Volume I

Research component

CANCER TREATMENT-RELATED DISTRESS: EVALUATING THE EFFECTIVENESS OF PSYCHOSOCIAL INTERVENTIONS

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Thesis submitted to the University of Birmingham for the degree of

DOCTORATE IN CLINICAL PSYCHOLOGY

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Overview

This thesis is submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D.Clin.Psy.) at the school of Psychology, University of Birmingham. This thesis is presented in two volumes. Volume I is the research component consisting of a literature review and empirical paper each concerned with the effectiveness of psychosocial interventions on cancer treatment-related distress and symptoms. Volume II is the written clinical component, comprising five Clinical Practice Reports.

Volume I

The literature review is a systematic evaluation and critique of empirical research published since 1990 to evaluate the effectiveness of psychosocial interventions on distress, symptoms and quality of life specifically in relation to cancer treatment. Thirty-one relevant studies were identified evaluating 38 different interventions. The review included an assessment of the quality of the interventions and study designs of included studies. Interventions were grouped into relaxation, cognitive-behavioural, hypnosis and supportive interventions. Relaxation interventions demonstrated considerable effectiveness in reducing anxiety related to cancer treatment. The impact of relaxation interventions on other psychological, symptom-related and quality of life outcomes were more variable. No firm conclusions could be drawn for cognitive-behavioural interventions due to the vast heterogeneity in interventions and equivocal findings. The evidence for hypnosis and supportive interventions was sparse. Further good quality research is needed to add to the evidence base for cognitive, hypnosis and supportive interventions to discern with more confidence their impact on cancer treatment-related symptoms.

The empirical paper presents a pilot study designed to evaluate the effectiveness of a psychological preparation session on women's distress prior to and following invasive internal radiotherapy treatment for gynaecological cancers. This brief intervention was found to prevent further deterioration in anxiety and depression prior to treatment. Significantly more patients in the control group were found to experience greater anxiety and depression prior to treatment compared to the intervention group. The limitations of this empirical study, suggestions for future research and clinical implications are also discussed. Both papers are prepared as if for submission to the Journal of Psycho-Oncology. Some changes have been made to the formatting of these papers to comply with regulations for submitting a thesis.

Volume II

Volume II contains five Clinical Practice Reports (CPR's). The first presents the assessment and formulation of a young female with needle phobia from a cognitive and psychodynamic perspective. CPR two is a small-scale service related research report, evaluating a consultation service delivered by the Child and Adolescent Mental Health Service to Child and Family Support Workers based in schools. The third CPR is a case study outlining the work carried out with the family of a 7 year old boy with autism whose behaviour presents challenges at home. CPR four is a single case experimental design that evaluates the effectiveness of cognitive-behavioural therapy with a 54-year-old woman in cancer remission with health anxiety. CPR five was presented orally and presented an individual and systems level formulation of an inpatient client from a cognitive-behavioural therapy perspective. An abstract of this case provides a brief overview of this work.

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Dedication

This thesis is dedicated to my parents. Thank you for your continual support in all my professional endeavours, for believing in me and for understanding how important this is to me. This thesis is for all the generations before me who did not have the gift of education, or the support to pursue their dreams and made sacrifices so that those generations after them could. I owe my every achievement to them.

Acknowledgements

Carrying out this substantial body of work is no easy task. It would not have been possible without the help of so many people and I would like to take this opportunity to thank them.

Thank you to my research supervisors, Jan Oyebode, Ruth Howard and Inigo Tolosa, for their time, guidance, support and enthusiasm from start to finish. I have learnt a lot through this process. Thank you to Chris Jones for his advice on statistics and for helping me to think about my data differently. Special thanks to Amy Perry for helping with the research project- you came just at the right moment and gave that 'little extra' that was needed. I am very grateful for the time you invested.

I had the honour to work with a welcoming team at the cancer centre. Thank you to Hilary Jefferies who was instrumental at the very start in assisting with the practicalities of the research project. Thanks also to Anne Cox and Karen Bassett who helped with the administrative tasks, always made time for me and for introducing me to the right people. This is very much appreciated. Thank you to the consultants, Dr Fernando, Dr El-Modir and Dr Anwar for supporting the research and welcoming me into your clinics.

This research could not have taken place if it were not for the participants who kindly volunteered their time to participate in the project. Without their generosity this thesis would not have been possible. Thank you all so much.

Thank you to Donna and Sam for being great friends and for your many words of encouragement. The biggest acknowledgement of all must go to my family for always being there for me, for their unwavering support, love and belief in me. Thank you to God for bringing someone into my life at the right time and place (KCB). Words cannot do justice to the support you have given me, without you this thesis would not have been possible. Thank you.

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Literature Review

ABBREVIATIONS

Literature Review

ANV	Anticipatory Nausea and Vomiting
EMG	Electromyographic biofeedback
PSMT	Professionally-administered Stress Management Training
RCT	Randomised Controlled Trials
SF-36	Medical Outcomes Study 36-item Short Form
SSMT	Self-administered Stress Management Training
ST	Skin temperature
VAS –	Visual Analogue Scale

Empirical Paper

IRT	Internal Radiotherapy Treatment
DT	Distress Thermometer

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ABBREVIATIONS

BPS	British Psychological Society (CPR 3)
CAMS	Child and Adolescent Mental Health Services (CPR 2 and 3)
CBT	Cognitive-behavioural therapy (CPR 4)
CFSW	Child and family support worker (CPR 2)
CORC	CAMHS Outcome Research Consortium (CPR 3)
CSQ	Customer Service Questionnaire (CPR 2)
DfES	Department for Education and Skills (CPR 2)
IES-R	Impact of Events Scale Revised (CPR 1)
SSM	Service Satisfaction Measure (CPR 2)

Literature Review

Psychosocial interventions for improving treatment-related symptoms and reducing distress in cancer treatment: a review

Abstract

Objective: Cancer treatments are found to be associated with heightened distress and treatment-related symptoms. The current review provides an up-to-date and detailed summary of the evidence regarding the effectiveness of a range of psychosocial interventions on treatment-related psychological distress and symptoms in patients receiving cancer treatment.

Methods: Relevant studies were identified via Medline and PsychINFO databases (1990 to April 2010) and from the reference lists of articles and reviews. Randomised controlled trials in a cancer population evaluating at least one psychological or symptom related outcome were included. Interventions had to be specifically targeting patients' distress or physical symptoms as a result of treatment. The quality of the interventions and studies was also assessed.

Results: 29 studies covering 36 interventions were evaluated. Relaxation interventions proved to have a significant effect on anxiety for cancer patients undergoing a variety of different medical treatments. The findings for other psychological, symptom-related and quality of life outcomes were more mixed. The heterogeneity and equivocal findings for cognitive-behavioural interventions made it difficult to draw any conclusions. The evidence for hypnosis and supportive interventions was sparse.

Conclusions: Relaxation training should be incorporated in clinical practice for cancer patients receiving treatment. Further good quality research is needed to ascertain the effectiveness of cognitive-behavioural, hypnosis and supportive interventions.

Keywords: Review, psychosocial interventions, oncology, cancer, treatment

Introduction

The treatment-related symptoms and heightened distress associated with cancer treatments are well documented (e.g. Roscoe, Morrow, Hickok & Stern, 2000; Jacobsen et al., 1999; Servaes, Verhagen & Bleijenberg, 2002). The severity of treatment-related side-effects correlates negatively with appraisals of quality of life (Longman, Braden & Mishel, 1999) and greater emotional distress is associated with increased physical symptoms (Graydon, 1994). A recent study found that preoperative anxiety had a detrimental effect on recovery (Kagan & Bar-Tal, 2008). Thus, helping patients to cope with treatment-related symptoms and distress may influence quality of life and recovery post-treatment. Reviews of psychosocial interventions for treatment-related distress and symptoms have reported that relaxation interventions have significant effects on symptoms, such as nausea and pain that result from non-surgical treatments of cancer (Leubbert, Dahme & Hasenbring, 2001). Similarly a systematic review by Redd, Montgomery & DuHamel (2001) found that behavioural interventions could reduce anxiety and distress associated with invasive cancer treatment and assist in the management of anticipatory nausea and vomiting associated with chemotherapy (Redd et al., 2001). This review, unlike the previous two reviews (Leubbert et al., 2001; Redd et al., 2001), which concentrated solely on behavioural interventions, evaluates a range of psychosocial interventions designed to target treatment related symptoms and distress. This will help to ascertain whether interventions, other than relaxation, also have an impact on treatment-related symptoms. This review will also include more recent evaluations of relaxation interventions for treatment-related symptoms.

To the best of my knowledge, there have been no recent reviews that have evaluated the effectiveness of a broad range of psychosocial interventions on treatment-related symptoms and/or distress in cancer patients receiving treatment. This is the aim of this review. Firstly, the methodology for this review will be described. Secondly, the categories of interventions identified will be reviewed, followed by an evaluation of studies which compared different types of interventions. The quality of the interventions and studies that are included will also be assessed.

Methods

Literature search strategy

Electronic literature searches were performed on the Cochrane Central Register of Controlled Trials, MEDLINE and PsychINFO (see appendix 3). A combination of MeSH (terms were exploded) and free text terms were utilised. The search criteria were adapted for the individual databases because of the different search terms embedded within them. References in retrieved articles were further searched for relevant citations. Keywords used in the searches included those related to cancer, different types of cancer treatment, psychological interventions and psychological and symptom outcomes.

Study selection criteria

Studies which described and evaluated a psychosocial intervention using a Randomised Controlled Trial (RCT) research design and published from 1990 onwards were eligible for inclusion in this review. The participants were required to be adult (aged 18 years or

above) cancer patients receiving active treatment for cancer. Patients who had completed their treatment were not eligible. There were no restrictions according to number of participants or types of cancer. The review focused exclusively on interventions which directly intended to assist patients in coping with their treatment related distress and / or symptoms while in active treatment. Therefore, the review was limited to interventions which were delivered prior to, during or post-treatment. Post-treatment interventions were only included if they were implemented within an hour following treatment and focused on distress and / or symptoms as a result of treatment. A broad range of interventions was considered, including relaxation, cognitive-behavioural, psychotherapy, hypnosis and supportive interventions. Individualised and group-based interventions were eligible, as were self-administered interventions which incorporated predominantly psychological components. Purely educational and physical activity interventions and multifaceted interventions which used minimal psychological techniques were excluded. Multifaceted interventions were only included if psychological approaches were equal to or more than half (50% or greater) of the intervention. At least one of the outcomes had to be psychological or symptom related. There were no restrictions on the method of assessment, frequency, intensity or duration of interventions.

Methods of the review

The titles and abstracts of identified studies were first reviewed and those clearly not meeting the inclusion criteria were eliminated. The full inclusion and exclusion criteria included:

- Randomised controlled trials –random assignment had to be mentioned
- Population had to have confirmed diagnoses of cancer

- Interventions needed to include a significant psychological component (50% or greater), such as relaxation, cognitive-behavioural techniques, and hypnosis. Interventions labelled as 'psychological support' and not described in further detail were excluded.
- English only references included
- Interventions had to be delivered prior to and/or during active treatment or within an hour following treatment.
- Outcomes assessed had to be directly as a result of the treatment (symptom-related and psychological).
- Studies which included all the main inclusion criteria but scored in the poor range on quality of study design and intervention (see quality assessment below) were excluded.

When it could not be discerned from the title and abstract that the full inclusion criteria had been fulfilled, then full paper copies were retrieved and reviewed. A data extraction form (see appendix 5) was used to organise data from the research papers.

Quality assessment

The Yates Scale (Yates, Morley, Eccleston & Williams, 2005; see appendix 6) designed specifically to assess the quality of studies evaluating psychological interventions was utilised in this review. The quality of interventions was assessed on factors related to manualisation of intervention, fidelity checks, the level of therapist training, and engagement of patients. The quality of study designs was measured by considering patient selection, attrition, methods of randomisation, allocation and measurement bias,

outcomes, follow-up, power and quality of control groups. The scale provides a score for the quality of the intervention (range 0 – 9) and for the quality of the study design and methods (range 0 – 26). There is no criterion included in the Yates Scale to categorise studies according to levels of quality therefore the following cut-offs were formed by the researcher to more clearly distinguish between poor and good quality research. The quality of the study design was categorised as poor for a score of nought to eight, moderate nine to 17, and good 18 to 26. The quality of the intervention was categorised as poor for a score of nought to three, moderate four to six and good seven to nine. Studies which scored in the poor range for study design and intervention were excluded.

Cognitive-behavioural interventions were broadly defined and included any intervention which specified using cognitive and behavioural techniques. The use of the term cognitive-behavioural has been applied to a wide range of interventions. Therefore, it was felt important to consider how many key elements of the cognitive-behavioural therapy approach the interventions met. A classification criterion developed by Jones, Cormac, Silveira da Mota Neto, and Campbell (2010) was utilised. To adapt its use for psychosocial interventions in physical health it was slightly modified (see Table 1). Interventions were categorised as well-defined or less well defined (Jones et al. 2010). Well-defined interventions satisfied criteria one and two, and one element of the third criterion. Less well-defined interventions did not meet this criterion (or did not provide enough information) but were described as using cognitive methods or cognitive-behavioural strategies. Less well-defined interventions could either satisfy criterion one or two, and one or more elements of the third criterion. Or fail to satisfy criterion one and two, but fulfil one or more elements of the third criterion.

Table 1. Criterion to classify cognitive-behavioural interventions as well-defined or less well-defined

Fulfil both of the following:	
1.	Links between thoughts, feeling and actions
2.	Correction of an individual's misinterpretations, irrational beliefs/thoughts, and reasoning biases, *illness perceptions
Fulfil one of the following:	
3a.	Monitoring of thoughts, feelings and behaviours
3b.	Promoting alternative coping methods
3c.	*Attempted modification of behavioural responses to symptoms and illness (e.g. rest, sleep, self management, activity pacing)

* Amendments made to the criterion established by Jones et al. (2010)

Results

Literature search results

Twenty-nine studies met the inclusion criteria and were included in the review (see Figure 1 for more details). Across the 29 studies, 36 interventions were evaluated (see Table 2). There were 14 studies which evaluated relaxation training interventions, covering 15 different interventions between them. Four studies evaluated interventions including a substantial hypnosis/hypnotherapy component. Eleven studies evaluated cognitive-behavioural interventions. One study contributed two interventions to this section of the review (Jacobsen et al., 2002). Six interventions were categorised as

supportive interventions and were evaluated in four studies. One study contributed three supportive interventions (Burton & Parker, 1995).

The designs of the majority of the studies (24; 77%) involved comparing an intervention group with a control group. The sample size of the studies varied from 28 to 411. Seventy-four percent of the studies focused on patients receiving chemotherapy or radiotherapy. Sixteen studies had one type of malignancy within their sample, mainly patients with breast cancer. (See appendix 7 for further information about the characteristics of the studies). A number of self-report measures were used in the studies to assess psychological, symptom-related and quality of life outcomes (see appendix 4 for a table of measures and reference list). The most commonly used measure for psychological outcomes was the State-Trait Anxiety Inventory (STAI) which was used in eight studies and the Multiple Affect Adjective Checklist (MAACL) which was used in six studies. For the investigation of quality of life outcomes the Medical Outcomes Study 36-item Short Form (SF-36) was utilised in six studies. Apart from the previous examples, there was little consistency in the measures employed across the 31 reviewed studies and some authors developed measures specifically for use in their studies.

In terms of the quality of study designs, the majority (71%, 22) scored in the moderate range according to the quality criteria described above (see appendix 9). In relation to the quality of the intervention, 55% (17) of the studies were rated as having interventions of moderate quality (see appendix 8). The interventions have been grouped as relaxation, hypnosis, cognitive-behavioural and supportive, and each will be discussed separately below.

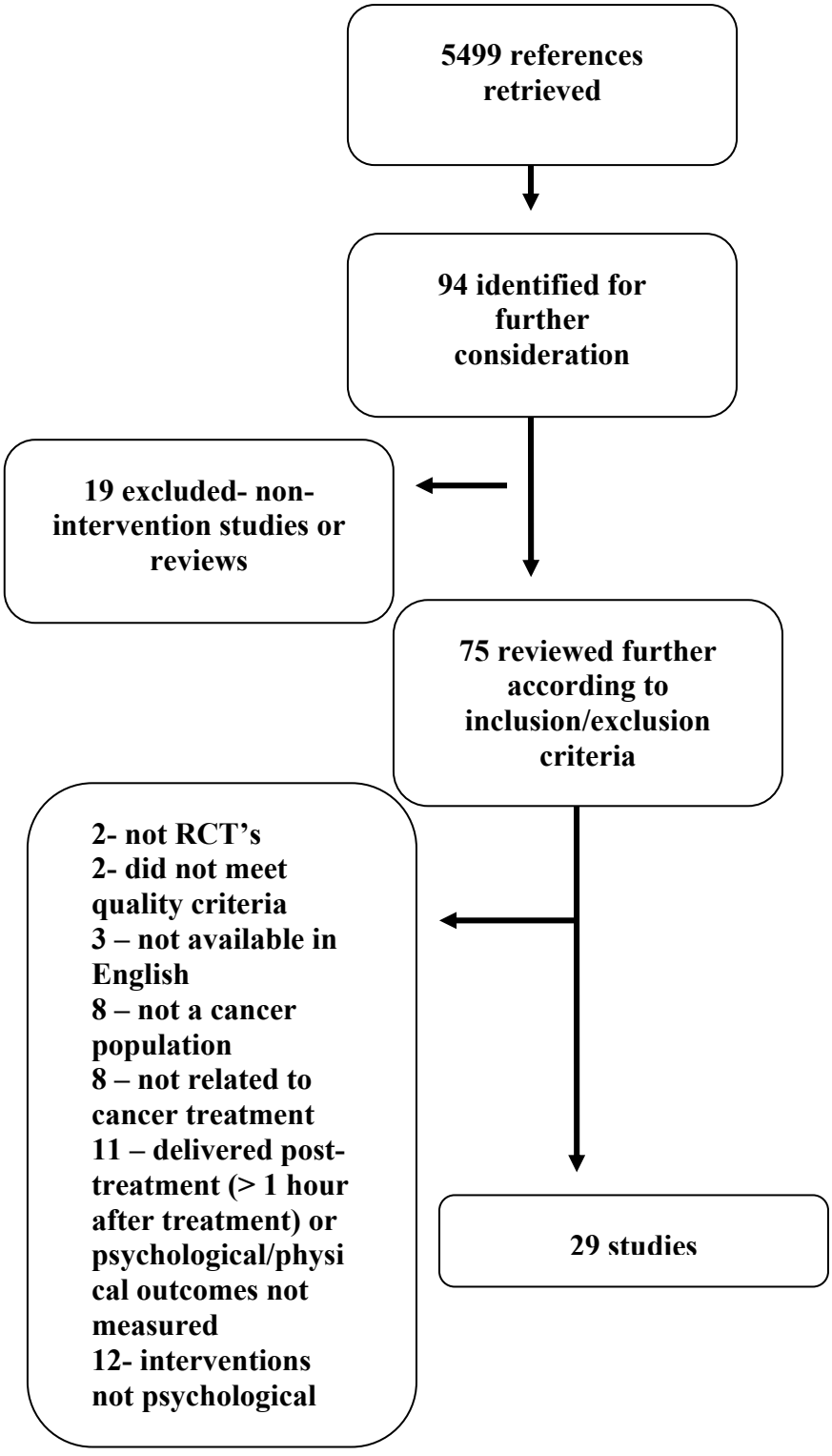

Figure 1. Process of selection for suitable studies

Relaxation studies

Fifteen relaxation interventions were reviewed. Four interventions (Syrjala, Donaldson, Davis, Kippes & Carr, 1995; Burish, Snyder & Jenkins, 1991; Walker et al., 1999; Yoo, Ahn, Kim, Kim & Han, 2005) scored poorly on quality and were thus weighted less in the review.

The majority of studies compared an intervention and control group. One study separately evaluated the delivery of the same intervention by clinical psychologists or clinical oncologists and oncology nurses, and compared these to a control group (Morrow et al., 1992). Burish and Jenkins (1992) evaluated five different types of interventions in a six-group design. These interventions involved various combinations of Electromyographic (EMG) biofeedback, skin-temperature (ST) biofeedback, no biofeedback and the provision and non-provision of relaxation training.

The interventions incorporated a number of different relaxation components (see appendix 10). Progressive muscle relaxation and guided imagery were the most commonly utilised relaxation techniques. The time points at which the interventions were delivered were diverse: including (1) from a few weeks to or a few hours prior to treatment (2) at the same time as treatment (3) mid-way through treatment and (4) immediately following treatment (to view further details of the studies refer to Table 2 and the measures used by studies are listed in appendix 4).

Psychological outcomes

Eleven of the 14 relaxation studies evaluated psychological outcomes, either by assessing emotional reactions to treatment or coping strategies. Relaxation interventions seemed to be effective in promoting changes in psychological outcomes in the desirable direction. Of these 11 studies, all but one found significant changes in psychological outcomes as a result of the intervention.

Morrow and colleagues (1992) found that a systematic desensitisation and progressive muscle relaxation intervention did not significantly reduce anxiety in chemotherapy patients compared to the control group. It is worth noting that this study's primary objective was to reduce anticipatory nausea and vomiting (ANV), and thus patients with these symptoms were selected. Therefore, an improvement in anxiety may not have been a prime objective of this intervention. In contrast, Burish and Jenkins (1992) whose intervention also aimed to reduce ANV and which also selected participants suffering with these symptoms did report a significant reduction in anxiety in the intervention group compared to the control group. A comparison of the components of these interventions shows that Burish and Jenkins (1992) offered guided imagery, while this was not utilised by Morrow and colleagues (1992).

Seven studies reported a significant reduction in anxiety as a result of the relaxation interventions (Leon-Pizarro et al., 2007; Nunes et al., 2007; Yoo et al., 2005; Arawaka, 1997; Burish & Jenkins, 1992; Burish et al., 1991; Lerman et al., 1990). However, reductions in anxiety were not always found at all time points. For example, Burish and Jenkins (1992) found that relaxation patients had significantly less anxiety than non-relaxation intervention patients for the fifth session of chemotherapy only. Lerman et al. (1990) investigated the influence of personality style, and found that

individuals with a blunting coping style who received the intervention had a significant reduction in anxiety before chemotherapy when compared to the control group. The findings for depression were more mixed. Two studies reported that their interventions significantly lowered depression compared to the control group (Leon-Pizarro et al., 2007; Nunes et al., 2007), while three studies failed to find any significant results (Lerman et al., 1990; Molassiotis, Kangas, David, Hallquist & Green., 2002; Yoo et al., 2005).

Relaxation interventions were also found to significantly reduce self-reported stress (Nunes et al., 2007), overall mood disturbance (Molassiotis et al., 2001), anger and tension (Decker, Cline-Elsen & Gallagher, 1992). There were other psychological outcomes in which no significant change was demonstrated, such as tension and anger (Molassitotis et al., 2001) and hostility (Yoo et al., 2005).

Treatment-related symptoms

Eight of the studies measured symptom severity as an outcome. In all but one study the main symptoms of interest were nausea and/or vomiting as a result of chemotherapy treatment. All studies reported a reduction in some aspect of nausea and/or vomiting outcomes, although significant outcomes were not found in all measures of nausea used in the studies or at all time points assessed.

Three studies found no differences in vomiting frequency (Vasterling, Jenkins, Tope, Burish, 1993; Arakawa, 1997; Burish & Jenkins, 1992) and one study reported no differences in the intensity of vomiting (Molassiotis et al., 2002). However, two studies reported significantly lower levels of vomiting in the intervention group (Molassiotis et

al., 2002; Burish et al., 1991) and two reported that the duration of vomiting was significantly less in the intervention group (Molassiotis et al., 2002; Morrow et al., 1992).

Four studies significantly reduced the duration of nausea (Molassiotis et al., 2002; Morrow et al., 1992; Lerman et al., 1990; Vasterling et al., 1993) and the severity or mean scores of nausea were found to be significantly lower in five studies as a result of the intervention (Yoo et al., 2005; Arakawa, 1997; Burish et al., 1991, Morrow et al., 1992; Burish & Jenkins, 1992). However, for some studies these significant differences were only found at particular time points (Burish et al., 1992; Lerman et al., 1990; Yoo et al., 2005; Vasterling et al., 1993). For example, Burish and Jenkins (1992) found these significant differences for the last three chemotherapy sessions only.

Burish and Jenkins. (1992) evaluated five different combinations of interventions which comprised of electromyographic biofeedback (EMG) or skin temperature (ST) feedback combined with or without relaxation. This study found significantly lower nausea in those interventions consisting of relaxation alone or relaxation combined with biofeedback, compared to the control and biofeedback only groups. Syrjala and colleagues (1995) measured pain associated with bone marrow transplant treatment and found that those in the intervention group who received training in progressive muscle relaxation, guided imagery and deep breathing reported significantly less pain than patients in the control group, but not compared to the supportive attention group.

Quality of life.

Quality of life outcomes were assessed by three studies (Leon-Pizarro et al., 2007; Walker et al, 1999; Yoo et al., 2005). In the study by Leon-Pizarro and colleagues (2007) the body discomfort component of the quality of life measure was found to be

significantly less at post-treatment in the intervention group compared to the control group. Two poorer quality interventions found that the intervention group had significantly better overall quality of life compared to the control group (Walker et al., 1999) and intervention participants were found to have a more positive quality of life in relation to the physical and emotional concerns for breast cancer (Yoo et al., 2005) compared to the control group. In the latter study these differences in quality of life were maintained at six months follow-up.

Hypnosis interventions

The components of the hypnosis interventions are shown in Table 2. In this section four interventions are reviewed. Two are solely hypnosis/hypnotherapy (Stalpers et al., 2005; Syrjala, Cunnings & Donaldson, 1992) and two are hypnosis combined with cognitive-behavioural techniques (Schnur et al., 2009; Montgomery et al., 2009). None of the studies or interventions was rated as poor. All interventions comprised one-to-one individual sessions and offered two pre-treatment intervention contacts. Of these four interventions, two assessed treatment-related symptom outcomes (Montgomery et al., 2009, Syrjala et al., 1992), two psychological outcomes (Schnur et al., 2009; Stalpers et al., 2005) and one quality of life outcomes (Stalpers et al., 2005).

