Patient experiences of the radiotherapy process and treatment

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To the men in my life

Christoffer, Max and Emil

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Abstract

Background

Most cancer patients undergo external radiotherapy (RT) at some stage during their treatment trajectory. RT is often associated with unfamiliar procedures where the technical environment, side effects and interaction with staff seem to play a major role in the patient's treatment experience. These experiences could sometimes lead to disruption of the treatment which may have negative consequences for the outcome. The overall aim of this thesis was to gain further knowledge about how patients experience RT and the related processes. Such knowledge is of vital importance when developing and improving care within a high-tech RT environment.

Aim

The overall aim of this thesis was to gain further knowledge about how patients experience RT and the related processes. Such knowledge is of vital importance when developing and improving care within a high-tech RT environment.

Methods

To gain further knowledge and understanding about patients experience of RT both quantitative (I, II, III) and qualitative (III, IV) methodology were used. The data in the thesis focused on patients undergoing external RT at different RT units in Sweden. Study I and II, focused on two regions, the northern region of Sweden and the region of Stockholm and Gotland. Study III and IV were performed at eight different RT units in Sweden.

Results

In Study I, two types of topical agents (Calendula Weleda cream vs. Essex cream) were compared regarding reducing the risk of severe acute radiation skin reactions (ARSR). No difference in severe ARSR was found between the groups and the patients reported low levels of ARSR. In Study II, the influence of an RT unit's psychosocial climate and treatment environment on cancer patients' anxiety during external RT was evaluated. Data was collected (questionnaire) from 892 patients. The results showed that both the treatment environment and the psychosocial climate of the RT unit significantly impacted cancer patient anxiety levels. In Study III & IV, a questionnaire to measure the patient´s experience during external RT was developed and tested. The results showed that the RT Experience Questionnaire (RTEQ), with 23 items, was a tentatively valid and reliable instrument to measure how patients

experience the RT process and the environment in the treatment room. In Study IV, written comments from the open-ended question “Is there anything else you want us to know?” in the preliminary RTEQ was analysed with qualitative content analysis. This data was abstracted into the following four major categories reflecting the experience of the RT process: Experiences in the high tech RT environment; Understanding the RT procedures and side effects; Dealing with daily life during RT and The nurses’ role and performance.

Conclusion

The RT environment and the RT related processes seem to impact cancer patients, both physically and psychologically. A person-centered care approach, as well as attention to the design, both of the treatment process and the physical environment could significantly improve the patient experience and patient involvement. The results also highlight the importance of taking patient experiences into account when introducing new RT methods and techniques.

Keywords

Cancer, radiotherapy, radiation skin reactions, patient experience, treatment environment, anxiety, person-centred care, questionnaire.

List of Abbriviations

ARSR	Acute radiation skin reactions
BMI	Body mass index
CT	Computed tomography
EBCD	Experience- based co-design
H&N	Head and neck
HRQoL	Health related quality of life
MOS-sleep	Medical Outcomes Study Sleep measure
PCA	Principal Component Analysis
PCC	Person-centred care
PCQ	Person-centered Climate Questionnaire
PRO	Patient reported outcomes
QLQ-C30	Quality of Life Questionnaire Core-30
RCT	Randomised controlled trial
RT	Radiotherapy
RTEQ	The Radiotherapy Experience Questionnaire
RTOG/EORTC	Radiation Therapy Oncology Group/The Organization for Research and Treatment of Cancer Acute Radiation Morbidity Scoring Criteria
STAI	The State Trait Anxiety Inventory
STAI-S	The State Trait Anxiety Inventory - State
STAI-T	The State Trait Anxiety Inventory - Trait
VAS	Visual analogue scale

List of publications

I. Lena Sharp, Kristina Finnilä, Hemming Johansson, Marie Abrahamsson, Thomas Hatschek, Mia Bergenmar.
No differences between Calendula cream and aqueous cream in the prevention of acute radiation skin reactions – Results from a randomised blinded trial.
European Journal of Oncology Nursing. 2013;17:429-435

II. Tara Mullaney, Kristina Olausson, Lena Sharp, Björn Zackrisson, David Edvardsson, Tufve Nyholm.
The influence of a department's psychosocial climate and treatment environment on cancer patients' anxiety during radiotherapy.
European Journal of Oncology Nursing. 2016;20:113-118

III. Kristina Olausson, Annette Holst Hansson, Björn Zackrisson, David Edvardsson, Ulrika Östlund, Tufve Nyholm.
Development and psychometric testing of an instrument to measure the patient's experience of external radiotherapy: The Radiotherapy Experience Questionnaire (RTEQ).
Submitted

IV. Kristina Olausson, Lena Sharp, Per Fransson, Tufve Nyholm, Björn Zackrisson, Ulrika Östlund.
What matters to you? – Free-text comments in a questionnaire from patients undergoing radiotherapy.
Manuscript

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Introduction

External Radiotherapy

Radiotherapy (RT) is one of the main treatment modalities for patients with cancer, and about 50% of all cancer patients receive external RT [1]. RT can be used alone or in combination with other treatment modalities such as chemotherapy, surgery and hormonal therapy. It is estimated that 40% of cancer patients are cured by RT alone or combined with other treatment modalities [2,3]. External beam RT is the most common technique to deliver a high dose of ionizing radiation to cancerous tissue and its success in eradicating tumors depends mainly on the total radiation dose [4]. For treatments with a curative intent RT is usually delivered in fractions with one fraction a day, five days a week, during five to seven weeks. In palliative situations, the treatment is often given in a smaller number of daily fractions (one to fifteen).

Acute side effects

RT is associated with a number of acute side effects with onset a few weeks after start of RT. The acute side effects are generally reversible and heal within the first 3-6 months after RT. Late side effects usually become evident several months after radiotherapy. They are usually irreversible. The side effects are related to the fact that normal tissue is included in the irradiated volume. The tolerance of normal tissues to RT sets the dose limit [4]. The acute side effects arise in tissues with a high cell turnover rate, for example skin, bone marrow and gastrointestinal mucosa. They normally appear after about two weeks of RT and continue to increase during a couple of weeks and typically start to resolve a few weeks after RT [5].

Acute radiation skin reactions

Acute radiation skin reaction (ARSR) is one of the most common side effects, in different degrees affecting up to 95% of the patients who receive RT [6-8]. ARSR are often characterised by erythema, swelling, dry and moist desquamation and sometimes ulceration of the skin. The patient discomfort ranges from mild irritation to severe pain [5]. Some patients experience the more severe reactions such as dry and/or moist desquamation, while most patients experience only mild reactions, e.g. different degrees of erythema and irritation [9]. The radiation dose, volume, RT technique and previous treatment, such as surgery and chemotherapy, are factors that impact the risk for ARSR. Also patient-related factors such as a high body mass index (BMI), smoking and previous skin damage are shown to be risk factors [9-11]. Management

of ARSR is essential given its high incidence and considerably negative impact on quality of life [12]. Severe ARSR may even require interruptions or postponed treatment [13]. A range of various topical agents, including plant extracts, topical sucralfate and corticosteroids, have been studied [11, 14-19] as well as dressings [20-22] to prevent and manage ARSR. Despite the high number of trials in this area, there is limited high-quality, comparative research that provides definitive results suggesting the beneficial effect from any single intervention against ARSR [23]. Therefore local guidelines on management of ARSR often are conflicting.

