluated robustly in terms of feasibility, fidelity and clinical and cost effectiveness.

7.5. Chapter summary

Based on the NGT, 11 comfort intervention components are recommended for development in a radiotherapy comfort intervention package, and they relate to Wilson and Kolcaba's (2004) comfort intervention categories: technical, coaching and comfort food for the soul. The synthesis of priority and feasibility data against the 'categories of feasible implementation' highlighted commonality and discordance, which revealed why some intervention components were accepted, accepted with caution or excluded. The findings of qualitative analysis produced categories for feasible implementation, which could be used as a checklist for service adoption. It is expected that a substantive feasibility trial will field test intervention components as a package for patients receiving radiotherapy to improve comfort, accuracy and support for adherence to life-saving cancer treatment.

8. Chapter eight: Discussion

In this chapter, the discussion of the research presented in the preceding chapters is extended in relation to the SLR as well as the interviews and consensus study with patients and TRs. The discussion starts with an overview of the PhD programme, followed by a discussion of each stage. The discussion of Stage 1 includes focusing on radiotherapy delivery, choosing clinical procedures similar to radiotherapy, achieving precision of data extraction and defining intervention categories. The discussion of Stage 2 includes credibility, trustworthiness, rigour, the sample of interview participants and the thematic analysis of interview transcripts. Additional discussion considers transferability, representativeness and representation, patient-centred care and assessment of compliance or comfort. The discussion of Stage 3 includes triangulation of the SLR and qualitative interviews as well as the online format of the consensus study. This is followed by an overall discussion of the complexity of comfort, PRP involvement, the novelty of the findings, key findings, clinical implications and a chapter summary.

8.1. Overview of the PhD programme

The overarching aim of this PhD programme was to develop recommendations for a comfort intervention package for patients receiving radiotherapy with extended treatment times. The research focused on radiotherapy interventions where patients are positioned and immobilised and must remain still for over 10 minutes to receive their treatment. In this PhD programme, by working with patients and TRs, comfort interventions were identified and characterised, comfort experience and comfort solutions reported and recommendations for components of a comfort intervention package in radiotherapy agreed upon. The underlying principle was that if patients can be made more comfortable, they will be more likely to comply with treatment, and their radiotherapy will be more accurate, thereby improving outcomes. The ethos was to individually tailor the intervention to the individual comfort needs of patients. The uniqueness of this research has been the inclusion of three main anatomical cancer sites – head and neck, breast/lung and pelvis – and the use of Kolcaba's (1994) comfort theory to inform this programme.

8.2. Discussion of Stage 1: Systematic review of comfort interventions in health and social care practice

8.2.1. Focusing on radiotherapy delivery

The focus of this thesis was to develop recommendations for a comfort intervention package for patients receiving radiotherapy with extended treatment times. This is important because radiotherapy involves targeting cancerous cells with high-energy radiation to destroy them. However, healthy tissues surrounding the tumour are sensitive to radiation (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). Comfortable, stable and accurate treatment ensures that the tumour receives the intended dose while minimising radiation to healthy tissues, and therefore minimising the risk of unnecessary side effects or collateral damage. The justification for focusing on times exceeding 10 minutes was to capture patients who must hold position for an extended period which may lead to discomfort resulting in a lack of stability and inaccuracy of the radiotherapy. Two studies investigating intra-fraction motion in patients receiving radiotherapy for prostate cancer, found that treatment accuracy decreased as treatment time increased (Gill *et al.*, 2014; Smeenk *et al.*, 2012). A later study of patients with head and neck cancer receiving radiotherapy similarly found decreasing accuracy over time (Mangesius *et al.*, 2019). The latter group of patients were rigidly immobilised in a thermoplastic mask, yet still there is movement. Patients are not easily able to control small movements although if they are comfortable, this could theoretically help them to remain still.

Kolcaba's (1994) conceptual framework of patient comfort in nursing care outlines how comfort can be met through ease, relief and transcendence within four domains and is used throughout this thesis and within the systematic review. This theory includes an expanded view that comfort is more than just a physical construct, and considers sociocultural, psychospiritual, and environmental comfort domains. With this holistic view of comfort, it may be a challenging task to address all the domains in radiotherapy. Some may consider that the sole focus on a radiotherapy treatment session constitutes a narrow view of the patient experience, that could be deemed not holistic (Frisch and Rabinowitsch, 2019). Some may argue that there is need to capture the patients experience throughout the oncology pathway. The validity of this view can be debated but the crux of the problem is the gap in evidence related to providing comfort interventions during radiotherapy. Moreover, there is a need to bolster the human experience of comfort against the highly technical life-saving treatment of radiotherapy.

The domains of psychospiritual, sociocultural and environmental comfort (Kolcaba, 1994) neatly complement physical comfort before and during radiotherapy and could be considered in the form of enhancing preparation for radiotherapy, improving facilities so they are more welcoming, or the use of relaxation methods or meditation. Wilson and Kolcaba (2004) provided a practical application of her comfort theory. This practical application includes the following intervention categories: technical, coaching and comfort food for the soul. The technical pertains to the standard interventions to maintain homeostasis such as repositioning in radiotherapy. Coaching pertains to the potential support given to alleviate anxiety such as TRs speaking to patients via the intercom
system during their radiotherapy treatment. Comfort food for the soul pertains to the warmth of the treatment room, a blanket, empathetic touch or patients having their preferred music (Wilson and Kolcaba, 2004). This structured approach is similar to the development of intervention categories defined in the PhD programme SLR; audiovisual technology interventions, psychological interventions, physical interventions and other interventions which included education and aromatherapy (Goldsworthy, Palmer et al, 2020). While Wilson and Kolcaba's (2004) structured approach may have provided inspiration to conduct this PhD research, further research was needed to explore the subjective, evolving experiences that patients and TRs create through their narratives and sense of agency.

8.2.2. Choosing clinical procedures similar to radiotherapy

Presently, many radiotherapy departments deliver complex radiotherapy with daily image guidance to ensure accuracy (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021). This means that each treatment usually exceeds ten minutes, and this time burden is increasing. The search strategy extended beyond radiotherapy because it is a small specialism with a limited number of published studies, and it was thought that searching beyond radiotherapy would extend unilateral thinking within the profession and expand the horizon of this research (Alvesson and Sandberg, 2022). A rigorous process for screening potential studies was guided by a registered SLR protocol (Goldsworthy, Cramp, et al., 2020). In this SLR, the intention was to seek clinical procedures with similar attributes to radiotherapy. The study eligibility criteria were determined with the research team, TRs, and PRPs. Eligibility of included studies were that patients had to be conscious during the clinical procedure; the procedure required stability, alignment and immobilisation of patients; and patients must endure and sustain the procedure for over 10 minutes. The challenge was determining the similarities between P&I for other clinical procedures and those adopted in radiotherapy. Most clinical procedures were observational investigations such as endoscopy (n = 14) which require precision although not to the same degree as surgery or radiotherapy where the slightest positional error can lead to collateral damage to healthy tissue (Appendix E). The subtle similarities and differences equated to many hours deciding on eligibility, with four studies needing arbitration from an independent researcher. This highlights the importance of integrating transparency, with clear objectives and a replicable process. The eligibility criteria were open to the interpretation of the researchers and were not without subjectivity. Bias may be due to their professional backgrounds as a TR (SG) and physiotherapist (MC) and how they view the world. However, a strict eligibility process guided both researchers and at each step of eligibility assessment researchers referred to the published SLR protocol.

8.2.3. Precision of data extraction

A SLR investigated flaws with systematic reviews and reported that many discrete problems in the conduct, methods and reporting can jeopardise validity and reliability of evidence (Uttley et al., 2023). Therefore, the intention was to ensure that the SLR in this PhD programme was planned meticulously to ensure validity and reliability. The PhD researcher had envisaged that an autonomous system to extract and screen data would save time and reduce researcher bias especially when screening the 5,269 papers identified in the SLR (Tsafnat et al., 2018). It would ensure an exact match to the registered protocol without deviation and that the process has repeatable precision (Basu, Goldsworthy and Gkoutos, 2021). The PhD researcher co-developed a machine learning natural language processing system to extract OMs from this SLR and later setup errors using Python (Basu, Goldsworthy and Gkoutos, 2021; Goswami et al., 2019). The latest system was built using Python code and can be viewed in Github[™]. Extracting setup error outcomes from text and tables, the prototype system demonstrated good levels of recall, precision and F measure using logistic regression, random forest, and support vector machine classifiers (Basu, Goldsworthy and Gkoutos, 2021). Even with this exciting promise, the PhD researcher suggests there is a requirement for human interaction even with the inception of this potentially game changing prototype software (Basu, Goldsworthy and Gkoutos, 2021). Using machine learning systems to auto extract data should be considered as a tool to support researchers, especially when there is a welldefined criterion for eligibility of included studies. The eligibility criteria of the SLR in this PhD programme was very specific and were strictly adhered to during screening although future researchers may need to change these criteria as radiotherapy evolves further. It must be acknowledged that producing the initial criteria of clinical procedure eligibility was challenging, it took time and discussion which may not suit an autonomous system.

8.2.4. Risk of publication bias

Publication bias refers to the tendency for studies with positive or significant findings to be more likely published, while studies with negative or nonsignificant results to be under reported or not published at all (Winters and Weir, 2017). Murad *et al.* (2018) stated that publication bias is the most difficult bias for reviewers to overcome. Publication bias can creep in at any phase, from the investigators not publishing their 'negative' studies or facing delays when submitted for publication. Murad *et al.* (2018) asserted that not including unpublished studies face the potential for optimistically estimating treatment effectiveness. However, these authors suggested that the studies with larger samples are less likely to remain unpublished. Brodeur *et al.* (2023) stated that 30% of studies remain unpublished. Moreover, journal editors will not accept the inclusion of unpublished data in systematic reviews because these potential studies will not have passed through peer

review (Brodeur *et al.*, 2023). Winters and Weir (2017) suggested that the first step for reviewers is to identify if there are any unpublished studies data. Step two is to estimate the treatment effect of unpublished studies using funnel plots analysed using a trim and fill method. This then could lead to the final analysis of effect sizes being 'nudged' possibly forming a new inference which may be favourable to intervention or control. Afonso *et al.* (2024) stated that assessing true publication bias is frequently not possible. In agreement with Maier *et al.* (2022), Afonso *et al.* (2024) concluded that using the commonly used funnel plots may be misleading and result in an incorrect inference or absence of risk of publication bias should be avoided. Afonso *et al.* (2024) promoted the methodological rigour for authors of SLRs such as registration, providing a wide search strategy with inclusivity of publication language and date with the belief that this will negate the effect of publication bias.

The PhD researcher also had concern that unpublished studies could have an uncertain methodological quality having not been through journal peer review. Without knowing how rigorously unpublished study data had been handled, the PhD researcher was sceptical about including it in the SLR. For this PhD programme, a search of clincialtrials.gov, the international clinical trials registry platform and search databases for published protocols was conducted at the outset of the SLR to determine if there were any unpublished studies, or soon to be published studies. None were found that met the inclusion criteria, but the grey search for unpublished studies was not repeated at the completion of the SLR. If unpublished data were found it would not have been used for the reasons given.

8.2.5. Defining intervention categories

Many interventions were identified from the literature search, and it became apparent there was a degree of similarity between them. Therefore, it was decided to categorise interventions to synthesise the available information and consider implications aligned to Kolcaba's (1994) comfort theory. For example, those with some type of sound (music, relaxation, spiritual/faith words) and those with some form of visual attribute (picture, optic display) were grouped into the category 'audiovisual' (<u>Appendix F</u>). Those with a physical (e.g. massage) or psychological (e.g. hypnosis) component were grouped into 'physical' or 'psychological' intervention categories. However, a wide range of interventions including educational and aromatherapy interventions were grouped into an 'other category'. The educational interventions were not felt to fit the existing categories and aromatherapy was felt to fit into both physical and psychological categories so both were grouped into the 'other category'. These intervention categories are not absolute and can be fluid in their interpreted effect on physical or psychospiritual comfort. For example, while audiovisual is a category, it may have an impact on the psychospiritual, physical and

environmental comfort for patients. While these intervention categories fit within Kolcaba's (1994) four contexts of comfort, it can be said that there is not a precise fit when it comes to comfort experienced or discomfort that is eased. Patient comfort is complex and is unlikely to ever be unidimensional and rather it should be considered as multidimensional. Furthermore, Chandra, Raman and Kolcaba (2016) concluded that comfort is not a one-shot intervention when applying Kolcaba's comfort theory to children post-surgery. Instead, they found an integrative approach to develop a comfort care bundle produced via Kolcaba's taxonomic structure, and iterative process using multiple comfort aids improved comfort when evaluated in a 5-year-old before and after laparotomy. Whilst the care bundle seemed favourable little can be inferred from a single participant case study.

The intervention categories presented in this SLR can be related to the three comfort categories, technical, coaching and comfort food for the soul defined by Wilson and Kolcaba (2004). Technical may refer to the physical comfort intervention category, coaching may refer to the psychological comfort intervention categories, and comfort food for the soul looks to cover all; physical, psychological, audiovisual and other (education/information) intervention categories in the PhD programme SLR. Wilson and Kolcaba (2004) and Stephens, Barkley and Hall (1999) recommended multiple interventions to address the complexity of comfort during anaesthesia recovery and for children during invasive procedures such as spinal tap. These multiple interventions included physical repositioning to ease discomfort, enabling family to support where possible and psychospiritual comforts such as providing tailored information and enabling spirituality for patients undergoing anaesthesia procedures and children undergoing invasive procedures (Wilson and Kolcaba, 2004; Stephens, Barkley and Hall, 1999). There is a dearth of research to confirm this inference in radiotherapy in adult patients, rather than in children. Kolcaba's (1994) comfort theory had a large influence how comfort interventions were developed in this PhD programme but, a newer framework, CALM, provides a more simplified view with great usability (Wensley et al., 2017). The two frameworks of comfort complement each other in developing comfort interventions and although only Kolcaba's framework was used, both would be considered for future research. Kolcaba's comfort theory could be used for the comprehensive development of interventions because it is multifaceted, while the simplified CALM framework is useful to situate the developed intervention for clinical implementation. Based on these two theories of comfort, this PhD programme encourages further research to establish if a single intervention or a bundle of interventions is more effective. Further work could also be conducted to elucidate the discrete nuances of comfort experienced to tailor intervention categories.

8.3. Discussion of Stage 2: Interviews with patients and TRs – Experiences of comfort during radiotherapy/comfort management during radiotherapy

8.3.1. Credibility, rigour and trustworthiness of interviews

In the context of interviews, the qualitative research process can evolve in different ways, depending on the research aims and objectives. This evolution starts when interviews are being conducted and is refined all the way through to the final steps of thematic analysis, as recommended by Braun and Clarke (2006). The process of qualitative analysis can change over time as the researcher interacts with the data and discovers new insights that modifies their understanding of the research topic. Changes can be spurred by several factors, such as the researcher's familiarity with the data, the emergence of new trends or patterns, or the influence of external events on the field of study (Creswell, 2014). Ensuring credibility, trustworthiness, and rigour in the interview process is essential for producing valid and reliable findings.

Credibility is the measure of truth of qualitative research and whether study findings are accurate. It is mostly about the credibility of the researcher and includes their familiarity with the methods they are using (Uhrenfeldt, Paterson and Hall, 2007). The credibility of the interview process can be enhanced by having researchers with appropriate training in qualitative research methods, interview techniques, and communication skills (McGrath, Palmgren and Liljedahl, 2019). Alternatively, an inexperienced or untrained interviewer may struggle to establish rapport with participants, leading to less credible data (Uhrenfeldt, Paterson and Hall, 2007). The doctoral candidate was supported by experienced doctoral supervisors who advised some preparatory work. First an interview guide was compiled. Careful development of open-ended and contextually relevant questions can improve credibility by eliciting rich and detailed responses from participants. Poorly worded or leading questions can introduce bias or limit the depth of responses (McGrath, Palmgren and Liljedahl, 2019). Therefore, the interview guide was drafted, and amended with feedback from the supervisory team and PRPs. This ensured the questions were open and not leading.

Rigour in qualitative research is achieved with systematic methodology, transparent processes, and accurate reporting (Johnson, Adkins and Chauvin, 2020). During interview, rigour can be improved by providing interviewers with extensive training and clear guidelines to ensure consistency in how questions are asked, and responses given. Conducting pilot interviews can help identify potential issues with interview questions, probes, or the overall process, which can be addressed before the main data collection (Malmqvist *et al.*, 2019). As per published guidance for novice researchers (Roberts,

2020) two pilot interviews were conducted, with feedback given based on the audio recordings. A debrief with doctoral supervisors was helpful to address issues of over leading the interviewees. However, it is known that pilot interviews may not represent the entirety of situations that may occur but can still be useful in modifying the interviewers conduct (Birt *et al.*, 2016). While the pilots provided extensive transcripts, the actual interviews were sometimes very short, although perhaps more to the point. The participants were aware that the PhD researcher was a TR which may have impacted on the interview dynamic and outcome providing a greater or lesser amount of data. The PhD researcher reflected on this and took steps to create rapport with interviewees and ensured that he maintained professional distance without leading them (Wilson, Janes and Williams, 2022).

The next step for ensuring trustworthiness was consideration of data collection processes. Trustworthiness in qualitative research is the degree of confidence in the data, interpretation, and methods to ensure they are genuine (Anney, 2014). Clearly defined procedures for conducting interviews and handling data (e.g. audio recording, transcription, and storage) contribute to trustworthiness. Inconsistent or poorly documented data collection procedures can compromise data integrity (Chenail, 2011). At the design phase of this study, there was discussion about how and where data were stored to ensure efficiency, reliability of equipment, confidentiality, data protection and privacy. Rigorous data management practices, including verbatim transcription and secure data storage, contributed to the reliability and rigour of the interview data (Chenail, 2011). Furthermore, trustworthiness and credibility were achieved via peer review with a fellow PhD researcher, and review with PRPs and the doctoral supervisory team. This then led to the researcher questioning his own assumptions on the interpretations of data and how this may be ameliorated. This was handled by writing reflexive field notes and discussing interpretations with PRPs, doctoral supervisors and peers. The routine recording of decisions about aspects of analysis provided transparency in aiming to avoid unilateral views of the researcher. The process enabled the patients' and TRs' voices to be heard by continuously gaining counterbalance through this process of reflexivity (Wilson, Janes and Williams, 2022). The interpretations of data were edited according to feedback on the recorded field notes.

The PhD researcher considered his philosophical positionality as a TR undertaking research in radiotherapy. Researcher positionality refers to the researcher's personal and social characteristics, experiences, and perspectives that can influence every aspect of the research process, from the formulation of research aims to data collection and analysis (Wilson, Janes and Williams, 2022; Fenge *et al.*, 2019). As a TR, the researcher was familiar with the context of the study which facilitated rapport with participants leading

to insightful data. It may also have prompted participants to provide closed answers confined to the researcher's field of practice, radiotherapy, without elaborating. However, bias can also creep in if researchers' preconceived notions or prejudices affect their interactions with participants or their interpretation of responses (Wilson, Janes and Williams, 2022). The PhD researcher reflected on his own notions and prejudices, particularly as a TR, treating patients in his care. For this reason, a counterbalance to the researcher's professional opinion or bias was required. This alternative view came from PRPs who gave feedback throughout the process. Doctoral supervisors from different professions also provided a counterbalance giving their expert input from their specialist areas of healthcare. Acknowledging and reflecting on researcher positionality can enhance the transparency and credibility of the research, as it allows readers to understand the potential biases and limitations. However, some researchers may not engage in sufficient reflexivity, leading to a lack of awareness of their own biases and their impact on the research (Olukotun *et al.*, 2021).

Olukotun *et al.* (2021) suggested the following questions to ensure positionality is addressed in qualitative research:

- What biases do I have regarding my research participants?
- What historical, social, cultural, and political factors shape the experiences of my research participants?
- What strategies can I employ to centre my participants' authentic experiences?
- What issues centred around researcher positionality can I preemptively address?

Looking at this in retrospect, the patient participants in this PhD programme had received radiotherapy for cancer and were interviewed at a place of their choosing, either at home or in the hospital away from radiotherapy. The TRs were interviewed over the phone, which was thought to have been less personable whereas in-person may be more personable enhancing an open dialogue. The PhD researcher found participants were open to questions and wilfully explored their experiences of managing comfort with telephone interviews. Participants may feel more open over the telephone giving a more open view than in person, where they can divulge experiences without embarrassment or other emotions. On the other hand, patient participants were offered interviews at a place of their choosing including at their homes if requested. This was intentional to make them feel more relaxed and open to be interviewed. The PhD researcher reflected that interviewing patient participants in their own homes was not beneficial to open dialogue. This is because patients have distractions at home, whereas in the hospital setting, there were less distractions. Maybe, participants could have been given the choice of in person, at home, over the telephone or online with their preference being the key to a more open and easier dialogue. Rahman (2015) undertook a literature review to compare telephone

to in-person interviews. The key findings were that telephone interviews were shorter, more cost effective, and less open to bias than in-person interviews and concluded that inperson and telephone interviews both have advantages and disadvantages. It was felt by the PhD researcher that the notion of participants feeling more open at home was not his experience and found participants more open in the hospital. It could be postulated that patients did not want to take the experiences of radiotherapy home, preferring to leave the experience at the clinic and return to their daily lives.

8.3.2. Sample of interview participants

The published literature of qualitative methodology recommends choosing an appropriate sample that is representative of the population (Creswell, 2018). However, the quest to determine representativeness may not always be straightforward as there may be many requirements for sample diversity (Vasileiou *et al.*, 2018). In this PhD programme, the patient participants interviewed were recruited from one radiotherapy department. It could be suggested that recruiting from one radiotherapy department may lead to a unilateral view of comfort experiences that may not represent or be transferrable to other regions of the UK where comfort may be experienced due to variation in TR practice in improving patient comfort (Carminati, 2018).