Psychological outcomes

Schnur and colleagues (2009) used the Mood Report Form to measure positive (happy, pleased) and negative (unhappy, depressed, frustrated) affect. This study found that the hypnosis and cognitive-behavioural intervention significantly reduced negative affect and

increased positive affect in patients receiving radiotherapy. Additionally, compared to the control group, the intervention group had significantly more intense positive affect and significantly less intense negative affect, and a greater number of days when they experienced more positive affect than negative affect (Schnur et al., 2009). In contrast, Stalpers et al. (2005) reported no change in the levels of anxiety between the intervention and control group for radiotherapy treatment.

Treatment-related symptoms

Side effects targeted by interventions included fatigue and muscle weakness as a result of radiotherapy (Montgomery et al., 2009), and oral pain and nausea as a consequence of bone marrow transplant treatment (Syrjala et al., 1992). Montgomery and colleagues (2009) reported a significant effect on rate of change in fatigue during treatment. Participants in the hypnosis and cognitive-behavioural group were not found to have increases in fatigue over time whereas there were linear increases of fatigue in the control group (Montgomery et al., 2009). Similarly, increases in muscle weakness were lower in the intervention group compared to the control group. An earlier study, found that participants in the hypnosis group had significantly lower pain compared to the cognitive-behavioural intervention and attention support control group (Syrjala et al., 1992). However, no differences were reported for nausea (Syrjala et al., 1992).

Quality of life outcomes

Stalpers and colleagues (2005) investigated the impact of their hypnosis intervention on quality of life outcomes. The study found no differences between the intervention and control group on the SF-36. It was suggested by the authors that perhaps the measure utilised was too insensitive to measure change in wellbeing over time. The authors also noted that at baseline the scores on the mental health component of the SF-36 were high, leaving little room for further improvement.

Cognitive-behavioural interventions

Four studies described their interventions as cognitive behavioural (Given et al., 2004; Syrjala et al., 1995; Phillips et al., 1998; Syrjala et al., 1992), four explicitly used the term cognitive-behavioural or cognitive in relation to the key strategies utilised in the intervention (Parker et al., 2009; Armes, Chalder, Addington-Hall, Richardson & Hotopf, 2007; Brown et al., 2006; Vasterling et al., 1993). There were five studies (Ream, Richardson & Alexander-Dann, 2006; Krischer, Xu, Meade & Jacobsen, 2007; Jacobsen et al., 2002; Larson, Duberstein, Talbot, Caldwell & Moynihan, 2000; Burton & Parker, 1995) which did not identify their interventions as cognitive. However, upon examination of the components of these interventions (see appendix 11 & 13) four interventions (Jacobsen et al., 2002 (professionally-administered stress management training (PSMT) and self-administered stress management training (SSMT)); Larson et al., 2000; Krischer et al., 2007), were not dissimilar in content to the cognitive-behavioural interventions. In fact, two of these studies had interventions which could be categorised as well-defined cognitive-behavioural interventions. Therefore, it was

decided that these three interventions would also be included in this section of the review. In total, 12 interventions were evaluated in this section (appendices 12, 13 and 14 show the various components of the interventions). Three studies did not incorporate relaxation strategies in their cognitive-behavioural interventions (Armes et al., 2007; Given et al., 2004; Vasterling et al., 1993). Two interventions were group-based and two interventions were self-administered. The time-points at which interventions were introduced were diverse, including before treatment, just prior to and during treatment (see Table 2 for characteristics of the studies and appendix 4 for the measures utilised).

Using the criteria described in the methods section for cognitive-behavioural interventions (see appendix 11), three studies fulfilled the criteria to be classified as well-defined (Jacobsen et al., 2002 (PMST); Larson et al., 2000; Armes et al., 2007). Four interventions were found to only fulfil one criterion for cognitive-behavioural interventions (Brown et al., 2006; Given et al., 2004; Parker et al., 2009; Vasterling et al., 1993) and these were weighted less.

Psychological outcomes

The evidence regarding the impact of cognitive-behavioural interventions on psychological outcomes was mixed. Anxiety and depression were measured by six studies. Three studies reported significant improvements in the intervention group on psychological outcomes compared to the control groups. Intervention groups were found to report less anxiety and depression during chemotherapy (Jacobsen et al., 2002 (SSMT)) and had lower disgust scores (Larson et al., 2000). A poorly defined cognitive-behavioural intervention was found to significantly reduce mood disturbance before surgery (Parker et al., 2009) compared to the control group. Significant differences in

outcomes were sometimes not found for the whole sample but for sub-groups. Krischer and colleagues (2007) found that significantly less depression in the intervention group was only evident when comparing highly distressed participants in the intervention and control groups. For some studies significant differences were not found for all psychological outcomes, including traumatic stress (Larson et al., 2000; Parker et al., 2009) and depression (Larson et al., 2000). Three interventions failed to detect any changes in psychological outcomes (Armes et al., 2007; Jacobsen et al., 2002 (PSMT); Syrjala et al., 1995).

Treatment-related symptoms

The symptoms considered included fatigue (Armes et al., 2007; Brown et al., 2006), pain (Syrjala et al., 1992; Syrjala et al., 1995), nausea (Syrjala et al., 1995; Syrjala et al., 1992; Vasterling et al., 1993), symptom severity (Given et al., 2004) and vomiting (Vasterling et al., 1993, Syrjala et al., 1992). Armes and colleagues (2007) reported a trend towards improved cancer-related fatigue in the intervention group and reported significant results in favour of the intervention group at four week follow-up compared to the control group. At week eight, Brown et al. (2006) found that the intervention group (poorly defined cognitive-behavioural intervention) reported significantly less fatigue than the control group. Differences in fatigue were not found for all measures of fatigue or at all time points.

Participants in a distraction intervention (poorly defined cognitive-behavioural intervention) reported less nausea prior to and during the first four cycles of chemotherapy (Vasterling et al., 1993). In contrast a few studies reported no differences

in nausea (Jacobsen et al., 2002; Syrjala et al., 1992; Syrjala et al., 1995) or frequency of vomiting (Syrjala et al., 1992; Vasterling et al., 1993).

Significantly less pain was reported in patients having bone marrow transplant treatment in the intervention group than the treatment as usual group, but not when compared to the "supportive attention" control group in a study by Syrjala and colleagues (1995). An earlier study reported no significant differences in pain (Syjala et al., 1992). Finally, a poorly defined cognitive-behavioural intervention was found to significantly lower symptom severity in participants who entered the trial with high levels of severity compared to the control group (Given et al., 2004).

Quality of life

The most common measure used to assess quality of life was the SF-36 (Ware & Sherbourne, 1992). This was utilised by four studies for five interventions (Krischer et al., 2007; Larson et al., 2000; Parker et al., 2009; Jacobsen et al., 2002). The SF-36 contains eight multi-item scales including general health perceptions, physical functioning, role limitations due to physical problems, bodily pain, general mental health, vitality, role limitations due to emotional problems, and social functioning. It is worth noting that studies which reported significant findings only found these for some of the subscales. Jacobsen et al. (2002) reported that the SSMT intervention group reported significantly better physical functioning, greater vitality and fewer role limitations because of emotional problems associated with chemotherapy treatment compared to the control group. However, no significant findings were found for the PSMT intervention. Krischer and colleagues (2007) found that participants with higher levels of distress at the initiation of radiotherapy and who received the intervention, reported significant

improvements in the mental health subscale. Parker et al. (2009) reported that their intervention group (poorly defined cognitive-behavioural intervention) had significantly better physical functioning at one year follow-up compared to the control group following radical prostatectomy treatment. However, no significant differences were found on the Prostate Cancer Index. Finally, Larson and colleagues reported no significant changes in quality of life using the SF-36. Using other measures, Armes and colleagues (2007) found improvements in the EORTC physical functioning at four weeks and nine months follow-up in chemotherapy patients.

Supportive interventions

The remaining six interventions were supportive in nature (Ream et al., 2006; Gaston-Johansson et al., 2000; Burton & Parker, 1995; and Burish et al., 1991). Ream and colleagues (2006) provided a "support intervention" and Gaston-Johansson and colleagues (2000) a "comprehensive coping strategy program" (see Table 2 for further details of the interventions). Burish et al. (1991) offered a "PREP" intervention which aimed to provide information and to elicit and address patients concerns about treatment. Burton and Parker (1995) contributed three interventions, all of which comprised a pre-operative session but with varying additional components. One group received the pre-operative session only, while another group received an additional non-therapeutic chat, and another group received an addition psychotherapeutic session.

Psychological and quality of life outcomes

Ream and colleagues (2006) found that patients receiving chemotherapy in the supportive group reported significantly less depression and anxiety compared to the control group. Burish et al. (1991) found that patients in the PREP intervention, which was rated as poor in quality, were found to have significantly less depression prior to treatment chemotherapy sessions. No differences in psychological outcomes were reported by Gaston-Johansson and associates (2000). The analysis of interview data by Burton and Parker (1995) found that participants who received the pre-operative session for mastectomy treatment had lower body image distress, lower depression and anxiety, and at one year follow-up had less worry and more fighting spirit compared to the control group. For participants identified as having stressful life events those who received the additional psychotherapeutic chat reported significantly lower distress. Ream and colleagues (2006) found that the intervention group had significantly higher perceptions of coping, used significantly more humour and less behaviour engagement compared to the control group. This study also found that intervention group had significantly greater vigour and better mental health compared to the control group.

Treatment-related symptoms

The side effects evaluated in these studies were fatigue (Gaston-Johansson et al., 2000; Ream et al., 2006), nausea (Burish et al., 1991; Gaston-Johansson et al., 2000), pain (Gaston-Johansson et al., 2000) and vomiting (Burish et al., 1991). Ream et al. (2006) found that the intervention group reported significantly less chemotherapy-related fatigue, lower fatigue-related distress, and less impact of fatigue on valued past-times compared

to the control group. In contrast, once Gaston-Johansson and associates (2000) controlled demographic variables there were no significant differences between the groups on fatigue outcomes for patients having autotologous bone marrow transplantation.

Burish and colleagues (1991) found that the PREP group had significantly lower levels of anticipatory nausea at all sessions of chemotherapy and vomited significantly less following chemotherapy. Gaston-Johansson et al. (2000) found that seven days after autotologous bone marrow transplantation the intervention group had significantly lower nausea than the control group. In relation to pain, no significant differences were reported by this study.

Comparisons of different interventions

Six studies made comparisons between different types of interventions (Burish et al., 1991; Burish & Jenkins, 1992; Jacobsen et al., 2002; Vasterling et al., 1992; Syrjala et al., 1992; Syrjala et al., 1995).

Burish et al. (1992) compared five interventions. These involved different combinations of EMG biofeedback, ST biofeedback, no biofeedback and the provision and non-provision of relaxation training. This study found participants who received relaxation training reported significantly less nausea in the last three chemotherapy sessions and less anxiety compared to non-relaxation groups. The authors concluded that relaxation training and not biofeedback were the active ingredients of the intervention which produced change.

Jacobsen and colleagues (2002) compared self-administered stress management training and professionally-administered stress management training. It was found that the self-administered intervention reported significantly better quality of life outcomes

when compared to the control group in patients receiving chemotherapy. The professionally-administered group was not found to significantly differ compared to the control group. The authors suggested that self-administered intervention may have promoted greater mastery in the participants and the patient testimonies, which were absent from the professional-administered intervention, may have through a process of modelling provided participants with a greater perception of the effectiveness and usefulness of relaxation techniques in improving quality of life.

Syrjala et al. (1995) compared a relaxation training intervention with a cognitive-behavioural intervention on patients receiving bone marrow transplant. The cognitive behavioural intervention also encompassed the complete relaxation training element of the other intervention. It was found that both interventions significantly reduced pain but had no effect on nausea compared to the control group. In this study the cognitive-behavioural components did not provide an additive affect beyond that of relaxation training alone. Syrjala et al. (1992) compared a hypnosis and CBT intervention. Analyses indicated that the hypnosis intervention group reported significantly less pain than the cognitive-behavioural group. However, no differences were found in nausea, emesis or opoid use for bone marrow transplant patients.

Vasterling and colleagues (1993) reported that both a relaxation training and distraction intervention resulted in significantly less nausea as they awaited their chemotherapy before the first and follow-up session compared to the control group. Burish et al. (1991) compared a coping intervention 'PREP' with a relaxation intervention, and a group who received both interventions. It was found that patients who received the PREP intervention were significantly more knowledgeable about the treatment, reported significantly less anticipatory nausea, were less depressed before treatment sessions and had significantly less interruption in their daily lives. Patients who

received the relaxation training reported significantly lower levels of anticipatory nausea across all sessions, had significantly less anxiety at session one and two of chemotherapy. Patients who received the PREP combined with relaxation training intervention had significantly less vomiting after chemotherapy compared to the control group.

Table 2. Characteristics and main findings of included studies

Authors/year / country/ treatment/ arms of trial	Description of sample	Intervention format	Intervention components	Control group	Outcomes			Main findings	Quality Score	
					Psych	Side effects	QoL		Int	Study
Montgomery / 2009 / America / radiotherapy / IG and CG **Hypnotherapy**	Breast cancer 42 (22 in IG & 20 CG)	2 pre-treatment sessions (15-30 minutes) and twice weekly booster sessions (5-15 minutes)	Individual format **Hypnosis:** Hypnotic induction Guided imagery Suggestions Cue word to induce individual hypnosis Audio of session **CBT:** Recognising negative beliefs Alternative more helpful belief Activity scheduling CBT workbook Weekly thought records	TAU		✓		IG had significant effect on fatigue over the course of the treatment. CG had significant increases in fatigue, while IG remained unchanged. Rate of increase in muscle weakness was significantly lower in IG compared to CG.	4	20
Parker / 2009 / America / radical prostatectomy / IG, SA, CG **CB**	Prostate cancer 159 participants, 53 in IG, 54 in SA, 52 in SC	2 pre-treatment sessions (60-90 minutes), 2 booster (10-12 minutes), including one	Individual format Deep breathing Guided imagery Imaginal exposure Audio Daily practice Coping skills Social support	SA & TAU	✓		✓	IG group had significantly less mood disturbance prior to surgery compared to CG. IG group had significantly higher scores on the physical	4	19

		after treatment.	Concerns and fears			component of the SF-36 compared to the CG. Significant findings only found between IG and CG, but not in relation to SA.		
Schnur / 2009 / America / radiotherapy / IG and CG **Hypnotherapy**	Breast cancer 40 participants (20 in IG and 20 in CG)	2 pre-treatment sessions (15-30 minutes) and twice weekly booster sessions (5-15 minutes)	**Hypnosis & CBT** Hypnotic induction Guided imager Suggestions Cue word to induce hypnosis Audio of session Negative beliefs Alternative beliefs Behavioural strategies CBT workbook Thought records	TAU	✓	IG significantly reduced levels of negative affect (every week) and increased levels of positive affect (week 1, 2, 3 &5).	7	18
Phillips / 2008 / America / mastectomy, lumpectomy, chemotherapy, radiotherapy / IG & CG **CB**	Breast cancer 128 participants (63 IG and 65 CG)	Unreported when started. 10 weekly 2-hour sessions Delivered by trained female facilitators	Group format Deep breathing Guided imagery Meditation Progressive muscle relaxation Daily practice Coping skills Cognitive restructuring Assertion training Social support	condensed seminar of intervention.	✓	IG had significantly greater reductions in cortisol levels across 12 months compared to CG- cautious interpretation. IG reported greater increases in ability to relax than controls- non significant	5	8

Armes /2007 / UK / chemotherapy / IG and CG **CB**	Various cancers. 60 (30 in CG and 30 in IG). Only 55 completed baseline assessments	Started just prior to treatment. 3 individual face-to-face, 60 minute sessions at 3 to 4 weekly intervals	Individual format Coping skills Alternative illness perceptions Identifying thoughts and feelings Self-monitoring Distraction Activity scheduling Written information	TAU	✓	✓		Significant improvement in physical functioning in IG at 4 weeks and 9 months. Significant differences in fatigue inventory at 4 weeks and 9 months. IG increased activity levels. No differences on other fatigue outcomes	8	18
Krischer / 2007 / America / radiotherapy / IG & CG **CB**	Various cancers. 310 participants (154 in IG and 156 in CG)	Self-administered Nurse gave materials	Self administered Paced breathing Guided imagery Progressive muscle relaxation Audio Self statements Thought monitoring Written Videotape	TAU	✓		✓	Participants with high levels of psychological distress reported significant improvements in their SF-36 mental health subscale and depression compared to the CG.	5	15
Leon-Pizarro / 2007 / Spain / brachytherapy / IG & CG *Psycho-oncology* **Relaxation**	Breast cancer and gynaecological cancers 66 (32 in IG and 34 in CG)	Pre-treatment. Single session 2 weeks prior to treatment	Individual format Guided imagery Deep breathing Audio, Daily practice Information provision and elicitation of concerns- the same as control group	Information provision & elicitat of concerns.	✓		✓	Compared with the control group the IG demonstrated a statistically significant reduction in anxiety, depression and body discomfort	3	15

Nunes / 2007 / Brazil / radiotherapy/ IG & CG/ **Relaxation**	Breast cancer 34 (20 in EG & 14 in CG)	24 daily 30 min structured groups (4 participants) delivered immediately following treatment Provider: Psychologist	Group format Progressive muscle relaxation Guided imagery Deep breathing Meditation Tumour visualisation Audio Daily practice	TAU	✓			IG showed significantly reduced levels of stress, anxiety and depression scores following the intervention. Cortisol levels as well as proliferation and sensitivity to glucocorticoid remained unchanged.	5	11
Brown / 2006 / America / Radiation therapy / IG & CG **CB**	Various cancers- Intermediate to advanced cancer. 115 participants (49 in IG and 54 in CG)	Unclear when started. 8x90 minute sessions over 4 weeks. Provider: Psychiatrist / psychologist Co-facilitated by nurse, chaplain, or social worker		TAU		✓		Intervention participants reported significantly less fatigue No other significant differences were found between the groups on outcomes.	8	15
Ream / 2006 / Uk / chemotherapy / IG and CG **Supportive**	Various cancers- 103 participants (IG 48, CG 55).	Provided over first 3 treatment cycles. W Weekly visits by support	Fatigue diary- monitor fatigue Education- exercising, relaxation, sleep enhancement Information pack	TAU	✓	✓	✓	IG reported significantly less fatigue, lower distress and less impact of fatigue on pastimes compared to CG. IG reported significantly	5	17

		nurse	Coaching self-care					less anxiety and depression and used more adaptive coping compared to CG.		
Stalpers / 2005 / Netherlands / radiotherapy / IG and CG **Hypnotherapy**	Various cancers-69 participants (IG 33, CG 36)	Pre-treatment and during treatment. Sessions at intake before 1st treatment and mid-way through Provider: Hypnotherapist	Describing a safe and secure place Symptoms discussed Progressive muscle relaxation Passive imagination Audio of session	TAU	✓		✓	No statistically significant differences found in anxiety and QOL between the groups. Analysis of interview data found that the IG group reported significantly greater improvements in mental and overall well-being.	6	14
Yoo / 2005 / South Korea/ chemotherapy / IG & CG **Relaxation**	Breast cancer 60 participants (30 in each group)	6 sessions – 1 hour duration prior to treatment Provider: Therapist	Individual format Progressive muscle relaxation Guided imagery Daily practice	TAU	✓	✓	✓	IG reported significantly less anxiety, depression and hostility than control group. IG experienced significantly less anticipatory and post-chemotherapy vomiting and nausea. At 6 months, quality of life in the IG was significantly higher on physical, emotional, concerns for breast cancer and overall.	3	14

Given / 2004 / America / chemotherapy / IG and CG **CB**	Various-breast, colon, lung, other (IG 97, CG, 94)	10 contact 20 week programme started prior to treatment. Provider: Nurse	Individual format Problem solving Self-management information Counselling	TAU		✓		Patients in IG who at baseline had higher reports of symptom severity reported significantly lower severity compared to the CG at 10 and 20 weeks	8	10
Jacobsen / 2002 / America / chemotherapy / Professionally administered stress management training (PSMT), self-administered stress management training (SSMT), CG **CB**	Various cancers-. 411 – CG 137, PSMT 134, SSMT 140.	PSMT- 60 minute session prior to treatment and 5 mins before 1st cycle SSMT- 10 minutes to give materials and 5 mins before 1st cycle	**PSMT** Individual format Deep breathing Guided imagery Progressive muscle relaxation Audio Self statements Identifying thoughts and feelings **SSMT** Self-administered Guided imagery Progressive muscle relaxation Audio Self statements Written Videotape	TAU	✓	✓	✓	SSMT compared to CG had significantly larger improvements on the mental component, physical functioning, vitality, role-emotional and mental health components of the SF-36. The SSMT also produced significantly greater reduction in anxiety and Depression.	9	18
Molassiotis / 2001 / Hong Kong /	Breast cancer 71	PMR session 1 hour before chemotherap	Individual format Progressive muscle relaxation	Therapist talked to	✓	✓		IG decreased duration of nausea and vomiting compared with control	5	15

chemotherapy / IG & CG **Relaxation**	participants (38 in IG & 33 in CG)	y and then every afternoon for 6 post-treatment days. Duration of sessions 25 mins. In total 36 sessions Provider: oncology nurse	Guided imagery Deep breathing Audio Video Daily practice	control participants prior to chemotherapy				group- these effects significant for first 4 days post chemotherapy. Significantly less severe overall mood disturbance over time in the IG.		
Gaston-Johansson / 2000 / America / Bone marrow transplantation / IG & CG **Supportive**	Breast cancer 110 participants (52 in IG and 58 in CG)	Session 2 weeks before hospital admission. Reinforced by brief contact. Main provider: clinical social worker. Reinforced by ABMT oncology nurse or project investigators.	Preparation information Education about pain and techniques to decrease pain and emotional distress Cognitive restructuring Positive self-statements Brief muscle relaxation Imagery Audiotape	TAU	✓	✓		No significant differences between the groups on pain or psychological outcomes. The IG reported significantly less nausea than the CG 7 days after treatment even when controlling for demographic variables.	4	13

Larson / 2000 / America / Surgery including radiotherapy and chemotherapy / IG & CG **CB**	Breast cancer 41 participants - 18 control & 23 intervention	Unclear when started. 2 90 minute sessions Most individually and a few in small groups (2-3) Provider: Clinical psychologists	Individual format and group format (participants only attended one) Progressive muscle relaxation Audio Daily practice Coping skills Cognitive restructuring Alternative illness perceptions Goal setting Identifying thoughts and feelings Self-monitoring Distraction Psychoeducation about stress Activity scheduling	TAU	✓		✓	Missing data meant that there were small sample sizes in the analysis. Evidence of suppression of interferon (IFN~y) in CG but not in the IG- however did not remain significant when baseline differences taken into account. Patients in the intervention group had significant decreases over time in measure of disgust.	4	11
Kolcaba / 1999 / America / radiotherapy / IG & CG **Relaxation**	Breast cancer 53 participants (26 in IG & 27 in CG)	Given tape (unsure when) and instructions	Self administered Guided imagery Audio Written Daily practice	TAU	✓			Significantly higher comfort scores for the IG across all time points. Qualitative feedback from diaries and telephone contact found that women often developed a routine for	5	9

							relaxation practice.		
Walker / 1999 / UK / chemotherapy / IG & CG **Relaxation**	Breast cancer 96 participants (48 in each group)	First 40 women in IG had five live training sessions during treatment. Intervention started before treatment-not specified when.	Individual format Progressive muscle relaxation Guided imagery Cue-controlled Tumour visualisation Audio Daily practice Diary	TAU	✓	✓	IG significantly more relaxed during study and had significantly better QoL. IG had significantly reduced emotional suppression. No differences on clinical or pathological outcomes but imagery ratings correlated with clinical response.	3	18
Arakawa / 1997 / Japan / chemotherapy / IG & CG **Relaxation**	Various cancers. 60 participants (30 in each group)	First session 45-60mins Daily (25 min) observation of participants PMR techniques. Not specified when intervention begins or ends	Individual format Progressive muscle relaxation Audio Daily practice	10-15 minutes daily to discuss concerns	✓	✓	IG had significantly lower nausea & vomiting scores 36 hours after initiation of chemotherapy. Similarly 48 hours after onset of chemotherapy the IG had statistically lower mean score of nausea. No differences reported in the rates of vomiting. IG significantly lower mean scores of post-treatment state anxiety.	6	11
Burton / 1995 / UK /	Breast Cancer	45 minute preoperative	Preoperative interview: Discussed diagnosis,	TAU & SA	✓		Preoperative interview-lasting effect on body	4	10

mastectomy / 4 groups- 1) preoperative interview, preoperative interview 2) preoperative interview and chat 3) preoperative interview and psychotherapeutic session, 4) CG **Supportive**	244 participants (group 1, 64; group 2, 62; group 3, 61; group 4, 57).	interview afternoon before surgery. Psychotherapeutic session or chat for 30 minutes on evening before surgery	worries, social support, stressful life events, past regrets and concerns. Psychotherapeutic chat: placed illness and surgery in patients life situation and explored feelings.	(chat evening prior to surgery)		image and distress. At 3 months and 1 year follow-up CG greater body distress compared to other groups. CG higher overall distress at 3 months 1 year follow-up in, CG higher scores on loss of breast and partner response and total number of worries. CG significantly less fighting spirit in 1 month follow-up. 3 months follow-up psychotherapeutic session superior to the chat for those participants who had experiences stressful life events.		
Syrjala / 1995 / America / bone marrow transplant / CG, therapist support, RT, CBT&RT **Relaxation**	Leukaemia, myelodysplasia, lymphoma 94 participants (CG 23, therapist support 24,	Both interventions 2 pre-hospital training sessions (unclear when) and then twice a week 20-40	**Relaxation:** Progressive muscle relaxation Guided imagery Deep breathing Audio Written Daily practice **Cognitive-**	TAU & SA (therapist equivalent time as intervention	✓	CB&RT and RT groups reported significantly less pain than CG. CBT&RT group did not have additive effects beyond the RT group.	9	15