Nursing care in the RT setting

In Sweden, in contrast to many other countries, registered nurses with one-year post graduate specific oncology and RT plan (RT nurses), coordinate and also deliver RT to cancer patients. In many other countries RT technicians or radiographers perform these tasks. RT nurses work closely with other health care professions, where they provide specialist clinical nursing care, education, information and counselling [24, 25].

The patient and the RT process

Receiving a potentially life-threatening cancer diagnosis usually creates a feeling of fear and psychological distress for most patients and their families [26]. The majority of patients have already begun their cancer journey before being referred for RT and have commenced other treatments such as surgery and/or chemotherapy. Consequently, at the time for RT, they may already experience stressful emotions as a consequence of previous information, experience and personal perception [27]. They therefore already may be facing difficult challenges in maintaining quality of life, managing side effects, and feeling comfortable with their decisions regarding treatment and care [24, 28].

Planning the treatment

The first contact a patient has with the RT unit is usually a visit to start the treatment preparation. In order to deliver a precise dose to a well-defined target area, while at the same time keeping the side effects to a minimum, detailed dose-planning and reproducibility are required. The treatment is delivered over several sessions, and it is crucial to reposition the patient in the correct position at every treatment, to ensure high precision to the targeted volume [29, 30]. Precision is achieved by minimizing uncertainties in the treatment chain, starting from the definition of the target volume, patient immobilization and

reproducibility, and highly conformal treatment techniques and modalities. Therefore, different devices that restrain patient movements are often used. The immobilization devices used may be specially designed pillows or thermoplastic facemasks, both for standardised or individual use [30]. Research has shown that immobilization devices may trigger patient anxiety [31], and patients who receive RT for head and neck cancer (H&N), immobilized in a thermoplastic face mask has reported this to be one of the worst experiences during the cancer trajectory [32]. When new immobilization systems or patient set-up procedures are introduced, they are carefully examined regarding influence on treatment delivery, precision, motion management and reproducibility [33, 34]. Sometimes the patient comfort is evaluated as secondary outcome [35] or in qualitative studies [36, 37]. To our knowledge there are few studies that specifically compare techniques and immobilization systems from the patient's perspective [38, 39].

The high-tech environment

In addition to having to manage potential side effects of RT, patients also need to deal with the complexities of the care environment. The high-tech environment and unfamiliar nature of RT plays a major role in the patient treatment experience and may cause feelings of emotional stress and anxiety [25, 31]. This can be caused by: lack of knowledge about the treatment procedures, concern over the treatment equipment and environment, fear of side-effects, and uncertainties about treatment outcome [40, 41]. Environmental aspects, both physical and psychosocial, seem to have a strong impact on patients' well-being. Therefore, it is important to create hospital environments that support both the physical and the psychological needs of the patients [42, 43]. In a qualitative study [42], the authors suggest that the RT-environment can be used as a nursing intervention and conclude that the physical environment in a hospital setting is not only a place for caring. It is also a part of caring. Williams et al. [44] described the patient's perspective of a therapeutic context in which a central feature of emotional comfort was the perception of personal control. In the RT setting it is not only the high-tech environment that may affect patients' emotional comfort. In a recent qualitative study, H&N patients were interviewed, and they described the fact that they were left alone in the treatment room during the RT session as an important factor, causing anxiety because it reminds the patients that they have a cancer diagnosis and that radiation can have negative side effects [45]. Patients may also be partly undressed and/or find the positioning on the treatment couch uncomfortable. All of these circumstances, as well as the patient's own concerns and fears, may cause uncertainty and distress for the patient

during the RT [45-47].

Anxiety

Anxiety is a common psychological response to cancer diagnosis and treatment. Research has shown that anxiety can affect patients undergoing RT at varying times throughout the course of their disease and treatment, and the RT impacts 10% to 50% of the patient population, although results have varied greatly across studies [48]. Lewis et al [49] examined anxiety over time during RT in breast cancer patients. They found that anxiety levels were highest before RT (RT planning) and at the first RT session, and then declined rapidly. Halkett et al. [50] suggested that anxiety prior to RT is associated with the lack of information about treatment and side effects, and the unfamiliar procedures. Mose et al. [51] suggest on the other hand, that anxiety at the first RT is associated with psychological distress and some characteristics of the environment in the waiting room and the linear accelerator room. Other researchers have concluded that there are ways to make the RT procedures less stressful, from altering the treatment environment to better provide educational resources and teaching coping techniques to patients [52-54].

Information

Providing patients with adequate information about treatment and care is very important to improve patient-related outcomes and involvement [55]. The impact of providing information to overcome anxieties about forthcoming RT is well documented [56, 57]. In a systematic review Waller et al. [58] found evidence that providing preparatory information impacted patient-related outcomes, such as improved patient satisfaction, knowledge and psychological health in patients undergoing RT. Understanding what type of information patients need, and from whom they receive that information, is essential to ensure quality care [59], and there seem to be unmet needs for information both prior to and during RT [60, 61]. A number of studies have examined patient satisfaction with information regarding RT [60, 62-64]. In a literature review, Rutten et al. [59] conclude that the most important area of information was treatment-related, and the most frequent information source was health care professionals. Adequate information is also crucial for patient involvement [55].

Person-centred care and information needs

There are challenges when providing patient information in most health care systems, RT is not an exception. There is a need for better dialogue between professionals and patients to identify the information needed

on an individual basis and support the clinical decisions [65]. A mutual exchange of information is also a prerequisite to ensure understanding of the information. Person-centred care (PCC) has become a powerful concept in health care and nursing over the last decade. The concept recognizes the need for a move toward information exchange - a two-way dialog where both patients and health care professionals contribute to, and then act on, the communication between them [66].

The concept of Person-centred Care

PCC is a basic philosophy of care, centred around the patient as a partner in care [67]. Central to this approach is respecting the personal rights and building mutual trust and understanding to meet their needs [68]. Moreover, treating each patient as an individual, with the person's perspective as the centre of care. Many different terms and factors are used to describe person-centredness. These often include the patient's need for more holistic aspects of care, such as physical, social, psychological, spiritual and physical environmental support [43, 68]. Given the profound and extensive impact of RT on many aspects of a person's wellbeing, the principles of PCC are likely to be ideally suited to the RT setting [25, 69].

McCormack et al. [70] developed a theoretical framework to be used to evaluate the caring outcomes from person-centred nursing - "The person-centred nursing framework"**.** The framework comprises four constructs:

1. *Prerequisites* focus on the attributes of the nurse and include being professionally competent;
2. *The care environment* focuses on the context in which care is delivered and includes appropriate skill mix;
3. *Person-centred processes* focus on delivering care through a range of activities and includes working with the patient's beliefs and values;
4. *Expected outcomes*, the central component of the framework, which are the results of effective person-centred nursing and include satisfaction with care.