A further consideration for recruiting patient participants was to seek an even distribution of experiences to explore commonality across the three main anatomical cancer sites. This led to the new knowledge that many experiences of comfort are found, to a greater or lesser degree, across all anatomical cancer sites. An even distribution of female to male patient participants were recruited ensuring diversity. However, there was little representation from different ethnic groups which might be due to the geographical location of the radiotherapy department. A common misconception is that comfort may be perceived and experienced differently within different ethnic groups and therefore inclusivity needs consideration (Hoffman *et al.*, 2016). Although not specifically looking at comfort, Hoffman *et al.* (2016) found that medical professionals underestimated pain in Black people compared to white people, and then systematically undertreated their pain. This study did not conclude that pain is experienced differently within different ethnic groups, concluding that healthcare professionals should not make assumptions based on ethnicity.

As there is no evidence of common comfort perception and experience within different ethnic demographics, all patients should be assessed and treated individually. Although Kolcaba (1994) does not directly address demographics in her theory of comfort, it would be reasonable to suggest that internal (factors intrinsic to the patients) and external (factors external to the patients, interventions or environment) behaviours, whilst uniquely experienced by the individual, are likely to be influenced by background. Demographics such as ethnicity or culture may contribute to the individual's experience, through how they perceive discomfort (individual behaviour) and then are expected by others to cope with discomfort (external behaviours). When applied to demographic attributes such as socioeconomic (SE) status, education level and sexuality, Kolcaba's comfort theory arguably implies that these attributes impact upon internal and external behaviours.

Those with a lower SE status may have reduced access to secure housing, transport, and food impacting internal and external behaviours. This may exacerbate stress and feelings of anxiety about their health leading to psychospiritual discomfort (Kolcaba, 1994). Concurrently physical discomfort may be experienced due to limited finances affecting the ability to travel for treatment, or purchase necessary food when visiting a radiotherapy centre, leaving symptoms potentially untreated or resulting in inconsistent care. The external behaviours of healthcare providers may mitigate the impact of lower SE status through financial assistance and affordable care pathways.

Education level influences a patient's health literacy, understanding medical terminology. Low literacy may impact internal behaviours of confusion and anxiety affecting psychospiritual comfort (Kolcaba, 1994). A higher level of education may correlate with better understanding of self-care and healthier internal behaviours. The external behaviours of health providers may be able to improve psychospiritual comfort by tailoring communication to the needs of the patients using accessible language or visual aids.

A patient's sexuality can impact their comfort level, specifically discomfort at discussing sexual concerns and fear of potential stigma and prejudice which can increase psychospiritual or sociocultural discomfort (Kolcaba, 1994). Additional internal behaviours such as perception of own body image, sexual function and intimacy may impact on psychospiritual and physical comfort (Kolcaba, 1994). The external behaviour of healthcare providers can build psychospiritual comfort through ensuring inclusive care practices, for example asking how a patient prefers to be greeted, addressed, and an objective understanding of their sexuality. Understanding sexuality means that patient concern with body image, sexual function and intimacy may be better addressed through tailored approaches.

It must be acknowledged that the sample frame was not developed to account for the above-mentioned range of demographics, therefore may not be representative. Although it was not practically possible to recruit a high level of demographic diversity during this PhD programme at the host centre. Elsewhere a more favourable range of demographic diversity may have been achievable.

TRs were recruited from across the UK to capture potential geographical differences in practice. This may have provided a counterbalance to the potential unilateral views of patients recruited at one radiotherapy department. The spread of female to male TRs reasonably replicated professional practice, as the profession is female dominated. This might be important because some have suggested that females are more empathetic than males (Toussaint and Webb, 2005) and therefore may perceive patient comfort differently. A more recent study (Löffler and Greitemeyer, 2023) found that women self-report that they are more empathetic, but no difference was observed when objective measures were used. Therefore, it is unknown whether female and male TRs perceive their patients comfort differently. The potential impact of a nondiverse sample has to be acknowledged as a limitation in the interviews for TRs. Recruiting TRs across the UK provided a broad view of practice, and more specifically, delivered enriched details about how comfort is managed at various centres.

The lack of diversity in both the patient and TR sample was acknowledged by the PhD researcher as a potential limitation. This may have led to findings that were not representative of a wider population of cancer patients receiving radiotherapy.

8.3.3. Thematic analysis of interview transcripts

The challenge for thematic analysis was how the data from patients and TRs was handled and combined. It was decided that transcript data would be analysed separately for patients and TRs to retain the original meaning from each group. However, there was also a need to know about the combined views and experiences of patient comfort based on the premise that a combined analysis would be most beneficial. This was in keeping with the objective of this research to explore experiences of comfort with the principle of seeking commonality from patients and TRs. Moreover, Braun and Clarke (2006) suggested that the strength of thematic analysis is to search for shared meaning between two groups (Kiger and Varpio, 2020).

The interviews focused on patients' and TRs' experiences and solutions to improve comfort (Appendix H). Early exploration of the data indicated that separate consideration of comfort experience and solutions to improve comfort management was required. The PhD researcher also considered whether the patient interview transcripts should be analysed prior to TR interview transcripts. As the emphasis of this thesis was to gauge the patient voice on comfort, patient interviews were analysed first followed by TR interviews. This would inevitably lead to patient derived themes impacting TR derived themes and this bias was accepted due to the principal focus of the study on patient comfort experience. The themes from both patients and TRs were combined via a simple process of first reviewing codes, subthemes and themes for complete commonality, partial

commonality and dissonance (Farmer *et al.*, 2006). Overall, there was complete commonality on two themes with two further themes arising from patients which was considered as understandable as they were the group experiencing discomfort or comfort (Appendix I).

Kolcaba's (1994) framework and the comfort intervention categories defined by Wilson and Kolcaba (2004) were used as conceptual inspiration to retrieve many different perspectives around the phenomenon of comfort. A significant influence on the participants was how health-seeking behaviours shaped the narratives for each patient participant, whether internal or external (Kolcaba, 1994). Nordberg (2023) suggested that theory, such as Kolcaba's (1994) comfort theory supports researchers to see 'better' or to see things 'differently'. Therefore, the PhD researcher was more open to receive experiences of comfort from a physical, psychospiritual, environmental and sociocultural context (Kolcaba, 1991) plus solutions across the three interventions categories: technical, coaching and comfort food for the soul in which patients may be eased, relieved, or reach a transcendent state (Wilson and Kolcaba, 2004). A significant influence on the participants was how health-seeking behaviours shaped the narratives for each patient participant, whether internal or external (Kolcaba, 1994). Utilising Kolcaba's comfort theory as inspiration, a flexible and open approach was upheld throughout the PhD programme embedding the principles of credibility, trustworthiness and rigour in keeping with an idealist philosophy (Nowell et al., 2017; Birt et al., 2016).

8.3.4. Transferability, representativeness and representation

In qualitative research, transferability, representativeness and representation are markers for appropriate conduct. Transferability in qualitative research refers to the extent to which the findings of a study can be applied to other services. It involves assessing the relevance and applicability of the research findings beyond the specific study participants or setting (Anney, 2014). Representativeness in qualitative research is controversial and refers to the degree to which the study's participants may reflect a larger population or group from which they were drawn (Cutcliffe and McKenna, 1999). It involves considering whether the selected sample is representative of the broader phenomenon under investigation. Representation is the researcher's interpretation of participants' experiences deducted from the data. Thompson and Webb (2017) suggested that representation should not be considered reproductions of participants' lived experiences but rather the researchers' interpretations or constructs of the participants' lived experiences.

The PhD researcher intended to show that the thematic findings can be meaningful, potentially transferable and representative to other radiotherapy services or a larger population. This meant ensuring that the experiences, perspectives, or phenomena

observed in the study were not unique to the specific individuals or context but were reflective of a broader reality (Johnson, Adkins and Chauvin, 2020). To do this would mean that the findings could be used to develop a comfort intervention that would be applicable to other radiotherapy services. A limitation previously stated is that patients were recruited from one site, therefore it is unknown whether the sample would be transferable to other larger radiotherapy services. The level of transferability is certainly greater when the thematic analysis of patients was considered in conjunction with the narratives of TRs. However, the assumption that the sample in this PhD programme is both transferable and representative cannot be substantiated.

It was also important to consider the representation of the thematic findings. It may be argued that the researcher imparts what they feel and think about participants' voices during interviews, with sceptics questioning the credibility and representation of qualitative analysis (Agius, 2013). The PhD researcher intended to explore comfort during radiotherapy, and it could be suggested that the PhD researcher will find what he was looking for especially when his interest is to seek favourable themes or complete his doctoral work (Chenail, 2011; Kolcaba, 1994). The PhD researcher can be said to provide one interpretation of many, in keeping with an idealist philosophical perspective with openness to there being other interpretations (Allison, 2020; Crull, 2018). There was a need to provide an accurate account of the participants' voices; therefore, an independent researcher and patient researcher partners sense checked the data to ensure sound interpretation as recommended by Thompson-Hayes and Webb (2017). Their contribution provided a counterbalance to the PhD researcher's position as a TR and improved the rigour of the analysis.

Transferability, representativeness and representation are crucial for enhancing the credibility and applicability of the qualitative research findings presented here (Anney, 2014). This has guided the PhD researcher to be explicit about the context and sampling processes, helping future readers assess the relevance of the research to their own practice while also contributing to the development of nuanced, context-specific knowledge such as the development of a comfort intervention package.

8.3.5. Patient-centred care/choice

The principal intention of this research was to develop recommendations for a comfort intervention for patients receiving radiotherapy with extended treatment times. Patient-centred care or choice is about focusing on the patient first and their disease or ailment second, treating them as equal partners in their own care (Coulter and Oldham, 2016). Coulter and Oldham (2016) noted that patient-centred care is a very old concept that was described by Hippocrates. These authors also suggest patient-centred care or choice is

about individualising and tailoring care to patients (Coulter and Oldham, 2016). Patientcentred care is also one of the founding principles of Kolcaba's (2002) comfort theory, to treat each patient as an individual and tailor interventions to each individual.

By valuing patient perspectives, TRs can better understand the individual needs and experiences of patients, leading to improved outcomes that are more aligned with their preferences (Carlisle et al., 2022). The term patient-centred care may not be that simple to implement in this study or in practice. The term patient-centred was not explicitly defined by the PhD researcher in either participant information or during the interview. Through exploring individual patient experiences of comfort and how they may be best managed during radiotherapy, it could be implied that this research is patient centred. One challenge is a lack of agreement in what constitutes patient-centred care. However, a solid argument could be given for patient choice as a good representation of patientcentred care (Carlisle et al., 2022). Patient choice is about individuals being able to make an informed choice about their treatment or care (National Institute for Health and Care Excellence, 2021). It must be acknowledged that choice for patients with cancer when undergoing treatment may be limited to having curative treatment, or not (Zhang et al., 2023). The patient choice agenda is also blurred by the intent of clinicians to present the risk and benefits of treatment. Zhang et al. (2023) stated that, in some cases, the clinician's agenda does not match their patients who may be focused on process. Fundamentally being able to choose, for example whether to have relaxing music or no music, is a crucial asset of person-centred care in radiotherapy. Carlisle et al. (2022) found that people who actively chose their own interventions in a range of settings (e.g. breast cancer patients choosing an audiotape consultation or not) had significantly less drop out and greater adherence to treatment. Thus, it may mean that patients may be more likely to complete their course of radiotherapy. Patient choice of interventions is an important component of patient-centred care (Zhang et al., 2023). The debate of what constitutes patient-centred care will continue but providing choice should be upheld even when it is limited to treatment or no treatment (Zhang et al., 2023). The founding principle is that patients should be able to choose interventions from a comfort intervention package when this is developed in future work.

8.3.6. Assessing compliance or comfort

A subtheme arising from TRs was 'assessing compliance'. In contemporary practice, all patients are assessed for compliance prior to receiving radiotherapy. TRs will assess if a patient can achieve the position (e.g. arms abducted), remain still, and breath hold. A binary response of either they can or cannot endure the specific technique may miss important information about patient comfort. Equally patients may endure something which they cannot sustain or find uncomfortable because they passively believe they

should be uncomfortable (Goldsworthy, Tuke and Latour, 2016). A more in-depth assessment of patient comfort may allude to the nuances of why a patient may not be able to endure the radiotherapy technique. By understanding the nuances of discomfort from a comprehensive assessment, it may be possible to support patients to achieve the required technique for accurate radiotherapy (Royal College of Radiologists, Society and College of Radiographers and Institute of Physics and Engineering in Medicine, 2021).

At present in radiotherapy, comfort is assessed and evaluated, usually in the context of physical comfort, using various methods including VASs, quality of life questionnaires and interviews (Barnes et al., 2021; Olausson et al., 2017; Valkenburg et al., 2011). In practice, comfort may be assessed daily by TRs asking if the patient is comfortable prior to the delivery of a radiotherapy treatment session. This is completed without empirical evidence or guidance, and practice may be variable within and between different radiotherapy clinics. Patient comfort has been evaluated in few radiotherapy clinical trials that tested novel techniques (Boisbouvier et al., 2023; Bartlett et al., 2015; Cox and Davison, 2005; Nutting et al., 2000). Predominantly, the comfort assessments used in these clinical trials were patient-reported questionnaires administered after the radiotherapy treatment session (Bartlett et al., 2015; Nutting et al., 2000). However, the comfort questionnaires used in these studies did not use standardised measures and have not been tested for validity. Other studies have examined comfort associated with radiotherapy treatment. Cox and Davison proposed that comfort could be a determinant of treatment position (prone or supine) in patients diagnosed with prostate cancer (Cox and Davison, 2005). They reported that patient comfort in both positions was rated highly and therefore had no bearing on selection of position. They also reported low patient anxiety levels. The authors used separate VASs to measure comfort and anxiety and only considered the context of physical comfort. The VAS is a generic assessment which is widely used in many disciplines, but it may be too simplistic to capture the complexities of comfort in radiotherapy.

A few comfort assessment tools have been developed based on Kolcaba's (1992) GCQ. Kolcaba and Fox (1999) adapted the GCQ to develop and validate the 26-item Radiation Therapy Comfort Questionnaire (RTCQ) and investigate the effect of guided imagery in women with early-stage breast cancer undergoing radiotherapy. This included the assessment of physical comfort, psychological comfort, sociocultural comfort and environmental comfort and contained several items specific to patients with breast cancer (Kolcaba and Fox, 1999). Cheng and Wang (2014) investigated comfort of patients with head and neck neoplasm receiving radiotherapy using a validated comfort assessment tool. They used a radiotherapy comfort questionnaire (RCQ) based on Kolcaba's four contexts of comfort (Wang *et al.*, 2013). The RCQ consisted of 29 items grouped into

physical, psychological, sociocultural and environmental comfort (Wang *et al.*, 2013). Cheng and Wang (2014) identified several factors, including the number of radiation treatments that impacted on comfort. A further tool was developed to measure patient experience during radiotherapy and was not based on Kolcaba's (1992) conceptual framework of patient comfort in nursing care (Olausson *et al.*, 2017). Olausson *et al.* (2017) developed and validated the 34-item Radiotherapy Experience Questionnaire (RTEQ) based on anxiety, depression, quality life and satisfaction OMs. There are no further published studies that utilised the RTEQ to review for this thesis.

Three validated comfort or experience assessment tools (Radiation Therapy Comfort Questionnaire, RCQ and RTEQ) have therefore been developed to assess comfort after a radiotherapy session (Olausson *et al.*, 2017; Kolcaba and Fox, 1999). All are extensively long to complete prior to a treatment with the known time constraints within a radiotherapy session. A novel solution developed by Boisbouvier *et al.* (2023) was to assess comfort globally across different limbs of the body for upright radiotherapy using a non-validated Likert scale. It is worth noting that they only assessed physical comfort.

In disciplines other than radiotherapy, comfort assessments have been used prior to therapeutic interventions. These comfort assessments have been validated through vigorous testing and proven invaluable to improve patients' experiences of comfort. These include comprehensive measurement scales such as the COMFORT behaviour tool primarily developed for children to assess pain and sedation in infants (van Dijk *et al.*, 2005). The same scale has been proven applicable to adults in the intensive care unit, and in children aged 0–3 years old with Down's syndrome who were admitted to the intensive care unit for cardiac or intestinal surgery (Ashkenazy and DeKeyser-Ganz, 2011; Valkenburg *et al.*, 2011). Similarly, Rogeau *et al.* (2014) developed a questionnaire, the Comfort Assessment Scale for Neurologic Patients, and then validated it for stroke patients admitted to a rehabilitation ward. These studies provide a good starting point; however, the assessments may not be directly transferable to explore patient comfort during radiotherapy sessions and to account for radiotherapy specific issues. A solution to assess the multidimensions of comfort prior to a radiotherapy session needs to be developed and validated in radiotherapy practice.

8.4. Discussion Stage 3: Recommendations for a radiotherapy comfort intervention package

8.4.1. Triangulation of systematic review and interviews

A two-step process was undertaken to draft an initial list of comfort intervention components to be used in the consensus study. Step 1 was the triangulation of an SLR

and qualitative interviews, and step 2 was the generation of comfort intervention components.

8.4.1.1. Step 1: Triangulation of an SLR and qualitative interviews

The findings were explored with respect to the meaning and interpretation of patient and TR interview subthemes against the comfort intervention categories of the SLR. The convergence coding scheme of complete convergence, complementarity, dissonance and silence was applied as seen in <u>Appendix K</u> (Farmer *et al.*, 2006). Complete convergence is when the context of findings of the SLR comfort intervention categories and interview subthemes directly agree. Complementarity is where the findings offer complementary information on the same issue. Dissonance is where findings seem to contradict each other, and silence is where findings appear in the SLR and not the interviews and vice versa. There was complete convergence for audiovisual interventions, and information and education. There was silence for pharmacological, environmental and aesthetic interventions which were removed from step 2.

8.4.1.2. Step 2: Generation of comfort intervention components

This step involved a process of clinical synthesis that was developed using the principles of triangulation, convergence, and sequential synthesis seen in <u>Appendix J</u> (Noyes *et al.*, 2019; Farmer *et al.*, 2006). The principle of clinical synthesis was to create a list of comfort intervention components with real-world meaning. The data from the systematic review and interviews were explored for potential interventions by reading through and cross checking between intervention categories from the SLR and subthemes from the interviews with patients and TRs. It was determined whether comfort solutions and intervention categories could be synthesised by either expanding or condensing the meaning. An intervention component list was written in simple form without details about how they might be delivered. The intervention component list was approved.

8.4.1.3. Discussion of Steps 1 and 2

There are many publications providing examples of triangulation and synthesis between qualitative and quantitative data (Noyes *et al.*, 2019; Humble, 2009; Farmer *et al.*, 2006). A review of more than 400 SLRs found that the main designs used for combining quantitative and qualitative data were convergent and sequential synthesis (Hong *et al.*, 2017). Convergent synthesis is when data is collected and analysed in parallel and then integrated using a third synthesis method in the design. Sequential is where, for example quantitative data is collected and analysed first, and influences the design of a second

qualitative study with later synthesis of the findings from each. For the PhD programme, a combination of synthesis methods was used. The SLR of comfort intervention categories was completed first which subtly influenced the design of the qualitative study and specifically the questions for the interview guide, including open questions incorporating the complexity of comfort. The process was successful but more precise guidance of how to synthesise and develop comfort interventions would have been welcome, a bespoke process is likely needed for all research projects.

8.4.2. The online format of the consensus study

The NGT consensus study was conducted online due to the COVID-19 pandemic restrictions which may have had positive or negative impacts on panel members and their participation. Contrary to the assertion by McMillan, King and Tully (2016), the NGT RAM consensus study can be deployed online and there are many examples of such use, including this PhD programme (Fisher et al., 2021; Mason et al., 2021; McMillan, King and Tully, 2016). There are, however, strengths and weakness of the online formats. Potential weaknesses are that panel members may be unwilling to participate because it was online, impersonal and they did not have the hardware. For inclusivity, panel members were offered equipment if required. Benefits of the online format were that it may have enabled participation where face to face may not have worked and being at home could have assisted panel members to give open responses (Mason et al., 2021). However, depending on the topic, panel members could become emotionally upset, and Mason et al. (2021) suggested that an in-person format may be more suitable. It was deemed by the PhD researcher that the research was low risk although a distress protocol was written to deal with potential upset. Moreover, the major advantage of NGT was that it avoids two problems caused by group interaction. Some members may be reluctant to suggest ideas because they are concerned about being criticised or are reticent and shy. Others may be reluctant to create conflict in groups. According to a psychologist participants may behave and answer prioritisation questions differently if alone (Gencer, 2019). The NGT RAM consensus meeting overcame these problems by ensuring participation through individually completed activities. Further advantages include prioritising many ideas in a shorter time and providing a sense of closure for panel members and researchers that is not found in DT or a consensus development panel (Arakawa and Bader, 2022). Arakawa and Bader (2022) stated that there may be difficulties setting up in-person meetings for a consensus NGT, especially during the COVID-19 pandemic. There was concern for the health and safety of patients and TRs attending in person, especially patients who could be immunocompromised. Therefore, the choice was to conduct the NGT RAM consensus meeting online to facilitate panel member engagement. The NGT RAM provided a

vigorous method to pool the quantitative and qualitative data and delivered comfort intervention components. It delivered the objectives as planned.

8.5. PRP involvement

The need to involve patients at different stages of the research process as knowledgeable experts, with expert experience, has been well recognised (NHS England, 2021; Sacristán *et al.*, 2016; Froggatt *et al.*, 2015). The government set out the *Best Research for Best Health* policy report in 2006, which states,

Patients and the public should be involved in all stages of the research process: priority setting, defining research outcomes, selecting research methodology, patient recruitment, interpretation of findings and dissemination of results. (Department of Health, 2006, pp. 34)

The National Institute of Health Research (2012; now the National Institute for Health & Care Research) also stated that PPI should contribute to research objectives and to informing the design and development of interventions because PPI helps to clarify and affirm the importance of the research objectives, ensuring the appropriateness of the methodology. In the research presented in this thesis, PRPs contributed throughout as recommended by the Department of Health and National Institute for Health Research, ensuring that the research remained patient centric. There was plenty of debate between PRPs and the researcher – especially around the development of interview guides and, later, the qualitative analysis. For example, in this PhD programme, PRPs steered the PhD researcher to use more accessible language. There has been controversy around PPI and whether it is just a check box (Staley, 2015). Staley (2015) questioned whether PPI is necessary and concluded that researchers are unaware of what they do not know until they discuss their research plans with patient experts. Throughout this PhD programme, PRPs were involved to ensure the research remains patient focused. However, there are no randomised studies comparing research outcomes with and without PRPs, so the real impact may not be known.