CB	RT 23, CBT&RT 24).	mins booster sessions for first 5 weeks of treatment	**behavioural**: Same as relaxation above and cognitive restructuring, self statements, distraction, activity scheduling, written information. Also included pain and theory and mechanisms of nausea.	giving support)					
Vasterling / 1993 / America / chemotherapy / high anxiety CG, high anxiety RT, high anxiety distraction, low anxiety CG, low anxiety RT and low anxiety distraction **Relaxation CB**	Various cancers: 60 participants (10 in each group)	Sessions provided after chemotherapy started for sessions 2,3 and 4. RT :3 sessions provided before chemotherapy- 45 minutes Distraction: 3 sessions provided before chemotherapy - 20 minutes	Individual format Relaxation: Progressive muscle relaxation Guided imagery Cognitive distraction	Control group given time to rest quietly before treatment started	✓	✓	Distraction group and RT group reported significantly less nausea prior to first and follow-up chemotherapy sessions. Both groups also had and significantly lower systolic blood pressure after the first and second sessions and for the RT group also for the third session. RT group had significantly lower diastolic blood pressure compared to the control group during the second session. No significant	4	9

							differences between RT and distraction.		
Burish / 1992 / USA / chemotherapy / 1) RT, 2) EMG, 3) ST, 4) RT+EMG, 5) RT+ST, 6) CG **Relaxation**	Various cancers-81 participants (RT-13, EMG-17, ST-12, RT+EMG-17, RT+ST-12, CG-15)	Biofeedback & RT delivered during treatment in 4 chemotherapy sessions and practice recommended at home. Intervention started mid-way through treatment.	Relaxation Individual format Progressive muscle relaxation Guided imagery Audio Daily practice Biofeedback Biofeedback.	TAU	✓	✓	RT group reported less nausea, reaching signif-icance in the 5th session compared to the other groups. RT and EMG had significantly lower blood pressure across all sessions. ST significantly lower pulse rate than RT. ST & RT significantly lower pulse rate. 5th session RT patients significantly less anxiety than none-RT groups. RT, EMG, RT+EMG & RT+ST significantly lower EMG scores than control group. RT patients during last 3 sessions significantly lower levels of nausea compared to non-RT patients.	3	9
Decker / 1992 / America /	Various cancers-82	6 – 1 hour sessions Unclear	Individual format Progressive muscle relaxation	TAU	✓		Significant decrease in tension & anger for the IG.	4	10

radiotherapy / IG & CG Patients needed to have anticipatory nausea & vomiting to be eligible for inclusion **Relaxation**	participants – 34 in IG & 29 in CG	when started (more details) Provider: 3 graduate students supervised by first author	Deep breathing Cue-controlled Audio Written information Daily practice				There was also a trend towards less depression in the IG. CG had statistically significant increase in fatigue.		
Morrow / 1992 / America / chemotherapy / clinical psychologist intervention (CPI), Medical personnel intervention (MPI) & CG. **Relaxation**	Not specified - Cancer patients with ANV reported- 2 successive experiences. 72 participants (29 in CPI, 29 in MPI, & CG 14).	Two 1 hour sessions between 3rd and 4th chemotherapy treatments Providers: clinical psychologists compared to clinical oncologist or oncology nurses.	Individual format Progressive muscle relaxation Systematic desensitisation Audio Daily practice	TAU	✓	✓	Both interventions were effective in significantly reducing Anticipatory and post-treatment nausea & vomiting severity and duration compared with control group. No differences found between the health personnel used to deliver the interventions	5	11
Syrjala / 1992 /America / bone marrow transplant /	Hematologic malignancy, lymphoma	2 Pre-hospital training sessions (unsure	Hypnosis Hypnotic induction Induction targeting treatment-related pain, nausea and emotional	TAU & SA (therapist support)		✓	Hypnosis group reported significantly less pain when compared to the other groups.	6	11

CG, therapist support, CB, hypnosis) **Hypnotherapy** **CB**	45 participants (CG 10, therapist support 12, CB 11, Hypnosis 12)	when) and then twice a week 20-40 mins booster sessions for first 5 weeks of treatment	reactions Inductions taped and daily practice. Cognitive-behavioural				Nausea, emesis and opioid use did not differ significantly between the groups		
Burish / 1991 / America / chemotherapy / intervention 1 (PREP), intervention 2 (RT), combined (PREP+RT) and control **Relaxation** **Supportive**	Various cancers: 60 (4 arms-15 participants in each)	Intervention 1: 90 minutes before first chemotherapy session Intervention 2: 45 mins before chemotherapy session 1-3. 4-5 self-instruction Combined: both of the above	**PREP** Tour of clinic Concrete and sensory information Video about chemotherapy Procedural information Discuss concerns and feelings Booklet **Relaxation** Individual format Progressive muscle relaxation Guided imagery Written Daily practice	TAU	✓	✓	Participants in the PREP intervention had significantly better knowledge in all areas and significantly lower levels of anticipatory nausea across all sessions. By final session patients in PREP and PREP+RT reported significantly less vomiting after chemotherapy. RT reported less anxiety for most sessions and this was significant for session 1 & 2. PREP group cancer interfered significantly less with their daily lives. PREP and RT groups reported significantly	3	9

							less vomiting at home in first 24 hours after chemotherapy		
Lerman / 1990 / America / chemotherapy / IG & CG **Relaxation**	Various-breast, lung, colon, ovary, Hodgkin and other 48 participants – 25 IG & 23 CG	30 minute session for relaxation training prior to (unclear when) treatment. Providers: Nurses and health educators	Individual format Progressive muscle relaxation Deep breathing Audio Written Daily practice	TAU	✓	✓	No significant differences between monitors and blunters in the use of relaxation. Intervention was effective in reducing the number of hours of nausea subsequent to chemotherapy. An effect of relaxation on anxiety before chemotherapy (data only for 3rd cycle) for participants classified as blunters in the intervention group.	4	12

Key to abbreviations:

CB	Cognitive-behavioural
CG	Control group
EMG	Electromyographic biofeedback
IG	Intervention group
INT	Intervention
Psych	Psychological
QoL	Quality of Life
RT	Relaxation Training
SA	Supportive Attention Group
ST	Skin temperature
TAU	Treatment as usual

Discussion

The aim of this review was to provide an overview of the psychosocial interventions designed to improve psychological and treatment-related symptoms in cancer patients undergoing treatment, and to evaluate the effectiveness of these interventions. Thirty-six interventions were found which were tested in RCTs. The quality of these studies and interventions was generally moderate and two studies were excluded because of poor quality ratings. The interventions were classified in this review as relaxation, hypnosis, cognitive-behavioural and supportive. The most common interventions were either relaxation or cognitive-behavioural.

In general, relaxation interventions provided the most convincing evidence for alleviating anxiety before and during treatment. Seven of the eight studies reported a significant reduction in anxiety as a result of the relaxation intervention. This supports the findings of two previous reviews by Leubbert and colleagues (2001) and Redd et al. (2000) which reported that behavioural interventions had significant effects on psychological adjustment for cancer treatment including anxiety. Therefore, according to the frequently utilised components of the interventions in this review, it can be deduced that relaxation interventions which incorporate at least progressive muscle relaxation, guided imagery, audio recordings and recommend daily practice have a greater chance of being effective. However, a number of factors need to be considered in relation to the findings in this review. Firstly, the effects of relaxation interventions on anxiety were not found at all time points prior to and during treatment and for one study the effects on anxiety were only found for a sub-group of participants (Lerman et al., 1990). Secondly, of the fourteen relaxation studies reviewed, only four conducted a power calculation, and two of these were unable to recruit a sufficient sample size. Thus, it is unclear whether

the majority of studies were adequately powered and therefore caution should be applied to the conclusions drawn. Despite these shortcomings the literature on relaxation interventions appears somewhat convincing and provides some evidence for its potential to influence anxiety. The effect of relaxation interventions on quality of life outcomes also seems promising; however, only three studies incorporated quality of life outcomes and therefore there were too few studies to draw any firm conclusions. In relation to treatment-related side effects and other psychological outcomes the findings were inconclusive.

The findings for the hypnosis and supportive interventions were mixed. The evidence base for these interventions is sparse and future research is needed to discern the effectiveness of these interventions more accurately. It was unclear whether supportive interventions which adopted a general approach were less effective than those interventions which were based on a theoretical approach because of the paucity of studies and mixed findings.

For the cognitive-behavioural interventions the findings were mixed for the psychological, side effects and quality of life outcomes. In terms of the interventions fulfilling the key elements of cognitive-behavioural therapy only three interventions could be classified as well-defined. These three studies, did not, however, seem to be more effective in influencing outcomes. Due to the considerable variability in the quality and the findings of the various studies it is not possible to draw any conclusions for the cognitive-behavioural interventions. The heterogeneity of the content of supportive and cognitive-behavioural interventions would make it difficult to establish if certain elements in the intervention could be essential in improving treatment-related outcomes and distress. In addition, all studies in this review varied considerably in the number of intervention contacts, the timing of contacts and the duration of the intervention.

For some studies the impact of the intervention was only found for later chemotherapy sessions (Burish et al., 1992; Lerman et al., 1990; Yoo et al., 2005). This, perhaps, points to a practice effect, with participants becoming more skilled in the coping skills offered. If this is the case, then perhaps interventions should incorporate pre-treatment sessions, to enable patients to develop coping techniques and prepare them so that they can gain benefits from the beginning of treatment. Follow-ups of at least six months were found in 6 studies (Yoo et al., 2005; Brown et al., 2006; Parker et al., 2009; Phillips et al., 2008; Armes et al., 2007; Burton & Parker, 1995). Of these five reported some differences at follow-up of six months, with some effects being observed at nine months to 12 months follow-up (Parker et al., 2009; Armes et al., 2007). This points to the possibility that interventions delivered prior to and during treatment might have lasting effects. There were only a handful of studies which directly compared different types of interventions, and it was not possible to draw any inferences from these.

Limitations of studies

There are several methodological aspects of these studies that had shortcomings. Very few studies (9; 29%) had a manual to accompany the intervention. In addition, the majority did not measure participants' adherence with coping skills, did not give providers specific intervention training, or check the fidelity of the intervention.

In terms of assessing participants' adherence, if an intervention is not effective then it could be due to the fact that people have not used the strategies learnt outside of the intervention. Furthermore, the increases in psychological mindedness and the rise in the popularity of yoga, relaxation and meditation make it quite feasible that greater numbers of the population may already practice effective coping strategies or use

techniques which are similar to those offered in interventions. This is partly demonstrated by Gaston-Johansson and colleagues (2000), who assessed the existing coping strategies of intervention participants and found that 40% of participants used some type of coping strategy and 30% used relaxation. Therefore, the ineffectiveness of an intervention may be due to the existing coping skills already utilised by the population of interest or patients not using skills/techniques learnt or practiced during intervention sessions.

Only nine studies gave information about the method of randomisation used, and very few studies considered allocation, or measurement bias, or reported power calculations. As it is very difficult in psychosocial trials to blind the participants and therapists, and in most studies data collection was not conducted by an independent person, it is possible that treatment effects could be attributed partly to the outcome expectations of both researcher and patient. Of the 10 studies which reported a power calculation, six studies achieved an adequate sample size. Thus, insufficient power carries a considerable risk that studies may have been unable to demonstrate differences between the groups which are present (Type II error; Pocock, 1983).

In this review only 19% (6) of studies incorporated a follow-up of six months or greater, and this provided very little insight into the expected duration of effects following the delivery of the intervention. Finally, only nine studies had a control group which could be described as an active alternative to the intervention group. In these studies there were instances where differences were not found between the intervention and supportive control groups (e.g Parker et al., 2009), indicating that intervention effects may be attributable to the non-specifics aspects of interventions, and not the specific therapy or coping skills delivered.

Limitations of the review

RCTs were excluded if it was not clearly specified that cancer patients were receiving treatment at the time of the intervention or if the intervention did not aim to address treatment-related symptoms and distress. It cannot be absolutely ruled out that relevant studies have not been missed out. This review is based on published studies only, and hence may be subject to publication bias. The possibility remains that studies which found no effects or negative results might not have been published, and therefore were not included in this review.

Recommendations and future research

There are several methodological aspects of studies evaluating psychosocial interventions for symptoms of cancer treatment that could be improved. Recommendations include having a treatment manual for interventions so that they can be replicated in future studies. Additionally, studies should aim to measure participants' adherence with the techniques of the intervention, train providers and check fidelity of the interventions. These factors would help to improve the quality of interventions. In relation to study design, more attention needs to be paid to reporting the method of randomisation, to limiting allocation and measurement bias, conducting intention-to-treat analyses and reporting power calculations. Every effort should be made to minimise the effect of biases in psychosocial trials, and where possible individuals independent to the research project should be used to randomise participants and / or researchers blind to participants' group allocations should be used to collect data. There is also a need for better reporting of studies, including more detailed descriptions of the interventions and detailing attrition

details in accordance with CONSORT guidelines (Moher, Schulz & Altman, 2001). More comparisons of interventions to attention control groups is needed, so that it can be more clearly determined whether the effects observed are due to the intervention or the non-specifics of contact with a provider/therapists.

At present there are substantial gaps within the literature. The non-existent or short-term follow-up of interventions has resulted in very little understanding of when, whether and how an improvement in treatment-related symptoms or distress deteriorates over time. Thus, for nearly all the studies it is difficult to determine whether improvements observed are sustained for short or long periods of time. A systematic review of psychosocial intervention studies in cancer patients reported that the strongest treatment effect often happens several months after the completion of the intervention (Newell, Sanson-Fisher & Savolainen, 2002). Having a longer term of follow-up in studies would help to establish more clearly the long or short term effects of interventions. The inconsistencies of intervention components within similar interventions, particularly within cognitive-behavioural interventions, hinder the accumulation of evidence that will enable identification of the elements within an intervention that are consistently effective or ineffective. It is also recommended that cognitive-behavioural interventions are designed to match more specifically the elements fundamental to cognitive-behavioural approaches. Researchers developing cognitive-behavioural interventions can be guided by pre-existing criterions, such as those designed by Jones et al. (2010), which outline the key elements that underpin cognitive-behavioural interventions. Such criterions are being used to classify whether interventions match cognitive-behavioural principles (see Jones et al, 2010).

Larger RCTs are required to supplement the initial findings of this review, and to add further information about the effectiveness of different types of interventions. Future

good quality studies are needed to test whether certain interventions have influences on psychological and treatment-related symptoms and to explore the potential mediators for the effects of interventions. It would also be useful to this literature if future studies also investigate the length of intervention which is effective, and to identify the optimal duration and best method of delivery. In particular, whether booster sessions are beneficial and result in greater improvements in desirable outcomes.

It is important to understand why some psychosocial interventions are successful or unsuccessful, and therefore adopting a theoretical approach is recommended. Future research should aim to ascertain for whom interventions might be the most beneficial. Are interventions which prepare patients for treatments and its symptoms more effective if they target patients more susceptible to distress or particular symptoms during treatment. Finally, as suggested by Armes et al. (2007) it needs to be more clearly specified whether interventions are designed to prevent distress or treatment-related symptoms or if they are to treat these.

Clinical implications

There are a variety of interventions available for patients who experience distress and symptoms prior to and during cancer treatment. Relaxation interventions demonstrated the most promising results, achieving significance despite variation in the types of treatments targeted. Relaxation is a skill that with some practice can be learnt and implemented very quickly, enabling individuals to feel greater control in stressful situations. Progressive muscle relaxation, guided imagery, audio materials and recommending daily practice were the most common elements of relaxation interventions, and incorporating these into interventions would be recommended. The

findings for cognitive-behavioural interventions were variable and no firm conclusions can be drawn. The possibility of preparing patients in group formats or using self-administered packages has not been adequately explored but may be of interest to clinicians in terms of cost effectiveness. Interventions to prepare patients for treatments and their symptoms should be routinely incorporated into clinical practice.

Conclusions

Although further research is needed, the present literature seems to suggest that relaxation interventions are generally effective in alleviating treatment-related anxiety. Beyond this, there is little that can be used to guide the design or selection of appropriate interventions. The overall indication is that hypnosis, cognitive-behavioural and supportive interventions have variable success in reducing treatment-related symptoms and distress. The incorporation of a theoretical basis to intervention development and evaluation, and larger good quality RCTs might provide answers to the many unanswered questions in this research area. Such an approach might help to unpack the reasons why an intervention has proven effective or otherwise in reducing treatment-related symptoms.

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Empirical Paper

The impact of a pilot preparation intervention for women undergoing internal radiotherapy treatment for gynaecological cancer on psychological outcomes.

Abstract

Objective: The primary objective of this study was to evaluate the effectiveness of a psychological preparation session, consisting of eliciting concerns, procedural information, cognitive-behavioural and mindfulness techniques, on distress in gynaecological cancer patients undergoing internal radiotherapy treatment. A secondary objective was to determine its impact on illness beliefs and coping strategies, and its feasibility and acceptability as an intervention.

Methods: A controlled before and after study design was used to evaluate this intervention. 19 participants scheduled to receive internal radiotherapy treatment participated in the study. Participants in the control group had treatment as usual. All participants were given questionnaires assessing anxiety and depression (HADS), general mood (SV-POMS), illness beliefs (BIPQ) and coping styles (COPE), which were administered four weeks prior to treatment, five days prior to and the day after treatment.

Results: The intervention group demonstrated a statistically significant reduction in anxiety from baseline to pre-and post-treatment. Analyses of reliable change and clinical significance showed that significantly more patients in the control group experienced deterioration in anxiety and depression compared to the intervention group. Qualitative feedback indicated that patients found the intervention acceptable and helpful, and used coping strategies taught to alleviate distress.

Conclusions: The findings are encouraging and provide evidence of the preparation session's benefits on anxiety and depression among women undergoing an invasive and emotionally challenging treatment.

Keywords: relaxation; cognitive-behavioural; radiotherapy; cancer; oncology

Introduction

The distress and symptoms associated with cancer treatment are well documented (e.g. Roscoe, Morrow, Hickok & Stern, 2000; Stiegelis, Ranchor & Sanderman, 2004; Servaes, Verhagen & Bleijenberg, 2002). Internal radiotherapy treatment (IRT; also called brachytherapy, intracavity radiation) is available for women with gynaecological malignancies. This treatment enables delivery of radiation directly to the site of the cancerous tumour. Applicators designed to hold radioactive sources are inserted into the vagina, and placed into and near the uterus. Patients are hospitalised and radiation protection requires a private room with restricted contact by health professionals only during at least a 24 hour period. Notwithstanding the potential of IRT in treating gynaecological cancers, the procedure is invasive and intimate, and can thus lead to a disturbance in psychosocial functioning.

The distress that women experience during IRT has long been established. Andersen, Karlsson, Anderson and Tewfik (1984) reported that women experienced significant increases in anxiety from a few days to the night before the procedure, and this did not significantly reduce the day after the end of treatment. More recently, Kramer et al. (2007) found that 68% of women scored within the borderline and abnormal ranges of anxiety prior to IRT. This is significantly more than the 10-20% of patients found to experience anxiety prior to external radiotherapy for a range of cancers (see review by Stiegelis et al. 2004). Indeed, research has found that more intrusive medical procedures result in significantly greater anxiety (Aksoy, Ozdemir & Yavuz, 2000). A retrospective study by Warnock (2005) found that 87% of women associated negative states such as anxiety, worry and fear with IRT. Qualitative studies have found that women feel isolated, vulnerable and helpless during IRT treatment (So & Chui, 2007), have a poor

understanding of the procedure and report a discrepancy between their doctor's explanations and their subsequent experiences of treatment (Wray, Markovic & Manderson, 2007).

The literature strongly indicates that women need support to cope with this treatment and this has been reflected by researchers working in this field (see So & Chui, 2007; Velji & Fitch). However, there is very little in the literature about management of pre- and post- psychological distress caused by IRT. Psychosocial interventions have been found to be effective in managing treatment-related symptoms and distress for cancer. Interventions designed to prepare patients for treatment and treatment-related symptoms have included: hypnosis, procedural information, psychoeducation, cognitive-behavioural approaches, relaxation, supportive therapy and counselling (Armes, Chalder, Addington-Hall, Richardson & Hotopf, 2007; Burish, Snyder & Jenkins, 1991; Montgomery et al., 2009; Parker et al., 2009; Phillips et al., 2008; Ream, Richardson & Alexander-Dann, 2006; Stalpers et al., 2005). A meta-analysis reported that relaxation interventions were effective in the management of anxiety, hostility and depression in patients undergoing non-surgical treatments for cancer (Luebbert, Dahme & Hasenebring, 2001). Similarly, a systematic review published the same year also found that behavioural interventions could relieve anxiety and distress in non-surgical and invasive cancer medical treatments (Redd, Montgomery & DuHamel, 2001). Procedural information, behavioural instruction, cognitive and relaxation interventions are more likely to reduce negative affect in patients preparing for surgery (Johnson & Vogele, 1993).

Specifically in relation to IRT, Leon-Pizarro and colleagues (2007) found that women with breast and gynaecological cancer taught relaxation and guided imagery

techniques prior to internal radiotherapy[1] scored significantly lower on anxiety, depression and body discomfort compared to a control group. The authors of this study noted that combining breast and gynaecological cancer patients may have reduced the analytical power of their study, as the experiences of these two groups are different during treatment. For example, greater pain was experienced by gynaecological patients, and during treatment breast cancer patients are able to move around while gynaecological patients must stay in a fixed lying down position. This perhaps indicates there are differences within the treatment experiences of IRT for breast and gynaecological patients. To date, there do not appear to be any studies evaluating the effectiveness of a multifaceted preparation session solely with gynaecological patients having IRT.

Overall, the literature appears to indicate that psychosocial interventions can be effective in reducing the burdens faced by patients prior to and during treatment. Pre-treatment preparation interventions are a means of preparing patients for the physical and psychological difficulties they are likely to face. This type of intervention may reduce psychological distress and improve recovery (Moline, 2000; Contrada, Leventhal & Anderson, 1994). The aim of this pilot study was to evaluate the effects of a psychological pre-treatment preparation session including procedural information, relaxation, mindfulness and cognitive strategies on patient distress. This pilot study would also enable the methodology employed to be tested and along with the findings from this study, could be used to inform the design of a larger definitive trial, should this be appropriate.

[1] Internal radiotherapy for breast cancer involves inserting a radioactive source in the breast

Theory-base of the intervention

The primary aim of the intervention in this study was to reduce women's pre-treatment and post-treatment anxiety. The overall theoretical framework used to guide the selection of strategies used in the intervention was the self-regulation model (Leventhal et al., 1980). This model posits that in response to a health threat (i.e. diagnosis, symptoms, treatment) cognitive and emotional systems are activated in parallel. The emotional system activates feelings such as anxiety, which influence coping strategies to manage the resultant distress. The cognitive system involves the development of illness representations related to the health threat, which are organised around five themes including symptom identity, time-line, cause, consequences and cure / control. These representations influence the coping strategies adopted by an individual to cope with the health threat (Leventhal et al., 1980). If inaccurate illness beliefs are held then an individual may adopt a method of coping that is not helpful for the stressful illness experience (see Horowitz, Rein & Leventhal, 2004).

The strategies adopted for the cognitive system of the self-regulation model were based on Beck's cognitive model of anxiety (Beck, Emery & Greenberg, 1985). This model proposes that individuals suffering from anxiety hold maladaptive distorted cognitions that tend to overestimate the likelihood of threat and underestimated the ability to cope with the threat. In the case of physical health, unlike mental health, beliefs held by individuals may be maladaptive but not involve a distortion because they are well grounded in the reality of ill health experiences (Sage, Sowden, Chorlton & Edeleanu, 2008, Taylor, 2006). Therefore, the focus of the intervention was on unhelpful thoughts and illness beliefs that interfered with patient's ability to cope, and to develop more helpful alternatives. The intervention in this study focused on normalising patient's

experiences of anxiety and influencing illness beliefs by providing women with information about the treatment and psychoeducation about anxiety based on cognitive-behavioural principles. Unhelpful illness beliefs and threat-orientated thoughts were identified and more helpful alternative beliefs developed to help patients to cope more effectively with the treatment process. To facilitate changes action plans were created where individuals set goals for areas of difficulty as part of the distress thermometer (Roth et al, 1998, see p68 for more information on the distress thermometer) and made plans for practicing new techniques.

Different relaxation strategies, such as deep breathing, guided imagery and progressive muscle relaxation, were offered in the intervention to help women to manage the treatment-related distress. Progressive muscle relaxation has been found to promote muscle relaxation (Bernstein & Borkovec, 1973) and guided imagery can reduce psychological distress (Dossey, 1988). Information and practice of brief cognitive and relaxation anxiety management strategies (e.g. deep breathing, coping self-statements, upper body progressive muscle relaxation, brief tense and relax relaxation) was included as quick coping skills that could be used during active treatment when they experienced anxiety.

Mindfulness based interventions are becoming increasingly common in healthcare. Mindful meditations are paying attention to moment-by-moment experiences in a non-judgemental way and with acceptance (Kabat-Zinn, 2003). Mindfulness meditation is a skill that patients can use to cope with the stresses of illness and treatment. A meta-analytic review found that mindfulness-based stress reduction interventions had a moderate effect on the clinical and non-clinical problems of people from patient and non-patient populations (Grossman, Niemann, Schmidt & Walach, 2004). A recent review of ten studies indicated that mindfulness-based stress reduction may be helpful for the

mental health of cancer patients (Ledesma & Kumano, 2009). In the intervention the three minute breathing space, mindfulness of the breath and a more visual mountain meditation were offered.

The self-regulation model also encompasses ongoing appraisals of strategies adopted for coping which can then feedback into the illness representations and emotional response. Firstly to facilitate the process of behaviour change action plans were developed using implementation intentions (see page 69 for further information about implementation intentions). To facilitate the appraisal process women were encouraged to reflect upon their experiences of using the techniques covered in the intervention via recording their practice and during the brief telephone booster session prior to treatment but following the hour long preparation session. It was envisaged that this would facilitate the appraisal process which would then feedback into modifying their regulation efforts. The strategies adopted in the intervention and how they are related to the self-regulation model are depicted in Figure 1 and the six stages of the preparation session are detailed on page 68.