All constructs relate to each other and suggest that the prerequisites and the care environment must first be considered to provide an effective care through person-centred processes to reach the expected outcomes [68]. When redesigning care practice towards PCC, there are a range of factors to be considered. It can be both complicated and challenging to implement the model regarding health care professions willingness and readiness to change their practice [71, 72]. Price [73]

states that nurses need to share a common philosophy of care with other professionals in the team, in order to successfully implement the PCC model. The continuing development of all team members is critical if a PCC model is to be achieved in the technologically-driven environment [25].

Patient experiences and quality care

High quality care is essential in all health care services where measuring the patient's experience is essential [74, 75]. Quality is defined in different ways and includes several quality categories such as staff characteristics, caring activities, pre-conditions for care, caring environment, caring processes and patient's empowerment [75-78]. In a systematic review by Doyle et al. [74] the authors conclude that patient experience data, robustly collected and analysed, help highlight strengths and weaknesses in effectivenss and safety. In addition, focusing on improving patient experiences will increase the likelihood of improvments in both these areas. The review also showed evidence across different areas of health care, indicating that patient experience is clinically important. The authors also report some evidence that patient involvment improves both effectivness and saftey. Another study by Edvardsson et al. [75] conclude that assessment of health care service including nursing care quality will benefit from including self-reported patient data to improve nursing practise.

Experiences-based Co-design

Experience- based co-design (EBCD) is an approach to improve healthcare. The goal is to combine participatory and user-experience to bring about quality improvements in healthcare organisations. Through a "co-design" process the approach entails staff and patients reflecting on their experiences of a service or process, working togheter to identify improvement, implementing changes, and jointly reflecting on their achivements [79]. EBCD, explained by Bate and Robert [80] has been developed by overlapping four strands of thoughts: participatorie action research, user-centred design, learning theory and narrative-based approaches to change. Thus, including patients in all parts of the process when improving and changing health care practice is of great importance, especially within high-tech environment found in RT-settings.

General aims

The overall aim of this thesis was to gain further knowledge about how patients experience radiotherapy and the related processes. Such knowledge is of vital importance when developing and improving care within a high-tech RT environment.

STUDY I

The aim was to compare two topical agents (Calendula Weleda® cream vs Essex® cream) in reducing the risk of severe acute radiation skin reactions (ARSR) in relation to adjuvant radiotherapy (RT) for breast cancer.

STUDY II

The aim was to determine whether there is a relationship between cancer patients' perceptions of the person-centeredness of their treatment experience and their anxiety levels during treatment.

STUDY III

The aim was to develop and test an instrument to measure patients' experience during external radiotherapy – the Radiotherapy Experience Questionnaire (RTEQ).

STUDY IV

The aim was to describe cancer patients' experiences during radiotherapy

Ethics

The studies were performed in accordance with the World Medical Associations Declaration of Helsinki [81] and ethical approval was obtained for all four studies.

The principle of autonomy was respected by voluntary participation, which includes the right of individuals to decide whether to participate in the studies or not. Participants were told that involvement was voluntary and that confidentiality was guaranteed. Information to patients and staff was provided, and informed consent from patients was obtained in all four studies. In Study I, an informative letter was sent to all participants prior to their first appointment at the RT unit, and informed consent was signed by all participating patients before inclusion. In Studies II-VI the study information was provided by RT nurses at the RT units. The nurses distributed the questionnaire with an informative letter about the study, and returning the questionnaire was considered as informed content.

For confidentiality reasons, no patient identification data was collected in Studies II, III and IV. Quotations (Study IV) were therefore anonymous. As a consequence there were no possibilities for patients to withdraw from the study (Studies II, III, IV) after returning the questionnaires to the RT unit. All results are presented at the group level with no possibility to identify any individual.

The principle of beneficence came into consideration in several ways. Responding to questionnaires (Studies I-IV) helped develop the questionnaire, but it also gave the patients the opportunity to reflect on issues not previously highlighted. The open-ended question in Study IV helped develop the questionnaire and gave the patients an opportunity to, in their own words, describe their experiences and reflections.

The principle of non-maleficence was respected by careful attention towards minimizing extra visits to the RT unit. In Study I, there was one extra follow-up visit to an RT nurse 10 days after completing RT. This may have caused inconvenience for some patients, although most patients expressed their appreciation for this opportunity to meet an expert nurse when the side effects were most intense. There were no extra visits for patients in Studies II, III and IV, and the patients had the possibility to fill in the questionnaires both at the RT unit or at home.

Ethical approval

STUDY I

Regional Ethical Review Board, Stockholm (2009/4:7)

STUDY II

Regional Ethical Review Board, Umeå (2010-371-31M)

STUDY III + IV

Regional Ethical Review Board in Umeå (Dnr 2014/40-31)

Materials and methods

The overall aim of the thesis was to improve knowledge and understanding of the RT procedure, and both quantitative (Studies I, II, III) and qualitative (Study IV) methodology were used (Table 1). In Study I, designed as a randomized controlled trial (RTC), both descriptive and comparative statistics were used. Studies II and III had a quantitative design and used both descriptive and comparative statistics. In Study III an instrument was developed using both quantitative and qualitative designs. Study IV had a qualitative design using content analysis.

Table1. Study overview

Study	**Data collection**	**Analysis**	**Design**
Study I	Different instruments with data collected from both nurses and patients	Descriptive and comparative statistics	Randomized controlled trial
Study II	Questionnaires	Descriptive and comparative statistics	Quantitative
Study III	Interviews with experts in field, patient interviews and questionnaires	Descriptive and comparative statistics Principal Component Analysis	Quantitative and qualitative
Study IV	Free-text comments written by patients	Content analysis	Qualitative

Settings

The data in the thesis focused on patients receiving external RT at different RT units in Sweden. Three different sets of data have been analysed. Studies I and II focused on two regions, the Northern region (the counties of Västernorrland, Jämtland-Härjedalen, Västerbotten and Norrbotten) and Stockholm (the counties of Stockholm and Gotland). Studies III and IV were performed at eight different RT units in Sweden. The hospitals used for recruiting patients are given in Table 2.

Table 2 provides the setting for the four studies.

Study	**Setting(s)**
Study I	Karolinska University Hospital, Stockholm.
Study II	Umeå University Hospital, Umeå
Studies III and IV	Akademiska University Hospital, Uppsala Karolinska University Hospital, Stockholm Sahlgrenska University Hospital, Göteborg Skåne University Hospital, Lund Sundsvall County Hospital, Sundsvall Umeå University Hospital, Umeå Örebro University Hospital, Örebro

Participants

Study I

Between February, 2011 and March, 2012, consecutive eligible women with breast cancer at the RT Unit, Department of Oncology, Karolinska University Hospital, were randomly assigned to receive Calendula Weleda® cream or Essex® cream for skin care during RT. Inclusion criteria: Breast cancer patients previously treated with partial/modified radical mastectomy and scheduled to begin external RT.