A question the PhD researcher had in the early stages was whether the PRPs involved in this PhD programme represented the voice of the population or were individuals representing a small proportion of society. Moreover, he did assert that involving patients directly in the research process was to ensure that research was more patient centred, relevant and impactful. This collaboration intended to bridge the gap between researchers and those who are affected by radiotherapy, and to ensure that their involvement would avoid steering away from the patient-centred emphasis. For the interviews and consensus study of this thesis, patient and TR participants were recruited as the knowledgeable experts who have either received or delivered radiotherapy. Patients have unique experiences of what it feels like to receive radiotherapy, the comfort or discomfort of being positioned and having to remain still for a prolonged period, so their participation was essential to gain a greater understanding of their experience and how comfort could be improved. TRs were equally critical to this thesis in gaining a greater understanding of patient comfort from their experiences of managing the comfort of many patients. Their experiences and views were invaluable for this research, and it could not have been completed without them.

The unique insights from PRPs have enriched the PhD programme, ensuring that the design through to analysis has remained central to patients. Their inclusion as research team members means that they have been valued and contributed much more than simply ticking a box (Staley, 2015). One of the PRPs supported dissemination with an oral presentation at a radiotherapy conference. This provided added value to the audience hearing from the perspective of someone who had received radiotherapy.

8.6. The complexity of comfort

Patient comfort is the focus of the PhD programme. Initially, the intention was to identify a discrete definition of patient comfort. However, the complexity of patient comfort is difficult to encapsulate in a definition, and Kolcaba's (1994) comfort theory, which reflects the complexity of comfort experienced, was utilised. The concept of patient comfort and its application in radiotherapy were developed for the first stage of the PhD programme, with articulation of the following:

In radiotherapy procedures the role and purpose of holistic comfort interventions aim to make the procedure more tolerable to patients and ensure compliance reducing discomfort, anxiety, distress and claustrophobia. (Goldsworthy, Palmer, *et al.*, 2020, pp. 315)

Use of the term 'holistic' was based on Kolcaba's (1994) framework t,o describe how comfort is more than a physical experience (Frisch and Rabinowitsch, 2019). Some authors have suggested that the term 'holistic' is used as a buzzword in healthcare and is not applied fully (Bullington and Fagerberg, 2013). Bullington and Fagerberg (2013) suggested that holistic care is a fuzzy concept because there is no clear definition of what it is and how it is conceptualised within a given speciality or field of healthcare. Others have suggested there is a lot of overlap with integrative care and patient-tailored care, which may also be viewed as newer buzzwords (Frisch and Rabinowitsch, 2019). The academic debate may continue, but for this PhD programme, holistic patient comfort is actualised in line with Kolcaba's comfort theory, which encapsulates the stimulus of

situation (obstructing, facilitating and interacting forces) and human development through health-seeking behaviours seated within the four contexts of comfort: physical, psychospiritual, environmental and sociocultural. The phenomenon of comfort is uniquely complex, meaning that it can include pain and anxiety as well as many other experiences (Kolcaba, 1994). This PhD programme applies Kolcaba's comfort theory within radiotherapy and demonstrates how the three comfort intervention categories can be focused on specific interventions in radiotherapy (Wilson and Kolcaba, 2004).

Kolcaba's (1994) comfort theory inspired the development of the initial intervention categories in the SLR and subsequent phases of work. The technical interventions defined by Wilson and Kolcaba (2004) were used to define the physical intervention category of the SLR, the P&I and modifications/adjustments to position and immobilisation and environmental themes of the interviews, and the physical aspects of the comfort intervention components derived from the NGT consensus study. Wilson and Kolcaba's (2004) coaching category was used to define the 'other' category of the SLR, specifically Education and Information and then the Information and Communication and Preparation, and Preparational Approach themes of the interviews and the coaching aspects of the NGT consensus study. Finally, Wilson and Kolcaba's (2004) comfort is food for the soul intervention category was used to define the audiovisual and psychological intervention categories of the SLR and then the emotional and supported coaching themes of the interviews and patient-centred intervention components (such as compassion) of the NGT consensus study.

It is possible that critics could suggest that the PhD programme was developed to fit Kolcaba's (1994) framework or that this theory has been retrofitted. In defence, Kolcaba's middle-range theory has materialised from contextualisation to the real world. In the real world, this was to improve patient comfort in the radiotherapy with recommendations of 11 prioritised comfort intervention components.

8.7. Novelty of findings

The first objective was to identify comfort interventions used for clinical procedures that involve sustained inactivity like radiotherapy, record the characteristics of the comfort interventions for future practice and determine the effectiveness of the comfort interventions. Kolcaba's (1994) comfort theory influenced the creation of comfort intervention categories in the SLR. Thirteen comfort interventions were identified and grouped into four categories: 'audiovisual technology interventions' (e.g. sociocultural/environmental), 'psychological interventions' (e.g. psychospiritual), 'physical interventions' (e.g. physical) and 'other interventions (education/information and aromatherapy – e.g. psychospiritual)' (Kolcaba, 1992). The SLR identified and

characterised potential comfort interventions and investigated their effectiveness (Goldsworthy, Palmer, *et al.*, 2020), thereby increasing the current knowledge and used novel methods to achieve the aims. All RCTs included in this SLR underwent RoB assessment using the Cochrane (5.1.0) checklist. An element of originality was using an artificial intelligence system known as RobotReviewer[™] (Marshall, Kuiper and Wallace, 2016) as a second researcher after the researcher initial assessment, achieving 90% agreement. The learned points were that using this system can improve the overall quality and efficiency of RoB assessment but cannot replace human systematic reviewers. Reviewers should embrace and work with changes such as the inclusion of Al in their teams so they can influence its operation and application rather than resisting the tide of change.

Going beyond a purely narrative review, this SLR deployed a novel meta-summary design in which anxiety OMs from the included RCTs were synthesised (Xiao and Watson, 2019). This SLR sought to evaluate clinical significance as a clinically meaningful way to determine the actual benefit to patients rather than knowing there is a statistical difference between intervention and control groups. However, unlike statistical significance, there are no empirical methods to undertake clinical significance judgements other than limited published suggestions (Page, 2014). Clinical significance was determined in this SLR when effect size exceeded 0.4, mean differences were greater than the MCID and the RoB was acceptable. The inclusion of all three criteria was novel but may also have a led to a very strict definition of clinical significance. The findings demonstrated that many interventions were statistically significant but were not clinically significant as defined in this SLR. Six interventions were clinically significant and could be used in radiotherapy for patients to improve comfort and maintain position over time. Twenty clinically insignificant interventions had effect sizes favouring the intervention, suggesting that some patients may benefit. This indicates that many interventions may be suitable for further investigation in radiotherapy. To the best of our knowledge, this is the only SLR that provides an evidence base to support further investigation of comfort interventions in radiotherapy.

A gap in the literature identified by our review was whether interventions can be combined as a package to increase clinical significance. Bice and Wyatt (2017) found a statistically significant difference favouring multiple interventions delivered concurrently in paediatric nursing. Although the authors used statistical rather than clinical significance, and the study involved children, the findings indicate promise for adult patients receiving radiotherapy. Another study utilising Kolcaba's comfort theory to develop care bundles found that comfort improved in paediatric patients admitted to the intensive care unit (Chandra, Raman and Kolcaba, 2016). This SLR provided the rich ingredients for clinicians and researchers to replicate and develop interventions for their own practice or further investigation. Specific interventions could be chosen for radiotherapy based on clinical significance or effect size. While the SLR provided the 'ingredients' of comfort interventions, a 'recipe' and a 'process' were required to further implement or investigate such interventions in radiotherapy.

Individual interviews with patients and TRs explored patients' experiences of comfort and how it is best managed (comfort solutions) during radiotherapy sessions, using Kolcaba's (1994) comfort theory for inspiration. This is important because it is the mainstay of the workload in the radiotherapy clinic, and if this can be better understood and improved, many patients may benefit. Moreover, there are few published qualitative studies exploring patient experiences during radiotherapy, and even fewer focus on patient comfort. Three key studies explored patient experiences involving the three main anatomical cancer sites: head and neck, breast/lung and pelvis (Probst et al., 2021; Nixon et al., 2018; Cox and Davison, 2005). The first study, published in 2005, explored comfort in patients with prostate cancer. The authors found that limbs peripheral to the body could be comforted using elbow supports (Cox and Davison, 2005). The qualitative research in that study seemed like an 'add-on' rather than the main focus of the research. While the reported details about methods and qualitative findings were limited, this was a novel paper at the time. A more recently published qualitative study explored the anxiety of patients having radiotherapy for head and neck cancers (Nixon et al., 2018). The thematic findings alluded to patients feeling vulnerable and responding psychologically and physiologically to treatment with a feeling of not being prepared. These authors specifically suggested screening to ensure early identification of patient anxiety and education to assist with preparation for wearing a mask. Nixon et al.'s (2018) study did not focus on patient comfort. The third related study focused on the experiences of patients with breast cancer (Probst et al., 2021). Patients reported feeling embarrassed about being naked and disappointed with poor information about their treatment. Probst et al. (2021) suggested that TRs should consider breast modesty gowns and methods to encourage patient empowerment during radiotherapy. This study provided greater understanding of radiotherapy patients' experiences but did not focus explicitly on comfort. In summary, some studies have explored patient experiences and solutions, although only one explicitly on comfort. The PhD programme converged comfort experiences and solutions across the three main anatomical regions (head and neck, breast/lung and pelvis) and was strengthened by including TRs' experiences of addressing patient comfort. An assessment of commonality indicated that TRs had extensive experiences to share. Areas of discordance in patient and TR themes and subthemes were valued as a potential insight into unaddressed needs. Themes arising from exploration of patients'

experiences of comfort and comfort solutions were congruent with Kolcaba's (1992) four contexts of comfort.

An NGT consensus study delivered recommendations of comfort intervention components as agreed by patients and TRs. These were developed with inspiration from the comfort intervention categories defined by Wilson and Kolcaba (2004). The novelty of the NGT consensus study stems from a combination of the methodological approach, clinical applicability and potential impact of the recommendations of comfort interventions on clinical practice.

The methodological approach merged NGT with RAM, adding some distinct modifications and additions. During the round robin discussion, the panel members were asked to make an initial vote to include or exclude interventions (had to be >50% for inclusion); this initial sift removed one intervention component. This was useful as a warm-up for panel members but also meant that entirely impractical intervention components were rejected so as not to waste time in the following NGT activities. It is popular to modify or adapt NGTs, but all have slightly different approaches depending on the topic; for example, Søndergaard *et al.* (2018) introduced an extra phase of anonymous reranking. NGT can be a blunt instrument if used alone; hence, many researchers adapt or modify it for their own topic. Additionally, the PhD researcher added an extra step by asking panel members to indicate whether each intervention component was feasible in radiotherapy practice. Those with below 50% 'yes' votes were considered not feasible in practice. In addition, the panel members were verbally asked to share their views on feasibility, and these data were qualitatively analysed. A greater understanding was generated from the rich descriptions given for the potential impact on radiotherapy practice.

8.8. Key findings

- In the qualitative studies, an overarching principle was that each patient experiences comfort differently, and therefore, patients should choose available comfort solutions.
- Four overall themes emerged from the exploration of patient experiences of comfort during a radiotherapy session with patients and TRs. Two common themes were coping and P&I experiences.
- Five common themes emerged from the exploration of comfort solutions that could be used for patients receiving radiotherapy.
- An NGT consensus study of patients and TRs concluded by recommending components for a comfort intervention package in radiotherapy.

- After the consensus study activities, the panel recommended 11 intervention components for development in a radiotherapy comfort intervention package based on the modified NGT RAM.
- Using directed content analysis, the outcomes of the study became clearer, specifically providing an understanding of why an intervention component was included or excluded.
- This PhD programme extends the knowledge of what is known about how to comfort patients having a course of radiotherapy based on consensus between patients and TRs.

8.9. Clinical implications

- TRs are encouraged to acknowledge and monitor the comfort experienced by their patients having radiotherapy and to take account of the wide variation in comfort experienced and how it might be best managed.
- Radiotherapy services should consider the wider aspects of comfort such as improving the environment by, for example, creating a warm and welcoming reception.
- Based on their patients' preferences, TRs are encouraged to consider supporting their patients with comfort intervention components suggested within this thesis.
- National and international radiotherapy guidelines should be updated to support improvements. At the time of writing this thesis, the PhD researcher had been approached by the UK Health Security Agency to write a chapter entitled 'Patient Comfort' for an update to the 'Advancing Safer Radiotherapy' guidelines.

8.10. Chapter summary

This chapter discussed the essence of patient comfort in radiotherapy, capturing the most meaningful elements from the rich narratives of patients and TRs. Similarities and discordance between the findings of the PhD programme and the existing literature were addressed and the novelty of the work highlighted. The SLR identified various comfort interventions that could be deployed in radiotherapy, congruent with studies published in the paediatric setting. The interviews with patients and TRs found complementary narratives with some discordance, providing new insights into the comfort experienced by patients receiving radiotherapy. The comfort experiences are echoed in the limited literature published, although many did not specifically focus on comfort. Similarly, the suggested solutions to comfort patients during radiotherapy overlap with the limited published evidence. TRs proposed more comfort solutions than patients, which could be due to their long experience of intimately treating many patients in practice. The findings provide a greater understanding of how comfort is experienced and managed across

Kolcaba's (1994) comfort theory from the PhD programme themes of the environment, psychological coping, physical repositioning and information and communication. Eleven comfort intervention components were recommended for development in a future radiotherapy comfort intervention package based on agreement between patients and TRs.

9. Chapter nine: Conclusion

9.1. Introduction

This PhD programme sought to address the gap in the understanding of patient comfort during radiotherapy, identify potentially suitable comfort interventions, explore patient comfort and how it is best managed and develop recommendations for a comfort intervention package in radiotherapy. The focus of this final chapter is to demonstrate how this research met the aim and objectives of the thesis. The implications and recommendations are then discussed, followed by the limitations, summary and reflections.

9.2. Addressing aim and objectives

The overarching aim of this PhD was to develop recommendations for a comfort intervention for patients receiving radiotherapy. This was achieved through an SLR of comfort interventions used in clinical procedures similar to radiotherapy that required patients to hold position for a prolonged period. It was followed by in-depth semi-structured interviews with patients and TRs to explore experiences and views of comfort and how it can be best managed in radiotherapy. Comfort intervention categories and solutions arising from both the SLR and interviews were synthesised into components for prioritisation in a consensus study providing recommendations to develop a radiotherapy comfort intervention package. The process concluded with a list of recommended comfort intervention components agreed upon by patients and TRs. This is the first step to developing comfort interventions in radiotherapy; the next steps could include a feasibility study prior to a definitive clinical trial in radiotherapy. Through the course of the studies, there have been many points of clinical consideration and for future ambition to improve patient outcomes.

The first objective was to identify comfort interventions used for clinical procedures that involve sustained inactivity like radiotherapy, record the characteristics of the comfort interventions for future practice and determine the effectiveness of the comfort interventions. Thirteen comfort interventions were identified through the SLR, and these were placed in four categories which could be applicable to radiotherapy. The effectiveness of these comfort interventions was evaluated for both statistical and clinical significance, and it was concluded that six interventions were both statistically and clinically significant, although many others were statistically significant with large effect sizes and were recommended for further investigation. Although this study delivered some potential ingredients for comfort interventions from other healthcare procedures, it was necessary to directly explore comfort in the context of radiotherapy in interviews with

patients and TRs. This was to ground the research within radiotherapy and extend the understanding and fill the gaps in knowledge of comfort experiences and solutions that could not be delivered with the SLR alone.

The second objective was to explore patient and TR experiences of comfort and how comfort is best managed (solutions) during radiotherapy through interviews with patients and TRs. This objective was split for thematic analysis into comfort experiences and comfort solutions, and these were reported separately in two papers. The objective was, in part, met through extending the knowledge of how comfort is experienced in patients with differing cancers. For example, discomfort such as distress may commonly be experienced by patients with head and neck cancers, but it also applies to patients with breast/lung cancer. Uniquely, patient-generated themes were common in TRs' views of patient comfort. The common themes and subthemes have met the objective and provided a greater understanding of patients' experiences of discomfort. The themes have also generated a greater awareness that something needs to be done to improve patient comfort. The second part of this objective was met with the provision of common comfort solution themes and subthemes generated from patients' and TRs' narratives. Many comfort solutions were proposed that extended knowledge of what was already known from the SLR, filling the gap and providing rich insights into how comfort may be better managed in radiotherapy. The findings of the SLR and interviews provided the ingredients for comfort interventions that were clinically synthesised into a list of comfort intervention components.

The final objective was to develop recommendations for a radiotherapy comfort intervention package via a consensus study with patients and TRs. An online NGT consensus study met this objective through the prioritisation of intervention components, resulting in 11 being 'included' or 'included with 'caution'. Patient and TR narratives provided a greater depth to the quantitative responses of inclusion and exclusion and specifically highlighted a wealth of considerations for the feasible implementation of the interventions in radiotherapy practice. This research concludes with recommendations for components that could form the basis of a comfort intervention package.

9.3. Implications and recommendations

Throughout this thesis, it has been argued that patient comfort is critical to ensuring the best outcomes from radiotherapy. This is based on the principle that greater comfort leads to greater stability and therefore greater treatment accuracy.

This thesis challenged conventional ideas that comfort is specific to the anatomical cancer site being treated with radiotherapy and that physical management should be the only focus of TRs as a way to ameliorate patient discomfort. Indeed, the inspiration of this work

came from Kolcaba's (1994) conceptual framework of patient comfort in nursing care, which is based upon three concepts (relief, ease and transcendence) and four domains (physical, psychospiritual, environmental and sociocultural) across the complexity of life which influence comfort (internal/external behaviours). While physical discomfort across anatomical cancer sites may be discretely different, psychological and other forms of discomfort can be common and present to a greater or lesser degree in all patients. For example, patients with head and neck cancers express distress at wearing a mask, but patients with breast cancer may also be distressed due to other triggers, such as being undressed (exposing breasts) or being anxious about the treatment machine moving around. TRs should be made aware of the breadth of discomfort experienced by patients receiving radiotherapy and the overall effect it may have on their outcomes. The findings demonstrated that each patient has a unique experience of comfort; some may feel physical discomfort while others distress as if they are in a science fiction horror film. Some patients experienced anxiety and stress entering a new environment with strange technology, such that patients may be tense or not able to remain still which is not desirable for accurate radiotherapy. A crucial factor is that a patient's experience of comfort begins from when they first enter the radiotherapy reception, which may affect their experience during treatment. Understanding that comfort is more than just a physical concern is essential. This thesis has demonstrated some original contributions to knowledge, including that there are many comfort interventions suitable for patients undergoing radiotherapy; discomfort is experienced to a greater or lesser degree by all patients, independent of cancer site; and there are many potential solutions to manage or ameliorate comfort in radiotherapy.

The sampled patients and TRs proposed several comfort solutions. The key message is that patients all have their own preferences of what comfort means to them and how discomfort is eased or relieved. These include modifications and support to maintain position, preparational approaches and supported coping where patients may transcend the discomfort. The preference for patients could be that they would like one or many solutions to manage comfort or, for some, nothing at all. An example is that patients may prefer lights on, dimmed or off as a comfort aid to get through treatment. Comfort is a complex phenomenon with no standard solutions to suit all patients; therefore, adaptable patient-centred solutions to manage comfort are required.

The comfort interventions from the SLR and comfort experiences/solutions from the interviews were uniquely synthesised into comfort intervention components. These intervention components were then prioritised by patients and TRs in order of importance using an NGT consensus study, which also facilitated discussions about feasibility. The final original contribution was the concluding list of intervention components, which could

be developed further into a future radiotherapy comfort intervention package. Utilising Kolcaba's conceptual framework of patient comfort in nursing care, Lin, Zhou and Chen (2023) wrote an evidence and gap map protocol which may further illicit potentially effective interventions.

A few substantive studies are recommended, including a field and feasibility study prior to a definitive clinical trial. It would also be important and relevant to further investigate the link between comfort and treatment accuracy to advance evidence in this area. The potential clinical benefits to patients could be twofold, first is to improve their experience of comfort and, second, to improve treatment accuracy and overall treatment outcomes.

Within radiotherapy practice, the key implication and recommendation is for TRs to ask patients if they are comfortable before and during treatment while stressing the need for stability and making reasonable adjustments within the constraints of radiotherapy practice. Considering the complexity of comfort, after TRs have introduced themselves, the following questions could be asked: How would you like to be greeted (by name/title/pronoun)? Would you like some music or relaxing sounds? Would you like the lights on or off? Do you have any preexisting health conditions, such as arthritis, and if so, where? Do feel physically comfortable under your head, neck, shoulders, elbows, upper/lower back, pelvis, thighs, knees, calves and heels?

9.4. Limitations

There are some broad limitations to this research, which are outlined below. The primary concern of this thesis was to develop recommendations for a comfort intervention package in radiotherapy using quantitative and qualitative methods with reference to the MRC framework for developing complex interventions. The interventions considered in the SLR extended beyond radiotherapy, which broadened the range of potential interventions for consideration but adds complexity for potential application in radiography. Interviews with patients and TRs provided contemporary evidence from experience and practice to further inform development of intervention components. However, it is impossible to assure the reader that all relevant interventions have been captured and that the findings are transferable to radiotherapy practice.

As a researcher, it is common to strive to maintain a neutral position, especially for qualitative studies. The PhD researcher had prior professional experience as a TR, which would have influenced their beliefs. With the best intentions to minimise the influence through debriefing with the supervisory team and PRPs, it has to be acknowledged there may have been some influence from prior experience.

