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Title: Pilot randomised controlled trial of a radiation therapist led educational intervention for breast cancer patients prior to commencing radiotherapy

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Running title: Pilot RCT of Radiation Therapist Led Educational Intervention

Abstract

Purpose

Although patients receive information prior to commencing radiotherapy, they often experience anxiety and distress. We conducted a pilot randomised controlled trial to determine whether a radiation therapist led psycho-educational intervention for breast cancer patients prior to radiotherapy is likely to be effective in reducing radiotherapy-related concerns, patient anxiety and depression.

Methods

The intervention comprised two face-to-face consultations with a radiation therapist (one prior to radiation planning, the other prior to treatment). Patients completed surveys at baseline, prior to treatment planning and on the first day of treatment. Outcome measures included the Hospital Anxiety and Depression Scale, Radiation Therapy Related Patient Concerns and Radiation Therapy Knowledge Scales.

Results

122 patients completed baseline measures. 58 patients received usual care and 64 received the intervention. After the first consultation, patient anxiety was significantly lower in the intervention group ($p=0.048$), as were concerns about radiotherapy ($p=0.001$). There were no differences between groups for depression. Patient knowledge for the intervention group was higher after the first consultation ($p<0.001$).

Conclusion

This intervention is likely to be effective in reducing patient anxiety and concerns, and increasing knowledge. Future research is required to test this intervention with a larger population.

Key words: anxiety, breast cancer, communication skills, patient education, radiotherapy, randomised controlled trial

Background

Evidence-based recommendations suggest that 50% of all cancer patients and 83% of breast cancer patients should receive radiotherapy at some stage during their illness [1]. However, radiotherapy utilisation rates for all cancers in Australia varied between 24% and 71% from 1990-2000 [1] and an estimated 15,000 failed to receive radiotherapy in 2002 [2]. Reasons for this include lack of access to treatment facilities, inadequate referral and refusal of treatment [1]. Patients who do not receive radiotherapy may be at higher risk of disease recurrence and a shorter life span [3]. Women with breast cancer have high unmet information needs [4] and little knowledge of radiotherapy [5-8]. Some breast cancer patients may refuse radiotherapy treatment because they lack knowledge of radiotherapy, fear side effects or treatment itself [9].

Sufficient and timely information provision reduces psychological distress [10]. Patients prefer information about radiotherapy to be staggered over time [11]. Patients' information needs peak at the time of treatment planning and prior to treatment commencement [12].

Information provision within Australian radiotherapy departments is inconsistent in terms of how and when information is provided and by whom [13]. Radiation therapists (RTs) can play a crucial role in providing information and support during treatment [14]. The challenge for RTs is that limited evidence is available to guide them in how best to provide information and support. RTs do not follow a standardised procedure for providing information and it is often delivered while the patient is on the treatment table

[13]. These practices fail to address pre-treatment anxiety, are not conducive to information recall and may not be effective in meeting information needs.

Previous studies [15, 16] report that 45% of breast cancer patients experience clinically relevant levels of anxiety [17] and 10% experience clinically relevant levels of depression. A recent longitudinal study of breast cancer patients found that prior to treatment planning 30% of women had clinically relevant levels of anxiety [17] and 10% clinically relevant levels of depression, which continued at these levels after radiation planning and treatment commencement [18].

Level I evidence from other areas of health recommend that preparation for potentially threatening medical procedures should comprise sensory and procedural information and address treatment related concerns and anxiety. Such tailored preparation assists in improving health outcomes and produces greater reduction in patient anxiety levels than other interventions [19-22]. Sensory information involves informing patients about what they are likely to experience (feel, hear, see) and procedural information involves informing patients about what will happen before, during and after their planning and treatment appointments. Aranda et al. found in a randomised controlled trial that when an educational intervention consisting of sensory and procedural information and anxiety reduction strategies was provided to chemotherapy patients they had significantly lower sensory/ psychological and procedural concerns. Patients with elevated levels of distress in the intervention group also indicated a significant decrease at the first follow-up time point [23]. Application of this evidence to a radiotherapy population is necessary to test whether the introduction of an educational intervention similarly reduces patients' levels of psychological and treatment-related distress.

The aim of this study was to pilot test a novel radiation therapist (RT) led psycho-educational intervention for breast cancer patients prior to commencing radiotherapy to determine whether it is likely to be effective in reducing radiotherapy-related concerns, patient anxiety and depression. It was hypothesised that the intervention would a) reduce patient anxiety and depression before treatment; b) reduce specific concerns about radiotherapy; c) increase patient knowledge of radiotherapy and d) increase patient preparedness for their radiation planning appointment and treatment.

Methods

Ethics approval was gained from the Human Research Ethics Committee at Curtin University and the tertiary hospital involved in recruitment.

Development of the RT led psycho-educational intervention

The MRC framework for developing and evaluating complex interventions guided development and pilot testing of the intervention [24]. A multidisciplinary team (radiation oncologist, radiation therapist, behavioural scientist, clinical psychologist, psychiatrist, general practitioner, nurse and a consumer) developed the tailored psycho-educational intervention.

The intervention comprised two face-to-face consultations with a trained RT: one prior to radiation planning and one prior to treatment (Figure 1). These time points were selected to address when patients information needs are highest prior to radiotherapy. RTs were trained to deliver the intervention.

The intervention comprised sensory and procedural information about radiotherapy and sought to elicit and respond to the patient's emotional concerns [25]. Level I evidence on preparing patients for threatening medical procedures was used to guide the content [19-22]. The procedural information drew upon relevant literature [26-29] and our own previous research [12]. A summary of the content of the two consultations and initial pilot testing for appropriateness and feasibility is provided in our previous work [30].