Study II

This study was conducted as part of a larger study carried out at Umeå University Hospital, Sweden. The larger study aimed to evaluate patients' experiences before and after design interventions in the environment at the RT unit. Patient recruitment was carried out 2011-2013, consecutive eligible patients were provided with the questionnaire during their seventh day of RT. Inclusion criteria: Adult outpatients with any type of cancer scheduled to receive curative external-beam RT.

Study III

This study was performed in two phases – construction of a questionnaire and then psychometric evaluation.

Construction of the questionnaire: Data were collected from workshops with a multi-disciplinary group with experts in RT. The group included six RT nurses, one physicist and one physician.

Short face-to-face interviews were conducted by five RT nurses at five different RT units, with 23 patients undergoing RT. Eligible patients were consecutively asked to participate. Inclusion criteria: Adult outpatients with any type of cancer scheduled to receive external-beam RT.

Psychometric evaluation: Data were collected from patients from eight RT units in Sweden. Patient recruitment was carried out during one treatment day, when consecutive eligible patients were provided with the questionnaire. Inclusion criteria: Adult outpatients with any type of cancer scheduled to receive external-beam RT.

Study IV

The data in Study IV were collected from free-text comments from patients recruited to the psychometric evaluation of the questionnaire in Study III.

Data collection

Both qualitative and quantitative data were collected. A range of different questionnaires and instruments were used in the Studies (I-III), interviews with both patients and staff were conducted (Study III) and written text from patients was collected (Study IV).

Instruments

Radiation Therapy Oncology Group/The organization for Research and Treatment of Cancer Acute Radiation Morbidity Scoring Criteria

In Study I, the RT nurses evaluated Acute Radiation Skin Reactions (ARSR) on patients, using the Radiation Therapy Oncology Group/The organization for Research and Treatment of Cancer Acute Radiation Morbidity Scoring Criteria (RTOG/EORTC scale) [82] at the first and final RT sessions, and at the follow-up visit five to seventeen days after the final RT. The RTOG/EORTC scale is a frequently used instrument to assess ARSR [8, 83, 84], with good intra- and inter-observer concordance compared with other scoring systems [9]. ARSR is graded from 0 to 4 where 0 represents "no change over baseline" and 4 represent "ulceration, haemorrhage, necrosis". Prior to the study, the RTOG/EORTC scale was translated to Swedish and an assessment guide was developed and introduced at the RT unit. The guide contained the RTOG/EORTC scale in the original language (English) and the translated version in Swedish. The guide also included detailed instructions on how to use the scale and perform the assessments. All nursing staff involved in evaluating ARSR on patients received education on how to use the RTOG/EORTC scale.

The visual analogue scale

In Study I, patients reported symptoms such as pain, burning, itching, pulling and tenderness from the treatment area. A self-rating scale, the visual analogue scale (VAS), was used to report the symptoms. The VAS is regarded as a valid and reliable tool for assessment [85]. It consists of a line with 0 at one end, representing no symptoms and 10 at the other, representing the worst possible symptom. Patients reported symptoms at the first RT session, the final RT session, and at the follow-up visit.

The European Organization for Research and Treatment of Cancer (EORTC), Quality of Life Questionnaire Core-30

Health related quality of life (HRQoL) was measured before randomisation and at the follow-up visit in Study I. The European Organization for Research and Treatment of Cancer (EORTC), Quality of Life Questionnaire Core-30 (QLQ-C30), is a commonly used and validated HRQoL questionnaire [86]. It is cancer-specific and covers important domains for patients undergoing treatment [87]. The questionnaire consists of 30 items, and incoporates five functional scales (physical, role, cognitive, emotional and social), three symptom scales (fatigue, pain, and nausea and vomiting), and a number of s single items (dyspnoea, loss of appetite, insomnia, constipation and diarrhoea), perceived financial impact and global quality of life.

Medical Outcomes Study Sleep measure

In Study I, sleep disturbances were measured with the Medical Outcomes Study Sleep measure (MOS-sleep) questionnaire. MOS-sleep is a validated instrument used to measure different aspects of patient-reported sleep problems and consists 12 items [88]. Sleep disturbances were measured before randomisation and at the follow-up visit.

The Person-centered Climate Questionnaire

The Person-centred Climate Questionnaire (PCQ) [42], was used to measure the extent to which the patients experienced the psychosocial climate as person-centred (Study II). The questionnaire was developed based on a theoretical framework consisting of the following dimensions that affect experiences of a person-centred psychosocial environment: a climate of safety, everydayness, and climate of hospitality. PCQ consists of 17 items formed as statements about the climate on the unit, and a seven-point Likert-type scale was used for response options, ranging from *No, disagree completely* (1) to *Yes, very much so* (7).

The tool has been shown to be valid and reliable to determine to what extent the hospitals' environments are person-centred [43, 89].

The State Trait Anxiety Inventory

In Study II, The State Trait Anxiety Inventory (STAI) [90, 91], was used to measure different types of anxiety. The 40-item STAI measures state (STAI-S) and trait (STAI-T) anxiety, and each subscale consists of 20 items. State anxiety represents an emotional state as a reaction to a particular stressor, e.g. being diagnosed with cancer, and fluctuates over

time. Trait anxiety is a stable susceptibility or proneness to experience anxiety and determines the individual's predisposition to anxiety. The STAI is a widely accepted self-reporting tool to measure anxiety levels in cancer patients [92-96]. In Study II, only the trait subscale (STAI-S) with 20 items was used. Respondents rated their current feelings specific to RT on a four-point Likert-type scale, scoring the intensity of their feelings from *not at all* (1) to *very much so* (4).

Study-specific questionnaires

In Study II, an additional 10 questions about the patients' experiences of the treatment environment were added to the questionnaire. The questions were formulated based on previous qualitative research of the RT patient experience [31], and other research linking patient anxiety to treatment-specific causes [40, 41]. The questions addressed two different aspects of how the RT environment is experienced by the patient: their perceived tolerability of the process, and their emotional experience while going through treatment. The respondents rated their feelings about the treatment environment on a 6-point Likert-type scale, scoring the intensity of their feelings from *not at all* (1) to *very much so* (6).

Construction of a questionnaire

Individual interviews

A preliminary 34-item questionnaire was generated in several steps [97, 98]. According to psychometric theory, the scale construction started with gathering items that represent the phenomena to be studied [99]. In Study III, to identify the most important issues considering patient experiences during the treatment session and to test the content of the items in the questionnaire, short individual face-to-face interviews were performed.

RT nurses at each RT unit interviewed patients by asking one question: "What questions do you consider are important for the staff to ask patients receiving their RT?" The duration of the interview was approximately five minutes, and the nurses took notes simultaneously. The interviews were conducted at the RT unit before or after the daily RT session, depending on what the patient preferred.

To test the content of the items in the questionnaire (Study III), patients were asked to fill in the preliminary questionnaire and give feedback on the clarity and readability. RT nurses conducted short face-to-face interviews with patients immediately after returning the questionnaire.

The duration of the interview was approximately five minutes, and the RT nurses took notes simultaneously.

Workshops

To generate items for the questionnaire in Study III, two workshops with experts in the field were conducted. The first workshop was conducted in the beginning of the item-generation process, and the second workshop was conducted three months later at the end of the process.