Furthermore, the NGT study, which prioritised and explored the feasibility of intervention components, was limited to a single consensus meeting. Ideally, the consensus process would be repeated with further stakeholders to strengthen the evidence to inform the progression of plans to assess the feasibility and acceptability of a future comfort intervention package. This thesis did not evaluate the effectiveness of the final list of recommended comfort intervention components. A larger substantive study of a comfort intervention package in radiotherapy is therefore required to make inferences in relation to effectiveness and clinical significance.

Finally, the lack of diversity in sample frames for the interviews and NGT consensus study means that there is an unknown effect on the themes produced and the prioritisation. This included recruiting patients from a single centre, the potential lack of ethnic diversity, the sex imbalance (more females), the potential lack of socioeconomic diversity and gender or sexual identity. Recruitment was not based on these characteristics, and data were obtained for only sex, indicating a disproportionate number of females. This may have over- or undercaptured a particular perspective that may be only present in a White British heterosexual population and not in a population with greater diversity. This limitation has to be acknowledged.

9.5. Final summary

Radiotherapy is an important life-saving treatment for cancer. The focus of the majority of research and development in radiotherapy has been to optimise therapeutic dose and technically deliver the treatment more precisely and accurately. Advances in radiotherapy are expected to increase the duration of treatment sessions; therefore, it is also important to consider patients' experiences and the role of TRs in improving patient comfort to enable them to remain in the same position for the time required. This was the first indepth research programme to review and explore comfort experience and management during radiotherapy with those directly involved – namely, patients and TRs. The contributions that this research makes are demonstrated in several ways. The SLR provided rich characteristics of how comfort intervention categories can be replicated in radiotherapy, as well as information about the clinical significance of these. The interviews uniquely explored comfort experiences and views of best management across major anatomical cancer sites. The NGT consensus study provided recommendations for the comfort intervention components that could be used to inform the development of a future comfort intervention package in radiotherapy.

9.6. Final reflections

At the end of this doctoral journey, there are many reflections both professionally and personally, and many positives can be taken. I have been able to work with and learn from expert clinical researchers (my supervisors) who I would strive to work with for future research in this area. I have also garnered a reputation in this area, building a network of clinical researchers with similar interests to improve comfort during radiotherapy.

There were many life events that occurred during the doctoral journey, owing to the time taken for completion. These events included celebrations of life and death and everything else sandwiched in the middle, including the COVID-19 pandemic. These events collectively led to a suspension of my PhD studies for one year. The pandemic also meant that the final study had to be conducted online, which in hindsight may have been more beneficial for inclusivity reasons because some patients may not have been able to travel.

At the outset, it was extremely difficult to foresee how I would develop both professionally and personally, but looking back this development is clear. I have learnt many research skills, including the design and conduct of studies and dissemination. Through the design of three studies, including the submission of applications to NHS research ethics committees for two studies, I have developed an appreciation for rigour from all angles. The data extraction of the SLR was onerous, as was refining the analysis into a format that would be interesting to readers. The many iterations of the SLR were rewarded when receiving the Editor's Choice Award for Publication. I have been coached by my supervisory team to professionally disseminate both posters and proffered oral presentations at conferences as well as conduct interviews and consensus studies in a less formal way. I have grown professionally in more ways than presented here, and this has influenced my personal life, specifically to keep calm and carry on. It is obvious to state that the most important facet of life is people, and if we can understand each other a little better, the world will be a better place to live. To explore comfort during radiotherapy provides that greater understanding of people and their experiences, revealing a road to make improvements.

Here at the end of my doctoral research, I have embarked on a new role as a consultant TR, and in this role, I have endeavoured to improve the experiences of patients with breast cancer. I aim to improve comfort through the future conduct of a definitive clinical study as a postdoctoral clinical academic.

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Appendices

Appendix A: Systematic review protocol

This appendix has been removed as it contains personal information

Appendix B: Electronic Supplement A – Search and mesh terms

COMFORT	CLINICAL	INTERVENTION	RESEARCH
	PROCEDURE		DESIGN
((((((uncomfortable).ti,ab	Radiotherapy*	AND (((ease*).ti,ab OR	(("randomised
OR	"radiation therap*"	(comfort*).ti,ab OR	control
(discomfort*).ti,ab OR	exp RADIOTHERAPY/	(transcend*).ti,ab OR	trial*").ti,ab OR
(anxiety OR anxious).ti,ab	((procedur*).ti,ab OR	(relax*).ti,ab OR exp	("randomised
OR exp ANXIETY/ OR	exp	RELAXATION/ OR	control
(distress*).ti,ab OR	"SURGICAL	(relieve OR relief).ti,ab	trial*").ti,ab OR
(stress*).ti,ab OR exp	PROCEDURES,	OR (alleviat*).ti,ab OR	exp
"STRESS,	OPERATIVE"/ OR	(distract*).ti,ab OR	"CONTROLLED
PSYCHOLOGICAL"/ OR	("local	(calm*).ti,ab) AND	CLINICAL
(fear*).ti,ab OR exp	anaesthe*").ti,ab OR	((intervention*).ti,ab OR	TRIALS AS
FEAR/ OR (fright*).ti,ab	("regional	(treat OR	TOPIC"/ OR exp
OR (scare*).ti,ab OR	anaesthe*").ti,ab OR	treatment*).ti,ab OR	"NON-
(emotion*).ti,ab OR	("conscious	(therap*).ti,ab OR	RANDOMISED
(tension OR tense*).ti,ab	surgery").ti,ab OR	(technique*).ti,ab OR	CONTROLLED
OR (misapprehen*).ti,ab	("awake surgery").ti,ab	(hypnosis).ti,ab OR exp	TRIALS AS
OR (apprehens*).ti,ab OR	OR (surgery).ti,ab OR	HYPNOSIS/ OR exp	TOPIC"
(panic).ti,ab OR exp	(immobil*).ti,ab OR	"MIND-BODY	
"PANIC DISORDER"/ OR	(invasive).ti,ab OR exp	THERAPIES"/))) AND	
(claustrophob*).ti,ab OR	"MINIMALLY		
exp "PHOBIC	INVASIVE SURGICAL		
DISORDERS"/)	PROCEDURES"/))		
	[DT 2000-2018]" NOT		
	((child*).ti,ab OR		
	(paediatric* OR		
	pediatric*).ti,ab))		

Appendix C: Electronic Supplement B – Characteristics of included studies

Sources	Setting	Design	Study participants	Comfort intervention	Clinical procedure	Clinical procedure timings (minutes)
Ahlander <i>et al.</i> (2018)	Outpatient: diagnostic imaging department at 1 hospital	RCT - two-arm parallel design	49 video information 48 comparator	Education/ information; administered before procedure	Cardiovascular magnetic resonance imaging	40–80
Angioli <i>et</i> <i>al.</i> (2014)	Outpatient: gynaecology day surgery at 1 hospital	RCT - two-arm parallel design	185 music 187 comparator	Audio: administered during procedure	Hysteroscopy	10–30
Argstatter <i>et al.</i> (2006)	Outpatient: cardiology day surgery at 1 hospital	RCT - multiple arm parallel design	28 music 28 coaching 27 comparator	Audio & coaching; administered before & during procedure	Intracardiac catheterization	30–40
Björkman <i>et al.</i> (2013)	Outpatient: endoscopy department at 1 hospital	RCT - two-arm parallel design	60 music 60 comparator	Audio; administered before & during procedure	Colonoscopy	30
Buffum <i>et al.</i> (2006)	Outpatient: interventional radiology department at 1 hospital	RCT - two-arm parallel design	89 music 81 comparator	Audio; administered before & during procedure	Vascular angiography	30–60
Chlan <i>et al.</i> (2000)	Outpatient: endoscopy department at 1 hospital	RCT - two-arm parallel design	30 music 34 comparator	Audio; administered during procedure	Flexible sigmoidoscopy	10–20
Choi <i>et al.</i> (2016)	Outpatient: bronchoscop y department at 1 hospital	RCT - multiple arm parallel design	89 verbal empathy 88 verbal empathy & touch 90 comparator	Empathic attention; administered before procedure	Impacted mandibular third molar removal	20
Diette <i>et al.</i> (2003)	Outpatient: endoscopy department at 1 hospital	RCT - two-arm parallel design	41 audio- visual 39 comparator	Audio-visual; administered before & during procedure	Flexible bronchoscopy	15–45
Drahota <i>et al.</i> (2008)	Outpatient: nail surgery clinics at 1 hospital & 1 community centre	RCT - two-arm parallel design	78 audio- visual 74 comparator	Audio-visual; administered before & during procedure	Minor surgery	60
Eslami <i>et</i> <i>al.</i> (2018)	Outpatient: urology department at 1 hospital	RCT - multiple arm parallel design	30 aromatherapy: <i>Lavandula</i> <i>angustifolia</i> Miller essence 30 aromatherapy: <i>Citrus</i> <i>aurantium</i> L. 30 comparator	Aromatherapy; administered before & during procedure	Laparoscopic cholecystectomy	30
Sources	Setting	Design	Study participants	Comfort intervention	Clinical procedure	Clinical procedur timings (minutes
--	--	--	--	--	--	---
Fang <i>et</i> <i>al.</i> (2016)	Outpatient: interventional radiology (IR) department at 1 hospital	RCT - two-arm parallel design	39 video glasses 44 comparator	Audio-visual; administered during procedure	Interventional radiology	20–30
Frank <i>et</i> <i>al.</i> (2007)	(2007) day surgery two-arm touch at 1 hospital parallel 40 compara design		42 therapeutic touch 40 comparator	Massage/ therapeutic touch & reflexology; administered before & during procedure	Stereotactic core breast biopsy	30–60
Hayes <i>et al.</i> (2003)	Outpatient: gastrointestin al diagnostic centre at 1 hospital	RCT - two-arm parallel design	100 music 98 comparator	Audio; administered before & during procedure	colonoscopy or esophagogastrodu odenoscopy	15–30
Heidaria <i>et al.</i> (2017)	Outpatient: coronary angiography department at 1 hospital	RCT - two-arm parallel design	45 h& reflexology 45 comparator	Therapeutic touch; administered before procedure	Coronary angiography	30–40
Hızlı <i>et al.</i> (2015)	Outpatient: urology day surgery at 1 hospital	RCT - two-arm parallel design	32 hypnotherapy 32 comparator	Hypnosis; administered before procedure	Transrectal ultrasound- guided prostate needle biopsy	30
Hozumi <i>et</i> <i>al.</i> (2017)	Outpatient: colonoscopy department at 1 military hospital	RCT - multiple arm parallel design	72 vehicle (placebo) 71 lavender 71 grapefruit 74 osmanthus fragrans 73 comparator	Aromatherapy; administered during procedure	Colonoscopy	30
Hu <i>et al.</i> (2010)	Outpatient: colonoscopy at 1 hospital	RCT - two-arm parallel design	14 neroli aromatherapy 13 comparator	Aromatherapy; administered before procedure	Colonoscopy	30
Hudson <i>et al.</i> (2015)	Outpatient: private clinic specializing in minimally invasive treatment of venous conditions	RCT - multiple arm parallel design	84 music 80 DVD 78 interaction 80 stress ball 76 comparator	Audio, audio-visual, interaction & stress ball; administered during procedure	Minimally invasive surgery of venous conditions	60
Jiménez- Jiménez <i>et al.</i> (2013)	ménez angiography two-arm 40 comp al. & vascular parallel 013) surgery design department at 1 hospital		40 music 40 comparator	Audio; administered during procedure	Varicose vein crossectomy with great saphenous vein versus Stripping	20–30
Kekecs <i>et</i> <i>al.</i> (2014)	•		34 education & therapeutic suggestion 50 comparator	Education/ information; administered before procedure	Cataract surgery	30–45
						200

Sources	Setting	Design	Study participants	Comfort intervention	Clinical procedure	Clinica proced timings (minute
Kola <i>et al.</i> (2013)	Outpatient: colposcopy department at 1 hospital	RCT - mixed factorial & multiple parallel design	40 high- information 39 low- information 38 comparator Each group split between high & low monitors based on Miller Behavioural Style Scale	Education/infor mation; administered during procedure	Colposcopy	10–20
Kwekkeb oom <i>et al.</i> (2003)	Outpatient: oncology clinic at 1 hospital	RCT - multiple arm parallel design	24 music 14 distraction 20 comparator	Audio & distraction; administered before & during procedure	Tissue biopsy or vascular port placement	20–40
Lang <i>et</i> <i>al.</i> (2000)	Inpatient & outpatient: interventional radiology department at 1 hospital	RCT - multiple arm parallel design	80 attention 82 hypnosis 79 comparator	Empathic attention & hypnosis; administered during procedure	Percutaneous transcatheter diagnostic & therapeutic peripheral vascular & renal interventions	30–60
Lee <i>et al.</i> (2017)	Outpatient: diagnostic imaging department at 1 hospital	RCT - two-arm parallel design	35 meditative music 37 comparator	Audio; administered during procedure	Positron emission tomography (PET) scans	30–60
McSherry <i>et al.</i> (2018)	Inpatient: burns ward at 1 hospital	RCT - two-arm parallel cross over design	10 immersive virtual reality (IVR) with first dressing change 8 IVR with second dressing change	Virtual reality; administered during procedure	Painful wound care procedures	10–20
Ng <i>et al.</i> (2016)	Outpatient: diagnostic imaging department at 1 hospital	RCT - two-arm parallel design	100 music 97 comparator	Audio; administered before & during procedure	cardiac computed tomography	15
NavidianOutpatient:et al.bronchoscop2018)y departmentat 1 hospital		RCT - two-arm parallel design RCT -	30 audio- visual 30 comparator	Audio-visual; administered during procedure	Flexible bronchoscopy	15–45
Nilsson <i>et</i> <i>al.</i> (2009)	al. (2009) percutaneou s coronary intervention unit at 1 hospital		121 music 117 comparator	Audio; administered during procedure	Coronary angiography	30–40
Nilsson <i>et</i> <i>al.</i> (2012)	Outpatient: percutaneou s coronary intervention	RCT - two-arm parallel design	34 music 34 comparator	Audio; administered during procedure	Coronary angiography	30–40
						201

Sources	Setting	Design	Study participants	Comfort intervention	Clinical procedure	Clinical procedure timings (minutes)
	unit at 1 hospital					
Packiam <i>et al.</i> (2018)	Outpatient: urology department at 1 hospital	RCT - two-arm parallel design	85 music 97 comparator	Audio; administered during procedure	Transrectal prostate biopsies	10
Padam <i>et</i> <i>al.</i> (2017)	Outpatient: department of physiology & gastroenterol ogy in 1 hospital	RCT - multiple arm parallel design	67 vedic chants 66 classical music 66 comparator	Audio; administeredbe fore procedure	Upper gastrointestinal endoscopy	30
Ripley <i>et</i> <i>al.</i> (2014)	Outpatient: cardiac catheterizatio n laboratory in 1 hospital	RCT - two-arm parallel design	36 music intervention 34 comparator	Audio; administered before & during procedure	Cardiac catheterization	30–40
J. Rosen <i>et al.</i> (2013)	Outpatient: haematology / oncology & multidisciplin ary clinics at 1 hospital	RCT - multiple arm parallel design	40 massage (7 did not receive) 20 structured attention (6 did not receive)	Massage, therapeutic touch & reflexology; administered before & during procedure	Placement of vascular access devices	20–40
Schupp <i>et</i> <i>al.</i> (2005)	Outpatient: radiology department in 1 hospital	RCT - mixed factorial & multiple parallel design	Low state anxiety group (<43) 37 attention 36 hypnosis 43 comparator High state anxiety group (≥43) 43 attention 43 hypnosis 34 comparator	Empathic attention & hypnosis; administered before & during procedure	Interventional radiology	20–30
Shabanlo ei <i>et al.</i> (2010)	Outpatient: haematology & oncology research centre at 1 hospital	RCT - two-arm parallel design	40 music 40 comparator	Audio; administered during procedure	Bone marrow biopsy & aspiration	30
Shahsava ri <i>et al.</i> (2017)	Outpatient: bronchoscop y department at 1 hospital	RCT - two-arm parallel design	40 reflexology 40 comparator	Reflexology; administered before procedure	Flexible bronchoscopy	15–45
Shenefelt <i>et al.</i> (2013)	Outpatient: dermatologic surgery clinic at 1 hospital	RCT - multiple arm parallel design	13 guided imagery live induction 13 guided imagery Recorded	Cognitive behavioural therapy; administered before & during procedure	Dermatologic procedures	10–90

Sources	Setting	Design	Study participants	Comfort intervention	Clinical procedure	Clinical procedure timings (minutes)
			induction 13 comparator			

Simmons <i>et al.</i> (2004)	Outpatient: ophthalmolo gy department in 1 hospital	RCT - multiple arm parallel design	20 massage 20 verbal coaching & slow breathing 20 massage, verbal coaching & slow breathing 20 comparator	Massage, verbal coaching & breathing techniques; administered before & during procedure	Cataract surgery	30–45
Snow <i>et al.</i> (2012)	Outpatient: cancer treatment centre at 1 hospital	RCT - two-arm parallel design	41 hypnosis 39 comparator	Hypnosis; administered before & during procedure	Bone marrow aspiration/ biopsy procedure	30
Sobana <i>et al.</i> (2015)	Outpatient: gastrointestin al endoscopy department at 1 hospital	RCT - two-arm parallel design	30 music 30 comparator	Audio; administered before procedure	Upper gastrointestinal endoscopy	30
Trambert <i>et al.</i> (2014)	Outpatient: breast care centre at 1 hospital	RCT - multiple arm parallel design	30 lavender- sandalwood 30 orange- peppermint 28 comparator	Aromatherapy; administered during procedure	Breast biopsy	30–60
Ugras <i>et</i> <i>al.</i> (2018)	Inpatient: otorhinolaryn gology surgery at 1 hospital	RCT - multiple arm parallel design	45 natural sounds 45 classical Turkish music 45 classical western music 45 comparator	Audio; administered before procedure	Otorhinolaryngolo gy surgery	15–720
M.R. Walker <i>et</i> <i>al.</i> (2014)	Outpatient: urology department at 1 hospital	RCT - two-arm parallel design	22 virtual reality 23 comparator	Virtual reality; administered during procedure	Cystoscopy	15–30
Weeks <i>et</i> <i>al.</i> (2011)	Outpatient: cardiac catheterizatio n laboratory in 1 hospital	RCT - multiple arm parallel design	30 loudspeaker music intervention 34 focused music intervention 34 comparator	Audio; administered during procedure	Coronary angiography	30–40
Wu <i>et al.</i> (2014)	Outpatient: cardiac catheterizatio n laboratory in 1 hospital	RCT - multiple arm parallel design	43 accessibility- enhanced multimedia informational education (AEMIE) 46	Education/ information; administered before & during procedure	Cardiac catheterisation	30–40

Sources	Setting	Design	Study participants	Comfort intervention	Clinical procedure	Clinical procedure timings (minutes)
			instructional DVD education 46 comparator			
Xiaolian	Outpatient:	RCT -	60 visual	Visual	Colonoscopy	30

				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re proced	eported bei Jure	ore clir	nical		Data re of redu		er clinio	al proced	ure/mea	n magnitude
			·	Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			Video information:	-	35	-	28, 43	<i>p</i> =0.10	-	28	-	22.5, 36	-	<i>p</i> =0.20
Ahlander	Education/	STAI	comparator:	-	35	-	28, 43		-	30	_	24, 38	-	
<i>et al.</i> (2018)	information	HAD	Video information:	-	6	-	2, 9	<i>p</i> = 0.01	-	-	-	-	-	-
			comparator: Music:	-	6.6	-	3, 8.5		-	-	-	-	_	_
Angioli <i>et al.</i> (2014)	Audio	STAI	Comparator:	39.75 39.15	_	8.94 7.42	_	<i>p</i> >0.05	27.59 32.66	_	6.3 11.6	_	_	<i>p</i> <.001
Argstatter et			Music:	00.10	_	1.72			7.3*		9.4	_		
al. (2006)	Audio & coaching	STAI	Coaching:	_	_	_	_	_	7.3*	_	9.4 9.4	_	-	<i>p</i> =0.05
	& coaching		Comparator:	_	_	_	_	-	7.3*	_	9.4	-	_	
			Music:	_	-	_	_	_	-	_	_	_	_	1
		STAI	Comparator:	-	_	-	_	_	-	_	-	_	-	<i>p</i> =0.007 [†]
			Music:	_	-	_	_	_	-	-	_	-	_	0.00 5 +
Björkman <i>et</i> <i>al.</i> (2013)	Audio	Relaxation	Comparator:	_	_	_	_	_	_	-	_	_	_	<i>p</i> =0.065 [†]
			Music:	_	_	_	_	_	_	_	_	_	_	<i>p</i> =0.006 [†]
		Wellbeing	Comparator:	_	_	-	_	_	-	-	-	_	-	[†] favours music
Buffum <i>et al.</i>			Music:	38.57	_	10.5	-		35.2	_	9.7	_	-	
(2006)	Audio	STAI	Comparator:	36.23	_	10.5	_	<i>p</i> =0.149	35.1	_	10.5 9	_	_	<i>p</i> =0.05
Chlan <i>et al.</i> (2000)	Audio	STAI	Music: Comparator:	36.9 40.2		12.5 11.9		<i>p</i> =0.28	34.5 41.8		10 13.5			<i>p</i> =0.002