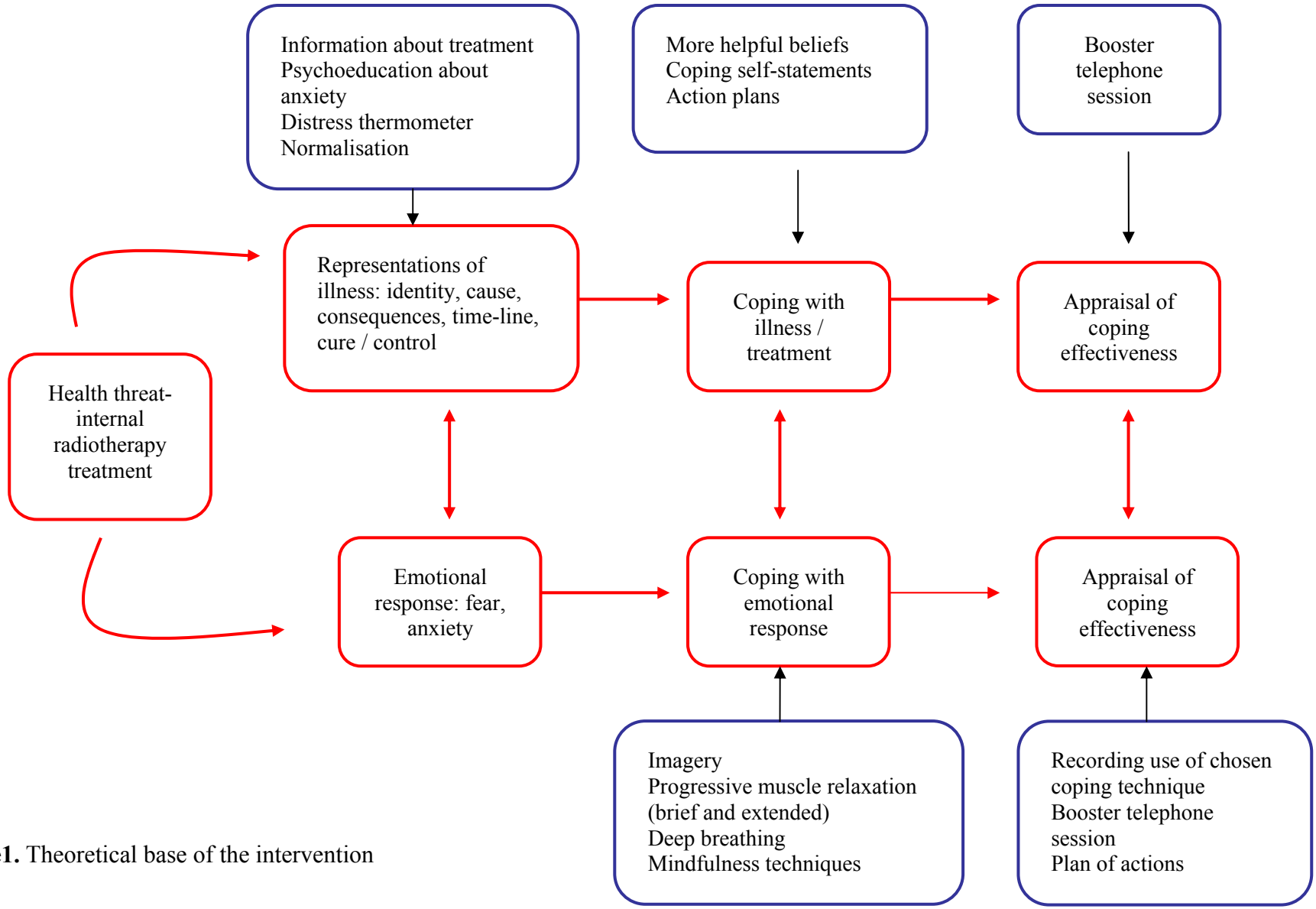

Figure1. Theoretical base of the intervention

Method

This pilot study utilised a controlled, before-and-after design to assess the effectiveness of a psychosocial preparation session on anxiety, depression, mood, illness beliefs and coping. As the primary objective, it was hypothesised that women in the intervention group would experience less anxiety prior to and post-treatment compared to the usual care group. The aims of secondary exploratory objectives were to test the effects of the intervention on depression, mood, coping style and illness beliefs.

Design and sample

Participants were patients with gynaecological cancers scheduled to receive low-dose IRT from a specialist cancer centre within a teaching hospital in an urban area. Eligible women were (1) aged 16 years or older (2) able to provide consent and therefore without signs of cognitive impairment, (3) without signs of severe psychopathology and (4) had working knowledge of English.

A power calculation (see appendix 22) estimated that 40 participants in total (20 per group) would be required for this study to achieve 80% power with a significance level of 0.05, on the basis of an effect size of 0.70 (based on a comparable study) for the primary outcome of anxiety as measured by the Hospital Anxiety and Depression Scale.

Patients were identified and approached during outpatient clinics from May 2009 to April 2010 and given a pack comprising an information sheet (see appendices 16 and 17), introductory letter from their consultant (appendix 18), consent form (appendix 19) and first questionnaire (appendix 20). An additional consent form (see appendix 21) completed upon introduction of the study noted a willingness to hear further about the

study in a telephone conversation with the researcher prior to entering the study. A gentle reminder was sent a week later to non-responders. Those women consenting to take part in the study from May 2009 to September 2009 were assigned to the intervention group and from October 2009 to April 2010 to the control group. Participants were aware of which group they would be assigned to prior to providing consent.

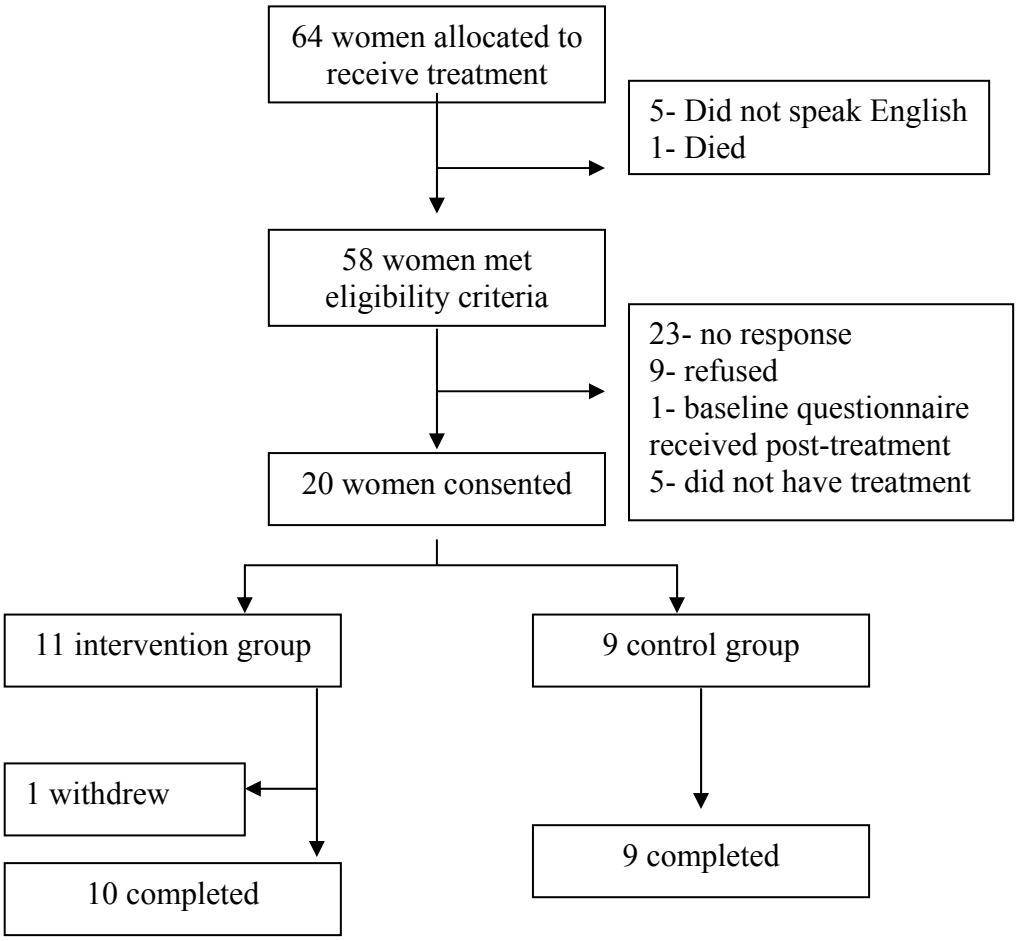

Figure 2. Flow of participants throughout the study

Details for the flow of participants in the study are shown in Figure 2. 34.5% (20) of the patients agreed to participate in the study. Of these 20 patients, 19 patients completed the study, 10 in the intervention group and 9 in the control group. In view of not obtaining the desired sample size, the analytical strategy was adapted as described in the statistical analysis section. The complete procedures for the study are outlined in

appendix 23. Due to the design of the study, participants were aware of the group to which they were allocated prior to giving consent. To reduce investigator bias the questionnaires were scored by an independent researcher.

Measures

A social demographic questionnaire contained items related to participants' age, marital status, ethnicity, educational level, time of cancer diagnosis and treatment.

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is the primary outcome measure for this study. It contains two 7-item scales, one for anxiety (HADS-A) and one for depression (HADS-D), with response options ranging from 0 to 3 and a score range of 0 to 21. The measure has been used to screen for emotional disorders using a criterion of 8 to 10 to indicate borderline caseness, and 11 or greater for caseness (abnormal levels of anxiety). The HADS has demonstrated reliability and validity for assessing anxiety and depression (Herrman, 1997). It has been shown to assess for symptom severity and caseness of anxiety and depressive disorders in somatic, psychiatric and primary care patients (Bjelland, Dahl, Haug & Neckelmann, 2002).

Secondary outcome measures included the Shortened version of the POMS (SV-POMS), Brief Illness Perceptions Questionnaire (BIPQ) and brief Coping Orientations to Problems Experienced (COPE). The SV-POMS (Shacham, 1983) includes 36 adjectives which measure the 6 domains of tension-anxiety, depression-dejection, anger-hostility, vigour-activity, fatigue-inertia, and confusion-bewilderment. Mean subscale scores were calculated by totalling responses and dividing by the number of adjectives in the subscale. A total score for mood disturbance was calculated by totalling the scores of tension-anxiety, depression-dejection, anger-hostility, fatigue-inertia and confusion-bewilderment

and subtracting the vigour-activity subscales. McNair, Corr and Droppleman (1992) suggest that the total mood disturbance score is useful and can be presumed to be highly reliable because of the intercorrelations among the SV-POMS subscales.

The BIPQ-brief provides a concise measurement of key illness perceptions central to Leventhal's self-regulation theory (Broadbent, Petrie, Main & Weinman, 2006). It consists of nine items which assess cognitive and emotional representations of illness. Eight items are scored on a 10-point Likert scale and the ninth item is an open-response item. This brief questionnaire has been shown to compare well with the more comprehensive Illness Perceptions Questionnaire - Revised (Moss-Morris et al., 2002). It has good test-retest reliability and good concurrent, predictive and discriminant validity (Broadbent et al., 2006). An overall score was computed which reflected the degree of threat associated with the illness, a higher score reflected a more threatening view of the illness.

The coping strategies used to cope with IRT were assessed using the brief COPE (Carver, 1997). This measure has a similar factor structure to the original COPE (Carver, Scheier & Weintraub, 1989) and has good internal reliability (Carver, 1997). It contains 14 distinct subscales of cognitive and behavioural coping strategies, with two items per scale, scored on a four-Likert scale. Coping strategies include acceptance, active coping, planning, behavioural disengagement, denial, substance use, humour, positive reframing, religious coping, self-distraction, use of emotional support, use of instrumental support, self-blame and venting. These subscales have acceptable alpha reliabilities (>.50) (Carver, 1997).

Assessments were performed at three time points. The first assessment was at least a month prior to IRT and involved completion of the HADS, SV-POMS, BIPQ and COPE. The second assessment comprised the HADS and SV-POMS and was completed

five days prior to IRT; this was following the preparation session for intervention participants. The third assessment was the day after IRT and comprised the same measures as time one. Qualitative feedback (see appendix 24) was obtained from intervention participants three to four weeks following the treatment via telephone interviews by a clinical psychologist who was not responsible for the study procedures or delivering the intervention. The interviews were semi-structured allowing the interviewer some flexibility to ask for clarification or to pursue ideas raised in the interview. They lasted approximately 10 minutes and detailed notes, as much as possible being verbatim, were taken by the interviewer. The interview schedule was designed with open-ended questions in order to elicit feedback about the session, helpfulness of the session, coping strategies discussed in the session, coping strategies used and recommendations for future improvements.

Intervention

Four women who had already received the treatment were consulted prior to the development of the intervention. These women shared their experiences, their coping strategies and feelings about the treatment. Feelings of isolation, anxiety and distress were reported by these women during treatment and all felt they could have benefited from being prepared for their treatment experiences, in terms of coping strategies, information and practical planning for the day of treatment. The intervention was informed by these findings, previous literature, feedback from professionals in cancer care and feedback from patients who had received pilot preparation sessions.

The preparation session lasted 50 to 60 minutes and was delivered five to seven days before IRT. A telephone booster session lasting 10 to 20 minutes was offered mid-

way between the delivery of the intervention and treatment; this was approximately three days prior to treatment. All intervention participants received this telephone booster session. The researcher delivered all the face-to-face intervention sessions and telephone booster sessions. The intervention was manualised and three sessions were recorded. Clinical supervision in relation to the delivery of the intervention was provided by a Counselling Psychologist independent to the study and fidelity checks were made in supervision by reviewing audio recordings of the interventions.

The session comprised six stages: (1) building rapport (2) identifying patients' concerns and illness beliefs and establishing an action plan to address these where necessary (3) information about procedure and practical planning (4) understanding and managing anxiety (5) abdominal deep breathing (6) option of guided imagery, progressive muscle relaxation or brief mindfulness exercise practice.

Patients' bio-psycho-social concerns were elicited using the Distress Thermometer (DT; Roth et al., 1998; see appendix 25). Regular screening of bio-psycho-social concerns is recommended by the NICE guidance on supportive and palliative care (NICE, 2004). In regard to gynaecological cancers, Maguire (1999) found that only 40% of concerns held by women with cervical cancer had been disclosed in the year after diagnosis. It has been shown that simply acknowledging concerns with a patient has proven to have a positive impact on their quality of life (Velikova et al., 2004). The DT enables identification of women's distress and brings forth their concerns in relation to their cancer and forthcoming treatment. The DT has a one-item visual analogue scale for screening distress, followed by a comprehensive problem list on which patients identify those which cause them distress (Jacobsen et al., 2005). Added to this is an element where patients rank their four main concerns and develop a plan of action to address these. Strategies utilised in the plan of action included information sharing with health

professionals, signposting, exploring practical options, and / or using cognitive-behavioural strategies. The Self Regulation Model (Leventhal, Meyer & Nerenz, 1980) posits that to understand an individual's reaction to a significant health event (e.g. cancer, treatment) it is important to understand their cognitive and emotional representations of the treatment and illness. Thus, one part of this intervention was to be aware of an individual's illness beliefs, (the researcher had an awareness of these from the BIPQ completed at baseline) and to explore those that might be having a negative effect on their coping, and to discuss cognitive and behavioural strategies which could help to manage these beliefs.

The third part of the session provided patients with information about the treatment and its procedure. Patients were given an option of seeing pictures of the treatment room. This was followed by discussions about practical planning for the treatment day, such as what they would like to take with them into hospital (e.g. distracting activities, objects of reference), and things they might have to consider to make the whole process less stressful (e.g. planning travel arrangements).

The next part, included psychoeducation about anxiety and helping patients to identify their cognitive, somatic, emotional and physiological responses associated with anxiety. Brief anxiety management techniques were taught, including deep abdominal breathing, developing more balanced beliefs, developing coping self-statements and quick methods of muscle relaxation.

In the final step patients could practice a coping strategy of their choice from a range of relaxation and mindfulness techniques. It was recommended that the relaxation strategies were practiced prior to treatment and a plan of practice was developed incorporating implementation intentions. Implementation intentions comprise a basic plan of action: An individual specifies when, where and how ('if situation Y is

encountered, then I will perform behaviour X') an intention to perform a behaviour will be enacted (Gollwitzer, 1999; Gollwitzer, 1993). The literature indicates that implementation intentions can be effective in facilitating behaviour (e.g. Sheeran & Orbell, 2000; Orbell, Hodgkins, & Sheeran, 1997; Orbell & Sheeran, 2002). Therefore, it was anticipated that the formulation of a plan based on implementation intentions might promote the use of relaxation after the session.

Patients were provided with written materials comprising their DT and plans of action, personalised practical planning for the day, written information of treatment procedure, guidance on the strategies in the session and audio recordings of all the relaxation and mindfulness exercises. Patients were encouraged to try the strategies they had not practiced in the session. A booster telephone session was completed mid-way between the preparation session and treatment. This was to ensure that women had understood the techniques discussed in the session, and plans for practice were revisited. Any barriers to meeting the plans established in the session and any further concerns or questions were addressed. The control group only received information about the treatment from their consultants as part of routine clinical practice.

Data Treatment

The range, minimum and maximum scores were checked on all variables. When two answers were given for the same question, they were treated as missing. Substitutions for missing data were made for the HADS, SV-POMS, and COPE with a participant's personal average for the subscale if more than half of the items for the subscale had been completed. No substitutions were made for single item scale data. The normality of distributions was statistically tested using the Kolmogorov-Smirnov test. The scores for

the BIPQ at baseline and several of the COPE subscales (denial, substance use, emotional support, behavioural engagement, venting, humour, acceptance, religion and self-blame) were not normally distributed and therefore non-parametric tests were used to analyse these data.

Statistical Analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) (Version 14). The following statistical analyses were conducted to test whether the preparation session group was more effective at improving outcomes compared to the control group. To test the primary hypothesis, participants' anxiety scores on the HADS-A were transformed into change scores between assessment points. The change scores were calculated by subtracting a participant's score at baseline from their score at pre-treatment, and subtracting the baseline score from the post-treatment score. Independent t-tests were conducted to determine whether there were significant differences in the change scores between the two groups. The same statistical analysis was conducted to test secondary outcomes, and to compare differences between the groups on HADS-D, SV-POMS, BIPQ and COPE. As noted above the BIPQ scores at baseline indicated a deviation from normality, and thus differences between the groups were tested using a non-parametric Mann-Whitney test. Finally, to explore coping strategies used, the descriptive and frequency data on the COPE was considered.

The analytical strategy was adapted to take the small sample size into account, and thus it was decided that conducting analyses to ascertain changes in outcomes at the individual level would help to assess more closely the effects of the intervention. Much of the existing work on the evaluation of interventions focuses on changes in outcomes

that occur at the group level. Achieving a significant change between two assessment points is considered adequate evidence that the intervention is effective. However, the variation in outcomes at the individual level is not considered and a statistically significant change does not provide information about the clinical meaningfulness of this finding. Jacobsen and Truax (1991) have suggested a supplementary means of analysis which considers significant change at the level of individual participants, thus giving an insight into the impact an intervention has on clients and the benefits or otherwise derived from it. Jacobsen and Truax recommend examining data according to two criteria: (a) the reliable change index (RCI) and (b) an established cut-off point of clinical significance (e.g. a score that distinguishes between caseness and non-caseness).

The RCI was used to assess for changes in scores from baseline to pre-treatment and baseline to post-treatment for the anxiety and depression subscales of the HADS because this was the primary outcome measure and the one that is most likely to be used in routine clinical practice to assess change. The RCI has a precise cut-off criterion for improvement which is psychometrically based. If the value of RCI is greater than 1.96 then the score is a reflection of a 'real' change ($p=0.05$) and not one due to the random error of an imprecise measuring instrument. Hence, in this study participants were classified as showing a change in anxiety and depression which was statistically meaningful if the value of RC exceeded 1.96 (95% confidence).

The cut-off of 8 for both the HADS-A and HADS-D has been established as providing the most optimal balance between sensitivity and specificity (Bjelland et al., 2001). This was the criterion used in this study, scores above 8 on the HADS-A and HADS-D were classified as caseness and scores below this as non-caseness. Scores which passed this threshold either as an improvement or deterioration between baseline and pre or post-treatment were considered clinically important. However, in terms of

mental health, cancer patients are a non-clinical population. Thus, it is possible that an individual could have a baseline score firmly in the normal range and demonstrate improvement or deterioration that does not cross the cut-off threshold but may still be clinically important (Jacobsen & Traux, 1991). Therefore, based on these two criteria, individuals were classified in the following ways (based partly on Jacobsen & Traux, 1991):

(1) Considerable improvement- individuals passed RCI criteria and passed cut-off on HADS from caseness to non-caseness
(2) Improved- passed RCI criteria but not cut-off for caseness to non-caseness
(3) Unchanged- passed neither criterion
(4) Decline – passed RCI criteria but not enough to go from non-caseness to caseness
(5) Deterioration- passed RCI criteria and passed cut-off from non-caseness to caseness.

Finally, a post-hoc sample size calculation was conducted to assess if the study had adequate power.

Results

20 patients consented to participate in the study, although one participant later withdrew from the intervention group. For a closer examination of the characteristics of the participants who completed the study please refer to Table 1.

No significant differences were found on the HADS-A, HADS-D, SV-POMS, BIPQ (see appendix 26) or demographic characteristics between the groups at baseline (see Table 1). In terms of the relaxation and mindfulness options selected by participants in the intervention, 7 opted for guided imagery and 3 for progressive muscle relaxation.

None opted for mindfulness in the intervention; however, two participants tried this outside the session. 8 participants reported that they had tried the techniques following the session.

Table 1. Characteristics of the sample

	Intervention group	**Control group**	**All group**
	Mean (SD)	Mean (SD)	Mean (SD)
Age (n=19)	57.00 (4.28)	54.33 (3.98)	55.74 (12.52)
	N (%)	N (%)	N (%)
Diagnosis (n=19)			
Cervical cancer	7 (70)	7 (77.8)	14 (73.7)
Endometrial cancer	3 (30)	2 (22.2)	5 (26.3)
Ethnicity (n=19)			
White British	9 (90)	8 (88.9%)	17 (98.5)
Mixed Heritage	1 (10)	1 (11.1%)	2 (10.5)
Marital status (n=19)			
Married / co-habiting	5 (50)	5 (55.5)	10 (52.6)
Single	1 (10)	1 (11.1)	2 (10.5)
Separated	4 (40)	2 (22.2)	6 (31.6)
Widower		1 (11.1)	1 (5.3)
Higher / further education (n=16)			
Yes	6 (75)	3 (37.5)	9 (56.3)
No	2 (25)	5 (62.5)	7 (43.7)
Treatment other than IRT			
Chemotherapy only	2 (20)	0	2 (10.5)
Radiotherapy only	1 (10)	2 (22.2)	3 (15.8)
Chemotherapy and radiotherapy	7 (70)	6 (66.7)	13 (68.4)
No other treatment	0	1 (11.1)	1 (5.3)

.

Table 2. Descriptive statistics for main outcome measures at baseline, pre-treatment and post-treatment time-points

Scale	Group	Baseline Mean (SD)	Pre-treatment Mean (SD)	Post-treatment Mean (SD)	Change scores Baseline to pre-treatment	Change scores baseline to post-treatment
HADS-A	I	9.30 (4.06)	7.6 (3.47)	7.7 (3.34)	-1.7 (2.63)	-1.6 (3.20)
	C	7.67 (4.61)	11.00 (4.58)	10.75 (4.50)	3.33 (6.20)	3.0 (3.74)
HADS-D	I	6.8 (3.55)	7.7 (4.00)	6.8 (3.08)	0.90 (3.14)	0.00 (2.05)
	C	6.11 (4.04)	9.0 (2.78)	8.75 (2.71)	2.89 (4.17)	2.33 (3.74)
SV-POMS	I	35.00 (22.81)	36.10 (23.39)	31.05 (29.01)	1.1 (23.11)	-3.95 (26.28)
	C	30.00 (31.14)	37.33 (25.12)	44.25 (20.29)	7.3 (25.85)	14.25 (21.46)

		Baseline Median	Post-treatment Median	Change scores from baseline to post-treatment median
BIPQ	I	43.5	39.5	-4
	C	34	30.5	-4

Anxiety and depression outcomes

The primary aim in this study was to test the effects of the preparation session on anxiety compared with the control condition. Secondary analyses included testing differences between the groups on depression, mood, coping and illness representations.

As shown in the descriptive statistics in Table 2 and Figure 2, the anxiety scores in the control group increased from baseline to pre-treatment, and then remained relatively unchanged to post-treatment. Anxiety in the intervention group lessened from baseline to pre-treatment, and then remained unchanged. In the intervention group anxiety on the HADS-A was scored as borderline and abnormal in 60% of patients at baseline, 50% at pre-treatment and 60% at post-treatment. In the control group anxiety was categorised as borderline and abnormal at baseline in 44% of participants, 66.7% at pre-treatment and 66.7% at post-treatment. The results of an independent samples t-test revealed that there were significant differences between the intervention group and control group for anxiety between baseline and pre-treatment ($t=-2.348$, $df=17$, $p=0.03$) and from baseline to post-treatment ($t=-2.887$, $df=17$, $p=0.01$).

The depression scores increased slightly in the intervention group at pre-treatment and then decreased slightly at post-treatment (see Table 2 and Figure 3). In the control group, depression increased from baseline to pre-treatment and remained unchanged at post-treatment. At baseline, 50% of participants in the intervention group scored in the borderline and abnormal range of depression, 50% at pre-treatment and 50% at post-treatment, compared to 22% of the control group at baseline, 67% at pre-treatment and 44% at post-treatment. T-tests showed that there were no significant differences between the groups (see Table 3).