During the first workshop the group of experts was asked to discuss the data from patient interviews, questions and content from a literature review, and to identify items for the questionnaire. During the second workshop, the group of experts was asked to examine a pool of items generated from literature and patient interviews, with respect to content, format and scaling, and to suggest improvements.

Psychometric evaluation

In Study III, a preliminary questionnaire, which had been generated from literature reviews, interviews and workshops, was distributed to patients at RT units. The questionnaire included questions within the areas of physical comfort, physiological comfort, i.e. anxiety, claustrophobia, dignity, patient empowerment, relation to staff, informational needs and treatment-environment experiences. The questions were formulated as a 6-point Likert–type scale for response options, which ranged from 1= I strongly agree to 6 = I strongly disagree. There was a possibility to answer "I cannot say/I don't know" and that option was handled as missing data.

Study IV – qualitative data

Free-text comments

In Study IV, data were collected from free-text comments collected from an open-ended question "Is there anything else you want us to know?" in the questionnaire developed in Study III. It is common practice to include open-ended questions at the end of study-specific questionnaires. Such questions represent an invitation to the respondents to add, in their own words, further information, for example "Is there anything else you would like us to know?" [100].

Data Analysis

To answer the overall aim of the thesis – improved knowledge and understanding – both quantitative (I, II, III) and qualitative (IV) data analysis methods were used (Table 1).

Study I - Descriptive and comparative analysis

The difference between the study groups was tested using Fisher's exact test. The risk ratio and 95% confidence interval were estimated using binomial regression analysis [101]. Differences between the two arms regarding EORTC QLQ-C30, MOS-sleep and symptoms from the treated area (VAS) were estimated using linear regression models. All single items in the EORTC QLQ-C30 were transformed to function or symptom scales according to the scoring manual [102]. The MOS Sleep Scale was similarly transformed according to the scoring manual [103].

Study II - Descriptive and comparative analysis

In Study II, descriptive and comparative analyses of data were performed in several steps (see Study II). Due to a printing error one question in the PCQ scale was missing, therefore correlation analyses of the PCQ total score and the everydayness subscale were not calculated.

Study III - Principal Component Analysis

In Study III, theoretical construct validity of the RTEQ was evaluated based on the hypothesis that this would be supported by a Principal Component Analysis (PCA) resulting in a statistically stable and theoretically meaningful solution explaining >50% of the variance in the data. PCA was performed to reveal underlying dimensionality of the data, i.e. to group the variables into different themes. Visual interpretation of the Cattell scree test plot was used to identify the number of underlying categories [104]. After the identification of the number of underlying categories, items with ambiguous interpretation, i.e. variables with significant loadings in more than one category, were excluded. Items with a weak association to the identified categories, i.e. variables for which a minority of the variation was explained by the underlying categories, were also excluded. The thresholds for exclusion were communalities < 0.5 and loadings > 0.3 in multiple categories. Finally, Cronbach's alpha was used as an estimation of the reliability of the estimation of the underlying categories.

Study IV – Qualitative Content Analysis

The written free-text comments in Study IV were analysed using qualitative content analysis inspired by Graneheim & Lundman [105]. Content analysis with an inductive approach is a method that can be

used to describe categories and characteristics in written text [106, 107]. The first step was familiarisation with the data by initially transcribing the text, and then each and every comment was read several times to obtain a sense of the whole [108]. In the next step, meaning units, e.g. the comments relevant for the study aim, were labelled with a code capturing its core. Codes with similar meanings were sorted into subcategories based on how different codes were related and linked, and finally categories were identified and their inter-relationships were examined. Peer debriefing was employed to enhance the credibility of the data analysis [105]. The codes and categories were discussed and negotiated between the authors until consensus was reached.

Results

STUDY I

This randomised clinical trial compared two topical agents: Calendula Weleda® cream vs. Essex® cream, to reduce the risk of severe ARSR in relation to adjuvant RT for breast cancer. A total of 686 patients were considered potentially eligible for the study of which 420 patients were randomised and 411 were analysed. 16 patients did not meet the study criteria and another 250 patients declined to participate. Nine patients discontinued the study after randomisation. The groups were well balanced, both regarding treatment-related factors and in terms of patient-related factors.

Incidence of ARSR

No statistically significant difference between the two treatment arms in severe ARSR was found. There were no differences regarding the proportion of patients with no or mild ARSR at any of the assessment points, and no grade-4 toxicity was reported. The incidence of severe ARSR at the follow-up visit was 23% (n=45) in the Calendula group and 19% (n=38) in the Essex group.

Patient-reported outcomes

There were no differences between the groups in patient-reported symptoms (pain, burning, itching, pulling, tenderness) at any of the evaluation points. Overall, the patients reported low levels of skin-related symptoms. Similarly, we found no statistically significant differences between the groups in HRQoL or sleeping patterns at the follow-up visit.

There were differences in how patients evaluated the application and absorption of the skin-care products, in favour of Essex® cream. No differences were found for patients' grading of the extent to which the skin-care product relieved redness, tightness, tenderness, pain and burning sensations in the treatment area nor in the evaluation of the scent of the skin-care product.

STUDY II

This study evaluated the relationship between cancer patients' perceptions of the person-centredness of their RT experience and their anxiety levels during treatment.

The study had 892 respondents, with a mean age of 65 years. 57% of the respondents were female and 43% male. The majority of patients were being treated with RT in the chest region (47%), but a representative sampling of all treatment areas was recorded: pelvis region (30%), Head & Neck (16%) and other (7%).

Relationship between person-centredness and anxiety

There was a negative relationship between anxiety and person-centred climate scores, which indicate that patients who experienced a higher climate of person-centredness within the RT unit reported lower situational anxiety levels. Further analyses showed that the two PCQ subscales of safety and hospitality were found to have a significant negative association with patients' reported situational anxiety levels.

Perception of person-centredness

In general the participating patient population experienced a high level of person centredness during the RT. The mean total score of the PCQ for the sample was 88. Individual scores for the PCQ ranged from 33 to 96, with higher scores representing a higher climate of person centredness.

Anxiety

The results show that in general the participating patient population experienced a low level of state anxiety during the RT. The mean total score of the STAI-S for this sample was 32, with a range in scores from 20 to 71, with higher scores indicating higher anxiety levels.

The safety and hospitality subscales

The hospitality subscale showed the strongest unique association with reported situational anxiety levels, with high hospitality climate scores having a significantly negative impact on patients' situational anxiety levels. Safety was also found to have a significant impact on patient anxiety level, high levels of safety seemed to reduce patient anxiety levels.

All of the 10 environment-specific treatment questions were found to be significantly correlated with patient anxiety levels (See Study II).

The PCQ subscale of safety had the strongest negative association with STAI-S scores, showing that a climate of safety significantly decreased patient situational anxiety levels. On the other hand, difficulty tolerating the overall treatment experience, worry about the treatment equipment, or feelings of isolation or claustrophobia within the treatment room all significantly increased patient-reported situational anxiety levels.