Appendix D: Electronic Supplement C – Data extraction table

				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re proced	eported bei Jure	ore clir	nical		Data re of redu		er clinio	cal proced	dure/mea	In magnitude
			·	Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
		Satisfaction	Music: Comparator:	_		_	-	_	_	-	_	_	_	<i>p</i> =0.11 [‡] [†] favours music
			Music:	_	_	_	_	_	4.3	-	2.1	_	-	0.000
		Discomfort	Comparator:	_	_	_	_	_	5.2	-	1.7	_	-	<i>p</i> =0.026
			Verbal empathy:	_	30	_	10, 55		-1.2*	_	_	_	−4.1, 1.8	
		VAS-A (1–10 mm)	Verbal empathy/ touch:	_	30	-	10, 55	<i>p</i> =0.682	-0.3*	_	-	_	-5.7, 1.9	<i>p</i> <0.05
Choi <i>et al.</i>	Empathic		Comparator:	_	37	_	20, 59		-0.3*	_	_	_	-2.9, 2.3	
(2016)	attention		Verbal empathy:	_	-	-	-	-	-	-	_	-	-	
		Satisfaction	Verbal empathy/ touch:	_	_	_	_	_	_	_	_	_	_	<i>p</i> >0.05 [‡] † in all groups
			Comparator:	_	_	_	_	-	_	_	_	_	_	
Diette	Audio-visual	STAI	Audio-visual:	43.2	_	_	_	<i>p</i> >0.05	44.8	_	-	_	_	<i>p</i> =0.084
et al. (2003)	Audio-visual	STAI	Comparator:	43.8	_	-	_	<i>p></i> 0.05	45.6	_	-		_	p=0.004
Drahota et al.	Audio-visual	STAI	Audio-visual:	41.4	-	12.5	-	-	27.91	-	9.86	-	-	-
(2008)	Audio-visual	31AI	Comparator:	39.2	_	13	_	_	27.2	-	7.44	_	_	-
Eslami <i>et al.</i> (2018)	Aromatherapy	STAI	Lavandula angustifolia:	43.9	_	9.71	_	_	31.1	_	6.44	_	_	<i>P</i> <0.001 [‡]

				Main o	utcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re proced	eported bef lure	fore clir	nical		Data re of redu		er clinio	cal proced	lure/mea	in magnitude
				Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			Citrus aurantium L.:	43.9	-	7.88	-	-	30.17	_	5.59	-	-	<i>P</i> <0.001 [‡]
			Comparator:	39.7	-	10.0 2	_	_	40.7	-	9.69	_	-	P=0.975 [†] Compared to comparator
Fang et al.	Audio-visual	STAI	Video glasses:	36	_	11.3	_	<i>p</i> =0.40	-7.7*	_	9.9	_	_	p=0.0335
(2016)		017.	Comparator:	33.8	_	12.3	_	<i>p</i> =0.10	-4.4*	_	9.4	-	-	p=010000
		Nervousness	Therapeutic touch:	69.9	-	42.6	_	<i>p</i> =0.76	-41*	-	46	_	_	<i>p</i> =0.77
			Comparator:	67.1	-	34.8	_	•	-44*	_	41	_	_	
Frank et al.	Massage therapeutic	Tense	Therapeutic touch:	66.1	_	33.4	-	<i>p</i> =0.71	-40*	_	46	-	_	<i>p</i> =0.80
(2007)	touch & reflexology		Comparator:	69.2	-	36.7	_	1	-37*	-	41	_	_	1
		Fearful	Therapeutic touch:	60.6	_	43.8	-	<i>p</i> =0.86	-35*	_	55	_	_	<i>p</i> =0.43
			Comparator:	67.7	_	34.8	_	,	-43*	_	48	_	_	,
Hayes			Music:	36.7	_	9.1	_	_	32.3	_	10.4	_	_	
et al. (2003)	Audio	STAI	Comparator:	36.1	_	8.3	_	_	34.6	_	11.5	_	_	<i>p</i> =0.007
Heidaria <i>et al.</i>	Therapeutic	STAI	Hand reflexology:	49.82	_	1.74	_	<i>p</i> =0.78	42.67	_	1.47	_	_	<i>p</i> =0.001
(2017)	touch		Comparator:	49.71	_	1.65	_	-	48.66	_	1.78	_	_	-
	Hypnosis	BAI	Hypnotherapy:	6	_	_	0–28	_	2	_	_	0–23	-	<i>p</i> =0.001

				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data ro proced	eported bef dure	iore clir	nical		Data re of redu		er clinio	cal proced	dure/mea	in magnitude
				Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			Comparator:	9	-	-	0–28	-	8	-	_	0–34	-	
Hızlı <i>et al.</i> (2015)		114.0	Hypnotherapy:	11	-	_	2 –29	-	6	-	_	0–22	_	
(2015)		HAS	Comparator:	11.5	_	-	0–31	_	11.5	_	-	1–38	_	<i>p</i> =0.005
			Vehicle (sham):	_	_	_	_	_	3	_	7 [‡]	_	_	<i>P</i> >0.05
			Lavender:	_	_	_	_	_	3	_	6 [‡]	_	_	<i>P</i> >0.05
Hozumi <i>et al.</i> (2017)	Aromatherapy	Anxiety VAS (1–10 mm)	Grapefruit:	_	_	_	_	_	2	_	8‡	_	_	<i>P</i> >0.05
(2017)		(1 10 1111)	Osmanthus:	_	_	_	_	_	2	_	7 ‡	_	_	<i>P</i> <0.05
			Comparator:	_	_	_	_	_	3	_	8‡	_	_	<i>P</i> >0.05
Hu <i>et al.</i>	A no no oth o no nu	STAI	Neroli:	41.79	_	10.2 8	_	n 0 704	30.79	_	3.89	_	_	- 0.070
(2010)	Aromatherapy	STAI	Comparator:	43.46	_	10.4 1	_	<i>p</i> =0.734	36.46	-	9.31	_	-	<i>p</i> =0.079
			Music:	38.6	_	8.78	_	_	38.6	_	10.3 1	_	_	
		STAI	DVD:	39.86	-	10.3	_	_	37.56	_	10.2 8	-	-	- 0.02
		STAI	Interaction:	37.74	-	9.19	_	_	35.29	-	8.94	_	_	<i>p</i> =0.03
	Audio,		Stress ball:	41.54	-	11.0	_	_	38.54	_	8.58	_	_	
Hudson <i>et al.</i>	Audio, Audio-visual,		Comparator:	39	-	7.72	_	_	41.29	_	9.72	_	_	
(2015)	interaction &		Music:	4.49	_	2.71	_	_	3.79	_	2.42	_	_	
	stress ball		DVD:	4.65	_	2.32	_	_	3.31	_	2.24	_	_	
		S-NRS	Interaction:	4.33	_	2.31	_	_	3	_	1.96	_	_	<i>p</i> =0.06
			Stress ball:	4.8	_	2.43	_	_	3.6	_	2	_	_	·
			Comparator:	4.33	_	2.13	_	_	4.38	_	2	_	_	
		A-NRS	Music:	_	_	_	_	_	4.76	_	0.06	_	_	_

				Main o	utcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re procec	eported bei lure	ore clir	nical		Data re of redu	-	er clinio	cal proced	dure/mea	an magnitud
			·	Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			DVD:	-	-	-	-	-	4.7	-	0.06	-	-	-
			Interaction:	_	_	_	_	_	4.64	_	0.06	_	-	_
			Stress ball:	_	_	_	_	_	4.7	_	0.06	_	-	_
			Comparator:	_	_	_	_	_	4.58	_	0.06	_	_	_
			Music:	33.7	_	9.3	_		_	_	_	_	_	_
Jiménez-		STAI	Comparator:	34.1	_	10	_	<i>p</i> =0.78	_	_	_	_	_	_
Jiménez <i>et al.</i>	Audio	Control of intraoperative	Music:	_	_	_	_	_	1.31	_	0.3	_	_	
(2013)		stress feeling	Comparator:	_	-	-	_	-	2.36	-	0.3	-	-	<i>p</i> =0.02
		STAI	Education / therapeutic suggestion:	41.59	_	10.1	_	<i>p</i> =0.254	_	_	_	_	_	_
			Comparator:	44.22	_	11.5	_		_	_	_	_	_	_
Kekecs <i>et al.</i> (2014)	Education/ information	Wellbeing (scale 1-9)	Education / therapeutic suggestion:	6	_	_	3–9	<i>p</i> =0.98	6	_	_	3–9	_	<i>p</i> =0.084
		(Comparator:	6	_	_	2–9		6	_	_	2–9	_	
		Calmness (scale 1–7)	Education / therapeutic suggestion:	4.5	_	_	2–7	<i>p</i> =0.37	4.5	_	_	2–7	_	<i>p</i> =0.039
			Comparator:	4	_	_	2–7		4	_	_	3–7	_	
Kola <i>et al.</i> (2013)	Education/ information	STAI	<u>High-info.</u> Low monitor: High monitor:	17.75 18.94		6.79 7.12	_	_	13.75 12.75	_	5.27 3.26	_	_	_

				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re proced	eported bei lure	iore clir	nical		Data re of redu		er clinio	cal proced	lure/mea	n magnitude
				Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			Low-info. Low monitor		_		_	_		_		_	_	_
			Low monitor:	17.39	-	6.59	-	-	13.33	-	4.41	-	-	_
			High monitor:	16.75	_	5.48	_	_	12.81	_	4.11	_	_	_
			Comparator		_		_	_		_		_	_	_
			Low monitor:	18.79	_	5.83	_	_	14.3	_	5.24	_	_	_
			High monitor:	16.89	-	5.09	_	_	13.42	_	3.43	-	_	-
			Music:	36.2	_	13.0	_	_	32.1	_	12.4 6	_	_	_
Kwekkeboom e <i>t al.</i> (2003)	Audio & distraction	STAI	Distraction:	42.8	_	13.0	_	-	36.5	_	12.4 6	_	_	_
			Comparator:	36.2	_	13.0	-	-	29.2	-	12.4 6	-	-	_
and at al	Empathic	A provint w \ / A C	Attention:	3.8	-	-	-	-	2.5	-	_	-	-	-
Lang <i>et al.</i> (2000)	attention &	Anxiety VAS (1–10)	Hypnosis:	3.8	-	-	-	-	1	-	_	-	-	-
()	hypnosis	(1 10)	Comparator:	3.5	-	_	-	-	3.8	_	_	_	_	-
Lee <i>et al.</i>	Audio	STAI	Meditative:	40.26	-	5.68	-	<i>p</i> =0.50	34.97	-	6.73	-	-	<i>p</i> =0.02
(2017)	Addio	01/1	Comparator:	37.73	-	6.73	-	μ=0.00	38.38	-	5.66	-	-	p=0.02
MaChar			Immersive virtual reality (IVR) - 1st dressing:	4.8	_	2.9	_	_	3.5	_	3	_	_	
McSherry <i>et al.</i> (2018)	Virtual reality	Anxiety VNS (1–10)	change IVR - 2nd dressing change:	4.1	_	2.4	_	_	3.5	_	2.6	_	_	<i>P</i> >0.05
Ng et al.	Annelie	0741	Music:	_	10	_	7, 13	D 0 000	_	8	_	6, 10	_	
(2016)	Audio	STAI	Comparator:	_	10	_	8, 13	<i>P</i> =0.328	_	9	_	6, 12.5	_	<i>p</i> =0.721

				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re proced	eported bei Jure	ore clir	nical		Data re of redu		er clinio	cal proced	dure/mea	In magnitud
Sources interv			·	Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
	Audio-visual	Willingness to repeat the clinical	Music:	-	-	_	-	_	-	-	_	-	-	<i>p</i> =0.04 [‡] ⁺favours
(2018)		procedure (% survey)	Comparator:	-	-	_	_	_	_	-	-	-	-	music
		Anxiety NRS	Music:	-	2	-	0, 4	<i>p</i> =0.479	_	-	-	_	-	-
		(1–10)	Comparator:	_	2	-	0, 4	<i>μ</i> =0.479	_	-	-	_	_	-
	n <i>et al.</i> Audio	Relaxation	Music:	-	_	-	-	-	-	8	_	5, 9	-	0.040
	NRS (1–10)	Comparator:	_	_	_	_	_	_	8	_	4, 9	_	<i>p</i> =0.218	
	Audio		Music:	_	_	_	_	_	_	15	_	<u>4, 5</u> 14, 15	_	
		Short STAI	Comparator:	_	_	-	_	_	_	15	_	13, 15	_	<i>p</i> =0.932
	Audio _	Discomfort	Music:	_	_	_	_	_	_	0.5	_	0, 2	_	
	I	NRS (1–10)	Comparator:	-	_	_	_	_	_	1	_	0, 3	_	<i>p</i> =0.193
		Anxiety NRS	Music:	5.3	-	2	-	_	_	-	_	_	_	-
		(1–10)	Comparator:	5.4	_	2.4	_	_	_	-	-	_	_	-
		Enviroment	Music:	-	-	-	-	-	9	-	1.7	-	-	
Nileson <i>et al</i>		NRS (1–10)	Comparator:	_	-	-	_	_	7.7	-	3	_	_	
	Audio	Relaxation	Music:	_	_	_	_	-	5.6	-	3	_	_	<i>p</i> <0.0001 [‡]
		NRS (1–10)	Comparator:	_	_	_	_	-	6	-	3.1	_	_	[†] favours music
		Discomfort	Music:	_	_	_	_	_	_	0.8	_	0–10	_	114510
		NRS (1–10)	Comparator:	-	_	_	_	_	-	2	_	0-8	_	
Packiam	Audio	STAI	Music:	33.7	_	8.9	_	n-0.61	_	_	_	_	_	_
<i>et al.</i> (2018)	Audio	STAI	Comparator:	34.4	-	9.9	-	<i>p</i> =0.61	_	-	_	-	-	-

				Main o	utcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data ro proced	eported bef lure	ore clir	nical		Data re of redu		er clinio	cal proced	dure/mea	ın magnitud
SourcesintervePadam et al. (2017)AudioRipley et al. (2014)AudioJ. Rosen et al. (2013)Massage therape touch				Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
		Satisfaction	Music:	_	_	_	_	_	8.8	_	1.6	_	_	
		VAS (0–10)	Comparator:	_	-	_	_	_	8.5	_	1.9	_	_	<i>p</i> = 0.29
		Willingness to	Music:	_	_	_	_	_	8.2	_	2.7	_	_	
		repeat VAS (0–10)	Comparator:	_	_	_	_	_	8.1	_	2.2	_	_	<i>p</i> = 0.92
	AU/0/0		Vedic chants:	40.4	_	8.8	_	_	38.5	_	10.7	_	_	_
et al. (2017) Audio	Audio	STAI	Music:	41.8	_	9.9	_	_	38	_	8.6	_	_	_
			Comparator:	40.5	_	8.7	_	_	39.1	_	8.8	_	_	_
			Music:	_	_	_	_	_	8	_	_	7–11	_	
	Audio	Short STAI	Comparator:	_	_	_	_	_	9	_	_	8–12	_	<i>p</i> =0.36
	Massage,		Massage:	37.67	_	12.5			31.15	_	1.54			
	therapeutic touch & reflexology	STAI	Attention:	40.45	_	12.9	_	<i>p</i> =0.427	31.83	_	2.23	_	_	<i>p</i> =0.9720
			Low STAI (<43)				_					_	_	
			Attention:	31.1	_	6.9	_		_	_	_	_	_	_
		STAI	Hypnosis:	33.5	_	5.7	_	<i>p</i> >0.05	_	_	_	_	_	_
att	Empathic		Comparator:	34	_	5.5	_		_	_	-	_	_	_
	attention & hypnosis	Time course	Attention:	_	_	_	_	_	4.85	_	-	_	-	
	1.9 010010	of patients' anxiety self-	Hypnosis:	_	-	_	_	_	1.98	_	_	_	_	<i>p</i> >0.05
		rating (0–10)	Comparator: <u>High STAI (≥43</u>)	-	-	-	-	-	2.03	-	-	-	-	

				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re procec	eported bef Jure	ore clir	nical		Data re of redu		er clinio	al proced	lure/mea	n magnitud
			·	Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			Attention:	53.8	_	7.5	_		_	_	_	-	_	_
		STAI	Hypnosis:	51.1	_	6.6	_	<i>p</i> <0.05	_	_	_	_	_	_
			Comparator:	53.3	_	7.7	_		_	_	_	_	_	_
		Time course	Attention:	_	_	_	_	_	3.84	_	_	_	_	
		of patients' anxiety self–	Hypnosis:	_	_	_	_	_	3.35	_	_	_	_	<i>P</i> =0.06
		rating (0–10)	Comparator:	_	_	_	_	_	2.03	_	_	_	_	
Shahanlooi et			Music:	52.9	_	6.94	_		43.24	_	5.41	_	_	
Shabanloei <i>et</i> Audio S al. (2010)	STAI	Comparator:	52.18	_	7.29	-	<i>P</i> =0.852	46.42	-	7.2	-	_	<i>P</i> =0.27	
Shahsavari	ahsavari Beflevelogu	Anxiety VAS	Reflexology:	4.35	-	0.33	_	- 0.0	2.83	_	0.23	-	-	T 0.001
et al. (2017)	Reliexology	(1–10 mm)	Comparator:	3.78	-	0.29	_	<i>p</i> =0.2	4.88	_	0.34	-	-	<i>p</i> >0.001
	0		Guided imagery live:	3.31	-	-	0–7		0.77	_	-	0–3	-	
Shenefelt <i>et</i> <i>al.</i> (2013)	Cognitive behavioural therapy	Anxiety SUD (0–10)	Guided imagery recorded:	3.38	_	-	0–8	<i>P</i> >0.05	0.77	_	-	0–5	-	<i>P</i> >0.05
			Comparator:	3.15	_	_	0–10		1.15	_	_	0–4	_	
			Massage:	_	_	_	_	_	3.65	_	_	1.7	_	_
Simmons <i>et</i> <i>al.</i> (2004)	(2004) breathing L	Anxiety Likert (0–10)	Verbal coaching/ slow breathing:	_	-	_	_	_	3.1	_	_	2.2	_	_
	techniques		Massage/ verbal coaching:	_	_	_	_	_	2.75	_	_	1.5	-	_

Sourcos				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data re procec	eported bef lure	ore clir	nical		Data re of redu		er clinio	al procec	lure/mea	n magnitude
				Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			Comparator:	_	_	_	_	_	5.85	_	_	1.9	_	_
			Massage:	-	-	-	-	_	4.3	-	-	2	-	-
		Discomfort Likert (0–10)	Verbal coaching/ slow breathing:	-	_	_	-	_	3.5	_	_	2.2	_	-
			Massage/ verbal coaching:	_	_	_	_	_	4.15	_	_	2.3	_	_
			Comparator:	_	_	_	_	_	5.95	_	_	1.9	-	_
Snow		VAS-A	Hypnosis:	_	_	_	_	_	-22*	_	18 [‡]	_	_	0.000
et al. (2012)	Hypnosis	(1–100 mm)	Comparator:	_	_	_	_	_	−13*	_	6 [‡]	_	_	<i>p</i> =0.026
Sobana <i>et al.</i>			Music:	_	_	_	_	_	-6.1*	_	4.19	_	_	_
(2015)	Audio	Short STAI	Comparator:	_	_	_	_	_	0.06*	_	1.2	_	_	_
			Lavender- sandalwood:	_	_	_	-	_	-11*	_	_	35,4	_	_
Trambert <i>et</i> <i>al.</i> (2014)	Aromatherapy	STAI	Orange- peppermint:	_	_	_	_	_	-6*	_	_	-33,10	_	_
			Comparator:	_	_	_	_	_	-4*	_	_	-28,23	_	_
			Natural sounds:	39.11	_	4.71	_		34.38	_	4.71	_	_	
Ugras <i>et al.</i> (2018)	Audio	STAI	Turkish music:	41.71	_	9.89	_	<i>p</i> <0.001	35.44	_	7.66	-	_	<i>p</i> <0.001
· · · · /			Classical music:	41.93	-	9.51	-		35.71	-	10.2 8	-	_	

Sourcas				Main o	outcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	Data ro proced	eported bei Jure	ore clin	ical		Data re of redu		er clinio	al proced	dure/mea	n magnitude
			·	Mean	Median	SD/ SE [‡]	IQR/ range	P- value	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value
			Comparator:	43.51	_	6.64	_		44.09	_	6.47	_	_	
		VAS–A (1–100 mm)		4.9	_	_	_	_	5.6	-	_	_	_	_
M.R. Walker	Virtual	Unpleasant VAS (1–100 mm)	Virtual reality:	5.2	-	_	_	-	5.1	_	_	-	_	_
et al. (2014) reali	reality	VAS–A (1–100 mm) Unpleasant	Comparator:	-	-	-	-	-	6.2	-	-	-	_	_
		VAS (1–100 mm)		_	_	_	_	_	5.3	_	-	_	_	-
Weeks <i>et al.</i>			Loudspeaker music:	-	-	_	_	_	2	-	-	1–9	-	<i>p</i> <0.05
(2011)	Audio	Anxiety NRS	Focused music:	-	_	-	-	-	2	-	-	1–8	-	<i>p</i> <0.05
			Comparator:	_	_	_	_	_	5	_	_	1–10	_	<i>p</i> >0.05
Wu <i>et al.</i> (2014)	Education/ information	STAI	Accessibility- enhanced multimedia informational education:	-	-	_	-	_	16.33	_	_	-	-	<i>p</i> <0.05
(2014) inf			Instructional DVD education:	-	_	-	_	-	13.25	_	-	_	_	<i>p</i> >0.05
			Comparator:	_	_	-	_	_	10.16	-	-	-	-	<i>p</i> >0.05
Xiaolian <i>et al.</i> (2015)	Visual & Audio-visual	STAI	Visual: Audio-visual:	33.35 34.13		10.3 8.85	_	p=0.637	28.2 29.18	_	6.93 7.08		-	<i>p</i> =0.169

				Main o	utcomes									
Sources	Comfort intervention	Outcome measures	Intervention/ comparator	procedure				Data re of redu	-	er clinio	al proced	ure/mea	n magnitude	
				Mean Median SD/ IQR/ P- SE [‡] range value			-	Mean	Median	SD/ SE [‡]	IQR/ range	95% Cl	P-value	
			Comparator:						30.88	_	9.32	-	_	