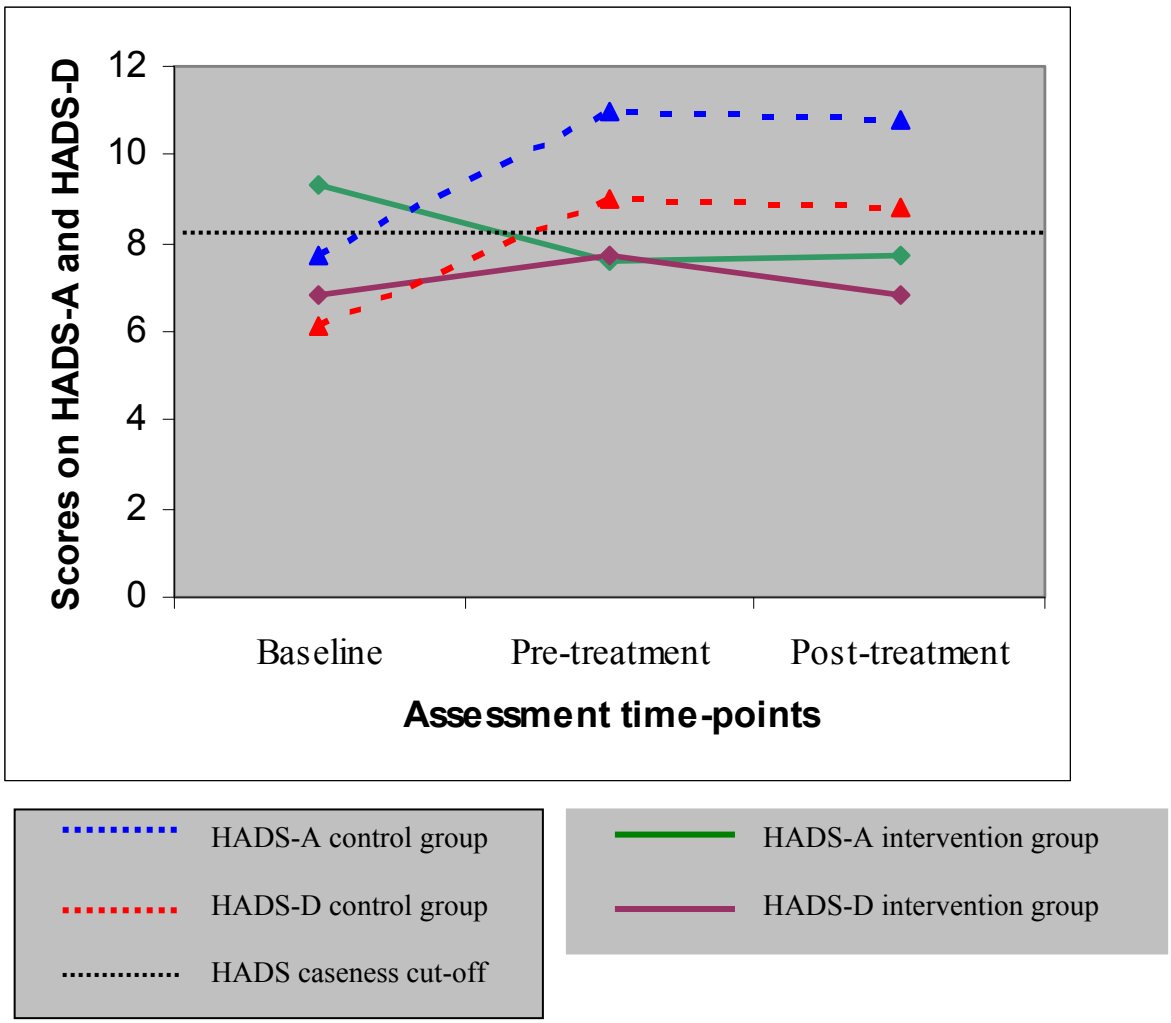

Figure 3. Mean scores for intervention and control participants at baseline, pre-treatment and post-treatment for anxiety and depression

Table 3: T-tests to assess group differences on main outcome measures

Measure	Time points assessed	t-value	Degrees of freedom	Significance level
HADS-A	Baseline to pre-treatment	-2.348	17	0.031*
HADS-A	Baseline to post-treatment	-2.887	17	0.010*
HADS-D	Baseline to pre-treatment	-1.183	17	0.253
[1]HADS-D	Baseline to post-treatment	-1.659	12.14	0.123
SV-POMS	Baseline to pre-treatment	-0.555	17	0.586
SV-POMS	Baseline to post-treatment	-1.829	16	0.086
COPE				
[1]Self-distraction	Baseline to post-treatment	-0.459	14.955	0.653
Active coping	Baseline to post-treatment	0.857	15	0.405
Instrumental support	Baseline to post-treatment	0.788	16	0.442
Positive reframing	Baseline to post-treatment	0.780	15	0.447
Planning	Baseline to post-treatment	0.573	16	0.575
Mann Whitney Test	**Time points**	**U value**	**N1, N2**	**Significance**
BIPQ	Baseline to post-treatment	43.000	9, 10	0.905
COPE				
Denial	Baseline to post-treatment	29.500	8, 10	0.360
Substance use	Baseline to post-treatment	35.500	8, 9	0.963
Emotional support	Baseline to post-treatment	21.000	8, 9	0.167
Behavioural engagement	Baseline to post-treatment	33.000	8, 9	0.815
Venting	Baseline to post-treatment	26.000	8, 9	0.370
Humour	Baseline to post-treatment	33.000	8, 9	0.815

Table 3 Continued

Mann Whitney Test	Time points	U value	N1, N2	Significance
Acceptance	Baseline to post-treatment	25.000	8, 9	0.321
Religion	Baseline to post-treatment	26.000	8, 9	0.370
Self-blame	Baseline to post-treatment	29.500	8, 9	0.541

* Significant at $p<0.05$

[1] Levene's test significant and statistics for equal variances not assumed as assumption of homogeneity of variance violated.

Mood disturbance and illness beliefs

At baseline the control and intervention group had similar total mood disturbance scores on the SV-POMS. At post-treatment the total mood disturbance scores decreased very slightly in the intervention group, while increasing somewhat in the control group. This seems to indicate that at post-treatment the distress experienced by the control group patients increased. However, analyses (see Table 3) indicated that there were no significant differences between the groups.

Although not significant, the median scores for the BIPQ at baseline were higher for the intervention group than the control group. This indicates that the intervention group perceived a somewhat greater threat from their illness compared to the control group. While the median scores for the BIPQ decreased a little from baseline to post-treatment in both groups, the median for the intervention group still remained higher than the control group, again, suggesting that after treatment patients in the intervention group perceived a greater threat from their cancer. A Mann Whitney test indicated that there were no significant differences between the groups ($U=43.000$, $N1=9$, $N2=10$, $p=0.905$).

Coping

T-tests on the coping styles at baseline and post-treatment found no significant differences between the groups (Table 3). Descriptive and frequency data for the coping styles commonly used by participants are shown in Table 4. The most common coping strategies utilised by participants included self-distraction, emotional support, instrumental support, positive re-framing, planning and acceptance. While the differences between the groups were not significant, it is worth noting that according to the frequency data, a larger proportion of participants in the intervention group used acceptance and planning compared to the control group post-treatment.

Table 4. Descriptive and frequency data for commonly used coping styles

Coping style	Mean and std deviation / median if non-parametric at baseline	Percentages for proportion of participants who rated using the coping strategy as quite a bit or extremely		
		Baseline	Post-treatment intervention	Post-treatment control
Self-distraction	5.17 (1.72)	50%	22.2%	50%
Emotional support	6.50*	61.1%	88.9%	62.5%
Instrumental support	5.17 (1.69)	38.9%	50%	37.5%
Positive reframing	5.00 (1.97)	39%	44.4%	25%
Planning	5.11 (1.20)	38.9%	60%	25%
Acceptance	6.00*	55.5%	88.9%	25%

* items not normally distributed and median reported

Reliable Change Index and clinical significance

The proportion of participants classified as showing considerable improvement, improvement, no change, decline and deterioration are shown in Tables 5, 6, 7 and 8 for anxiety and depression outcomes (to see individual scores at each assessment point for anxiety and depression see appendix 27).

Anxiety

Table 5. Clinical significance and reliable change index analyses on anxiety between baseline to pre-treatment

Groups	Considerable Improvement	Improvement	Unchanged	Decline	Deterioration
Anxiety baseline to pre-treatment					
Intervention	1/10	0/10	9/10	0/10	0/10
Control	1/9	0/9	4/9	0/9	4/9
Difference between groups	0.94	0.99	<0.05*	0.99	P=0.03*

* Significant at p<0.05

As seen in Table 5, five participants in the control group and one participant in the intervention group had a score above 1.96 (scores of 1.96 or greater indicated significant deterioration and scores of -1.96 or greater indicated significant improvement) indicating change on HADS-A between baseline and pre-treatment beyond that of random error. Nine participants' anxiety (90%) in the intervention group remained unchanged between baseline and pre-treatment compared to four (44%) in the control group. This difference was significant, indicating that significantly more patients in the intervention group had stable levels of anxiety from baseline to pre-treatment (i.e. not resulting in significant deterioration or improvement) (see Table 5). Four control participants (44%) showed deterioration in anxiety between baseline and pre-treatment, i.e. the RCI criterion was met and scores moved from non-caseness to caseness levels, compared to no participants in the intervention group meeting these criterion. This difference was significant, indicating that the intervention may have been effective in preventing further deterioration in anxiety from baseline to pre-treatment.

Table 6. Clinical significance and reliable change index analyses on anxiety between baseline to post-treatment

Groups	Considerable Improvement	Improvement	Unchanged	Decline	Deterioration
Anxiety baseline to post-treatment					
Intervention	0/10	2/10	7/10	0/10	1/10
Control	1/9	0/9	5/9	1/9	2/9
Difference between the groups	0.29	0.17	0.52	0.3	0.48

* Significant at $p<0.05$

Three participants in the intervention group and four participants in the control group had an RCI score above 1.96 on the HADS-A (see Table 6) between baseline and post-treatment. One participant in the intervention group was found to show deterioration and three participants in the control group had a decline or deterioration between baseline and post-treatment. There were no significant findings between the intervention and control group in anxiety from baseline to post-treatment.

Depression

Table 7. Clinical significance and reliable change index analyses on depression between baseline and pre-treatment.

Groups	Considerable Improvement	Improvement	Unchanged	Decline	Deterioration
Depression baseline to pre-treatment					
Intervention	0/10	1/10	6/10	2/10	1/10
Control	1/9	0/9	3/9	0/9	5/9
Difference between the groups	0.29	0.34	0.26	0.17	<0.05*

* Significant at $p<0.05$

Between baseline and pre-treatment four participants in the intervention group and six participants in the control group had an RCI score above 1.96 (see Table 7). Analyses for depression found that five of the participants in the control group showed deterioration between baseline and pre-treatment compared to one participant in the intervention group. This difference indicated that significantly more patients in the control group showed deterioration in depression from baseline to pre-treatment.

Table 8. Clinical significance and reliable change index analyses depression between baseline and post-treatment

Groups	Considerable Improvement	Improvement	Unchanged	Decline	Deterioration
Depression baseline to post-treatment					
Intervention	1/10	0/10	8/10	0/10	1/10
Control	1/9	0/9	3/9	1/9	4/9
Difference between the groups	0.94	0.99	0.05*	0.29	0.11

* Significant at $p<0.05$

At baseline to post-treatment, two participants in the intervention group and six participants in the control group had a RCI score above 1.96 (see Table 8). Eight participants in the intervention remained unchanged between baseline and post-treatment, compared to three participants in the control group. This was significant indicating that more patients in the intervention group had stable levels of depression from baseline to pre-treatment. Finally, four participants showed deterioration and one participant showed decline in the control group compared to one participant in the intervention group who showed deterioration. Combining the scores for deterioration and decline, shows that

significantly more patients in the control group showed a decline or deterioration compared to the intervention group (<0.05).

Post-hoc sample calculation

Using a statistical method for determining trial size (Pocock, 1983) based on this pilot study it was found that 66 participants in total (33 per group) would be required for this study to achieve 80% power with a significance level of 0.05, two tailed for the primary outcome measure of anxiety for a more definitive trial.

Discussion

The present study was designed to evaluate the potential psychological benefits of a preparation session for women undergoing IRT compared to treatment as usual. To our knowledge, this is the first time that a pre-treatment preparation session comprising cognitive-behavioural techniques, eliciting and addressing concerns, and procedural information has been attempted exclusively with gynaecological patients undergoing IRT. The results indicate that participants in the intervention group had significantly lower anxiety at pre- and post-treatment compared to the control group. Clinical significance and RCI analyses found that significantly more patients in the control group showed significant levels of deterioration from baseline to pre-treatment compared to the intervention group for anxiety and depression. The majority of participants in the intervention group were found to have unchanged levels of anxiety and depression prior to IRT treatment. The findings seem to suggest that the preparation session had a prophylactic effect, in that patients' anxiety and depression did not significantly increase

as treatment approached. Significantly more patients in the intervention group had unchanged levels of depression at post-treatment compared to baseline, than was the case for the control group. Significantly more patients in the control group either had a decline or deterioration in depression post-treatment compared to baseline. This again indicates that perhaps the intervention may have prevented further deterioration in depression at post-treatment. This study adds to the growing literature which demonstrates that brief psychologically-informed interventions can influence psychological outcomes in cancer patients undergoing treatment.

The preparation session did not have an effect on overall mood disturbance, coping skills or perceived threat of illness. This study conducted a preliminary assessment of coping strategies to explore the mechanisms by which the intervention may have had an impact on psychological outcomes. While exploratory data analysis of frequency data seemed to suggest that intervention participants used more acceptance and planning coping skills compared to the control group, these findings were not significant.

A number of possible factors may explain the effects of the intervention on anxiety. Firstly, relaxation techniques have been shown to be effective in reducing psychological distress associated with a wide range of different cancer treatments and the management of treatment-related symptoms (Leon-Pizarro et al. 2007; Nunes et al, 2007; Burish & Jenkins, 1992; Burish et al, 1991; reviews: Luebbert et al., 2001, Redd et al, 2001). Procedural information, cognitive, and behavioural interventions have been found to reduce negative affect in preparing patients for surgery (Johnson & Vogele, 1993). The booster session and provision of written and audio materials may also have contributed to the effectiveness of the intervention. This study replicates the findings of Leon-Pizarro and colleagues (2007) who reported that patients with breast and gynaecological cancer undergoing IRT who received information provision about

treatment and training in guided imagery, had significantly less anxiety, depression and body discomfort.

Patients did not generally tend to view the mindfulness strategies as coping techniques that would be helpful for them. Of the two participants who attempted the mindfulness strategies, neither found them useful. Patients may need more direction in using these techniques. Mindfulness interventions usually tend to consist of at least 8 weeks of training (Speca, Goodey & Angen, 2000; Carlson, Speca, Patel & Goodey, 2003; Tacon, Caldera & Ronaghan, 2004). Further research is required to ascertain whether mindfulness techniques could be helpful in helping clients to manage distress and / or symptoms related to cancer treatment.

Patients in this study were self-selecting. Sixty-five per cent of patients opted not to participate, and this raises questions about whether there were differences between the patients who participated and those who did not wish to participate. As participants were aware of whether they were in the control or intervention group, it is feasible that they had different reasons for wishing to take part depending on the group that was on offer during their treatment. It is, therefore, possible that those in the intervention group were more motivated to seek further information about the treatment and /or considered the learning of new coping skills as being important for helping them to manage their distress, possibly because they were experiencing more or less distress compared to other patients. There were no means of identifying whether the patients who entered the study differed from the general population of gynaecological patients. However, Kramer's study (2007) which evaluated patient anxiety just prior to IRT treatment found that 32% of participants had anxiety within the normal range and 68% in the borderline and abnormal ranges of anxiety. The findings of anxiety for this study in the control group at pre-treatment (five days prior) were very similar with 33% with anxiety in the normal

range and 67% in the borderline and abnormal range. This suggests that the characteristics of anxiety in this group were comparable to findings in previous studies with this patient population.

The feasibility of the study design was established through the successful recruitment of patients into the intervention arm of the study. There was only one participant who decided to withdraw their participation from the study because they did not want to obtain any further information or talk about IRT. The remaining participants attended the preparation session, and 100% completed assessments pre- and post-treatment, and eight also provided feedback on the intervention two to four weeks post-treatment. The retention of participants in this study indicates that future research in this area will be feasible.

Limitations of the study and directions for future research

Despite every effort to try to increase recruitment, it was impossible to attain the sample required for adequately statistical power for this study. A strategy adopted by other researchers in response to low recruitment has been to extend the recruitment period (Chang, Hendricks, Slawsky, & Locastro, 2004). However, this was not a feasible option due to the limited time period available for this research programme.

A sample size calculation for a more definitive trial based on this pilot study indicated that the study was inadequately powered to fully determine differences between the groups. Therefore, this study carries a considerable risk of being unable to demonstrate differences between the groups (Type II error; Pocock, 1983) and precise estimate of treatment effect was not possible. The results of this study should be interpreted taking this into consideration and this limits the weight that can be placed on

the findings. It is also possible that the small sample size hindered the identification of mechanisms (e.g. coping strategies, illness beliefs) that enabled the intervention to influence outcomes. It is possible that changes in general mood disturbance were not achieved because the intervention failed to influence illness beliefs and coping skills, however, testing this definitively was not possible. Future studies should strive to adopt appropriate theoretical models to inform the evaluations and development of interventions, particularly as a meta-analysis by Graves (2003) found that treatment packages for adult cancer patients which consisted of a larger number of social cognitive components had larger effect sizes.

The utility of psychological and social cognitive theories in the development of interventions to improve outcomes in cancer patients should be explored further. To facilitate the development of theoretically informed interventions the causal modelling approach (Hardeman et al., 2005) can be used. This process enables researchers to identify and link all elements of their interventions and its evaluation by theoretical pathways, thus, ensuring that theoretical components, alongside end-points such as psychological distress and symptoms, are incorporated into the evaluation and the mechanisms via which the intervention will influence outcomes is defined.

It was not possible to minimise the effect of observer bias by blinding the researcher regarding the group to which patients were allocated, because the researcher was also responsible for recruitment and delivering the intervention. Due to resource limitations, it was only possible for the scoring and entry of study data and the qualitative interviews to be conducted by an independent researcher. Patients were also aware of group allocation prior to recruitment. It is therefore possible that the outcome expectations of both researcher and patient may have contributed to the treatment effect and patients may have overestimated the benefits they obtained.

Not adopting the gold standard of a randomised controlled trial was also a limitation of this study. This methodology is preferred because it more effectively distributes extraneous external factors between trial groups, and therefore, differences found between the groups can be more confidently assigned to the intervention (Eccles, Grimshaw, Campbell & Ramsay, 2002). Although significant baseline differences were not found in this study, the existence of differences cannot be ruled out because of the small sample size. Indeed, it is worth highlighting that at baseline 60% of participants in the intervention group had anxiety levels in the borderline to abnormal range compared to 44% in the control group. In addition, 50% of patients in the intervention group had depression levels in the borderline to abnormal ranges compared to 22% in the control group. This does raise questions about whether patients who chose to participate in the intervention group had higher levels of distress.

A further limitation in this study was the lack of measurement for practice of coping skills covered in the session and in the additional materials provided. It is uncertain whether patients practiced the coping skills regularly. It has been found in the literature that the extent to which patients practiced relaxation skills was related to the extent of emotional suppression and levels of unhappiness (Walker et al., 1999). The absence of a follow-up assessment resulted in no information being gathered on the duration of effects observed from the intervention or possible longer term effects. It has been documented in the literature that effects from psychosocial interventions for treatment-related symptoms have at times resulted in significant benefits six months or longer following the intervention (Armes et al. 2007; Parker et al., 2009). Future studies should include an attention equivalent control group, to ascertain whether the impact of an intervention is beyond that which is due to the non-specific aspects (e.g. rapport,

attention). The limitations of this study should be adequately addressed in future more definitive trials of this preparation intervention.

Clinical implications

The analyses using the reliable change index and clinical significance criterion provided information useful for making clinical decisions. These preliminary findings do indicate that the preparation session may be effective in preventing further significant anxiety in four in every nine patients prior to IRT and preventing further significant depression prior to IRT in about half of patients. Furthermore, the intervention seemed to prevent further deterioration in depression at post-treatment. Patient feedback indicates that the intervention was acceptable to this patient population, and techniques practiced and discussed in the preparation session were used to manage distress they experienced. This gives adequate justification for advocating the use of preparation sessions routinely in clinical practice for gynaecological patients undergoing invasive IRT. It might also be worth considering whether the preparation session could be adapted for use with patients undergoing other medical procedures. In this study a trainee clinical psychologist administered the preparation session, it is quite feasible for other members of the primary oncology team to deliver this intervention after training, thus further reducing the costs of the session's delivery.

Conclusions

This research programme was developed to provide a preliminary evaluation of a brief psychologically-informed preparation session, in a control before-and-after study design, on psychological outcomes. It appears that the preparation session functions by preventing significant exacerbation of anxiety or depression prior to or as an immediate result of the invasive internal radiotherapy treatment. These preliminary findings are encouraging, although they are limited and it is difficult to interpret them in the absence of an adequate sample size. The study does suggest that this topic is worthy of further research and provides a justification for evaluating the effects of this preparation session in a larger more definitive trial. Future research should seek to incorporate a longer follow-up period, in order, to establish whether the preparation session can also influence outcomes over a longer duration.

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Executive Summary

Cancer treatment-related distress: evaluating the effectiveness of psychosocial interventions

Cancer treatment-related distress:

Evaluating the effectiveness of psychosocial interventions

This study was conducted by Narinder Shergill in partial fulfilment of the requirements for the Doctorate in Clinical Psychology, at the University of Birmingham. This study was supervised by Dr Jan Oyebode, Dr Ruth Howard and Dr Inigo Tolosa.

Background

Internal radiotherapy treatment (IRT) is available for women with gynaecological cancers. This treatment enables radiation to be directed specifically at the site of the tumour. Notwithstanding the effectiveness of IRT for treating gynaecological cancers, the procedure is invasive and intimate. It has long been established that women find IRT distressing. It was found that 68% of women scored within the borderline and abnormal ranges of anxiety prior to IRT (Kramer et al., 2007) and negative states such as anxiety, worry and fear were associated with the treatment (Warnock et al., 2005). It is clear from the previous research that women need support to cope with this treatment.

This research carried out consists of a literature review and a clinical study. The review summarises evidence regarding the effectiveness of psychosocial interventions on the distress and symptoms related to cancer treatment. The report of the clinical study evaluates the impact of a psychological preparation session on psychological distress in women undergoing IRT.

Literature Review

Published research looking at different psychosocial interventions, such as relaxation, cognitive-behavioural interventions, hypnosis and supportive interventions, was summarised and critically evaluated. Relaxation techniques were found to be the most effective for patients undergoing various cancer treatments, particularly for symptoms of anxiety. The evidence of impact of relaxation interventions on other psychological outcomes, symptoms and quality of life was more mixed. The differences in the components of cognitive-behavioural interventions and the mixed findings about their impact on psychological, symptom and quality of life made it difficult for definite conclusions to be drawn. There were too few studies looking at hypnosis and supportive interventions to draw firm conclusions about their effectiveness.

Empirical study

Aims

The first aim of this study was to evaluate the impact on patients' anxiety of a brief psychological preparation session for women before they have IRT. The project also aimed to understand the impact of the session on women's levels of depression, mood disturbance, perceived threat of cancer and coping strategies.

Study design and participants

A controlled, before-and-after design was used. Nineteen women participated in the study – 10 received the preparation session (intervention group) and 9 acted as a control group. All were due to receive IRT for gynaecological cancer at a large cancer centre. The participants had a mean age of 55.74 years, 74% had cervical cancer and 26% had

endometrial cancer. Ethical approval was obtained from North Staffordshire Research Ethics Committee.

Intervention

The psychological intervention session being tested lasted one hour and was given five to seven days prior to IRT. The intervention had several parts: (1) building a rapport (2) identifying patients concerns using the distress thermometer (3) providing information about the procedure (4) understanding and managing anxiety (5) abdominal deep breathing (6) one of the following: guided imagery, progressive muscle relaxation and brief mindfulness techniques. Written information and audio tapes of the relaxation and mindfulness exercises were provided. A booster telephone session was offered mid-way between the preparation session and their IRT. Women in the control group received routine care.

Measures and procedures

Packs were provided to eligible women at outpatient clinics, including an information sheet, consent form, and questionnaires. The questionnaires included: (1) Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) (2) Shortened version of the POMS (Shacham, 1983) (3) Brief illness perception questionnaire (Broadbent et al., 2006) and (4) Brief Coping Orientations to Problems Experienced (Carver, 1997).

The questionnaires were completed at three time-points.

1. At least a month before IRT, including all the measures.
2. Five days before IRT (following the preparation session) including the HADS and SV-POMS

3. The day after IRT and including all the measures.

Qualitative feedback about the session was obtained from intervention participants via a telephone call to the women after the IRT was complete.

Results

The women receiving the intervention experienced significantly less anxiety from baseline to pre and post-treatment compared to those in the control group. Statistical analysis showed that significantly more women in the control group experienced a deterioration in anxiety and depression compared to the intervention group. The findings suggested that the preparation session was effective in preventing increases in the womens' distress. There were no differences found on the outcomes of mood disturbance, perceived threat of cancer or coping strategies. Qualitative feedback indicated that patients found the preparation session acceptable and helpful, and used some of the coping strategies they learned in the session to alleviate distress.

Shortcomings and recommendations

The study needed a larger sample size in order to provide firm conclusions. The study did not use a randomised controlled trial design. Patients and researchers were aware of the group they were participating in. Therefore, the expectations of both researcher and the patients may have influenced the findings. Future studies should include a longer follow-up period. Nevertheless the findings are clinical very useful and it is recommended that similar preparation sessions are used routinely in clinical practice for patients undergoing invasive and difficult treatments. It is also feasible for members of the cancer team to be trained to deliver brief preparation sessions such as the one described here.

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Appendix 1: Psycho-oncology Guide for Authors

Appendix 2: Reference list of reviewed studies

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Walker, L. G., Walker, M. B., Ogston, K., Heys, S. D., Ah-See, A. K., Miller, I. D. et al. (1999). Psychological, clinical and pathological effects of relaxation training and guided imagery during primary chemotherapy. *British Journal of Cancer, 80(1-2),* 262-8.