STUDY III

This study aimed to develop and test an instrument to measure the patient's comfort and experience of the RT procedures. The findings showed that the developed questionnaire, the "RadioTherapy Experience Questionnaire" (RTEQ), is a tentatively valid and reliable instrument to measure the patient's comfort and experiences of the RT procedure.

The study had 825 respondents, with a mean age of 65 years. 54% of the respondents were female, 42% male and 4% data missing. The majority of the patients were being treated with RT in the chest region (36%), but a representative sampling of all treatment areas was recorded: pelvis region (29%), Head & Neck (15%) and other (20%).

Preliminary 34-item questionnaire

The whole item-generation process resulted in a preliminary questionnaire of 34 items about patients' experience of the RT session (Appendix I). The questionnaire included areas within physical comfort, physiological comfort, i.e. anxiety, claustrophobia, dignity, patient empowerment, relation to staff, informational needs and treatment environment experiences.

Item analysis – Principal component analysis

A principal Component Analysis (PCA) was performed to reduce the number of items on statistical grounds, and to determine the nature and number of factors that could explain the correlations among items representing the patients' experience of the RT session. Most items were highly skewed towards positive responses. Scree plot analyses of the 34-item correlation matrix identified six underlying themes explaining 68% of the total variance. After item reduction, the 6 themes explained 73% of the variance in a 23-item questionnaire. The following themes were identified: Situational discomfort, Physical discomfort, Situational coping, Informational needs, Environmental coping and Psychological coping. A reliability analysis was performed, and resulted in high or very high Cronbach's alpha for all themes (between 0.79 and 0.9).

Theme scores

A multivariate analysis revealed that there was no statistically significant difference when the survey was completed early (RT 2-15) or later (RT ≥16) during the treatment period. However, the general tendency was that questionnaires collected on the first RT day gave

slightly lower scores in all themes, except for informational needs, than questionnaires handed out later in the RT period. The multivariate analysis did not show any difference between the genders, while the treatment area had a significant impact.

STUDY IV

The purpose of Study IV was to explore how patients experience the RT and the RT process, described in free-text comments in Study III. Out of 825 returned questionnaires in Study III, 261 contained free-text comments from patients (32%). The sample consisted of 38 % men and 62% women with a mean age of 63 years. The most common treatment-sites were chest (43%), abdomen (27%) and "other" (14%). Two percent of the patients had just completed their first RT session, 56% had completed 2-15 sessions, and 42% had completed 16 or more sessions.

The hand-written free-text comments were between one and 161 words long. The qualitative content analysis resulted in four major categories, with sub-categories, reflecting the experience of the RT process: Experiencing the high-tech RT environment; Understanding the RT procedures and side effects; The nurses' role and performance and Dealing with daily life during RT.

Experiencing the high-tech RT environment

This category describes the patients' experiences from the environment at the RT unit and comprises two subcategories: "An uncomfortable experience enhanced by environmental details" and "The atmosphere at the RT unit is due to encounters with the staff".

Understanding the RT procedures and side effects

This category describes the patients' different needs for information and support during their RT experience and comprises the following two sub-categories: "A need to understand what RT is and does" and "Better information improves my understanding of the RT process".

The nurses' role and performance

In this category the patients describe their relationship with the nursing staff, and it comprises two sub-categories: "The nurses' care for me with compassion" and "The nurses are professional and improve my experience".

Dealing with daily life during RT

This category describes how patients' daily lives were impacted by the visits to the RT unit, and three sub-categories emerged from the texts: "Involvement in scheduling my RT appointment", "Waiting for the daily RT session is frustrating" and "The disease and treatment affect my life".

Discussion

The findings of these four studies provide an increased knowledge of the patients' experience during their RT process. Together the four studies describe how RT and the environment impact the patients' experience of care.

STUDY I

Managing ARSR is an important priority for patient undergoing RT, and in a systematic review by Chan et al. [23], there was no strong evidence in favour of any of the included trial products in reducing ARSR. The authors concluded that the evidence base is extremely wide, with many products and interventions tested, and still, the evidence for any particular product remains weak.

We found no differences in ARSR between skin care using Essex® cream or Calendula Weleda® for patients with breast cancer undergoing adjuvant RT. These results contradict the previously published data [14], where the effect of Calendula cream was investigated. In [14] patients in the experimental group had a significantly lower incidence of severe ARSR, pain and treatment interruptions in comparison with the patients in the control group, treated with trolamine.

There are several similarities in the design between the current study and [14]. Both are RCTs, have a similar study population, use the same assessment tool for the primary endpoint (RTOG), and have Calendula cream in one of the treatment arms. We also found some results in the present study, which were similar to [14]. In both studies, patients using Calendula cream reported significantly poorer absorption of the cream than patients in the control groups.

The current study also showed an overall lower rate of severe ARSR than in [14]. The lower incidence of ARSR in the current study, regardless of the skin care product, could be a consequence of different RT techniques in the studies. For example, in the present study, strictly photon therapy was used, whereas in [14] electrons were used to boost the tumour bed. Patient-related factors that might influence the results include a relatively low proportion (12%) of smokers in the present study. On the other hand, the frequency of smoking among Swedish women was only 11% in 2015 [109]. The proportion of smokers [14] is unknown.

Systematically measured PRO and compliance with skin care guidelines is important during evaluation of new treatments. Even some non-clinical outcomes, such as cost for the skin care products, can be

important for clinical decision making or for the patient's choice of products.

STUDY II

Anxiety affects many patients undergoing RT. The results in this study show that, in general, the patients experienced a low level of state anxiety and a high level of person-centredness during the RT. In this study we found that both the psychosocial climate and the treatment environment affect cancer patients' cancer situational anxiety level as they go through the RT.

The mean anxiety levels in this study were similar to other studies that have investigated patients undergoing RT [110-112]. Comparing this population to other studies using the same measures for safety and hospitality, we find our mean results in line with results reported by Bergland et al. [113] and Edvardsson et al. [43].

The analysis of factors relating to the patient's experience of the treatment environment also show a significant association with state anxiety levels, and when combined with the psychosocial factors, the analysis of factors will provide an improved ability to predict anxiety levels in patients. Patients' anxiety is a complex emotion, with many influencing factors. Factors in this study that raised anxiety levels were: difficulty tolerating RT, worry about the medical equipment and feelings of isolation or claustrophobia during treatment. These findings are unsurprising, given that several studies have reported that anxiety during RT can be linked to feelings of isolation, concern over the treatment equipment [40, 41, 45, 114], and that immobilisation devices can trigger claustrophobia [32, 38]. Even patients' encounters with RT nurses seem to have an impact on anxiety, as there is research which indicates that patients' anxiety levels increase when RT nurses show professional incompetence [45]. In contrast, when perceiving the psychosocial climate of the department as one of safety, hospitality, and person-centred, all factors contribute to decreasing patient anxiety levels.

Taken together, the PCQ, which explores the psychosocial environment, and the study-specific questions, which explore patient experiences of the treatment environment, form a logical approach to measuring environmental influence on anxiety for patients undergoing RT.