Appendix E: Raw data for the clinical procedures

	Clinical p	rocedures						
Sources	Bone marrow biopsy/aspiration	Observational investigations: Bronchoscopy Colonoscopy Colposcopy Cystoscopy Gastrointestinal endoscopy Hysteroscopy Sigmoidoscopy	Dermatologic/ dressing change	Diagnostic imaging	Intravenous access	Interventional radiology (guided biopsy and angiography)	Minor/conscious surgery	Shockwave lithotripsy
Ahlander <i>et al.</i> (2018)				\checkmark				
Angioli <i>et al.</i> (2014)		\checkmark						
Argstatter et al. (2006)						\checkmark		
Björkman <i>et al.</i> (2013)		\checkmark						
Buffum et al. (2006)						\checkmark		
Chlan <i>et al.</i> (2000)		\checkmark						
Choi <i>et al.</i> (2016)		\checkmark						
Diette et al. (2003)		\checkmark						
Drahota <i>et al.</i> (2008)							\checkmark	
Eslami <i>et al.</i> (2018)							\checkmark	
Fang <i>et al.</i> (2016)						\checkmark		
Frank <i>et al.</i> (2007)						\checkmark		
Hayes <i>et al.</i> (2003)		\checkmark						
Heidaria <i>et al.</i> (2017)						\checkmark		
Hızlı <i>et al.</i> (2015)						\checkmark		

	Clinical p	rocedures						
Sources	Bone marrow biopsy/aspiration	Observational investigations: Bronchoscopy Colonoscopy Colposcopy Cystoscopy Gastrointestinal endoscopy Hysteroscopy Sigmoidoscopy	Dermatologic/ dressing change	Diagnostic imaging	Intravenous access	Interventional radiology (guided biopsy and angiography)	Minor/conscious surgery	Shockwave lithotripsy
Hozumi <i>et al.</i> (2017)		\checkmark						
Hu <i>et al.</i> (2010)		\checkmark						
Hudson <i>et al.</i> (2015)							\checkmark	
Jiménez-Jiménez <i>et al.</i> (2013)								
Kekecs et al. (2014)							\checkmark	
Kola <i>et al.</i> (2013)		\checkmark						
Kwekkeboom et al. (2003)					\checkmark			
Lang et al. (2000)								
Lee et al. (2017)								
McSherry et al. (2018)								
Ming <i>et al.</i> (2016)								
Navidian <i>et al.</i> (2018)		\checkmark						
Nilsson <i>et al.</i> (2012)						\checkmark		
Nilsson <i>et al.</i> (2009)								
Packiam et al. (2018)	\checkmark							
Padam <i>et al.</i> (2017)		\checkmark						
Ripley <i>et al.</i> (2014)						\checkmark		

	Clinical p	rocedures						
Sources	Bone marrow biopsy/aspiration	Observational investigations: Bronchoscopy Colonoscopy Colposcopy Cystoscopy Gastrointestinal endoscopy Hysteroscopy Sigmoidoscopy	Dermatologic/ dressing change	Diagnostic imaging	Intravenous access	Interventional radiology (guided biopsy and angiography)	Minor/conscious surgery	Shockwave lithotripsy
J. Rosen <i>et al.</i> (2013)					\checkmark			
Schupp <i>et al.</i> (2005)				\checkmark				
Shabanloei <i>et al.</i> (2010)						\checkmark		
Shahsavari <i>et al.</i> (2017)		\checkmark						
Shenefelt et al. (2013)			\checkmark					
Simmons et al. (2004)							\checkmark	
Snow <i>et al.</i> (2012)	\checkmark							
Sobana <i>et al.</i> (2015)								
Trambert et al. (2014)						\checkmark		
Ugras <i>et al.</i> (2018)							\checkmark	
M.R. Walker et al. (2014)								
Weeks et al. (2011)						\checkmark		
Wu <i>et al.</i> (2014)						\checkmark		
Xiaolian et al. (2015)								
SUM	2	14	2	4	2	13	7	0

Appendix F: Raw data for the comfort interventions

						Com	fort Inte	rventio	ns					
Sources	Aromatherapy	Audio	Audio- visual	Breathing techniques	Cognitive behavioural Therapy/ Coping styles	Education/ information	Empathic attention	Hypnosis	Massage, therapeutic touch	Reflexology	Relaxation techniques	Therapeutic suggestion, verbal coaching	Visual	Virtual reality
Ahlander et al. (2018)			V											
Angioli <i>et al.</i> (2014)		٧												
Argstatter et al. (2006)		٧												
Björkman <i>et al.</i> (2013)		٧												
Buffum et al. (2006)		٧												
Chlan <i>et al.</i> (2000)		٧												
Choi <i>et al.</i> (2016)							V		V					
Diette et al. (2003)			V											
Drahota et al. (2008)			V											
Eslami <i>et al.</i> (2018)			V											
Fang et al. (2016)									V					
Frank <i>et al.</i> (2007)		٧												
Hayes et al. (2003)										V				
Heidaria <i>et al.</i> (2017)								٧						
Hızlı <i>et al.</i> (2015)	V													
Hozumi <i>et al.</i> (2017)	V													
Hu et al. (2010)			٧				V				V			
Hudson et al. (2015)		٧												

Jiménez-Jiménez <i>et al.</i> (2013)						V					٧	
Kekecs et al. (2014)					V	V						
Kola <i>et al.</i> (2013)												V
Kwekkeboom <i>et al.</i> (2003)		V										
Lang <i>et al.</i> (2000)							V	V				
Lee et al. (2017)		V										
McSherry et al. (2018)												V
Ming <i>et al.</i> (2016)		V										
Navidian <i>et al.</i> (2018)			v									
Nilsson <i>et al.</i> (2012)		V										
Nilsson <i>et al.</i> (2009)		V										
Packiam et al. (2018)		V										
Padam <i>et al.</i> (2017)		V										
Ripley et al. (2014)									V			
J. Rosen <i>et al.</i> (2013)							V	V				
Schupp et al. (2005)		٧										
Shabanloei et al. (2010)										V		
Shahsavari et al. (2017)								V				
Shenefelt et al. (2013)				V					V		V	
Simmons et al. (2004)								V				
Snow <i>et al.</i> (2012)		٧										
Sobana <i>et al.</i> (2015)	٧											
Trambert et al. (2014)												V
Ugras <i>et al.</i> (2018)		V										

M.R. Walker <i>et al.</i> (2014)						v								
Weeks et al. (2011)			٧										V	
SUM	3	18	6	1	1	3	4	5	4	2	1	2	1	3

Appendix G: Berkshire B NHS Research Ethics Committee's favourable opinion

This appendix has been removed as it contains personal information
Appendix H: Electronic material – Interview guides

Patient interview guide

• How has your experience with radiotherapy been so far?

Prompts

How did you find your initial appointments in radiotherapy such as your CT planning scan?

Can you tell me how you felt before you were about to have your radiotherapy CT planning scan?

Can you tell me whether you were comfortable during your radiotherapy CT planning scan?

Can you tell me whether you were comfortable after your radiotherapy CT planning scan?

When you come into the centre to have your treatment, what is it like for you (or how do you find it)?

 How do you feel being positioned and maintaining position for radiotherapy on the couch for more than 10 minutes during treatment?

Prompts

Can you tell me how you feel before you are about to have the radiotherapy treatment?

Can you tell me whether you are comfortable or not during radiotherapy treatment?

Can you tell me whether you are comfortable after radiotherapy treatment?

• Have you or you're the radiographers tried anything to help with getting into position and keeping in position during treatment?

Prompts

If yes, what have you tried to improve your comfort?

If no, have you any thoughts about what could be done to improve your comfort during your radiotherapy treatment?

• Have you any thoughts about what we could do to improve your comfort during radiotherapy?

Prompt

If anything were possible, what would you do?

• Is there anything else you would like to add?

Therapeutic researcher interview guide

• What are your experiences when delivering radiotherapy to patients with more than 10 minutes?

Prompt

Thinking about your recent experiences working with patients having extended treatment times, what do you think is important to provide effective/efficient treatment?

• Tell me what you think about the comfort of your patients during radiotherapy?

Prompt

What is it like positioning patients for stability and ensuring they do not move for more-than 10 minutes?

• What do you do to improve patient comfort during extended treatment times?

Prompt

If you intervene to improve comfort, what have you tried?

If you have not, have you any thoughts about what could be done to improve your comfort during your radiotherapy treatment?

If uncertain, is there anything you would want to change or improve about your practice?

• Is there anything else you would like to tell me about your experience?

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
Emotional health				Shared experience
	Stressed, anxious, distressed, frightened or scared	 P01: I was frightened. But, it still is frightening it is but when I had it made I didn't know what was going on in my head it wasn't nice and then didn't know what was going to happen and its was on my face and then its not a nice thing the mask is not nice at all I, am actually frightened to open my eyes. Cos if I open my eyes the laser might go. P12: I actually felt as though I was in a horror film, only because I had been watching a lot of horror film. Ooh no I just think that's my imagination running away with me really. 	R01: It's always frightening and scary and they have got no idea what to expect. Wham bam thank you ma'am. But they have got to t take that for the next 10 weeks every day. R11: You know you get some patients that say fine come in quietly and then you get other patients that come in and they're very anxious.	Shared experience. There was a good balance of quotes highlighting the impact of stress, anxiety distress, fright from the perspective of patients and therapeutic radiographers. Some quotes completely match the context for example the use the word 'frightened' and 'frightening' by both patients and therapeutic radiographers.

Appendix I: Electronic Supplementary Material 1 – Themes and subthemes

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
	Vulnerability	P12: Yes, so I knew what to expect apart from my feelings of being in the horror film and vulnerable a little bit.	No quotes for this subtheme	Patient only sub-theme
		P17: So, although the people couldn't be in the room while it is going on. it is radiotherapy so I do understand the whys and where for so although the comfort level was as hard as it could be, mentally I wasn't prepared for the feeling of being quite so vulnerable.		
	Beyond control	P01:and then didn't know what was going to happen and its was on my face	No quotes for this subtheme	Patient only sub-theme
		P08: They always let me know when they are going out the room because for those two to five minutes that you are on there you are kind of at their mercy.		
	Consequence of pain	No quotes for this subtheme	R02: I mean we have already talked about the palliative patients and you know people in pain find it difficult to keep still.	Therapeutic radiographer only sub- theme.
			R19: If they are being treated for some time it can be painful.	

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
	Privacy in care	No quotes for this subtheme	 R04: Again comfort comes in a different number of definitions. For breast patients comfort may be body perception. So their perception of themselves with no top on. Self-conscious because of post-surgical scars or a double mastectomies they may not be overall happy with the condition that their breast area has been left in they might feel, I think I've seen a lot of reports it reduces their femininity as it where it reaches that female identity somewhat. So they might feel that is a key issue in terms of their emotional comfort. R10: No one really got covered up no matter what their treatment was for dignity. That's just sounds hard but they are suitable due to the metal studs and then were before we tried to use tissue the air conditioning blew it off. 	Therapeutic radiographer only sub- theme.

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
	Expectations	No quotes for this subtheme	R12: What comes to mind initially is the head and neck shell. I think for anybody who has a shell for over 10 minutes a big ask for people I think.	Therapeutic radiographer only sub- theme.
			R23: I think we're all guilty of perhaps pushing patients a little bit more than we should to get them in a position that's going to mean that they have no control over what is happening to them.	

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
	Side effects	No quotes for this subtheme	R02: You've got to tell them to not drive for a bit and that's where you know you're not knocking them out, but you know that's all about getting him in the position and keeping him in the position. I know that in the past and other places I've worked where they've done stereotactic radiotherapy, I've talked about actually we could do stereotactic for treating certainly brain patients.	Therapeutic radiographer only sub- theme.
			R24: Yeah, patients they get a lot of swelling, changes that are often easy to monitor and we are much better at treating things, even though their skin is getting sore, and they get difficult to swallowing and breathing, which has an emotional strain for patients.	
Positioning & immobilisation experiences				Shared experience
	(<u>Dis</u>) Comfort of position or preparation	P06: Well radiotherapy, its very uncomfortable I've noticed. Its nobody's fault though. If that means I will be uncomfortable for 20 minutes then damn it I will be	R13: Patients would often get uncomfortable during those that get and the bolus material to warm up they don't have to be specific position with their knees. So it wasn't always the most comfortable position especially for	Shared experience between patients and therapeutic radiographers.

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
		uncomfortable for 20 minutes on a daily basis. It is for my own good to get rid of this thing.	patients so they would often feel cramping like some things they would usually be able to tolerate without having to stop always.	
		P15: Well it is not that comfortable having your arms up and I did think oh crumbs and I thought how long am I going to have to hold them up , there was one day I thought I am going to really ,they felt really numb because they were up and the blood was going downwards I guess . I thought if I have to stay here a long time, I am not going to feel my arms so that slightly freaked me out.	R17: Well yeah I would say it's not very comfortable for patients to have their arms up because you find that they end up with pins and needles in their arms so high up they end up losing the sensation in the fingers as well.	
	Challenges of holding position	P06: The hardest part is to relax into the table. The moment they touch you and you are tensing again , then as soon as you relax they move you again you tense up again. That is the hardest part really' is to relax. It is not that it's because they want you in a certain position and you are trying to hold that position for them and at the same time they are saying relax now.	R05: Some patients manage 10 minutes quite easily whereas other patients struggle with 10 minutes even less than that really. So, it's kind of just managing it on how the patient is. I mean from personal experience because last week I was actually made to lie on the bed have a treatment mask made and ever since I was on the bed for 20 minutes and I was not a patient it is actually quite difficult for me to think about my patients having to be on the bed for just 10 minutes when they have got issue with the machine or what have you. I was genuinely empathetic	Shared experience between patients and therapeutic radiographers.

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
		P21: There were times with my arms where I had to hold	with them quite a lot.	
		them in the cups during radiotherapy, and it didn't feel natural at all. An odd position.	R10: Well the first thing that we do is question is the patient was actually capable of holding position. Okay so if they were unable to keep the arms above their heads and it was causing a lot of strain because then they would constantly stop over course of the treatment.	

Pre existing health conditions	P05: That was really caused by an accident that I had 50 odd years ago ,I lost the muscles in my chest . you don't use those muscles very often until I came here really basically. So that was one thing that was slightly uncomfortable to start with.	No quotes for this subtheme	Patient only sub-theme
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Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
		P16: But that's only because I've got a lot of back problems and it wasn't hard at the time, but it was afterwards that it hurt. But you can't do anything about that, that's not your fault. That happens to be my back that's all.		
Information & communication experiences				Patient only experience
	Reassuring (non) verbal communication	P03 I was really worried that if I had a problem, how would they know. I guess I could have waved and they would have stopped the radiotherapy but I was not told it was safe to do this. P03: But I mean you know your not going to suffocate, and anytime you can of course wave and they will	No quotes for this subtheme	Patient only sub-theme

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
		stop. So, the key thing really is the reassurance that your given by the radiotherapists because they know exactly what's happening, they know how you might react. I think they have been really good here. Explaining what's going on and reassuring.		
		P14: Sometimes I want to know more. Other times I am Just quite happy to going along with the people that knows.		
	Overload of written information	P16: Yes, I am overrun with booklets and other bits of paper telling me what to do.	No quotes for this subtheme	Patient only sub-theme
		P17: It is one of those experiences, your brain is so overloaded with information especially with being and all the elements before treatment could start the feeding tube that they wanted to put in my stomach.		
		P14: Yeah, I mean I wouldn't have known anything more. They gave me all these leaflets to read and I never read them because I didn't want to.		

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
		P21: I would have liked to choose the type of information, such as a video explanation where I could click to different sections so I could look at my cancer, then how I would get treated by radiotherapy otherwise I threw the leaflets away it was too much.		
Environment				Patient only experience
	Efficiency of the service	P04: So I found the whole thing really efficient and really well put together. I think the XX centre works on the basis that this is my theory anyway, that people coming through the door are having a bad day. So lets not make that any worse. And its almost as if someone's put that together at some point and said right this is the vision.	No quotes for this subtheme	Patient only sub-theme
		P23: It's easy to check yourself in; you don't have to wait for anybody in reception which I think is a good thing. They've been holding back automating all that sorts of things and obviously to come		

Themes	Subthemes	Examples of patient quotes	Examples of therapeutic radiographer quotes	Shared experiences
		straight through to the radiotherapy. P7: Although check in was easy I found the automatic check in very impersonal.		
	Pleasant Hospitality	P01: Definitely a tea machine, even a little bit of music. Before we go in, liven it up a bit. Not like a disco. You would feel warmer. Its got a warmer feel in the main waiting area than in the radiotherapy waiting area.	No quotes for this subtheme	Patient only sub-theme
		P12: The atmosphere was nice, and I didn't feel like a cancer patient I felt like I had nothing wrong with me. But I thought I'm just going for a bit of treatment to sort a problem out. P12: The reception and waiting areas had that clinical feel and smell, and radiotherapy was something like I have never seen.		

Appendix J: Electronic Supplementary Material 2 – Emergent themes and subthemes of comfort solutions

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
Information & Communication Preparation (Patient)				Patient only comfort solution
		P02: Even video would be ok. So you know what your going into.		
		P05: Yes they kept you informed of what was happening and exactly what you needed to do, to stay still.		
	Information & Communication Provision (Patient)	P12: When I first found out that I had to go for radiotherapy I had already read the book, so I had put myself in the picture. My first experience on the machine.		Patient only sub theme
		P17: That's why I said I would like to say I didn't want to be informed of everything because I have a filter system on this and only want to know about stuff on a really need to know basis.		

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		PO3: Difficult to say I mean it maybe helpful to, I mean actually did have the chance to look around the department which we didn't take up because we were so far away. We are an hour away. But I think for most people it would be important to look around. To see the machines, see the masks, and to know exactly what's going to happen. Because a booklet is not quite the same. Because when I had a mask made and I actually saw ones, I went oh my goodness. That's quite a mask. I didn't think it would be as big as that, I didn't think it would be as rigid as that. I kind of had this vision of a mesh thing. Because it looks mesh again in the booklet. I didn't expect it to be quite so hard.		
	Preparation (Patient)	P04: So I got lots and lots of information and leaflets in. Some were given to me and some I've picked up from Macmillan here. I probably did at some point when I was having the CT scan saw a picture of the machine and saw how it worked. So it might be even an online area where you go to it, and it says do you want to see a video of it. This is head and neck, tummy, legs or what ever it is bang bang bang, a 30 second video this is what to expect in the room. I didn't find it a problem but it might quite a nice way of saying. I quite right in saying when your treating you can take people in and show them around. There might be a way of putting those journeys on to a video somehow. Then maybe put it online.		Patient only sub theme

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P07: I think it would have been a improvement to have a session before coming for the actual thing. Yes. I would say yes to that. But for other people perhaps who are less familiar with medical terms and the like may have been quite frightened. I think it would have been a big help for them.		
Preperational Approaches (TR)				
	Proactive communication chanels		R02: Sometimes it's about cancer but oncologists don't tend to get too involved in patients either. Medication, yeah you know, passing things on no matter what it is, really slows that down the line but you can do something about it so you can be proactive rather than being reactive. R05: I think the biggest the lack of communication between	TP only sub
		No quotes for this subtheme	different hospitals when a patient's in one hospital then coming over to ours. That's where I've noticed that has a really big impact especially if you're doing an on-call service and a patient comes and the nurse comes with them and they've said they had pain relief so many hours ago and actually it's worn off now. I know there's nothing we can do until there's a doctor or nurse available to prescribe and get the medication that's appropriate.	TR only sub theme

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R18: In my previous trust there were advanced practitioners who probably meet the patients at the consent stage and get to know them at the personal level so that they would have better insight. Communicate with a treatment team and any of the special needs of the patient were noted. That doesn't necessarily happen where I work now. R24: Like I said, we touched on it earlier, first day chats they are very important, patients have first days chats before radiotherapy but before that they would meet CNS's, they would meet new Therapeutic radiographers, they would meet CT team which again they do firsta chat there to explain everything, I think once patients are more aware of what happens, they are more accepting.	
	Tailored Verbal & Written Information and Pre-Treatment Communication (TR)	No quotes for this subtheme	 R06: Yes we did a lot of SRS and that helps. We give them information and tell them outside the room that they were still attached to them. R07: We give them written information and ensure they are treated with dignity. R19: I try to make sure our patients think that they get what they need and that they know enough information prior to and during radiotherapy treatment." R23: I think it's important that we give them more information. To make them feel better mentally as well as physically because we're not just now. We got to treat the whole patient not just their physical issues. Yeah. 	TR only sub theme

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R11: The training videos and things, the DVD for patients even the training DVD you have patients on that. And sometimes we have dementia as well. We've got specific books that go through step by step what's happening in the machines. And sometimes you know with dementia and learning difficulties patients. It is really beneficial to sort of go through a picture store, that is really good.	
	Pre-Treatment Preperation & Tours of Radiotherapy (TR)	No quotes for this subtheme	R14: "He did an animation of a couple of setups with the head and neck setup that actually showed them like an X- ray or the spine and showed them the position that we were putting them into and why we would do that. And that works to care for the head and neck but the one that really worked quite well for was prostate patients. So we did it for the prostate and the bladder patients regarding bladder and rectal filling. Why we did it for effects of rectal gas and how it might move the prostate around as well.	TR only sub theme
			R17: So it's just a case of just having more coaching with patients as a kind of help so we don't have to get them off the bed as much as what we were finding that they were coming off the bed quite a bit because it's uncomfortable.	
			R23: I think coaching patients before their treatments is really important. Because so often they can't even sign and communicate with you generally when they're in the treatment position.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R03: I just think not having that hard couch is sort of quite nice and you always want things to be more sort of patient centred like I really wish there was some way we could sort of set sessions beforehand. This is how you know how the machine works. And this is what it looks like and this is what happens when you have your scan just to sort of reduce those anxieties before we have a chat with them on the first day and before they go into the room because most times they have their treatment and then we get back and we're all done like.	
			R06: The coaching is an initial thing that takes place with the doctors to see what is needed. They've got the clinic. At a clinic before they have to take these guys to the centre half an hour before their scan. So it's a TR that tells them what's going to happen, explains everything in detail as well. I believe that they are having this at other hospitals.	
			R11: Oh yes the open even or coaching education. So basically some session before they come in just to give them an overview.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R23: I quite like an open day. I guess it could be called Focus Group. But for those patients that want to they can come along and have a tour of the place and see what goes on, what it's like because most people have never seen one. You know show them treatment plans and let them meet other patients that can help patients go through the same thing although that can be a hindrance in some cases but it can also be really good for them to have a hindrance in some cases but it can also be really good for them to have a support network with other people that are going through the same things.	
Modification to Position or immobilisation (Patient) and Supporting & adjusting patients to maintain position (TR)				Shared comfort solution