Yoo, H. J., Ahn, S. H., Kim, S. B., Kim, W. K., & Han, O. S. (2005). Efficacy of progressive muscle relaxation training and guided imagery in reducing chemotherapy side effects in patients with breast cancer and in improving their quality of life. *Supportive Care in Cancer, 13(10),* 826-33.

Appendix 3: Search strategies for Medline and PsychINFO

MEDLINE SEARCH

Database: Ovid MEDLINE(R) <1950 to November Week 1 2009>

Search for: limit 34 to yr="1990 - 2009"

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1 CANCER KEYWORDS- Neoplasms or Carcinoma or Cancer

2 TREATMENT TYPES- Radiotherapy or Drug Therapy or Chemotherapy or Surgical (General Surgery, Surgical Procedures, Minor, Operative, Elective, Minimally Invasive) or Therapeutics or Treatment or Preoperative Care or invasive

3 PSYCHOLOGICAL THERAPIES- Cognitive Therapy or Gestalt Therapy or Behavior Therapy or Psychoanalytic Therapy or Marital Therapy or Relaxation Therapy or Couples Therapy or Mind-Body Therapies or Psychology, applied or Counseling

4 OUTCOMES- Stress, Psychological or Stress, Physiological or Pain or Anxiety or Anxiety Disorders or Depression or Quality of Life or Emotions or Nausea or Postoperative nausea and vomiting or Fatigue or Self Care

Step 1: Combine keywords for cancer and treatment types
Step 2: Combine step 1 with keywords for psychological therapies and outcomes.

PsychINFO SEARCH

Database: PsycINFO <1987 to November Week 3 2009>

Search for: limit 34 to yr="1990 - 2009"

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1 CANCER KEYWORDS- Neoplasms or Carcinoma or Cancer

2 TREATMENT TYPES- Radiation Therapy or Drugs or Chemotherapy or Surgery or Surgical patients or Invasive or Medical treatment or Medical Patients or Treatment

3 PSYCHOLOGICAL THERAPIES- Behavior modification or Cognitive techniques or Pain management or Psychotherapeutic techniques or Psychotherapy or Relaxation therapy or Cognitive Behavior Therapy or Cognitive Therapy or Progressive Relaxation Therapy or Muscle Relaxation or Stress management

4 OUTCOMES- Physiological Stress or Psychological Stress or Stress (Chronic, Acute, Reactions) Pain or Anxiety Disorders or Depression or Quality of Life or Emotions or Nausea or Fatigue or Self Care Skills or exp Self Management

Step 1: Combine keywords for cancer and treatment types
Step 2: Combine step 1 with keywords for psychological therapies and outcomes.

Appendix 4: Table, glossary and reference list of outcome measures

Table. Chosen outcome measures of included studies

Measures	Type of intervention	Studies
Psychological		
STAI	Relaxation	Nunes et al. 2007; Molassiotis et al. 2001; Arawaka, 1997; Morrow et al. 1992
	CB	Jacobsen et al. 2002; Krischer et al. 2007
	Hypnosis	Stalpers et al. 2005
	Supportive	Gaston-Johansson, 2000
MAACL	Relaxation	Yoo et al. 2005; Burish et al. 1992; Lerman et al. 1990; Burish et al. 1991
	CB	Vasterling et al. 1993
POMS	Relaxation	Molassiotis et al. 2001; Decker et al. 1992
	CB	Parker et al. 2009
HADS	Relaxation	Leon-Pizarro et al. 2007
	CB	Armes et al. 2007
	Supportive	Ream et al. 2006
BAI	Relaxation	Nunes et al. 2007
BDI	Relaxation	Nunes et al. 2007
	Supportive	Gaston-Johansson, 2000
CECS	Relaxation	Walker et al. 1999
MRS*	Relaxation	Walker et al. 1999
	Hypnosis	Schnur et al. 2009
ISSL	Relaxation	Nunes et al. 2007
7-point	Relaxation	Burish et al. 1991
Anxiety scale*	CB	Vasterling et al. 1993
CES-D	CB	Larson et al. 2000; Krischer et al. 2007; Jacobsen et al. 2002
DES IV	CB	Larson et al. 2000
IES	CB	Larson et al. 2000, Parker et al. 2009
LOT	CB	Larson et al. 2000
COPE	Supportive	Ream et al. 2006
VAS for coping*	Supportive	Ream et al. 2006
Interview data*	Supportive	Burton et al. 1995
Physical side effects		
Nausea and vomiting		
7- point scales*	Relaxation	Yoo et al. 2005; Burish et al. 1991; Lerman et al. 1990 Burish et al. 1991
	Supportive	
MANV	Relaxation	Molassiotis et al. 2002; Morrow et al. 1992
INV-2	Relaxation	Arakawa, 1997, Troesch et al. 1993
VAS for nausea*	CB	Syrjala et al, 1992; Syrjala et al. 1995
	Hypnosis	Syrjala et al. 1992
	Supportive	Gaston-Johansson, 2000

Nausea questions*	CB	Jacobsen et al. 2002
Patient and Nurse Rating*	CB	Vasterling et al. 1993
Physical symptoms		
SSI*	CB	Given et al. 2004; Sikorskii et al. 2006
Fatigue		
Fatigue		
EORTC-QLQc30c	CB	Armes et al. 2007- physical functioning subscale only
VAS fatigue*	CB	Armes et al. 2007
	Hypnosis	Montgomery et al. 2009
	Supportive	Gaston-Johansson, 2000; Ream et al. 2006
VAS muscle weakness*	Hypnosis	Montgomery et al. 2009
Fatigue-vigor-POMS	CB	Brown et al. 2006
MFI	CB	Armes et al. 2007
FOM*	CB	Armes et al. 2007
LASA*	CB	Brown et al. 2006
Pain		
VAS*	Relaxation	Syrjala et al. 1995
	CB	Syrjala et al. 1992; Syrjala et al. 1995
	Hypnosis	Syrjala et al. 1992
POM	Supportive	Gaston-Johansson, 2000
Quality of life		
QL-CA-A-A-Fex	Relaxation	Leon-Pizarro et al. 2007
FACT-B	Relaxation	Yoo et al. 2005
	Hypnosis	Montgomery et al. 2009- fatigue subscale only
GQOL*	Relaxation	Walker et al. 1999
SF-36	CB	Larson et al. 2000; Parker et al. 2009; Krischer et al. 2007; Jacobsen et al. 2002 (short form)
	Hypnosis	Stalpers et al. 2005
	Supportive	Ream et al. 2006
PCI	CB	Parker et al. 2009

* Measure designed specifically for study

Key to abbreviations:

CB	Cognitive-behavioural
VAS	Visual Analogue Scale

Glossary and reference list of outcome measures

BAI	Beck Anxiety Inventory: Beck, A.T., Epstein, N., Brown, G., & Steer, R.A. (1988). An inventory measuring clinical anxiety: Psychometric properties. *Journal of Consulting and Clinical Psychology, 56,* 893–897.
BDI	Beck Depression Inventory: Beck: A.T., & Steer, R.A. (1987). *Manual for the Beck Depression Inventory.* San Antonio, TX: Psychological Corporation.
CECS	Courtauld Emotional Control Scale: Watson , M & Greer, S. (1983). Development of a questionnaire measure of emotional control. *Journal of Psychosomatic Research, 27 (4),* 299-305
CES-D	Centre for Epidemiologic Studies Depression Scale: Radloff, L.S. (1977). The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement, 1,* 385-401
COPE	Coping Orientations to Problems Experienced: Carver, C. S., Scheier, M. F., & Weintraub, J. K. (1989). Assessing coping strategies: a theoretically based approach. *Journal of Personality & Social Psychology, 56(2),* 267-83.
DES-IV	Differential Emotions Scale-IV: Izard, C.E., Libero, D.Z., Putnam, P. & Haynes, O.M. (1993). Stability of emotional experiences and their relations to traits of personality. *Journal of Personality and Social Psychology, 64,* 847-60.
EORTC QLQc30c	European Organization for Research and Treatment of Cancer Quality of-Life Questionnaire Core 30, version 3: Aaronson N.K. (1993). The EORTC-QLQ-30: a quality of life instrument for use in international clinical trials in oncology. *Quality Life Research, 2,* 51.
FACT	Functional Assessment of Chronic Illness Therapy: Yellen, S.B., Cella, D.F., Webster, K., Blendowski, C. & Kaplan, E. (1997). Measuring fatigue and other anemia-related symptoms with the Functional Assessment of Cancer Therapy (FACT) measurement system. *Journal of Pain and Symptom Management, 13,* 63-74. Cella, D. (1997). *Manual of the Functional Assessment of Chronic Illness Therapy (FACIT) scales.* Centre on outcomes research and education (CORE) (1997). Evanston Northwestern Healthcare and Northwestern University.

FOM	Fatigue Outcome Measure: Designed specifically for study by Armes, J., Chalder, T., Addington-Hall, J., Richardson, A., & Hotopf, M. (2007). A randomized controlled trial to evaluate the effectiveness of a brief, behaviorally oriented intervention for cancer-related fatigue. *Cancer, 110(6), 1385-1395*.
GQOL	Global Self-rated Quality of Life: Assessed by a five-point Likert Scale specifically for the study by Walker, L. G., Walker, M. B., Ogston, K., Heys, S. D., Ah-See, A. K., Miller, I. D. et al. (1999). Psychological, clinical and pathological effects of relaxation training and guided imagery during primary chemotherapy. *British Journal of Cancer, 80(1-2),* 262-8.
HADS	Hospital Anxiety and Depression Scale: Zigmond, A. S. & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica, 67(6),* 361-70.
IES	Impact of Events Scale: Horowitz, M., Wilner, N. & William, A. (1979). Impact of Events Scale: a measure of subjective stress. *Psychosomatic Medicine, 41,* 209-18.
INV-2	Rhodes Index of Nausea and Vomiting Form 2: Rhodes, V.A., Watson, P.M. & Johnson, M.H. (1986). Association of chemotherapy related nausea and vomiting with pretreatment and posttreatment anxiety. *Oncology Nursing Forum, 13*, 41-7.
ISSL	Lipp's Inventory of Stress Symptoms: Lipp M.N. (2000). *Lipp's Inventory of Stress Symptoms for Adults [in portuguese],* 1st edn. Sa˜o Paulo: Casa do Psico´ logo,
LASA	Single-item Linear Analogue Self-Assessment: Single item visual analogue scale designed for study by Brown, P., Clark, M. M., Atherton, P., Huschka, M., Sloan, J. A., Gamble, G. et al. (2006). Will improvement in quality of life (QOL) impact fatigue in patients receiving radiation therapy for advanced cancer? *American Journal of Clinical Oncology, 29(1),* 52-58.
LOT	Life Orientation Test: Carver, C.S. et al. (1994). Optimisim versus pessimism predicts the quality of women's adjustment to early stage breast cancer. *Cancer, 73,* 1213-20.
MAACL	Multiple Affect Adjective Checklist: Zuckerman, M, Lubin, B, Vogel, L. & Valerius, E. (1964). Measurement of experimentally induced affects. *Journal of Consulting Psychology, 28,* 418-425.
MANV	Morrow Assessment of Nausea and Vomiting: Morrow, G.R. (1984). The assessment of nausea and vomiting: past problems, current issues, and suggestions for future research. *Cancer, 23*, 2267-2278.

MFI	Multidimensional Fatigue Inventory: Fitzpatrick R, Davey C, Buxton M.J. & Jones D.R. (1998). Evaluating patient-based outcome measures for use in clinical trials. *Health Technology Assessment, 2(14),* 1–74.
MRS	Mood Rating Scale: Mood Rating Scale MRS (six visual analogue scales (relaxation, happiness, energy, confusion, easy-goingness and confidence) each of which has five defined anchor points). Used in Walker, L. G., Walker, M. B., Ogston, K., Heys, S. D., Ah-See, A. K., Miller, I. D. et al. (1999). Psychological, clinical and pathological effects of relaxation training and guided imagery during primary chemotherapy. *British Journal of Cancer, 80(1-2),* 262-8.
CCV	Cuestionario de Calidad de Vida QL-CA-Afex: Font A & Baye´s R.(1993). Desarrollo de un instrumento para la medida de la calidad de vida en enfermedades cro´ nicas. En Aportaciones recientes a la evaluacio´n psicolo´gica, Foros Santacana M, Anguera Argilaga MT (eds). Universitas-53: Barcelona.
PCI	Prostate Cancer Index: Litwin, M.S. et al. (1998). The UCLA Prostate Cancer Index: Development, reliability and validity of a health-related quality of life measure. *Medical Care, 36,* 1002-1012.
POM	Painometer: Gaston-Johansson, F. (1996). Measurement of pain: the psychometric properties of the pain-o-meter, a simple, inexpensive pain assessment tool that could change health care practices. *Journal of Pain and symptom management, 12,* 172-81.
POMS	Profile of Moods State: McNair, D. M., Lorr, M., & Droppelman, L. F. (1971). *Manual for the Profile of Mood States.* San Diego: Educational and Industrial Testing Services.
SF-36	Short Form-36 Health Survey: Ware, J.E. (1993). *SF-36 Health Survey: Manual and Interpretation Guide.* Boston, MA, The Health Institute. New England Medical Centre.
SSI	Symptom Severity Index. Designed for study by Given, C., Given, B., Rahbar, M., Jeon, S., McCorkle, R., Cimprich, B. et al. (2004). Effect of a cognitive behavioral intervention on reducing symptom severity during chemotherapy. *Journal of Clinical Oncology, 22(3), 507-516.*
STAI	State-Trait Anxiety Inventory: Spielberger, C.D. (1983). *Manual for the State-Trait Anxiety Inventory.* Palo Alto, CA, Consulting Psychologists Press.

Appendix 5: Data Extraction Form

Title and author of study:
Year:
Country:
Setting:
Study design
Number of participants
Attrition
Allocation to group
Sample characteristics (cancer type, treatment status)
Eligibility criteria
Treatment
Intervention
Provider
Sessions/how long/when given
Comparison group
Outcomes
Results
Conclusions
Strengths and limitations
Important notes

Appendix 6: The Yates Scale (Yates, Morley, Eccleston & Williams, 2005)

Quality Rating Scale – Coding Notes

Treatment Quality

The aim of this section is to ensure that in the report a clear account of the treatment is given and that there is evidence that the investigators took steps to ensure that the treatment was delivered as intended by trained and competent personnel. Each item is therefore a judgement about whether this has been achieved.

Item #	Question and Items	Score & Coding Notes
1 1 part	**Has a clear rationale for the treatment been given and an adequate description of its content?**	
	Treatment Content / Setting The aim of this item is to make a judgment of the quality of the treatment in the trial by ascertaining whether a coherent rationale is given e.g. reference to the relevant evidence base for the treatment. Another consideration is whether an adequate description of the treatment content is given such that there may be sufficient information to stratify studies for example.	**2 - Adequate:** A clear rationale for the treatment has been reported along with an adequate description of its content. **1 - Partial:** Either a clear rationale or a description of the content of the treatment is reported. **0 - Inadequate:** Neither the rationale for treatment or the treatment content are adequately reported.
2 1 part	**Has the total treatment duration been reported?**	
	Treatment duration Total treatment duration includes both number of treatment sessions and duration of each session. Issues relating to the actual number of sessions attended i.e. attrition is dealt with in a later section.	**Reviewer decides.** **1 - Reported** **0 - Unknown**

3 2 parts	**Is there a treatment manual that describes the active components of treatment?**	
	Manualisation Treatment manuals should clearly prescribe the active components of the treatment and ideally proscribe activities that should not be included within the treatment. Trials with more than one treatment arm should demonstrate that manuals were utilised for each of the treatments where appropriate, e.g. for relaxation training and coping skills training but not for treatment as usual.	**2 - Adequate:** there is reference to use of a manual that describes the active components of the treatment of study. If more than one treatment arm, manuals were used for all the appropriate treatments. **1 - Partial:** In trials with more than one treatment arm, the use of a manual is described but not for all the treatments that would be expected to be manualised. **0 - Inadequate:** no evidence that a manual has been used, but reference is made to various principles.
	Adherence to the manual Treatment manuals are also considered essential as they provide a benchmark for various checks of validity e.g. whether therapists are adhering to the treatment under study and whether patients are doing what is required of them.	**1 - Adequate:** there is evidence that the investigators have checked adherence to the manual during the period of study via direct observations, tape recording or supervisory processes that explicitly state adherence to the manual. **0 - Inadequate:** no evidence of adherence checks reported.
4 1 part	**Have the therapists been appropriately trained in the relevant procedures for this trial?**	
	Therapist training The important issue here is not just whether the therapists have the appropriate qualifications and experience *per se,* as a multidisciplinary team may implement the treatment. Of importance is whether the therapists involved have been trained appropriately to conduct the particular treatment of the trial.	**2 - Adequate:** there is documentation of explicit training for the treatment of the trial. **1 - Partial:** the general level of therapist training is reported and is adequate (professionally qualified) but there is no mention of explicit training for the trial. **0 - Inadequate:** there is no convincing evidence that the therapists have an adequate level of training (e.g. graduate level) or explicit training for the trial.

5	**Is there evidence that the patients have actively engaged in the treatment?**	
1 part	**Client Engagement** This item assesses whether the investigators took steps to check that the patients actively engaged in the therapy and complied with the instructions of the treatment e.g. checks for evidence of skills practice, reviews of homework.	**1 - Adequate:** documented that evidence of engagement was sought e.g. checks on homework were made, skills practice in sessions. **0 - Inadequate:** no evidence that checks were made on level of engagement.

Quality of study design and methods
The aim of this section is to ensure that investigators made attempts to ensure that the design of the study was appropriate for its aims and that rigorous methodological effort were made to reduce the potential for bias. Each item is a judgement about whether this has been achieved.

Item #	Question and Items	Score & Coding Notes
1	**Are the inclusion and exclusion criteria clearly specified?**	
2 parts	**Sample Criteria** This item explores the context of the patient selection and allows the generalisability of the trial to be examined. Detailed information of the sample can also be used for stratifying in meta-analyses.	**1 - Adequate:** the inclusion and exclusion criteria are clearly specified and there is evidence of adherence to the criteria. **0 - Inadequate:** criteria not clearly specified.
	Evidence that the criteria have been met It is equally important to check for evidence that the inclusion and exclusion criteria have been met.	**1 - Adequate:** clear evidence is reported that the criteria have been met. **0 - Inadequate:** no evidence that any criteria have been met.

2 2 parts	**Is there evidence that CONSORT guidelines for reporting attrition have been followed?**	
	Attrition It is considered essential that good quality trials follow the CONSORT guidelines for reporting attrition i.e. "For each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons". It should be noted that this criteria automatically biases against pre-CONSORT trials i.e. prior to and during 1996.	**2 - Adequate:** documented evidence that the CONSORT guidelines have been followed. **1 - Partial:** a reasonable account of how attrition was dealt with is given, but without reference to CONSORT. **0 - Inadequate:** there is no documented evidence or insufficient evidence reported of how attrition was dealt with.
	Rates of attrition It is also important to ascertain whether final sample could be biased due to differential dropout rates between the treatment groups.	**1 - Adequate:** there is evidence that any differential rates of attrition were **not** statistically significant. **0 - Inadequate:** there is insufficient evidence that differential rates of attrition have not resulted in significant bias.
3 2 parts	**Is there a good description of the sample in the trial?**	
	Sample Characteristics This criterion is concerned with there being an adequate description of the actual sample obtained in terms of demographic information, concurrent treatments, treatment history, gender, diagnosis, site of pain and chronicity.	**1 - Adequate:** there is a good description of the sample in the trial detailing areas such as demographic details, treatment history etc. **0 - Inadequate:** insufficient information is reported to allow adequate comparisons to be made.
	Group equivalence Good descriptions of the sample characteristics and testing are essential for ascertaining whether there is equivalence between the treatment groups.	**1 - Adequate:** there is evidence that the groups are broadly equivalent shown by testing or examination of reported data. **0 - Inadequate:** either equivalence of groups is not reported or there is evidence of non-equivalence.

4 4 parts	**Have adequate steps been taken to minimise biases?**	
	Randomisation This item examines the steps taken to ensure that each participant of the trial has an equal chance of being allocated to the different treatment arms. In particular, it asks for evidence that an adequate method of randomisation has been used e.g. random number table or computerised random number generator (CONSORT, 1996).	**2 - Adequate:** a convincing method for generating a random allocation sequence is reported that used an independent person not involved in enrolment or allocation of participants. **1 - Partial:** a convincing method of randomisation is reported but this did not involve an independent person. **0 - Inadequate:** randomisation is mentioned but there is not an adequate description of the methods used.
	Allocation bias Were steps taken to ensure that the allocation sequence of patients to the treatment arms was concealed so that investigators could not have biased it? Ideally, an independent person should make assignment; alternatively, assignment can be enclosed in sequentially numbered, opaque sealed envelopes (CONSORT, 1996).	**1 - Adequate:** an adequate method is reported that removes the potential biases of investigators e.g. use of an independent person or sequentially numbered opaque sealed envelopes. **0 - Inadequate:** there is not an adequate description of attempts to deal with potential allocation bias.
	Measurement bias In order to reduce the risk of measurement bias a third party who is blind to the patient's study group should be responsible for the collection of data.	**1 - Adequate:** a convincing effort to reduce bias in outcome measurement is reported e.g. 3rd party blind data collection. **0 - Inadequate:** efforts to reduce measurement bias are not reported or are insufficient e.g. outcomes collected by therapist.
	Treatment expectations It is impossible for participants to be blind to the treatment they are receiving therefore it is imperative that steps are taken to check for equivalence in treatment expectations.	**1 - Adequate:** credible checks for equivalence in treatment expectations are reported. **0 - Inadequate:** checks have not been reported or are insufficient.

5 3 parts	**Are the outcomes that have been chosen justified, valid and reliable?**	
	Justification of outcomes This item is concerned with whether the outcomes measures that have been chosen encompass the aims of the treatment and are therefore justified with regard to those aims.	**2 - Adequate:** all of the outcome measures are justified. **1 - Partial:** most of the outcome measures are justified. **0 - Inadequate:** most or all of the measures used are not justified.
	Validity of outcomes for context A report stating that measures with known validity were used is not sufficient as measures cannot be said to be valid *per se*, only that they have validity in a particular context. This item therefore requires an informed judgement as to whether the measures chosen are valid given the context of the study population and the treatments implemented.	**2 - Adequate:** all of the outcome measures are valid given the context of the study. **1 - Partial:** most of the measures are valid. **0 - Inadequate:** most or all of the measures are not valid given the context of the particular study.
	Reliability and sensitivity to change It is important that the outcome measures chosen have both good reliability (generally defined as $r \geq 0.8$) and sensitivity to change.	**2 - Adequate:** all the outcome measures chosen were shown to be reliable and sensitive to change. **1 - Partial:** most of the measures were reliable and sensitive to change. **0 - Inadequate:** most of the measures were not reliable or sensitive to change.
6 1 part	**Has there been a measure of any sustainable change between the treatment and control groups?**	
	Follow up This item examines whether attempts have been made to measure sustainable changes between the treatment and control groups e.g. over a period of at least 6 months.	**1 - Adequate:** follow up measurements for at least 6 months are reported. **0 - Inadequate:** the follow up period was inadequate to measure sustainable change e.g. less than 6 months.

7 5 parts	**Are the statistical analyses adequate for the trial?**	
	Has a power calculation been used? The report must state that power calculations were calculated a priori.	**Reviewer decides.** **1 - Yes** **0 - No**
	Has a sufficient sample size, based on the power calculation been obtained?	**Reviewer decides.** **1 - Yes** **0 - No**
	Has the data analysis been adequately planned to assess the hypothesis and aims of the trial?	**Reviewer decides.** **1 - Yes** **0 - No**
	Is there adequate reporting of summary statistics? The means, standard deviations and numbers should be reported for the variables. The proportions or frequencies should be reported for dichotomous variables.	**Reviewer decides.** **1 - Yes** **0 - No**
	Did the analysis include an intention to treat analysis? It is important to account for any potential biases in rates of attrition by performing an intention to treat analysis as well as an analysis per protocol.	**Reviewer decides.** **1 - Yes** **0 - No**

8 1 part	**Has a good, well-matched alternative treatment group been used?**	
	Control group This item is concerned with the quality of the control condition in the trial and the efforts made to ensure that as many features as possible have been controlled for.	**2 - Adequate:** an active alternative treatment group has been used that is well matched in terms of structural features of the treatment and its meaningfulness. **1 - Partial:** an active alternative treatment group has been used but it is not matched for structural features e.g. bibliotherapy. **0 - Inadequate:** a poor control group has been used that merely controls for the duration of time e.g. waiting list control.