Other researchers have attempted to decrease patient anxiety levels by making the RT procedures and treatment environment less stressful by providing educational resources and teaching coping techniques to patients [52-54]. However, they did not detect any significant decreases

in anxiety levels from these interventions. The results of the present study suggest that a more holistic approach is needed to reduce patient state anxiety levels during RT. That is because of the multiple factors that induce anxiety. Therefore, implementing PCC and making improvements in the treatment environment, with focus on the patient experience of RT, might decrease patient anxiety levels.

STUDY III

The aim of this study was to develop an instrument, the Radiotherapy Experience Questionnaire (RTEQ), to measure the patient's experience of the RT process, the environment in the treatment room, and to evaluate the instrument's psychometric properties. The resulting 23-item questionnaire, RTEQ, assesses the patient's experience of the RT procedure, includes psychological stress, physical discomfort and coping during the RT process.

In terms of content validity, the scale was regarded as satisfactory since the scale contains items, which reflects dimensions that are described in the literature and by patients as being central aspects of their experience during RT.

The items within Psychological discomfort and Psychological coping capture anxiety and feelings of isolation [40, 41, 69, 112]. Informational needs became apparent from the short patient interviews because the patients asked what is going to happen during the treatment? and what kinds of side effects are common? The impact of providing information to overcome anxiety is well documented in the literature [56-59]. Situational discomfort captures claustrophobia that is a distinct problem for H&N patients [32, 37, 38]. Claustrophobia is a negative experience of the treatment, as indicated in the analysis of the subcategories. Claustrophobia is most likely due to more uncomfortable fixations for this patient group, and it is captured within items in Physical discomfort subcategory.

In Study IV, data from the open-ended question at the end of the 34-item questionnaire were analysed. In the written comments in Study IV, the results reflected the patients' experience of the RT process where both physical discomfort and environmental coping were captured under a sub-category "An uncomfortable experience enhanced by environmental details". The patients described discomfort, for example when lying on the treatment couch, and some patients wrote about sharp lighting in the treatment room as very uncomfortable. These dimensions are captured both in Physical discomfort and Environmental coping in the RTEQ.

In conclusion, the RTEQ seems to have captured several aspects that are specifically pertinent to patients undergoing RT. The questionnaire can be used as a tool to measure the patient experience during RT and enables evaluation of newly introduced techniques or different workflows from a patient perspective.

STUDY IV

In Study IV, the findings represent an attempt to explore patients' experiences of the RT process in their own written texts. The results embrace descriptions of a wide range of items: the patients' experience of the high-tech RT environment, understanding procedures and side effects from RT, relating to the nurses' activities, and dealing with daily life during RT.

The high-tech RT environment was found to contribute to feelings of worry and discomfort for patients, but positive encounters with staff could contribute to more positive experiences and make the patients feel safer. These results are in line with other studies, which also found that patients experience the RT environment as unfamiliar and that it increases anxiety [115], as well as patients describing a higher person-centred psychosocial climate at RT units, which report lower levels of situational anxiety [69].

Both providing good information about treatment procedures and appropriate communication is particularly relevant for patients undergoing RT [116, 117]. This is confirmed in the current study where patients described a need to understand the process of RT, technical issues and how side effects affect the body. In addition, the patients gave several suggestions to improve the information, e.g. improved written information with clarifying illustrations. Therefore, there are potential benefits of repeating information during the RT to increase the patients' knowledge and understanding. The information may be more beneficial if it is individualized, presented in multiple formats, and if it provides both procedural and sensory information.

The findings in this study also showed that the RT nurses influence the patients' experiences during the RT treatment both by how they interact with the patients and how they perform the treatment. Previous studies have shown that nurses' guidance and support help improve the quality of care [37, 45, 116, 118]. Our findings agree with the findings in Halkett et al. [119], who concluded that the radiation therapists played a central role in enabling patients to achieve a sense of emotional comfort.

Furthermore, one of the most important issues raised in this study was related to the daily appointments. Several patients offered suggestions

to improve the patient experience, particularly regarding planning of appointment times. Not having enough impact on the daily RT appointment time makes the patient's daily life more difficult. Seikkinen et al. [78] also found similar results. The fact that many patients report no, or very little possibilities to impact this important factor, is a great concern.

Methodological considerations

In this thesis both qualitative and quantitative methods were used. Hence, the quality of the research needs to be assessed with different criteria to measure validity, reliability and trustworthiness [120]. The combination of methods and perspectives, and the use of different samples and different sources of data, provided a broad picture of the patient experience of RT.

Study I was designed as a double-blinded randomised controlled trial (RCT). RCTs are the most stringent way of determining whether a cause-effect relation exists between the intervention and the outcome [121]. The findings in Study I are strengthened by the high response rate for the primary endpoint and for patient-reported outcomes (PRO). The inclusion of PRO, data directly from patients without modification or interpretation by another observer, i.e. "true-experience", contributes to a more complete and accurate measure of the patient's experience, together with results assessed by health care providers.

The sampling in Study I was highly homogenous and the groups were well balanced, both regarding treatment-related factors and patient-related factors.

In the construction of the questionnaire (Study III), only 23 patients from five different RT units were interviewed, and this may be considered as not representative for the entire population. However, we regard it to be a purposeful sample with representation from different patient set-up and immobilization groups.

In Studies II and III, a large group of patients were sampled, and the response rates to the questionnaires were very high, which strengthens the results from the studies. Using questionnaires in the RT setting is a quick way of collecting data from a large number of persons in a relatively cost-effective way.

All respondents of the questionnaire in Study III were given the opportunity to write, with their own words, comments in an open-ended question: "anything you would like the researchers to know?"

261 respondents (32%) took the opportunity to write comments. It has been argued that respondents may not be representative of the population surveyed, and it may be difficult to estimate how many participants will take the opportunity to write comments [122-125]. However, the sampling is a matter of judgement of the quality of the data and its relevance for the study aim [126]. Relevant to this is, the reader should consider if the findings are transferable to another context, instead of its generalization [120]. The reasons why respondents do or do not write comments to the open-ended question are speculative. Respondents who write comments may be more articulate than those who do not, or they may have a critical or negative comment to make [127]. It could also be lack of time, or finding it difficult to express themselves in writing, or simply not having anything more to add. In our case, the last reason may be relevant because the patients in our study meet the RT nurses on a daily basis and have the possibility to ask questions and give comments directly to the nurses instead of writing them down in a questionnaire. The results may have differed if the questionnaire had been provided a couple of weeks after finishing RT when the patients had some time to reflect over the RT process.

A use of validated instruments when assessing skin toxicity does not always guarantee sound and precise assessment. It also depends on the grade of inter-observer reliability and the degree to which different observers give consistent estimates of the same phenomenon. As Sharp et al. [8] conclude: systematic education, even for experienced staff, and tests of inter-observer agreement of the assessment instrument before initiating research are essential. Hence, prior to Study I, to increase the inter-observer agreement, systematic staff training and improved guidelines in using RTOG/EORTC scale were conducted. That may be one of the reasons why Study I showed a smaller proportion in ARSR than the prior pilot study [8], despite similar treatment and patient-related factors. In study I, the point of assessments seems to have captured the patient-reported peak of symptoms from the treatment area. However, there might by a possible limitation concerning the points of assessments. In comparison with some other studies [23], they are relatively few, and even if the follow-up assessment captured the ARSR peak, the window was rather broad, 5- 17 days.