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P11: They would ask. Are you comfortable or whatever and then move down a bit move up a bit. No very helpful they were doing their job.	R03: Oh no. I think that we've had it before where our patients can say I have this is the headrest and it is far too low. It's the sort of a slim line I'm trying, and we just put another six centimetres on. And as long as you notice I think we wouldn't accept anything drastic, but we would always be like oh yeah we'll put something else in and when they were scanned they haven't noticed it. We've given them something to hold. I think sometimes that you're sort of holding it.	Shared solutions between patients and Therapeutic
	Adjusting position before or during treatment course	P14: They took something out, so it wasn't so tight on the head pad.	R04: It is a carbon fibre it's not going to have give in it. So I ask a lot of patients do you have any back problems things like that to pre-empt issues. We have standard bits of kit. They can be adjusted however they are not entirely bespoke for the patient. So we try and make sure the patients get themselves into a position or we get them into a position that they can manage but it also is suitable for the radiotherapy.	 radiographers. There was a good balance of quotes highlighting an overlap of context and similarities of examples.
		P22: And they made sure that if I wasn't comfortable to help by repositioning me. I have I've lost some weight so I don't know if that had any effect.	R09: Obviously if on treatment the patient tells you it's not comfortable maybe it wouldn't be changed just because you wouldn't want to change your rotations too much. Obviously you have a bit of leeway with some patients where the treatment area is further away.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P24: No just initially when they set me up every day. But the devices were not specifically for people like me who don't conform. Initially it wasn't quite right but after some time and your getting through the actual radiotherapy treatment itself. And then after a while it takes very little adjustment to get me into position.	R13: 70 percent of patients usually at the start have problems and we have to make adjustments but then once they settle down I guess things improve but then it can start to go the other way when it's very long treatment.	
	Querratina		 R07: Yes, we ask ourselves can this patient get through it together with the patient. The more likely they are to cope and also determine if they are in any pain and if they can tolerate the experience. R08: Clearly this question is going to be is she able to cope. I remember I just called the superintendent and I also called Physics and said well is there any way these patients could be scanned and be treated with both arms down. 	
	Supporting patients to cope with holding position	No quotes for this subtheme	R10: Well the first thing that we do is question is the patient was actually capable of holding position. Okay so if they were unable to keep the arms above their heads and it was causing a lot of strain because then they would constantly stop over the course of the treatment.	TR only sub theme
			R19: I think we have occasional patients who are really distressed and uncomfortable. We're going to have to change that and that kind of patient might not be an effective position for them that means they cannot tolerate treatment and then we can have to make adjustments to their position and the immobilisation.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
	Accomodating preexisting health conditions	P12: As for comfort I was so pleased I had the flexi gel for my back. That stopped any pain that I knew that I was going to get.	R03: I think it is more of problematic if you've got those with comorbidities coming in that would induce more pain in other areas. We have done a lot of work really trying to improve all of our positioning so I know that we've considered that if it's a pelvic patient, we have thoughts about putting the mattress a little bit thinner abutting the remedial section just to aid a little bit more comfort light.	Shared solutions between patients and Therapeutic radiographers. There was a good balance of quotes
		P15: I wouldn't necessarily expect that but if that was added that would be a bonus wouldn't it. And I think if you have got a back problem something under this bit of your back, the small of your back might be good. Because you are putting your legs over that raised bit aren't you.	R04: I'll give a physical comfort example. That's a lot of patients who I see with late stage sort of changes in the upper spine they require more padding underneath the head and therefore if we can't achieve that with a standard block scoop wedge approach I might need to make a vac bag or if they have rheumatoid arthritis in their shoulders because they can't get their arms up to the right position I try to make something custom and that's physically comfortable."	highlighting an overlap of context and similarities of examples.

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P16: But a little cushion may have helped with that. I've also got spinal stenosis which is sore and jumping legs and all sorts of things so	R10: There is an ideal position but maybe the patient has a shoulder problem. I treated a patient that had suffered from polio in my childhood and then they were confined to a wheelchair. So we had to put all of that out and then move one of his arms. So there's all sorts of things involving not quite a lot of involvement in discussing this with my colleagues but my heart is kind of overcome those issues. They would usually be single treatment positioning immobilization and we are using them for this very fragile patients.	
		P25: Um maybe it would be an idea if you know that the patient has got something else so you can help them.	R15: We have also had patients before in the past who haven't been able to lie flat due to things like scoliosis problems with the spine and things like that and they actually ended up creating a device that the patient could have a leg up in the air completely so that he could like foster the treatment and he was able to manage that position really well and ended up managing.	
			R05: I've come across many situations with patients and trying to make them more comfortable and things give me a minute to think.	
	Time to think of solutions	No quotes for this subtheme	R06: We tend not to have to spend a lot of time with patients. It's about pulling out all the stops but you know it's not just position you know I mean the comfort. I've been getting it right and making sure they come for treatment. They're taking the time they're in treatment and not spending ages and fiddling around and we are just being quite precise in the room getting it done.	TR only sub theme

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R14: The limiting factor is that the time. Yes if you can spend a little bit more time at the treatment end. Getting it right to start with and if that helps the treatment go smoother. For one thing you're not wasting time on your machine. The smoother the treatment the more confidence the patient has in you. The more relaxed they are. And again the smoother the treating goes . It's like it's a win win.	
			R02: Open mask that would be less claustrophobic than a mask, I don't know anybody that actually does that, but you know what I mean it's like there's an alternative potentially out there I don't know. I mean you know in my career we've come a long way because we don't have to come up with plaster bandages to make them still, but we've come up with the mask and that's pretty horrendous for the patient.	
	Open face or modified masks	No quotes for this subtheme	R05: If you really can't endure the treatment for this length of time and it's not comfortable enough for you then we'll have to go through the whole process of making a new mask for you.	TR only sub theme
			R15: If we have had patients in the past where we've been able to cut parts out of the mask in order so they can see a bit better maybe given that a little bit of comfort means a little bit less anxious about the mask and claustrophobic and things like that. We've had patients in the past that have post-traumatic stress disorder from things that happened previously in their lives.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R18: I think there is a move to deliver frameless stereotactic surgery and I have treated again in a previous Trust a non-fixed frame SRS and also a frameless delivery so these patients would be in an open faced mask but because we needed to use patients surface intrafraction motion monitoring we used vision so yeah I mean the stability of the shell was very good there was like pitch issues which have been reported by the manufacturer but generally speaking we were delivering with sub millimetre accuracy.	
			R01: We do tell the patients that when they when they get on the bed. Advise them that if they want to stretch out their arms and just have a little stretch or wriggle that's okay.	
	Preparation to support maintaining position	No quotes for this subtheme	R10: It was just for patients to lie there for 10 minutes with arms up look quite simple and basic but it really useful. We give them instructions and provide exercises to show them what they need to do for a few days. Some of the patients who were on the back for up to an hour trying to get the position right.	TR only sub theme
			R19: Okay so exercises and then practice the breath hold as well suppose. And of course, in regard to audio I guess you can't play any music to them for obvious reasons. Patients that are doing a breath hold can have music.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		R12: I did discuss with you in that little room about making it more comfortable on your back, didn't I? It could be lined with something soft.	R01: So that's always been our aim from the very beginning to make the patient as comfortable as possible so we don't always use what would seem to be the most restrictive immobilization because it's not always all that comfortable.	
	Prioritising Patient Comfort with Soft Pads or Mattress (Patients) and Prioritising patient comfort with soft pads or mattress (Therapeutic radiographers)	P15: Maybe the arm thing could be a bit more cushioned.	R03: The protocol for the patients is that are set-up if they do a lot of pelvic or thorax or even the spine, they are always on either a comfortable mattress or a thick foam of about five centimetres.	Shared solutions between patients and Therapeutic
		P16: Well I suppose a small rectangular cushion of some sort maybe. It would be my lumbar spine.	R05: We try to make it as comfortable as we can for them. We had a patient, I think it was the way that she was immobilized. Actually, when she came downstairs for treatment, she was a lot flatter. She wasn't seated because being flatter for her treatment on that day. It was better for her than what she was positioned with.	radiographers. There was a good balance of quotes highlighting an overlap of context and
		P19: What about something on the bed that would softly clamp your head or something? I don't know. A bed that could move to adjust for comfort and positioning.	R11: But I'd like to say that sometimes we have patients that come with spine this is really deformed and they have to have lots and lots of pillows and things under that head.	similarities of examples.
		P11: "No, they were very helpful. Are you comfortable or whatever and then move down a bit move up a bit. No very helpful they were doing their job.		

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P19: Yeah. As I say the Therapeutic radiographers were very patient orientated and they kept saying are you comfortable with And if it wasn't comfortable they took it off and started again. Where you put your arms it's a bit hard, isn't it? I suppose it's got to be, hasn't it? Unless it's got to be hard for your arms, I guess it could be lined with something soft I suppose.		
			R13: Yes just sort of hold things of sentimental might be of the grandchild, a piece of jewellery or something like it."	
	Holding objects to maintain position	No quotes for this subtheme	R15: We have these small rings, kind of squishy and what we use them for particularly are for patients where are you treating stuff like that those elbows can get in the way or if they've got their hands on the chest. We used to use them for patients to hold under their chin so they kept their arms are up a bit more out of the way but we actually found the patients struggling with something maybe a bit anxious and fidgety if you ask them if they want something to hold on to give them one of those rings to hold on so that it really helps because it gives them something to kind of focus on something to squeeze something to hold. That has been useful in the past as well.	TR only sub theme
			R19: Also, we will ask what about holding something clasping something.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R20: we've done things where we can have a string they have a hold one end and their carer can hold the other end and you can pull the string just so you can feel that somebody is there.	
Supported coping				Shared comfort solution
	Audio-visual distraction	P01: They make you feel supported and tell everything that there going to do like. They say we are leaving the room now, then they'll tell me what stage. Through the microphone. I, am actually frightened to open my eyes. Cos if I open my eyes the laser might go.	R01: We also give the patients music to listen to if that's what they'd like to which is very sort of standard thing in radiotherapy treatments. Generally the lights are up in the room but if patients do feel that they'd like to go to sleep and they want to rest their eyes and the glare and lights we can tap we can turn them down. The other thing that we have in all of our treatment rooms is we've got a sort of a light tunnel a light installation exactly what you'd call it, a light box above the treatment couch.	Shared solutions between patients and Therapeutic radiographers. There was a
		P03: The music playing is a great help to me. If its something I really enjoy, once they had the greatest showman and I was singing along in my head and I was gone. The time went in no time at all. But the music is not always so good. In which case I try to think about nice things, holidays to come. Things like that.	R05: We always say we try and talk them through it. I apologise over the microphone and say, we're really sorry. We're almost there.	good balance of quotes highlighting an overlap of context and similarities of
		P04: Often there's music on and often it's the music I'll ask for which is great as well.	R06: So they're on the bed for like 40 minutes but we spend a lot of time talking to them coaching them through microphones.	examples.

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P07: There was music going which sometimes I almost blanked it out I think. If it was something I specifically liked I may keep an ear on it. But, I wasn't that bothered about the music.	R08: I don't think we always did anything about the lights. But obviously like I'm thinking now yeah holy shit. I think some people might like the lights down. It's like when you when you just assume the person would prefer the lights on and walk out and assume that.	
		P18: All I can say is look up at the sky for 90 seconds and then the machine moves. And then another two minutes to the machine moves over.	R17: So I will speak to them over the intercom as well to count down.	
			R18: We had movies that were of nature scenes or whatever. So that was quite nice for them. We had like a library of DVDs or we would give them information about their treatment.	
			R24: Yeah, in general we try out music on backgrounds, or silence.	
	Empathetic Support (Patients) and Empathetic approaches (Therapeutic radiographers)	P03: But I mean you know your not going to suffocate, and anytime you can of course wave and they will stop. So, the key thing really is the reassurance that your given by the radiotherapists because they know exactly what's happening, they know how you might react. I think they have been really good here. Explaining what's going on and, but I mean, you know your not going to suffocate, and anytime you can of course wave and they will stop. So, the key thing really is the reassurance that your given by the radiotherapists because they know exactly what's happening, they know how you might react. I think they have been really good here. Explaining what's going on and reassuring.	R03: We always have blankets because I've seen people on the machines who feel exposed and cold. Obviously the more nervous you must be warm enough. I think it doesn't mean you could be massaging but sometimes the hand holding I will always provide support. But we felt within our scope of practice if it means that we have an extra person in the room while we're setting up just talking to them and then we have while we're matching images or somebody is just chatting over the microphone.	Shared solutions between patients and Therapeutic radiographers. There was a good balance of quotes highlighting an overlap of context and similarities of examples.

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P05: Just their professionalism and their calmness. And their friendliness that's the bit that really struck me. Right from the word go that took all the worries from coming in and getting it done. And that's was it was nice to see them.	R05: Sometimes the patients from time to time want to us to hold their hand.	
		P17: They came to talk to me and held my hand, the mask felt very tight to start off with and obviously you are not used to such things.	R06: But yeah talking about a lot of the tactile things. We have a lot of things for children and sometimes we exclude the adults. Okay so we've got the comfort of the teddy bear with one patient in terms of touch and things like that. You have to have patience.	
			R07: I think using some of the stuff we use for paediatrics such as a string fed into the treatment room, if we think more about the environment that would really help.	
			R17: We also kind of have squeezy stars as well. If there's anything else that they want to hold off also.	
			R02: You know I think sometimes people think my God I can't do this because it is not absolutely perfect. Well you know sometimes some treatment is better than no treatment. You know that requires you to know a little bit about the person.	
			R06: So adapting individually, tailoring everything to with SABR or SRS 40 minutes more of a challenge for in terms of managing comfort and for the patients to try to keep that position.	
			R07: I think staff wellbeing as well as the place and time is important. Then you've got more time to communicate with the patient. Build a rapport. Obviously, we wish people would be the best that they can for patients.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R09: In terms of like with the patients just ask them. They're the ones who are lying there. They are the only ones who really know how it feels. Every single patient we see is an individual and just ask them more.	
		P01: Definitely a tea machine, even a little bit of music. Before we go in, liven it up a bit. Not like a disco. You would feel warmer. Its got a warmer feel in the main waiting area than in the radiotherapy waiting area.	R14: Well one of our treatment centres has got moved and it's basically got sofas and all sorts of decoration to relax patients including mood lights.	Shared
	Hospitality (Patients) and Hospitality & Aesthetics (Therapeutic radiographers)	P16: I think the atmosphere they create that they're smiley and welcoming, that's comforting isn't it. As I say they were welcoming and courteous and light-hearted I mean I didn't feel I was coming into some sort of death sentence or anything like that.	R15: I think it's something that maybe hasn't been considered as much as it should be. I think that's something we should consider more is the environment before a patient even gets into the treatment room. I mean like what it's like actually in the waiting area. I mean in terms of visually and audio I think it's something going on that's a bit more relaxing might be a bit difficult when you're in a hospital as a patient, but I think visually it's quite important. I suppose it's different from patient to patient. Again, what really matters taking that into account what patients think is important.	between patients and Therapeutic radiographers. There was a good balance of quotes highlighting an overlap of context and similarities of examples.
			R01: And we always get them to sit and have a cup of tea afterwards in the waiting room just to make sure they're feeling okay before they leave the building.	

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R12: Everyone's drinking coffee. I know even if you can get the Wi-Fi for all these things. People expect nowadays wherever they go. I don't know about you but they don't want magazines anymore on the tables, they're listening to and watching films in the waiting room they're escaping. Brilliant.	
	Pharmacological interventions		R02: I suppose head neck patients or anybody in a shell which is you know a whole different league in terms of comfort. Patients often talk about them digging into their neck and stuff, not everybody's neck is the same size and shape. People have daily Lorazepam to get through treatment in a shell."	
		No quotes for this subtheme	R03: "But I would say you do notice that these are the patients that might have slightly more prophylactics or pain relief we will have these prescriptions waiting just before they start, anticipating that they might be slightly more uncomfortable it might require some management.	TR only sub theme
			R04: We have Valium we had Diazepam. We make sure the patient can get through that for treatment because we had gotten more open treatment of the breast treatments and nothing's going too close to the face or head for treatment.	
			R12: Some of the sleep medications, we try that at the time but in my experience I think it's such a small dose to start with five milligram and then they got through.	_

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
			R02: It wouldn't have to be you know you don't want to do the complete works of Shakespeare, but they could be you know be mindful meditation or you know relaxation type or you know that kind of realistic alternative.	
	Referral to external services	No quotes for this subtheme	R03: Absolutely, you always offer complimentary therapies to sort of try and go alongside. They always offer things like that. I really wish there was some way we could have a psychiatrist on hand because I think that it's a major problem.	TR only sub theme
			R07: We try to take their feelings on board and acknowledge spirituality and faith. I believe in Psycho policy and referring when needed.	
			R13: We used a play specialist therapy could be considered a kind of therapy. But not so much for the adults.	
	Self-initiated Coping (Patients) and Percieved Coping Techniques (Therapeutic radiographers)	P06: But the last few weeks I've had a touch of sciatica in my back so some days has been more uncomfortable than others. It's a lot better than it has been. As I say its for your own good so if you can put up with some discomfort for 15 minutes. I just don't complain, I just let them get on with it, if that's how they want me then that's how they get me and I won't complain. I am not a complaining type although many would. On this occasion they know their jobs and its got to be done.	R01: Some people do just want to drift off and go to sleep.	Shared solutions between patients and Therapeutic radiographers. There was a good balance of quotes highlighting an overlap of context and

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
		P14: Well that was the first time I panicked was day one but after that I was fine. So you get used to it and yes I thought to myself you can do this, man up.	R05: If you really can't endure the treatment for this length of time and it's not comfortable enough for you then we'll have to go through the whole process of making a new mask for you. And sometimes when they realize that they're just like okay I'll just go I'll just get on with it then.	similarities of examples.
		P21: No, but it was okay I coped with it. It wasn't that bad. It was a little struggle, but I got used it to it over time and let everyone do their work.	R23: They know it's not that comfortable but actually they're aware of it. They know how long it's going to be. And I think if you knew why something is happening why you've got to do it then that is okay.	
		P22: Well it was a little intimidating but you had to survive and radiotherapy was the way to do that.		
		P01:Oh my mind just goes off onto what I'm having for dinner although my mind does wander, I don't just sit there and think at machine. If I did that I would have the treatment.	R02: But yes, people are stressed and anxious. And you have evidence to suggest that you know mind over matter.	Shared
		P06: That's it, I just stare directly ahead and focus on one thing. And just let people get on with what they've got to do, I literally just zone myself out of it.	R05: I had a few experiences recently with patients who've been extremely anxious and wanted to know the Monitor units how many they've had so far out of their total. Counting it down you know you've had to monitor 21 units and so forth because they find that reassuring.	solutions between patients and Therapeutic radiographers. There was a good balance
	Self-initiated distraction techniques	P15: Yes it is nice that there is the count down and I know I can do it now but it was only the first two or three times I thought I hope it is going to be easier. It did reassure me if I couldn't do it if I had to stop that would be alright, they would be aware of that. They were very helpful."	R07: Others that take themselves to somewhere in their minds, but that's on an individual patient basis.	of quotes highlighting an overlap of context and similarities of examples.
	(Patients) and Percieved Self- initiated	P16: I suppose I just listened to the counting.	R11: The patients sometimes use stress balls. We had the patient bringing in their own stuff. And then we had these extra. Which patients could just squeeze.	p

Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
	distraction techniques	P18: I listened to the machine; I listened to the noises that were going on so I knew what's happening. Okay so I don't really know what's happening to me yet I have a bit of a sense of its working.		
		P03: Yes, I called it 'zenning' out. What I tend to do is take a deep breath, then the mask goes on and I kind of take my mind elsewhere really. I take my mind to my happy place. Or think about something nice or just concentrate on the lyrics if it's a really good song. But apart from that no.	R04: Patients have tokens with themselves. So lucky heather or whatever they have on themselves you know whatever they want to bring in to make sure they have tokens to remind themselves of what's happening. They can have that on them if they want to make themselves feel a bit more grounded. I think they want this kind of thing. I think that it becomes a kind of spiritual thing. You know I've had one lady who brought in her grandson's toy to make sure because the grandson said this will keep you safe now. And so, it was my understanding is that Shes' having radiotherapy and she bought that into the room to make sure she's got something to remind her of the family and what's happening.	Shared solutions between patients and Therapeutic radiographers. There was a good balance
		P12: Because of my Christian faith there were sometimes when I was praying and most of the time I shut myself off.	R08: Obviously, it's like if you see the patient struggling even if they want to bring in quite a lot of religious people back home would actually bring some images. So that's quite traditional back in Portugal and a cross somewhere on the chest or around the neck. We would have to say sometimes, actually we will have to take that necklace off and you could see that especially back home like there's a lot about these religiously come from Portugal and I especially liked them a bit more like old ladies they would get like super upset and to offer them to hold it was a good compromise.	of quotes highlighting an overlap of context and similarities of examples.
Themes	Subthemes	Examples of patient quotes	Examples of TR quotes	Shared solutions
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		P15: I do but I am a Christian. So I pray so I think my first, before my first session one they asked me to breath in for twenty seconds that felt like an awfully long time and I don't know whether I can do that so I built up a slight panic about that now I think I can go on a lot longer. So the first few times I could feel that panic rising and then of course it is much worse isn't it, so I just concentrate on a verse or a prayer.	R09: I mean it was just one example, it could be something from almost like maybe a religious background we would promote like we will promote a Roman Catholic you can bring your rosary beads or you know often we send our patients our Muslim patients would want the Koran play back to them to get I'm not sure if this really fits into comfort but having female staff if they really need.	
			R13: People often have their music on if they want to get more people would bring in meditation beads.	