Appendix 7: Characteristics of the studies included in the review

Criteria	RT	Hypnosis	CB	Psychological support	RT & PREP	RT & CB	CB & hypnosis	All studies
Treatment								
Chemotherapy	8		4	1	1	1		15
Radiotherapy	3	3	2					8
Brachytherapy	1							1
Radical prostatectomy			1					1
Mastectomy, lumpectomy, chemotherapy & radiotherapy			1					1
Surgery and/or chemotherapy and/or radiotherapy			1					1
Bone marrow transplant				1		1	1	3
Mastectomy				1				1
Cancer type								
Breast cancer	5	2	2	2		1		12
Various	5	1	6	1	1			14
Breast cancer and gynaecological	1							1
Prostate			1					1
Leukemia						1		1
Hematological							1	1
Not specified	1							1
Quality of studies								
0-8	1		3					4
9-17	10	1	4	3	1	2	1	22
18-26	1	2	2					5
Quality of intervention								
0-3	6		1		1			8
4-6	6	3	4	3		1		17
7-9			4			1	1	6

Key to abbreviations:
RT Relaxation training
CB Cognitive-behavioural

Appendix 8: Quality of the interventions in reviewed studies

Quality criteria	Arakawa 1997	Armes	Brown 2006	Burish 1992	Burish 1991	Burton	Decker 1992	Gaston-Johansson 2000
Rationale & description ○ ◖ ●	●	●	◖	●	●	●	●	●
Session details ○ ●	○	●	●	●	●	●	●	●
Treatment manual ○ ◖ ●	●	●	●	○	○	○	○	○
Adherence to manual ○ ●	○	●	●	○	○	○	○	○
Provider training ○ ◖ ●	○	●	●	○	○	◖	◖	◖
Participant engagement ○ ●	○	○	○	○	○	○	○	○
Total score	4	8	7	3	3	4	4	4

Quality criteria	Given 2004	Jacobsen 2002	Kolcaba 1999	Krischer 2007	Larson 2000	Leon-Pizarro 2007	Lerman 1990
Rationale & description ○ ◖ ●	◖	●	●	●	●	●	●
Session details ○ ●	●	●	●	●	●	●	○
Treatment manual ○ ◖ ●	●	●	○	●	○	○	○
Adherence to manual ○ ●	●	●	○	○	○	○	○
Provider training ○ ◖ ●	●	●	◖	○*	◖	○	○
Participant engagement ○ ●	●	●	●	○	○	○	●
Total score	8	9	5	5	4	3	3

* Was not applicable- self administered intervention

Key to symbols
- ● Fulfils criteria
- ◖ Partly fulfils criteria (this option is only available for some criterion)
- ○ Does not fulfil criteria

Quality criteria	Molassiotis 2002	Montgomery 2009	Morrow 1992	Nunes 2007	Parker 2009	Phillips 2008	Ream 2006
Rationale & description ○ ◖ ●	●	●	●	●	●	◖	●
Session details ○ ●	●	●	●	●	●	●	○
Treatment manual ○ ◖ ●	○	○	○	○	○	◖	●
Adherence to manual ○ ●	○	○	○	○	○	○	○
Provider training ○ ◖ ●	◖	○	●	●	◖	●	◖
Participant engagement ○ ●	●	●	○	○	○	○	○
Total score	5	4	5	5	4	5	5

Quality criteria	Schnur 2009	Staplers 2005	Syrjala 1995	Syrjala 1992	Vasterling 1993	Walker 1999	Yoo 2005
Rationale & description ○ ◖ ●	●	●	●	●	●	●	●
Session details ○ ●	●	●	●	●	●	○	●
Treatment manual ○ ◖ ●	○	○	●	○	○	○	○
Adherence to manual ○ ●	○	○	●	○	○	○	○
Provider training ○ ◖ ●	◖	●	●	◖	◖	○	○
Participant engagement ○ ●	●	●	●	●	○	●	○
Total score	5	6	9	5	4	3	3

Appendix 9: Quality of studies in review

Quality criteria	Arakawa 1997	Armes 2007	Brown 2006	Burish 1992	Burish 1991	Burton 1995	Decker 1992	Gaston-Johansson 2001
Sample criteria ○ ●	●	●	●	○	○	○	●	●
Evidence met ○ ●	●	●	●	○	○	○	○	●
Attrition ○ ◖ ●	○*	◖	●	◖	●	◖	○	○
Attrition rates ○ ●	○*	○	○*	○	○	○	○	○
Sample Characteristics ○ ●	●	●	●	●	●	●	●	●
Sample Equivalence ○ ●	●	○	●	●	●	●	○	○
Randomisation ○ ◖ ●	○	●	○	○	○	●	○	○
Allocation bias ○ ●	○	●	○	○	○	○	○	○
Measurement bias ○ ●	○	○	○	○	○	○	○	○
Treatment expectations ○ ●	○	○	○	○	○	○	○	○
Justification of outcomes ○ ◖ ●	●	●	●	●	●	◖	●	●
Validity of outcomes ○ ◖ ●	●	●	●	◖	◖	◖	●	●
Reliability of outcomes ○ ◖ ●	●	●	●	◖	◖	◖	●	●
Follow-up ○ ●	○	●	●	○	○	◖	○	○
Power ○ ●	○	●	○	○	○	○	○	●
Sample size ○ ●	○	○	○	○	○	○	○	●
Planned analysis ○ ●	○	●	●	●	●	○	●	●
Reporting ○ ●	○	●	●	●	●	●	●	●
Intention to treat analysis ○ ●	○	●	○	○	○	○	○	○
Control group ○ ◖ ●	◖	○	○	○	○	◖	○	○
Total	11	18	15	9	9	10	10	13

* did not have to address

Key to symbols ● Fulfils criteria ◖ Partly fulfils criteria (this option is only available for some criterion) ○ Does not fulfil criteria

Quality criteria	Given 2004	Jacobsen 2002	Kolcaba 1999	Krischer 2007	Larson 2000	Leon-Pizarro	Lerman 1990	Molassiotis 2001
Sample criteria ○ ●	●	●	●	●	●	○	●	●
Evidence met ○ ●	●	●	●	○	○	○	●	○
Attrition ○ ◖ ●	◖	◖	●	●	◖	◖	○*	◖
Attrition rates ○ ●	●	●	○	○	○	○	○*	○*
Sample Characteristics ○ ●	●	●	●	●	●	●	●	●
Sample Equivalence ○ ●	●	●	●	●	○	●	●	●
Randomisation ○ ◖ ●	○	●	○	●	○	○	○	◖
Allocation bias ○ ●	○	●	○	●	○	○	○	○
Measurement bias ○ ●	○	○	○	○	○	○	○	●
Treatment expectations ○ ●	○	●	○	○	○	○	○	○
Justification of outcomes ○ ◖ ●	●	●	●	●	●	●	●	●
Validity of outcomes ○ ◖ ●	○	●	○	●	●	●	●	●
Reliability of outcomes ○ ◖ ●	○	●	○	●	●	●	●	●
Follow-up ○ ●	○	○	○	○	○	○	○	○
Power ○ ●	○	○	○	○	○	●	○	●
Sample size ○ ●	○	○	○	○	○	●	○	○
Planned analysis ○ ●	●	●	●	●	●	●	●	●
Reporting ○ ●	●	●	●	●	●	●	●	○
Intention to treat analysis ○ ●	○	○	○	○	○	○	○	○
Control group ○ ◖ ●	○	○	○	○	○	●	○	◖
Total	10	18	9	15	11	15	12	15

* did not have to address

Quality criteria	Montgomery 2009	Morrow 1992	Nunes 2007	Parker 2009	Phillips 2008	Ream 2006	Schnur 2009
Sample criteria ○ ●	●	●	●	●	●	●	●
Evidence met ○ ●	●	●	○	●	○	●	●
Attrition ○ ◖ ●	◖	○*	○*	◖	◖	●	◖
Attrition rates ○ ●	○	○*	○*	○	○	○	○
Sample Characteristics ○ ●	●	○	●	●	○	●	○
Sample Equivalence ○ ●	●	○	●	●	○	●	●
Randomisation ○ ◖ ●	●	○	○	○	○	●	◖
Allocation bias ○ ●	●	○	○	○	○	●	●
Measurement bias ○ ●	●	○	○	●	○	○	●
Treatment expectations ○ ●	○	●	○	○	○	○	○
Justification of outcomes ○ ◖ ●	●	●	●	●	◖	●	●
Validity of outcomes ○ ◖ ●	●	●	●	●	◖	●	●
Reliability of outcomes ○ ◖ ●	●	●	●	●	○	●	●
Follow-up ○ ●	○	○	○	●	●	○	○
Power ○ ●	●	○	○	○	●	●	●
Sample size ○ ●	●	○	○	○	○	○	●
Planned analysis ○ ●	●	●	●	●	●	●	●
Reporting ○ ●	●	●	●	●	○	●	●
Intention to treat analysis ○ ●	●	○	○	●	○	○	●
Control group ○ ◖ ●	○	○	○	●	◖	○	○
Total	20	11	11	19	8	17	18

* did not have to address

Quality criteria	Staplers 2005	Syrjala 1995	Syrjala 1992	Vasterling 1993	Walker 1999	Yoo 2005
Sample criteria	●	●	○	○	●	●
Evidence met	●	○	○	○	○	○
Attrition	●	●	○	○	◖	◖
Attrition rates	○	●	●	●	●	○
Sample Characteristics	●	●	●	○	●	●
Sample Equivalence	○	●	○	●	●	●
Randomisation	○	○	○	○	○	◖
Allocation bias	○	○	○	○	○	●
Measurement bias	●	○	○	○	○	●
Treatment expectations	●	○	○	○	○	○
Justification of outcomes	●	●	●	●	●	◖
Validity of outcomes	●	●	●	◖	●	◖
Reliability of outcomes	●	●	●	◖	●	◖
Follow-up	○	○	○	○	○	●
Power	○	○	○	○	●	●
Sample size	○	○	○	○	●	○
Planned analysis	●	●	●	●	●	●
Reporting	○	●	○	●	●	●
Intention to treat analysis	●	○	○	○	●	○
Control group	○	●	●	◖	○	○
Total	14	15	11	9	18	14

*did not have to address

Appendix 10: Table of components of the relaxation interventions

	IS	G	SA	PMR	GI	DB	Cue-controlled	SD	Meditation	Tumour visualization	Audio	Written	Video	Daily practice	Adherence	Bio-feedback
Arakawa, 1997	✓			✓							✓			✓		
Burish et al. 1992– relaxation	✓			✓	✓						✓			✓		✓
Burish et al. 1992-biofeedback														✓		✓
Burish & Jenkins 1992	✓			✓	✓							✓		✓		
Decker et al. 1992	✓			✓		✓	✓				✓	✓		✓		
Kolcaba et al. 1999			✓		✓						✓	✓		✓	✓	
Leon-Pizarro et al. 2007	✓				✓	✓					✓			✓		
Lerman et al. 1990	✓			✓		✓					✓	✓		✓	✓	
Molassiotis et al. 2002	✓			✓	✓	✓					✓		✓	✓	✓	
Morrow et al. 1992	✓			✓				✓			✓			✓		
Nunes et al. 2007		✓		✓	✓	✓			✓	✓	✓			✓		
Syrjala et al. 1995	✓			✓	✓	✓					✓	✓		✓		
Vasterling et al. 1993	✓			✓	✓											
Walker et al. 1999	✓			✓	✓		✓			✓	✓			✓	✓	
Yoo et al. 2005	✓			✓	✓									✓		

Key:to abbreviations

IS- individual sessions
G- group
SA- self-administered
PMR- progressive muscle relaxation
GI- guided imagery
DB- deep breathing
SD- systematic desentization

Appendix 11: The key elements of CBT satisfied by the interventions according to the criterion developed by Jones et al. 2010

Study	**Both of these criterion**		**One of these criterion**		
	Establishing links between thoughts, feelings and actions. Including psychoeducation.	Correction of person's misinterpretation, irrational beliefs and reassuring bias	1. Monitoring thoughts, feelings or behaviours	2. Promotion of alternative ways of coping	3. Attempted modification of behavioural responses to symptoms and illness
Armes et al. 2007	✓	✓	✓	✓	✓
Brown et al. 2006				✓	
Given et al. 2004					✓
Jacobsen et al. 2002 PMST	✓	✓		✓	
Jacobsen et al. 2002 PMST		✓		✓	
Krischer et al. 2007		✓	✓	✓	
Larson et al. 2000	✓	✓	✓	✓	✓
Parker et al. 2009				✓	
Phillips et al. 2008		✓		✓	
Syrjala et al. 1995		✓		✓	✓
Syrjala et al. 1992		✓	✓	✓	✓
Vasterling et al. 1993				✓	

Appendix 12: Table of general and relaxation components of cognitive-behavioural interventions

Study	IS	G	SA	Relaxation	DB	PB	GI	M	PMR	Cue Controlled	Audio	Daily practice	Imaginal exposure	Autogenic relaxation
Armes et al. 2007	✓													
Brown et al. 2006		✓		✓	✓		✓		✓					
Given et al. 2004	✓													
Jacobsen et al. 2002 PSMT	✓			✓	✓		✓		✓		✓			
Jacobsen et al. 2002 SSMT			✓	✓			✓		✓		✓			
Krischer et al. 2007			✓	✓		✓	✓		✓		✓			
Larson et al. 2000	✓	✓		✓					✓		✓	✓		
Parker et al. 2009	✓			✓	✓		✓				✓	✓	✓	
Phillips et al. 2008		✓		✓	✓		✓	✓	✓			✓		
Syrjala et al. 1995	✓			✓	✓		✓		✓		✓	✓		
Syrjala et al. 1992	✓			✓					✓		✓	✓		✓
Vasterling et al. 1993	✓													

Key:
IS- individual sessions
G-group sessions
SA- self administered
DB- diaphragmatic breathing
PB- paced breathing
GI- guided imagery
PMR- progressive muscle relaxation
M- Meditation
PSST- professional-administered stress management training
SSMT- self-administered stress management training

Appendix 13: Table of cognitive, coping and problem solving components of cognitive-behavioural interventions

Study	SM	Coping skills	CR	Assertion training	Problem solving	Alternative illness percpetions	GS	SS	Thought monitoring	Identifying thoughts & feelings	Self montoring
Armes et al. 2007		✓	✓			✓	✓			✓	✓
Brown et al. 2006	✓			✓	✓		✓				
Given et al. 2004					✓						
Jacobsen et al. 2002 PSMT	✓							✓		✓	
Jacobsen et al. 2002 SSMT	✓							✓			
Krischer et al. 2007	✓							✓	✓		
Larson et al. 2000		✓PF	✓			✓	✓			✓	✓
Parker et al. 2009	✓	✓PF									
Phillips et al. 2008	✓	✓	✓	✓							
Syrjala et al. 1995			✓					✓			
Syrjala et al. 1992			✓				✓	✓			✓
Vasterling et al. 1993											

SM- stress management
CR- cognitive restructuring
GS- Goal setting
SS- self statements

Study	Distraction	Prioritising	Self-management information	Psychoeducation about stress	Activity scheduling
Armes et al. 2007	✓				✓
Brown et al. 2006		✓			
Given et al. 2004			✓		
Jacobsen et al. 2002 PSMT					
Jacobsen et al. 2002 SSMT					
Krischer et al. 2007					
Larson et al. 2000	✓			✓	✓
Parker et al. 2009					
Phillips et al. 2008					
Syrjala et al. 1995	✓				✓
Syrjala et al. 1992	✓		✓		
Vasterling et al. 1993	✓				

Appendix 14: Table of general components of cognitive-behavioural interventions

Study	W	V	Spirituality	Social support	Concerns & fears	Physical component	Pain and theory	Counselling	Mechanisms of nausea	Information about treatment	Exploration of meaning
Armes et al. 2007	✓										
Brown et al. 2006	✓		✓	✓		✓					
Given et al. 2004								✓			
Jacobsen et al. 2002 PSMT											
Jacobsen et al. 2002 SSMT	✓	✓									
Krischer et al. 2007	✓	✓									
Larson et al. 2000	✓				✓						
Parker et al. 2009				✓	✓						
Phillips et al. 2008				✓							
Syrjala et al. 1995	✓						✓		✓		
Syrjala et al. 1992	✓									✓	✓
Vasterling et al. 1993											

Key:
W- written information
V- videotape

Appendix 15: Letter of Ethical Approval

[redacted]

INFORMATION SHEET

Evaluation of a preparation session for internal radiotherapy (selectron) treatment

My name is Dr Nina Shergill and I am a trainee Clinical Psychologist (not medical doctor). This information sheet tells you about a research study that I am doing jointly with the [redacted] as part of my doctoral training in clinical psychology. You are being invited to take part in this research study.

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. You will be given an opportunity to consent to the researcher contacting you in a few days time to answer any questions you may have and to go through the study information with you. Please ask us if anything is not clear or if you would like more information.

The information sheet consists of two parts:

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

If you have filled in the slip consenting to be contacted about this research then Dr Nina Shergill (chief investigator) will contact you in the next couple of days. You can contact Nina Shergill at any time if you have any questions about the research study. Thank you for taking the time to read this.

PART 1

Reasons for the study:

In this research study we want to find out how people cope with internal radiotherapy treatment (selectron) and whether they can be helped with a simple preparation session before the treatment. We know from previous research that some women having internal radiotherapy feel stressed, worried or nervous before and during the treatment. We want to know more about how patients cope with internal radiotherapy and whether a preparation session will benefit patients and in what way.

The aim of this research is to find out:

a) How patients are feeling before they have internal radiotherapy and afterwards
b) Whether a simple preparation session will help patients to cope better with internal radiotherapy.

Why have I been chosen?

You have been invited to take part in this research because you are going to have internal radiotherapy as part of your treatment for gynaecological cancer and we are interested in how you may cope and feel about having this treatment. We are hoping that at least 40 women will take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. This is your decision. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. You will still be free to withdraw from the study at any moment without any reason. The decision to withdraw at any time will not affect your treatment in any way.

What group can I be put in?

To find out if providing people with additional brief support is useful we need to compare different ways of doing things. We will do this by putting people into groups and compare them to see if one is better. In this study we have two groups.

The first group (a control group) will receive usual care and fill in questionnaires 2 and 3 at two further time-points. The second group will attend an hour long preparation session which is only available for a few months in 2009 and fill in questionnaires 2 and 3 at two time-points. We have these two groups so that we can find out by comparing the groups if the preparation session helps patients to cope better with internal radiotherapy.

If you take part in this study you will be in the control group.

What do I have to do?

You will be asked to fill in questionnaires on three separate occasions. Questionnaire 1 will be filled in shortly after you have been told that you will have internal radiotherapy. Please note that questionnaire 1 is longer than questionnaires 2 and 3. The second questionnaire will be filled in about 7-10 days before you have your internal radiotherapy and the final questionnaire will be filled in the morning after you have had your internal radiotherapy.

What will happen to me if I take part?

If you agree to take part in this study, you will be asked to do the following:

1) Fill in consent form and questionnaire

If you decide to take part, fill in the consent form and questionnaire 1 which is enclosed with this letter and return them in the pre-paid envelope provided. You will then be contacted by us over the next few weeks to fill in another two questionnaires.

2) Follow-up questionnaires

Questionnaire 2: We will send you a questionnaire 2 to fill in and return two weeks before you have your internal radiotherapy treatment. If we do not receive this questionnaire within a week then you will be contacted by phone and have the opportunity to complete the questions over the phone. This is to make sure that we have all the information we need for this study.

Questionnaire 3: You will be visited by Nina Shergill, lead researcher for this study, on the morning following your internal radiotherapy, before you are discharged. You will fill in questionnaire 3 on this morning. If, for any reason we are unable to meet with you that morning we will contact you within two days to complete the questions over the phone.

What are the possible disadvantages and risks of taking part?

There are no health risks involved in taking part in this study and your normal treatment will take place whichever group you are in. The questionnaire may make you think about your treatment and we recommend that you talk to your consultant oncologist or nurse about this. If you feel that you are overly worried about the treatment then please talk to the health professionals involved in your care, and they can make a referral to psychology services if they feel this is appropriate.

What are the possible benefits of taking part?

Your participation in this study may help future patients like yourself because

a) we will understand more fully how patients cope with internal radiotherapy and have screening methods in place to identify patients who are suffering from feelings of anxiety or sadness, and who may need further support.

b) we will collect information about whether a preparation session is beneficial to patients and in what way. This will help us to support patients who are going to have internal radiotherapy in order to achieve better patient care.

What happens when the research study stops?

Your medical care is independent of this study and your consultant will continue to provide the care for your current illness.

What if there is a problem?

If you are unhappy or unsure about anything that happens during the study, please feel free to contact the researchers at any time. They will do their best to listen to and address any concerns you may have. Their contact details are printed below. If you feel unable to do this, or are not satisfied with the response that you receive in reaction to your concerns, the normal NHS complaint procedures apply.

Will my taking part in the study be kept confidential?

Yes. All the information which is collected about you during the course of the research will be kept strictly confidential. Personal information will be securely stored at the University of Birmingham and will not be released or viewed by anyone other than the researchers in this study. The questionnaire data will not be linked to you as an individual, they will be anonymous. If you consent to take part in the study, your GP and other doctors treating you will be notified of your participation in the study. By signing the consent form you are agreeing for this to be done.

PART 2

What will happen to the results of this research study?

The researchers plan to submit the findings to a peer reviewed scientific journal for publication. We will also produce a summary sheet of the main findings for participants of the study. You will be given the opportunity to express your interest in receiving this summary in questionnaire 1 and at the end of the study. Results of the study will not include your name or any other identifiable characteristics and you will not be identified in any of the reports/publications.

What will happen if I don't want to carry on with the study?

Nothing. The only thing we ask you to do is let the researcher know that you no longer wish to participate. You don't have to give them a reason. This decision will not affect your treatment in any way.

Who is organising and funding the research?

This research is being conducted as part of Nina Shergill's Doctoral research and is hence not funded.

Who has reviewed the study?

The scientific study review has been undertaken by the School of Psychology at the University of Birmingham.

If you have any questions or require any further information then please do not hesitate to contact me.

Contact details

Dr Nina Shergill, [redacted]

For concerns or complaints with regard to this study, please contact [redacted]

Thank you for taking the time to read this-
please ask any questions if you need to.

[redacted]

INFORMATION SHEET

Evaluation of a preparation session for internal radiotherapy (selectron) treatment

My name is Dr Nina Shergill and I am a trainee Clinical Psychologist (not medical doctor). This information sheet tells you about a research study that I am doing jointly with [redacted] as part of my doctoral training in clinical psychology. You are being invited to take part in this research study.

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. You will be given an opportunity to consent to the researcher contacting you in a few days time to answer any questions you may have and to go through the study information with you. Please ask us if anything is not clear or if you would like more information.

The information sheet consists of two parts:

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

If you have filled in the slip consenting to be contacted about this research then Dr Nina Shergill (chief investigator) will contact you in the next couple of days. You can contact Nina Shergill at any time if you have any questions about the research study. Thank you for taking the time to read this.

PART 1

Reasons for the study:

In this research study we want to find out how people cope with internal radiotherapy treatment (selectron) and whether they can be helped with a simple preparation session before the treatment. We know from previous research that some women having internal radiotherapy feel stressed, worried or nervous before and during the treatment. We want to know

more about how patients cope with internal radiotherapy and whether a preparation session will benefit patients and in what way.

The aim of this research is to find out:

c) How patients are feeling before they have internal radiotherapy and afterwards
d) Whether a simple preparation session will help patients to cope better with internal radiotherapy.

Why have I been chosen?

You have been invited to take part in this research because you are going to have internal radiotherapy as part of your treatment for gynaecological cancer and we are interested in how you may cope and feel about having this treatment. We are hoping that at least 40 women will take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. This is your decision. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. You will still be free to withdraw from the study at any moment without any reason. The decision to withdraw at any time will not affect your treatment in any way.

What group can I be put in?

To find out if providing people with additional brief support is useful we need to compare different ways of doing things. We will do this by putting people into groups and compare them to see if one is better. In this study we have two groups.

The first group (a control group) will receive usual care and fill in questionnaires 2 and 3 at two further time-points. The second group will attend an hour long preparation session which is only available for a few months in 2009 and fill in questionnaires 2 and 3 at two time-points. We have these two groups so that we can find out by comparing the groups if the preparation session helps patients to cope better with internal radiotherapy.

If you take part in this study you will be in group 2, the group that receives the preparation session.

What do I have to do?

You will be asked to fill in questionnaires on three separate occasions. Questionnaire 1 will be filled in shortly after you have been told that you will have internal radiotherapy. Please note that questionnaire 1 is longer than questionnaires 2 and 3. The second questionnaire will be filled in about 7-10 days before you have your internal radiotherapy and the final questionnaire will be filled in the morning after you have had your internal radiotherapy. Participants will attend an hour long preparation session and

have a short telephone session before the treatment. They will also be contacted two weeks following their treatment to hear their views about the preparation session.

What will happen to me if I take part?
If you agree to take part in this study, you will be asked to do the following:

2) Fill in consent form and questionnaire
If you decide to take part, fill in the consent form and questionnaire 1 which is enclosed with this letter and return them in the pre-paid envelope provided. You will then be contacted by us over the next few weeks to fill in another two questionnaires.

2) Preparation session
Preparation session: We will contact you shortly after receiving your consent form to arrange a time to have the preparation session. The preparation session is a hour long and you will be given the opportunity to talk about any concerns you have about the treatment and ways in which you can cope before and during the treatment. This session will take place at a time that is convenient to you.

Telephone session: A week before you have your treatment we will contact you by phone to see how you are feeling and whether you have been able to think about what was discussed in the preparation session.

3) Follow-up questionnaires
Questionnaire 2: We will send you a questionnaire 2 to fill in and return two weeks before you have your internal radiotherapy treatment. If we do not receive this questionnaire within a week then you will be contacted by phone and have the opportunity to complete the questions over the phone. This is to make sure that we have all the information we need for this study.

Questionnaire 3: You will be visited by Nina Shergill, lead researcher for this study, on the morning following your internal radiotherapy, before you are discharged. You will fill in questionnaire 3 on this morning. If, for any reason we are unable to meet with you that morning we will contact you within two days to complete the questions over the phone.

4) Feedback after preparation session
Feedback over telephone: We will contact you by phone approximately two weeks following your treatment to find out what your experience was of the preparation session and what you found useful, and what we can improve. This information will help us to think about how we could make this preparation session better for other patients in the future.

What are the possible disadvantages and risks of taking part?

There are no health risks involved in taking part in this study and your normal treatment will take place whichever group you are in. The questionnaire may make you think about your treatment and we recommend that you talk to your consultant oncologist or nurse about this. If you feel that you are overly worried about the treatment then please talk to the health professionals involved in your care, and they can make a referral to psychology services if they feel this is appropriate.

What are the possible benefits of taking part?

Your participation in this study may help future patients like yourself because

a) we will understand more fully how patients cope with internal radiotherapy and have screening methods in place to identify patients who are suffering from feelings of anxiety or sadness, and who may need further support.

b) we will collect information about whether a preparation session is beneficial to patients and in what way. This will help us to support patients who are going to have internal radiotherapy in order to achieve better patient care.

What happens when the research study stops?

Your medical care is independent of this study and your consultant will continue to provide the care for your current illness.

What if there is a problem?