However, Study I included assessments by both health care providers (observer-rating) and patients (self-rating), and the results showed similar patterns. Similar patterns have been reported in other studies [8, 14, 17, 19]. In studies comparing steroidal cream with non-steroidal cream [18, 128], results showed a significantly beneficial effect on

quality of life and reduced ARSR, in favour of the steroidal topical cream [128] whereas, Boström [18] showed a significant decrease of ARSR in the steroidal cream arm but no significance regarding PRO as pain, burning and itching. Hindley et al [128] used validated instruments (Dermatology Life Quality Index and Hospital Anxiety and Depression questionnaire) and ARSR was observed by health care providers using RTOG score, and Boström et al [18] evaluated the ARSR using a reflectance spectrophotometer together with visual scoring of the skin reactions (study-specific scoring), and PRO as pain, burning and itching were reported by patients using a Visual Analogue Scale (VAS). This highlights the challenges in comparing and translating results due to the use of different measurements of outcomes.

In Study II, the use of validated instruments (PCQ and STAI) for measuring state anxiety and PCC strengthens the results. However, due to a layout and printing error within the questionnaire there was an accidental elimination of one question in the PCQ. The question was in the subscale of everydayness and had impact on the ability to assess the everydayness subscale and compare this study's total PCQ score with other studies using the PCQ. Nevertheless, the scale's reliability was indicated by a Cronbach's alfa coefficient (0.92) calculated both with and without the everydayness subscale, which is considered as satisfactory [97]. The results in this study indicate that individuals who perceive the RT unit to have a low climate of person-centredness, specifically regarding hospitality and safety, will experience higher levels of anxiety during their RT, in comparison with those who experience a more person-centred atmosphere. However, using the person-centeredness of the psychosocial climate of RT seems to be a poor predictor when used alone.

In Study II, we chose to use the STAI questionnaire rather than other validated assays of anxiety such as the Hospital Anxiety and Depression Scale [128-131] because of its ability to distinguish state anxiety levels, rather than overall trait anxiety levels and depression. We also excluded the STAI-Trait subscale, designed to assess an individual's predisposition to anxiety determined by his/her personality, due to the intention to measure the anxiety levels triggered by the RT environment. However, trait anxiety could have added valuable information about a patient's anxiety trait levels and how that correlates to psychosocial climate and the treatment environment. Lewis et al [49] examined anxiety over time during RT in breast cancer patients and found that anxiety levels were highest in the beginning of RT and declined rapidly. The timing of the questionnaire in this study was set to the seventh day of the patients' RT. The results might have been

different if the questionnaire had been provided in the beginning of the RT process or at the end of the RT process. In further research it might be interesting to follow patients throughout the whole RT process and measure both anxiety levels and the experience of person-centredness during the RT.

In Study III, there was no difference within the dimensions if the survey was completed early (RT 2-15) or late (RT ≥16) during the treatment period. However, in the written comments in the open-ended question, a few patients commented that it wasn't relevant to answer a couple of questions because they had only received one treatment. This provides different options for when to administer this survey. One option would be to use specific days when all patients at the department receive the questionnaire, as done in Study II. Another possibility would be to always hand out the questionnaire on a specific day for a given patient group, or a third possibility would be to hand out the RTEQ several times during a patient's treatment period.

Regarding the psychometric evaluation in Study III, the individual responses were highly skewed and using a Pearson correlation matrix may involve a risk for an incorrect estimation of the factor structure. However, it is a well-established method, and we consider the result to be reasonable. The choice of using orthogonal components instead of non-orthogonal factors, in the exclusion of items, was based on a theoretical perspective where we assumed that the factors are uncorrelated, e.g. that Situational discomfort is independent of Situational coping. We found the use of orthogonal components to be mathematically sounder from a theoretical perspective. For example, our results showed that discomfort is related to distinct experiences during the treatment, whereas coping is related to the emotions surrounding the treatment, which seems theoretically reasonable. The theoretical construct validity was estimated as satisfactory since PCA separated the items into six themes that explained nearly 73% of the total variance in the sample. Regarding reliability, all themes had a Cronbach's alpha value between 0.79 and 0.9, which is considered satisfactory [97].

Establishing construct validity is an ongoing process, and this study mainly focussed on the theoretical dimensions of construct validity. Using principal component analysis, further testing and cross-validation of the findings with new samples is necessary to establish psychometric properties. Furthermore, a few patients took the opportunity to give feedback on the questionnaire when writing comments. For example: "I didn't understand question number x and y", "the questionnaire could have been less complicated, it would have been easier for me to answer

yes or no", "a nice questionnaire, I appreciated it", and one patient wrote that the questionnaire was irrelevant. These comments are valuable to understand the close-ended questions in the further development and testing of the RTEQ, together with the results of analysis in Study IV.

The value of free-text comments in questionnaires with close-ended questions is an ongoing discussion [100]. One of the challenges with using open-ended questions can be the analysis of the data due to the lack of structure or design, where the data are not purposefully or systematically collected [100]. The 261 free-text comments in Study IV were both short and long. The amount of words in the comments was between one to 161 words and varied from short statements, e.g. "thanks" to longer stories. Altogether, the comments gave enough material to conduct a qualitative content analysis. The rigorous analysis was conducted in several steps inspired by Graneheim & Lundman [105], and three of the authors discussed codes and categories for trustworthiness [106] and to guarantee methodological expertise throughout the whole analysis [100].

Conclusions

In Study I we were not able to confirm a reduced risk for ARSR by using topically applied Calendula Weleda® cream. ARSR in patients undergoing adjuvant RT for breast cancer is a relatively limited problem, probably more influenced by treatment techniques than by choice of skin care products. The study shows the importance of including outcomes such as Patient Reported Outcomes (PRO) and identifying risk factors for the development of severe ARSR in future studies.

In Study II we found that both the psychosocial climate and the treatment environment significantly impact patient situational anxiety levels as they go through RT.

In Study III an instrument, RTEQ, was developed to measure patients' experience during external RT. The instrument was shown to be tentatively valid and reliable for measuring the patients' comfort and experience of the RT procedure. Further studies are planned for cross validation of the findings to improve the possibility to use the instrument for comparisons between e.g. different clinics, workflows and techniques

Study IV describes patients' experiences during radiotherapy. The main conclusion was that RT-services must find ways to give patients better

possibilities to influence their care. One of the most important issues was related to the daily appointments. The fact that many patients report no, or very little, possibility to impact this factor should be a matter of concern.

The RT environment and the RT related processes seem to impact cancer patients, both physically and psychologically. A person-centered care approach, as well as attention to the design, both of the treatment process and the physical environment could significantly improve the patient experience and patient involvement. The results also highlight the importance of taking patient experiences into account when introducing new RT methods and techniques.

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Appendix I