Appendix K: Supplementary Material 1 – Triangulation of the systematic literature review and qualitative interviews

	_		7	
Qualitative subthemes from		Systematic review identified		
interviews - comfort solutions	\approx	comfort interventions	Convergence	Convergence of Qualitative
Goldsworthy et al 2022 ^{x1}		catagories		Interviews ^{x1} & systematic
		Goldsworthy et al 2020 ^{x2}]	review ^{x2}
			Complete convergence	
		_	of subtheme with SLR	The findings of systematic
Audio-visual coping &		Audio-visual interventions:	intervention catagories -	literature review and interviews
distraction	$\langle \cdot \rangle$		direct agreement. However this subtheme	with patients and radiographers
	\sim		and category would also	were explored with respect to the
	$-\lambda$	Audio	fit within the scope of	meaning and interpretation of
	\sim	Audio	psycological	subthemes against the
	/	Visual Audia viewal	interventions - move	intervention catagories of the
		Audio-visual Virtual reality	for clinical synthesis	systematic literature review. Then
				the Convergence Coding Scheme
Empathetic support $lacksquare$		Psychological interventions:		was applied.
Referral to external services	1	Breathing technique		
Self-initiated acceptance &	/		of subtheme with SLR	
coping	/	Cognitive behavioural therapy	intervention catagories -	
Self-initiated distraction		Distraction	Many subthemes that	
techniques	/ //	Distraction	are complementary to	
Self-initiated Spirituality 🛛 🖌	///	Empathic attention	SR intervention	
	/ ///	Hypnosis	catagories	
/				
Assessments of compliance	///	Physical interventions:		Convergence coding scheme
prior to radiotherapy				1. <u>Convergence:</u> where findings
Accommodating pre existing		Massage		directly agree. Subthemes and
health conditions		-		catagories are similar in context.
Coaching session	/////	Therapeutic touch	Complementarity	2. Complementarity: findings offer
Individually tallored care 🧹	////	Reflexology	of subtheme with SLR	complimentary information on the
Adjusting position before		Distraction	intervention catagories -	same issue
or during treatment course	/////		Many subthemes that	3. Dissonance: findings appear to
Individualised positioning			are complementary to	contradict one another.
Mask modifications			SR intervention	4. <u>Silence</u> : themes arising from
Preparation to support			catagories	one component study but not
maintaining position				others
Pre-radiotherapy preparation				
Prioritising patient comfort • Tactile touch or other support				
to maintain position				
to maintain position			Complementarity	
			of subtheme with SLR	
			intervention catagories -	
			Many subthemes that	
Information &			are complementary to	
communication provision	1	Other interventions:	SR intervention	
Personable communication	_//	Education/information	catagories.	
Preparational information			Aromtherapy fits in	X1: Goldsworthy S, Palmer S,
provision	/	Aromatherapy	scope of psycological	Latour JM, McNair H, Cramp M.
Tailored verbal & written	/		interventions - move	Patient and Radiation Therapist
information			Complete convergence	exploration of solutions to
-		•	of subtheme with all	improve comfort during
•		•	SLR intervention	radiotherapy: a qualitative study.
		-	catagories - direct	Journal of Medical Imaging and
Expertise of RTTs		All of the above catagories	agreement; all	Radiation Sciences. 2023
•		-•	catagories required	Dec;54(4):603-610X2:
			expertise of a health	
			professional	
Removed			Silence between	X2: Goldsworthy S, Palmer S,
Pharmacology 🗱			subthemes and and SR	Latour JM, McNair H, Cramp M. A
Environmental aesthetics			components - mainly	systematic review of effectiveness
Hospitality 🗱			because pharmcology	of interventions applicable to
			excluded from SR	radiotherapy that are
			search and others can	administered to improve patient
			not be developed into	comfort, increase patient
			an intervention suitable	compliance, and reduce patient
			for treatment delivery.	distress or anxiety. Radiography.
			These interventions are	2020;26(4):314–24
			useful and should be	
			considerd for service	
				L

Appendix L: Supplementary Material 2 – Generation of comfort intervention components

information

	Sustamatic review identified	CLINICAL SYNTHESIS	
Qualitative subthemes from interviews - comfort solutions Goldsworthy et al 2023 ^{x1} \approx	Systematic review identified comfort interventions categories Goldsworthy et al 2020 ^{x2}	= Intervention component list for Nominal group technique consensus study	Clinical synthesis process The principle of clinical synthesis was to create a list of comfort intervention components with real world
Empathetic support Referral to external services Self-initiated acceptance & coping Self-initiated distraction techniques Self-initiated Spirituality Audio-visual coping & distraction	Psychological interventions: Breathing technique Cognitive behavioural therapy Distraction Empathic attention Hypnosis Aromatherapy Audio Visual Audio-visual Virtual reality	 Patient advice/training in meditation including talking to self, faith readings, chants, counting down or visualising going on holiday focusing on machine lights/lasers or noise Referral to talking therapies (e.g., counselling, hypnosis, or cognitive behavioural therapy) by radiographers at patient request Compassionate & empathetic communication training for radiographers Aromatherapy provided at patient request Sound & music interventions such as nature sounds, music audio books, relaxation, instructions, and updates during treatment delivered at patient request Visual interventions such pictures or projections of nature or similar on walls or screens delivered at patient request 	 meaning. The following 5 steps were followed: 1) After Convergence, data from study the systematic review and interviews were explored for potential intervention by reading through and cross checking. 2) Then it was determined whether comfort solutions and intervention categories could be synthesised by either expanding or condensing the meaning. 3) An intervention component list was written in simple form without details for delivery.
Assessments of compliance prior to radiotherapy Accommodating pre existing health conditions Coaching session Individually tailored care Adjusting position before or during treatment course Individualised positioning Mask modifications Preparation to support maintaining position Pre-radiotherapy preparatione Prioritising patient comfort Tactile touch or other support to maintain position	Physical interventions: Massage Therapeutic touch Reflexology Distraction	 Stretching and exercises coaching before and after positioning for radiotherapy treatment Patient practice run of treatment position with radiographer Workshop by radiographers on what to expect e.g., position, mask, bladder/bowel preparation Adjustments & supports provided for arms or legs during treatment by radiographers Soft pads/ mattress under the body to alleviate body discomfort managed by radiographers Customized immobilization provided by radiographers e.g., head moulds, vacuum bags, or mask modifications Human touch in person (hand holding) or having something to remind them of human contact (e.g., holding a soft item like a blanket) provided at patient request 	 4) The intervention component list was reviewed by research team and patient research partners. 5) After editing the final list was approved. X1: Goldsworthy S, Palmer S, Latour JM, McNair H, Cramp M. Patient and Radiation Therapist exploration of solutions to improve comfort during radiotherapy: a qualitative study. Journal of Medical Imaging and Radiation Sciences. 2023 Dec;54(4):603-610X2: X2: Goldsworthy S, Palmer S, Latour JM, McNair H, Cramp M. A systematic review of effectiveness of interventions applicable to radiotherapy that are
Information & communication provision Personable communication Preparational information provision Tailored verbal & written information	• Other interventions: • Education/ information	 Tailored information e.g., radiographers provide the required information only as part of preparation for treatment Tour of radiotherapy in person or video provided at patient request 	administered to improve patient comfort, increase patient compliance, and reduce patient distress or anxiety. Radiography. 2020;26(4):314–24 274

Appendix M: South West – Frenchay Research Ethics Committee

This appendix has been removed as it contains personal information

Appendix N: Supplementary Material 3 – Schedule for the nominal group

technique consensus meeting

Time	Activity
09:00–09:15	Registration & welcome brief
	Presentation of comfort intervention
09:15–09:30	components
09:30–10:00	Group discussion phase
10:00–10:30	Participant choice setting phase
10:30–10:50	Tea Break (20 minutes)
10:50–11:35	Participant prioritisation setting phase
11:35–12:00	Tea Break (25 minutes)
	Feasibility of delivering the radiotherapy
12:00–12:45	comfort intervention package
12:45–13:00	Close and final remarks

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Adjustments & supports provided for arms or legs during treatment by Therapeutic radiographers	Comfortable adjustments could be made prior the initial planning CT scan or on treatment where permissible due to the restriction of the environment. A slight adjustment outside of the treatment area may be permitted on treatment if it does not change position.	Adjustment consideration & risk Assessment of position for individualisation	P3: "Very feasible, especially for patients in un-natural positions or experiencing pain and discomfort from prolonged treatment." P7: "Point concerning movement was really important. Not just about exercising, but straight up assessing our movement beforehand if required. Making the whole procedure more tailored and more comfortable."	R1: "And for example, the mattress. Yes, we want to make someone comfortable on the couch, but how far do we go?" R1: "The point concerning arm movement was really important - not just about exercising but straight up assessing arm movement beforehand if required - making the whole procedure tailored and more comfortable."

Appendix O: Supplementary Material 4 – Directed content analysis of prioritised intervention components

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Aromatherapy provided at patient request	Aromatherapy using essential oils with a tab on clothing, or an infuser can relax and comfort patients by alleviating anxiety and stress	Smells are person dependent and can be like 'marmite' Smells can linger	P4: "Smells can be like marmite, maybe not everyone will like the sent".P6: "Smells or aromas will linger which may have made me feel sick."	R1: "I thought aromatherapy was a nice option as some people find smells more comfortable than visual/audio. Aromatherapy I think is very person dependent? As X said some smells may not be great for other people"
Compassionate & empathetic communication training for Therapeutic radiographers	Compassion is a powerful aspect of the human experience and is one that can be trained. Compassion can be cultivated with training and that greater altruistic behaviour may emerge from an increased understanding of the suffering of	Natural compassion from staff appreciated Don't over medicalise Education in compassion & empathy	P1: "Personal interaction ++++. You can't beat personal interaction." P2: "Don't over medicalized that bit of informality that bit of humanity, that bit of real right what I was finding cause I live alone." P3: "Although I never personally	 R2: "I think any advanced communication skills (and/or clinical supervision) should be as available to Therapeutic radiographers as it is to nurses - as a profession we sometimes get overlooked as there is a lack of general understanding of the nature of what we do and how much we support our patients during treatment - we are not operators!" R3: "Compassion and empathy – should be in UG training." R1: "I do think it would be nice to have a balance of having some package that we can practically implemented to the support of the supervise of the source of th

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
	other people. Compassion training focuses		experienced anything other than amazing treatment from	because many others have fed back that they would like human touch."
	not only on suffering but also on supporting and encouraging compassion for the good of the self and others.	Choosing from a 'toolbox' of interventions	fantastic individuals, compassion and empathy are essential when handling patients who are experiencing some of the worst lows in their lives."	R2: "I mean, personally I feel like as many of these left on the list as possible. It's good because then you can just select from them. Depending on the patients needs
			P2: "Upon request is vital."	

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Customized immobilization provided by Therapeutic radiographers e.g., head moulds, vacuum bags, or mask modifications	Immobilisation maybe customised: thermoplastic masks may be modified (sections over eyes cut out), patient specific vacuum bags or head pads could be modified for patient comfort.	Availability of customisation devices Customisation to aid overall position	P3: "On both occasions when I have required radiotherapy treatment a custom mask was supplied to immobilise the head. If this were expanded to include patients requiring help to remain in a position, then it is a very good idea."	R1: "Providing the centres has customisable immobilisation available." R2: "Modifying the patient positioning to make it reasonably comfortable and stable (as far as is possible) should surely be standard practice."
Human touch in person (hand holding) or having something to remind them of human contact (e.g. holding a soft item like a blanket) provided at patient request	Care conveyed through human empathetic touch promotes comfort, individual attention, and presence. The unique characteristic of empathetic touch is that it provides both psychological and physical	Human touch is essential Holding something may help Holding something during treatment is not feasible	 P2; "I'm just surprised that the human touch didn't make it through, given how technological and how clinical the whole system is and has to be." P3:"Possibly feasible to hold a soft item, etc. should treatment allow but human 	R2: "And things that people can hold to remind them. For obvious reasons handholding during treatment is impossible, but if someone wanted to hold an object of comfort I don't see why not."

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
	comfort at the same time.		contact during treatment unfeasible."	
Patient advice/training in meditation including talking to self, faith readings, chants, counting down or visualising going on holiday focusing on machine lights/lasers or noise	Patients may find specific meditation delivered by a therapist or simply talking to self, focusing on something or counting down useful to get through radiotherapy treatment as a way of coping and dealing with discomfort.	Specialist training required Not everyone can meditate Do It Yourself	P1: "A bit niche and would require specialised training." P2: "Uncertain about thisnot everyone goes on holiday?!" P4: "And I think me and then you just find you just think. Well, it's I'm here now. It's not going to be too long and you find your own way through it, really."	 R1: "In terms of how much they could, maybe you know chant or you know, we certainly put the Koran on a lot and how much they can say that out loud given you know where their treatment area is located. Can they do that? Can they do it in their mind or is it actually they can verbalize it out loud? So I'm actually a bit sad to see that one go because maybe it comes under the audio a little bit." R2: "I don't think that I am able. It's not in my skill set to train people in meditation or chanting." R3: "Techniques like I say, I don't feel able to actually train people to meditate."

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Patient practice run of treatment position with TR	A run through of position, breath gating, or even to practice accessory devices such as rectal obturators may alleviate anxiety prior to treatment, improving comfort.	Time & resources for practice run through of position	P1: "This could happen during the planning appointment if not already achieved." P2: "Seems almost a prerequisite." P4: "I think this is very important."	R1: "I think it would be really difficult in a lot of radiotherapy departments to do this as we don't have the rooms to do so. I think it would be great for some patients, but unfortunately not feasible?" R3:"Time implications and machine availability implications."
Referral to talking	Referral to talking therapies may help patients to accept and cope with any	Some would benefit from talking therapies or coping strategies	P2: "Could be an extremely useful tool for worried patients. I personally was extremely	R2: "I mean, it's not by no means going to be necessary for all patients, but this does say at patients request, and certainly we would always want to be able to offer that to people if they asked for it."
therapies (e.g. counselling, hypnosis, or cognitive behavioural	discomfort in receiving radiotherapy.	Surprised that Talking therapies were excluded	anxious during treatment and would have benefitted from	R2: "Yeah, I mean I'm a bit surprised about the referral to talking therapies as well?"
therapy) by Therapeutic radiographers at patient request	Whether its about having someone listen to emotional issues, or hypnotherapy may	Should be standard of care already	being taught coping strategies or methods with which to calm myself down. Also wouldn't add to TR	R1: "That is a really relevant point that some of the interventions may be better at different times in the radiotherapy pathway and in order to practically apply these interventions it could be useful to think about this."
	help patients relax, cope with	Elsewhere in the patient pathway	workload being a referral process."	R2: "Modifying the patient positioning to make it

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
	treatment and also ameliorate pain, and cognitive behavioural therapy to change the way patients think and behave.		P3: "Meditation and talking therapies, I feel have a role in the wider scope as a way of managing your emotions and feelings when you have been affected by cancer." P6: "I do yoga and found this sort of exercise invaluable as a prep for the treatment. xx who is running your Prehab programme at the xx is providing guidance on this". Do this anyway and should be standard practice."	reasonably comfortable and stable (as far as is possible) should surely be standard practice."

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Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Soft pads/ mattress under the body to alleviate body discomfort managed by Therapeutic radiographers	Soft pads or mattresses can be made prior the initial planning CT scan or on treatment for discomfort caused by e.g. co- morbidities where permissible due to the restriction of the environment. A soft pad outside of the treatment area may be permitted if it does not change position, or if needed up front radiotherapy.	Caution to using soft pads due to reproducibility Soft wedges & mattresses to assist position of limbs	P4: "All I said really, is that so long as you get the original position in right, and if you could add a perhaps some of these soft pads elsewhere." P5: "Wedges and foam blocks were used when I received treatment, but I know my father suffered when having to raise his hands above his head during treatment for cancer to his rib cage."	R1: Providing a balance is struck - i.e., a mattress which is too soft and thick may cause the patient to move more? R2: "Large proportion of treatments are VWAT and therefore the impact of a 1cm foam mattress on skin dose is minimal - we use this as standard for SABR treatments with no reduction in reproducibility and patients are more stable if comfortable."
Sound & music interventions such as nature sounds, music audio books, relaxation, instructions, and updates during	Sounds or music, such as nature sounds, music, relaxation (sound/music/ther apy), audio books,	Choice and selection	P1: "I was given the opportunity to have music playing. Easy enough to provide or have patient bring their own iPod/mobile	R2: " Should always be tailored to patient's wishes where possible - some patients find communication ove the intercom reassuring whilst others prefer the distraction of music etc."

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
treatment delivered at patient request	machine sound or instructions may help to distract patients to get through the procedure more comfortably.	Distraction & coping	phone. (Maternity have floor standing Bluetooth speakers in labour rooms.)" P5:"Sound & music interventions such as nature sounds, music audio books, relaxation, instructions, and updates during treatment delivered at patient request. Broad agreement with this as a coping strategy."	R3: "Uhm, a distraction with music or sounds are beneficial."
Stretching and exercises coaching before and after positioning for radiotherapy treatment	Stretching, exercise or coaching prior to radiotherapy may increase flexibility, reduce muscle cramp/spasms helping patients hold position more comfortably.	TR Time & training Self-direction (video) in stretching to save time Specific anatomical stretches	P5: "This could be covered fairy easily face to face and save time with video."P3: "I think it's a great idea, particularly for patients receiving treatment to the torso region".	R1: "Staff time is required to specifically discuss this. Training required for staff, so they are up to date with most recent research/ practice in exercise e.g., pelvic floor exercises."

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Tailored information e.g., Therapeutic radiographers provide the required information only as part of preparation for treatment	Providing patients with information that's tailored to them, in the right format, right amount, that's easy for them to digest will alleviate the feeling of being overwhelmed improving comfort.	Time for Therapeutic radiographers to tailor information Do not overload patients Provide information when required during radiotherapy (not all at #1)	P6: "Perhaps just some documents signposting where such guidance can be found. Training issues for Therapeutic radiographers." P4:"It might be a good idea to have maybe have six or eight sessions, and then for someone just to say, right? You know we've been through some of it. Is there anything you're puzzled about? Or is there anything we can make clear and for you it etc? cause it's quite hard to take everything in my in one go."	R1: "But time for Therapeutic radiographers to do this is required." R2: "I think we instinctively tailor the verbal information we give already, although I think sometimes patients are swamped by all the written information they receive."

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Tour of radiotherapy in person or video provided at patient request	A tour of radiotherapy can be delivered in person out of hours, virtually or by video recording to alleviate pre- conceived anxieties about radiotherapy.	Online or video tour or information is time efficient	P3: "I would consider this a quick win, easy to implement and execute and not overly taxing on existing resources once it becomes part of the treatment pathway."	R3: "Video definitely could be done. Difficult to do in the working day in a busy department and staff may not want to do it after their working day."
Visible or audio countdown clock of treatment length	A countdown verbally over intercom or visually on a screen may help patients to manage their own isolation and how long they must hold their position.	Challenging logistics of having a countdown clock at treatment delivery	P1: "I understand the complexities of having a countdown but giving some indication of start/middle/end of treatment would be great, especially during the first few sessions."	R3" Our treatment delivery times change each day so a countdown will be challenging. We can tell patients wher halfway through."
Visual interventions such pictures or projections of nature or	Visual interventions such as pictures,	Cost implication of visual interventions	P6: "Feasible but not sure if practical. Maybe good if therapy	R2: "Cost implication - maybe need to make it a standard when new Linac installed."
similar on walls or	ceiling light boxes,	Simple & calming	duration extends past	R3: "Training in meditation is outside our remit, but

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
screens delivered at patient request	usual lighting or other may help to distract patients to a more comfortable state.	visualisation possible	the current time." P7: "Calming images or videos would have allowed me to put myself elsewhere."	advice to try simple visualisation techniques/ counting etc is reasonable."
Workshop by THERAPEUTIC	Verbal explanation using visual aids describing what to expect, including self-care, will support patients understanding and	Choice & format of workshops important	P2:"Upon request."	R1: "I undertook them in person which was lovely but required a room, I think these could be online too."
RADIOGRAPHERS on what to expect e.g., position, mask, bladder/bowel preparation	the importance of what they have been asked to do. This will support them to comfortably comply with	Efficiency of workshops	P1: "Good idea but would need separate room/area to do this. Also requires extra appointment and staff."	R2: "There are some resource implications but if patients are grouped together this is feasible."R3: "What is quite big cause of discomfort can be having to maintain a full bladder throughout the whole course of treatment and it's a bit difficult to see what the intervention was and if we knew how he could help
	expectations during their radiotherapy treatment.	Specificity of workshops		people with this."

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
Resource considerations Overarching category applicable to all intervention components	There are many logistical and resource considerations when introducing new interventions to radiotherapy. These may include having the right staff, staff time, service time, the cost and whether the interventions is compatible to radiation.	Do we actually need an intervention Financial considerations Logistics, equipment, training & access Online or video Time efficiency Radiation environment considerations	 P3: "Feasible as a very good idea and would be fantastic in a perfect world but I recognise this could be unworkable or severely restricted by departmental budgets, staffing levels, workloads and space." P6: "Quite often there's a difference between what's nice and what's needed." P1: "Good idea over and above what is already used. Financial input and staff training needed." P6: "Probably not in person. Hygiene issues + time but a 	R2:"Cost implication - maybe need to make it a standard when new Linac installed." R1: "Uhm, this it's the one on" the patient advice and training in meditation. It's not quite. I agree that I wouldn't feel comfortable to give the training in it." R1: "We also found we could give information on exercises etc. in these workshops. I undertook them in person which was lovely- but required a room, I think these could be online too." R3: "Time implications and machine availability implications."

Intervention component	Descriptor	Categories for feasible implementation	Patient narratives	Therapeutic radiographer narratives
			video would be useful."	
			P4: "I think this may be difficult to carry through due to time restraints of treatment."	