If you are unhappy or unsure about anything that happens during the study, please feel free to contact the researchers at any time. They will do their best to listen to and address any concerns you may have. Their contact details are printed below. If you feel unable to do this, or are not satisfied with the response that you receive in reaction to your concerns, the normal NHS complaint procedures apply.

Will my taking part in the study be kept confidential?

Yes. All the information which is collected about you during the course of the research will be kept strictly confidential. Personal information will be securely stored at the University of Birmingham and will not be released or viewed by anyone other than the researchers in this study. The questionnaire data will not be linked to you as an individual, they will be anonymous. If you consent to take part in the study, your GP and other doctors treating you will be notified of your participation in the study. By signing the consent form you are agreeing for this to be done.

PART 2

What will happen to the results of this research study?

The researchers plan to submit the findings to a peer reviewed scientific journal for publication. We will also produce a summary sheet of the main findings for participants of the study. You will be given the opportunity to express your interest in receiving this summary in questionnaire 1 and at the end of the study. Results of the study will not include your name or any other identifiable characteristics and you will not be identified in any of the reports/publications.

What will happen if I don't want to carry on with the study?

Nothing. The only thing we ask you to do is let the researcher know that you no longer wish to participate. You don't have to give them a reason. This decision will not affect your treatment in any way.

Who is organising and funding the research?

This research is being conducted as part of Nina Shergill's Doctoral research and is hence not funded.

Who has reviewed the study?

The scientific study review has been undertaken by the School of Psychology at the University of Birmingham.

If you have any questions or require any further information then please do not hesitate to contact me.

Contact details

Dr Nina Shergill, [redacted]

For concerns or complaints with regard to this study, please contact [redacted]

Thank you for taking the time to read this-
please ask any questions if you need to.

Appendix 18: Invitation letter from consultants

[redacted]

Re: Birmingham University Study
Evaluation of a preparation session for internal radiotherapy (selectron) treatment

The cancer centre is participating in a study researching how women cope with internal radiotherapy treatment (selectron) and whether they can be helped to cope better by a simple preparation session before treatment. This is a joint research project between [redacted] and the University of Birmingham. You have been invited to take part in this study because you are going to have internal radiotherapy treatment. This study has been approved by the local research ethics committee.

It is important for you to know that:

1. Taking part in the research will not affect your care
2. It is entirely up to you if you wish to take part
3. You can withdraw from the study at anytime without giving a reason

Over a six to eight week period you will be asked to fill in 3 questionnaires. Questionnaire 1 is enclosed with letter and should be filled in and sent with your consent form. Questionnaire 2 will be filled in 7-10 days before you have internal radiotherapy and the final questionnaire will be filled in the morning after you have your internal radiotherapy. The research wants to find out if providing an additional brief preparation session is useful and therefore you will be put into a group. There are two groups in this study, Group 1 will receive usual care and Group 2 will have a brief preparation session. Initially the preparation session will only be available for a few months in 2009. The group you are placed in depends on whether the session is being offered when you receive your internal radiotherapy treatment.

It is hoped that the study will lead to a better understanding of how women cope with internal radiotherapy and will help to make services better for other women who will have this treatment in the future. Whatever you decide your medical and legal rights are not affected in any way and your future care will not be influenced.

Enclosed with this letter are an information sheet, consent form and questionnaire provided by the researchers. The information sheet describes the study in more detail. It also includes the researcher's details if you have any questions about the study. If you think you might be interested in helping with this research please read the information and follow the instructions provided.

Many thanks for taking the time to read this letter.

Yours Sincerely,

Consultant and Nurse

CONSENT FORM

Title of Project: Evaluation of a preparation session for internal radiotherapy (selectron) treatment.

Name of Researcher: Dr Nina Shergill

Please initial box

I confirm that I have read and understand the information sheet dated 6th February 2009 (version 2) for the above study. I have had the opportunity to consider the information, ask questions if I wish and have these answered satisfactorily. ☐

I understand that my taking part is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

I agree to take part in the above study ☐

Please sign:

Name _____ Signature_____ Date _____

Leave for researcher to fill in:

Researcher_____ Signature _____ Date_____

Name of Person taking consent (if different from researcher): _____

Signature_____ Date_____

School of psychology

University of Birmingham
Edgbaston
Birmingham
B15 2TT

Telephone:
Email:

QUESTIONNAIRE 1

Thank you for agreeing to help us with our research.

- Before starting the questionnaire please make sure you have read the information sheet and **signed the consent form**
- **PLEASE RETURN THIS QUESTIONNAIRE IN THE PRE-PAID ENVELOPE ENCLOSED WITH YOUR CONSENT FORM**
- Please note that this questionnaire is longer than questionnaire 2 and 3

All the information that you give us will be **COMPLETELY CONFIDENTIAL** and will not be seen by your doctor.

Instructions for Questionnaire:

- Please answer **ALL** the questions
- There are no right or wrong answers
- Tick the box next to the answer that you think applies to **YOU** the most- not what you think 'most people' would say or do

QUESTIONS ABOUT YOUR VIEW OF YOUR ILLNESS

The following questions ask you **what you think** about your illness. For the following questions, **please circle the number** that best describes what you think:

How much does your illness affect your life?

0	1	2	3	4	5	6	7	8	9	10
No affect at all										Severely affects my life

How long do you think your illness will continue?

0	1	2	3	4	5	6	7	8	9	10
A very short time										forever

How much control do you feel you have over your illness?

0	1	2	3	4	5	6	7	8	9	10
Absolutely no control										Extreme amount of control

How much do you think your treatment can help your illness?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Extremely helpful

How much do you experience symptoms from your illness?

0	1	2	3	4	5	6	7	8	9	10
No symptoms at all										Many severe symptoms

How concerned are you about your illness?

0	1	2	3	4	5	6	7	8	9	10
Not at all concerned										Very concerned

How well do you think you understand your illness?

0	1	2	3	4	5	6	7	8	9	10
Don't understand at all										Understand very clearly

How much does your illness affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?

0	1	2	3	4	5	6	7	8	9	10
Not at all affected emotionally										Extremely affected emotionally

Please list in rank-order the three most important factors that you believed caused your illness. The most important causes for me:-

1. _____
2. _____
3. _____

QUESTIONS ABOUT HOW YOU FEEL

Please **tick the box next to the statement which best describes your feelings** during the **past week**. Try not to think about your answers for too long

I feel tense or 'wound up':

- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

I still enjoy the things I used to enjoy:

- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

I get a sort of frightened feeling as if something awful is about to happen:

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

I can laugh and see the funny side of things:

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

Worrying thoughts go through my mind:

- ☐ A great deal of time
- ☐ A lot of time
- ☐ From time to time, but not too often
- ☐ Only occasionally

I feel cheerful:

- ☐ Not at all
- ☐ Not often
- ☐ Some of the time
- ☐ Most of the time

I can sit at ease and feel relaxed:

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

I feel as if I am slowed down:

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

I get a sort of frightened feeling like 'butterflies' in the stomach:

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

I have lost interest in appearance:

- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

I feel restless as I have to be on the move:

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

I look forward with enjoyment to things:

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

I get sudden feelings of panic:

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

I can enjoy a good book or radio or TV program

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Please **tick a box next to the mood descriptions that describe best** how you have been feeling for the **past 48 hours**.

	Not at all	**A little**	**Moderate**	**Quite a bit**	**Extremely**
Active	☐	☐	☐	☐	☐
Angry	☐	☐	☐	☐	☐
Annoyed	☐	☐	☐	☐	☐
Anxious	☐	☐	☐	☐	☐
Bewildered	☐	☐	☐	☐	☐
Bitter	☐	☐	☐	☐	☐
Blue	☐	☐	☐	☐	☐
Bushed	☐	☐	☐	☐	☐
Cheerful	☐	☐	☐	☐	☐
Confused	☐	☐	☐	☐	☐
Discouraged	☐	☐	☐	☐	☐
Energetic	☐	☐	☐	☐	☐
Exhausted	☐	☐	☐	☐	☐
Fatigued	☐	☐	☐	☐	☐
Forgetful	☐	☐	☐	☐	☐

	Not at all	A little	Moderate	Quite a bit	Extremely
Full of pep	☐	☐	☐	☐	☐
Furious	☐	☐	☐	☐	☐
Grouchy	☐	☐	☐	☐	☐
Helpless	☐	☐	☐	☐	☐
Hopeless	☐	☐	☐	☐	☐
Lively	☐	☐	☐	☐	☐
Miserable	☐	☐	☐	☐	☐
Nervous	☐	☐	☐	☐	☐
On edge	☐	☐	☐	☐	☐
Peeved	☐	☐	☐	☐	☐
Resentful	☐	☐	☐	☐	☐
Restless	☐	☐	☐	☐	☐
Sad	☐	☐	☐	☐	☐
Tense	☐	☐	☐	☐	☐
Unable to concentrate	☐	☐	☐	☐	☐
Uncertain	☐	☐	☐	☐	☐
Uneasy	☐	☐	☐	☐	☐
Unhappy	☐	☐	☐	☐	☐
Vigorous	☐	☐	☐	☐	☐
Weary	☐	☐	☐	☐	☐
Worn out	☐	☐	☐	☐	☐
Worthless	☐	☐	☐	☐	☐

QUESTIONS ABOUT HOW YOU COPE

There are lots of ways to try to deal with stress. This questionnaire asks you to indicate what you generally do and feel, when ***you*** experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you ***usually*** do when you are under a lot of stress.

- Respond to each following items by **ticking the box under the category that you think fits you the most.**
- Please try to respond to each **item *separately in your mind from each other item*.**
- Choose your answers thoughtfully, and make your answers as true **FOR YOU** as you can.

	I usually don't do this at all	I usually do this a little bit	I usually do this a medium amount	I usually do this a lot
I've been concentrating my efforts on doing something about the situation I'm in	☐	☐	☐	☐
I've been trying to come up with a strategy about what to do	☐	☐	☐	☐
I've been trying to see it in a different light, to make it seem more positive	☐	☐	☐	☐
I've been accepting the reality of the fact that it has happened	☐	☐	☐	☐
I've been making jokes about it	☐	☐	☐	☐
I've been trying to find comfort in my religion or spiritual beliefs	☐	☐	☐	☐
I've been getting emotional support from others	☐	☐	☐	☐
I've been trying to get advice or help from other people about what to do	☐	☐	☐	☐
I've been turning to work or other activities to take my mind off things	☐	☐	☐	☐
I've been saying to myself 'this isn't real'	☐	☐	☐	☐
I've been saying things to let my unpleasant feelings escape	☐	☐	☐	☐

	I usually don't do this at all	I usually do this a little bit	I usually do this a medium amount	I usually do this a lot
I've been using alcohol or other drugs to make myself feel better	☐	☐	☐	☐
I've been giving up trying to deal with it	☐	☐	☐	☐
I've been criticising myself	☐	☐	☐	☐
I've been learning to live with it	☐	☐	☐	☐
I've been taking action to try to make the situation better	☐	☐	☐	☐
I've been thinking hard about what steps to take	☐	☐	☐	☐
I've been looking for something good in what is happening	☐	☐	☐	☐
I've been making fun of the situation	☐	☐	☐	☐
I've been praying or meditating	☐	☐	☐	☐
I've been getting comfort and understanding from someone	☐	☐	☐	☐
I've been getting help and advice from other people	☐	☐	☐	☐
I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping or shopping	☐	☐	☐	☐
I've been refusing to believe that it has happened	☐	☐	☐	☐
I've been expressing my negative feelings	☐	☐	☐	☐
I've been using alcohol or other drugs to help me get through it	☐	☐	☐	☐
I've been giving up the attempt to cope	☐	☐	☐	☐
I've been blaming myself for things that happened	☐	☐	☐	☐

INFORMATION ABOUT YOU

First name:_____ Surname:_____

Address: _____

_____

_____

Postcode: _____

Date of birth: _____ Age: _____

What is your gender? ☐ Female ☐ Male

What is your marital status? ☐ Married ☐ Single ☐ Separated/divorce

☐ Widower ☐ Cohabiting

What is your ethnic group?
Please read the list below and tick one box that most describes your ethnic origin.

White

☐ British ☐ Irish

Any other White background. Please describe:

_____

Black or Black British

☐ Caribbean ☐ African

Any other black background. Please describe:

_____

Asian or Asian British

☐ Indian ☐ Bangladeshi ☐ Pakistani

Any other Asian background. Please describe:

_____

Chinese or other ethnic group

☐ Chinese

Any other ethnic group. Please describe:

_____

Mixed

☐ White and Black Caribbean ☐ White and Black African ☐ White and Asian

Any other Mixed background. Please describe:

_____

Have you had any full or part time further or higher education since you left school?

☐ Yes ☐ No

How long have you had your cancer diagnosis?

_____

Are you having or will you shortly be having any of the following treatments?

☐ Chemotherapy ☐ Radiotherapy (external)

☐ Other treatment

Please explain: _____

Thank you for taking the time to fill in this questionnaire

Appendix 21: Consent form to receive further information about the study

CONSENT TO RECEIVING FURTHER INFORMATION ABOUT THE STUDY

Evaluation of a preparation session for internal radiotherapy (selectron) treatment.

If you think you might wish to take part of if would like more information before deciding to take part please do the following:

1. **Fill out your name, address and telephone number below and e-mail address if you have one.**
2. **Tear off the information about yourself, place it in the envelope and seal it. Give this envelope to the health professional in the consultation with you now who will give it to the researchers for this study.**
3. **The envelope will only be opened by a member of the research team, and Dr Nina Shergill will phone you in a couple of days to explain the study further and answer any questions you may have.**
4. **Talking with the researcher will not in any way commit you to taking part in the study. We just want to make sure you understand the study fully before making a decision and/or know what is involved in taking part.**

Many thanks for taking the time to read this information.

If you are interested in hearing more about the study or might wish to take part please complete this response slip.

TEAR OFF
✂_____

Response slip: Evaluation of a preparation session for internal radiotherapy (selectron) treatment

Name: _____

Address:

_____

_____

_____

Telephone number:

_____

E-Mail address:

_____

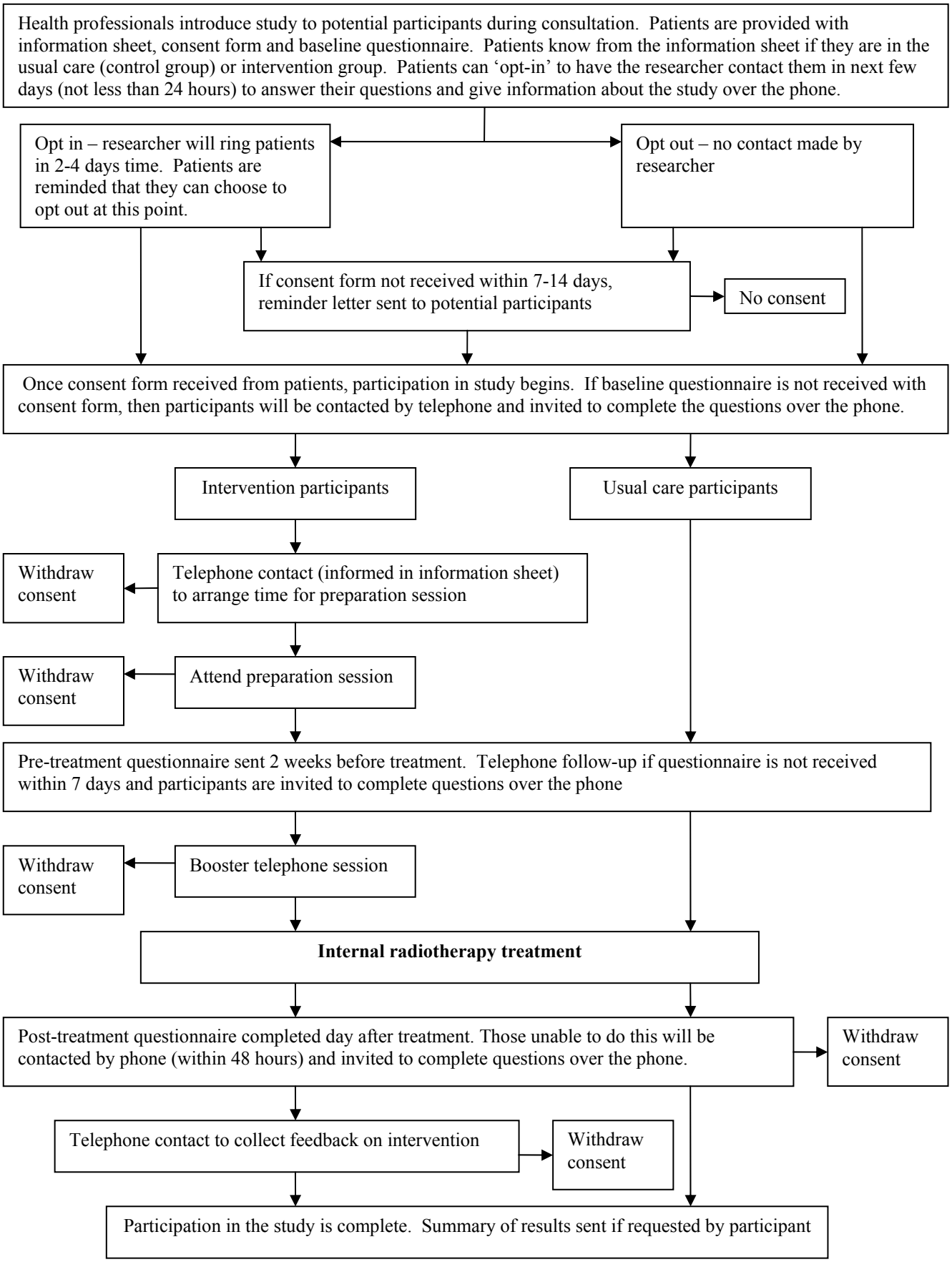
Please pass to the professional who has spoken with you about our study.

Appendix 22: Power calculation

Study Power

The estimation of the number of patients to be included was performed using the Gpower programme. This found that 40 participants in total (20 per group) would be required for this study to achieve 80% power with a significance level of 0.05, calculated on the basis of an effect size of 0.70 for the primary outcome of anxiety. There were no comparable studies in the literature which had used a psychosocial intervention preparing women for IRT. The effect size used was based on the Spanish study by Leon-Pizarro et al (2007) which evaluated a relaxation only intervention on breast and gynaecological patients undergoing internal radiotherapy. This study found a medium effect size (0.54) and the authors suggested that the heterogeneous patient group used may have reduced the power of the study. As this study's intervention goes well beyond relaxation (i.e. addressing concerns, cognitive and behavioural coping strategies), is conducted with a homogeneous group of patients, a power calculation was conducted on the basis of finding a somewhat larger effect size. Thus an effect size of 0.70 was selected.

Appendix 23: Figure of procedure in the study



Appendix 24: Distress Thermometer

Appendix 25: Table of tests to assess group differences at baseline

T-tests	**Time points assessed**	**t-value**	**Degrees of freedom**	**Significance level**
HADS-A	Baseline	0.822	17	0.42
HADS-D	Baseline	0.395	17	0.70
POMS	Baseline	0.402	17	0.70
Mann Whitney Test	**Time points**	**U value**	**N1, N2**	**Significance**
IPQ	Baseline	23.500	9, 10	0.079

Appendix 26: Individual scores for anxiety and depression as measured by the HADS.

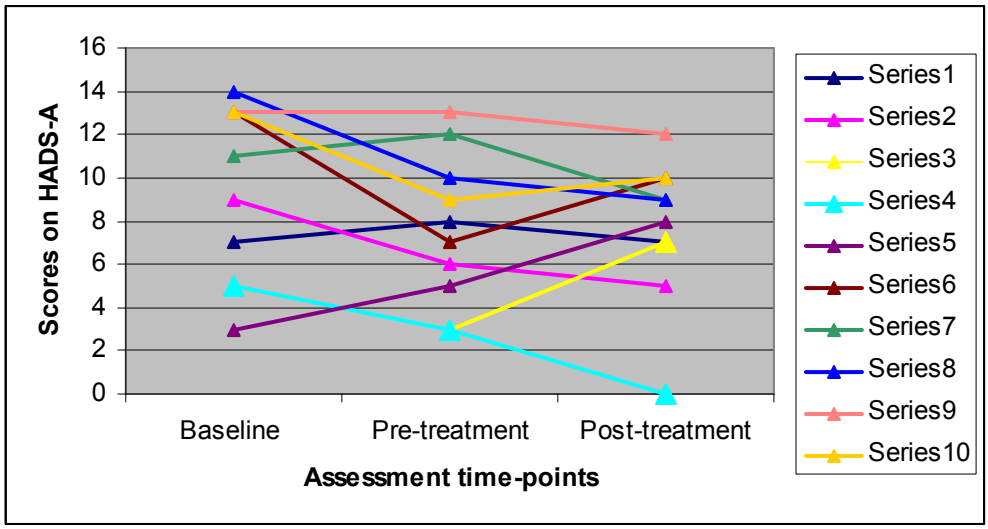


Figure showing individual scores on the HADS anxiety sub-scale at baseline, pre-treatment and post-treatment for the intervention group.

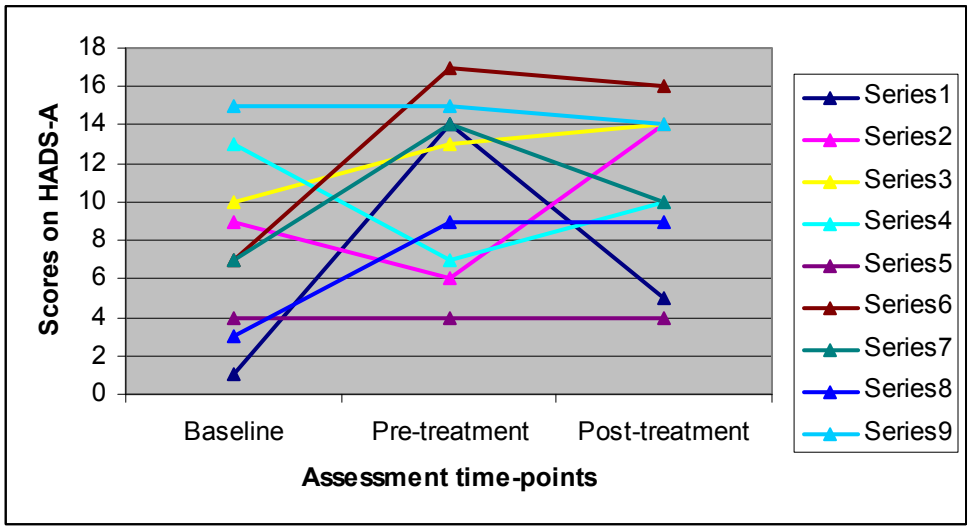


Figure of individual scores on the HADS anxiety sub-scale at baseline, pre-treatment and post-treatment for the control group

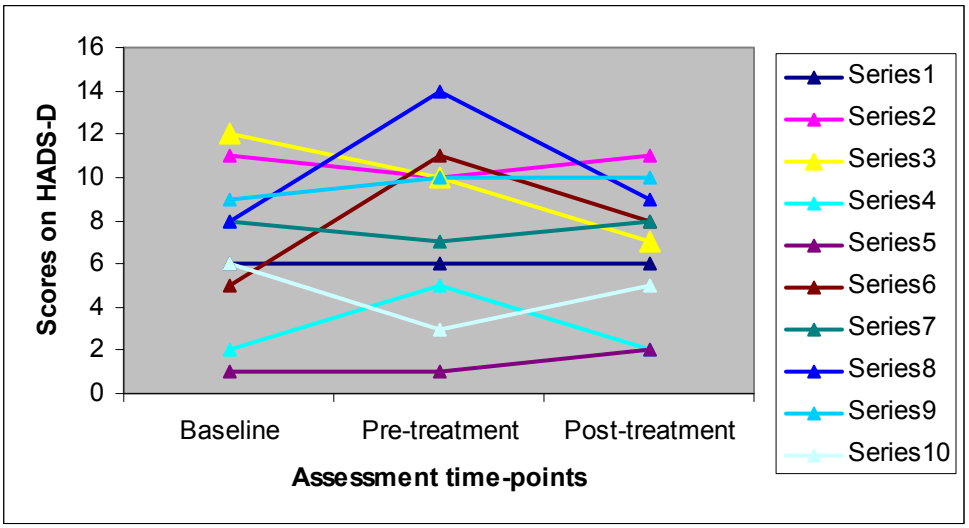


Figure of individual scores on the HADS depression sub-scale at baseline, pre-treatment and post-treatment for the intervention group

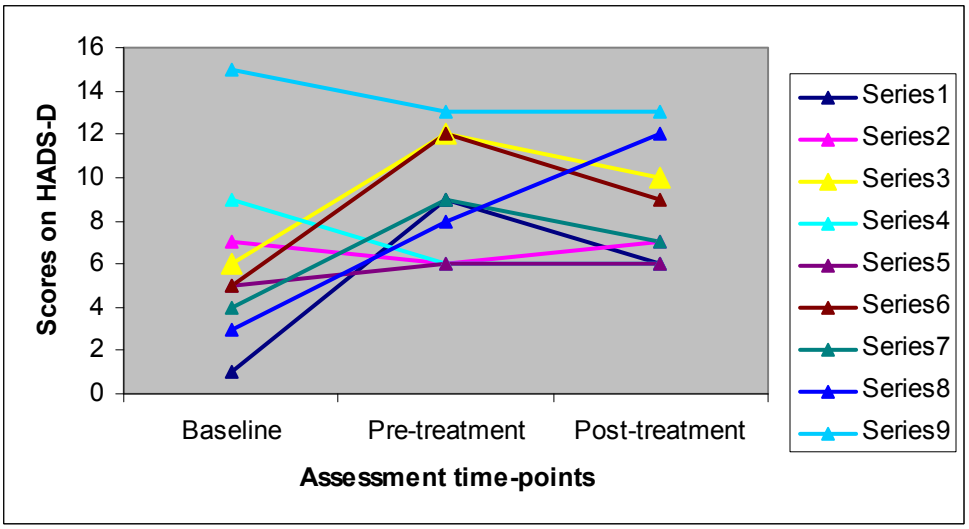


Figure showing individual scores on the HADS depression sub-scale at baseline, pre-treatment and post-treatment for the control group