Pilot Randomised Controlled Trial

Participants

Patients were eligible for the study if they had been diagnosed with breast cancer, were scheduled for external beam radiotherapy, were referred for the study at least one week prior to radiation planning, over 18 years of age and could speak English. Patients were ineligible if they had previously received radiotherapy, were too unwell or had serious cognitive or psychiatric impairments.

Recruitment

Patients were informed about the study by their radiation oncologist during their first radiation oncology consultation. They were then contacted by a research assistant who provided additional information, an information sheet and obtained written informed consent.

Data Collection

Patients completed surveys at the following time points: baseline (following their consultation with their radiation oncologist and prior to radiation planning), immediately prior to radiotherapy planning and on the first day of treatment. Questionnaires were completed by participants at home at baseline and in the radiotherapy department for follow-up one and two. Surveys were returned via mail and/or using a collection box within the department.

Randomisation

Patients were randomised post baseline data collection to receive the intervention or usual care using randomisation figures obtained from the website randomizer.org. Patients were stratified according to whether had received or were receiving concurrent chemotherapy or not. This stratification occurred because patients who had received chemotherapy or were receiving chemotherapy may have received additional information and have had different levels of information needs and anxiety levels than those patients who were not receiving chemotherapy at all. Randomisation was completed in groups of 50.

Training of Intervention RTs

Intervention RTs participated in two training workshops to assist them in preparing for their intervention role: Preparing patients for Radiotherapy (RT prepare) Workshop; and Eliciting and Responding to Emotional Cues Workshop. Ten RTs completed both workshops.

RT Prepare Workshop: This workshop oriented RTs to the content and delivery of the two consultations and trained them to prepare patients for their radiotherapy planning

and treatment. The focus was on the sensory, procedural and side effects information about radiotherapy required by patients [5-7, 9, 12, 13, 18, 28, 31]. This workshop is described further in our previous work [30].

Eliciting and Responding to Emotional Cues Workshop [25]**:** This workshop was provided to assist the intervention therapists to detect patients' emotions and respond to them appropriately. The trained facilitator focused on eliciting and responding to the following emotional cues: anxiety, distress, anger and depression.

Each workshop was conducted over a four hour period. In both workshops, RTs practiced skills in role plays involving simulated patients (trained actors).

Measures

The following instruments were included: Hospital Anxiety and Depression Scale (HADs)[32]; Concerns about Radiotherapy Scale [33] and Knowledge of Radiotherapy Scale [33]. Single item indices were used to measure participant preparedness and understanding.

Demographic details were also collected: age, education level, marital status, employment status, location of residence and previous treatment.

HADS: This scale contains 14 items; 7 items measure anhedonic depression and 7 anxiety. It has established reliability and validity and is commonly used for cancer patients[32]. Questions have four response options ('Not at all' to 'Most of the time'), with a mean score of between 0 and 3 calculated for each sub-scale. This scale was administered at all three time points.

Concerns about Radiotherapy Scale: This 9-item scale measures breast cancer patients' concerns about specific aspects of radiotherapy using a 9-point visual scale (options from 'Not concerned' to 'Very concerned'). This scale was previously shown to have high internal consistency, achieving a Cronbach's alpha of 0.91, and adequate stability over time [33]. The mean of the nine items was calculated at each time point.

Knowledge of Radiotherapy Scale: This scale asks patients to identify their current level of knowledge about different aspects of radiotherapy (response options: 'I am sure this is definitely false', 'I think this is probably false', 'Unsure', 'I think this is probably true' and 'I am sure this is definitely true'). It is based on The RT Information Needs Scale[33] and has high internal consistency (Cronbach's alpha of 0.86), and adequate stability over time (mean Intraclass Correlation = 0.55 (SD = 0.18)). This scale was separated into two components – knowledge of radiation planning (20 items) and knowledge of treatment (10 items). Participants' responses were identified as correct or incorrect. Total knowledge scores were then calculated for each component (radiation planning /10 and treatment /20).

Patient preparedness and understanding index: A single item index [34] was used to determine whether the patient was feeling prepared for treatment planning and treatment as well as their level of understanding. When commencing this study no appropriate instrument existed for measuring patient preparedness and understanding in relation to radiotherapy. Each item was measured on a visual scale from 1-9. The items used are shown in Table 3.

Intervention Delivery

All intervention and usual care patients were provided with information as per current practice. This included written and verbal information from their radiation oncologist, nurse and RTs as part of usual care. Nurses routinely meet with patients after their radiation planning to provide information about the treatment and side effects. This practice was not changed for the study.

Intervention patients were provided with additional information and education prior to radiation planning and prior to treatment (Figure 1). To prevent contamination and diffusion of the intervention, the intervention RTs were required not to provide information to the usual care group and were discouraged from talking about the intervention with other RTs.

Patients assigned to the intervention were provided with a scheduled appointment immediately prior to their radiation planning and treatment appointments in order to receive the face-to-face consultations.

Intervention Fidelity

Intervention delivery was digitally tape recorded and content analysis carried out to assess ease of delivery of the intervention, intervention fidelity, consistency over time, and diffusion into routine care. Checklists were completed to assess completeness of the intervention delivery [23]. The checklist focused on eliciting and responding to emotional cues and the content patients need to know prior to each procedure. Twenty randomly selected intervention recordings were analysed by two trained reviewers for each time point (total of 40 recordings). The time taken to deliver the consultations was recorded. The reviewers completed the analysis separately and then met to assess adherence to the intervention. The variance in checklist scores between the two reviewers was $\leq 5\%$. When intervention RTs did not deliver the intervention appropriately they were provided with immediate feedback.

Data Analysis

Descriptive statistics were calculated as appropriate. T-tests and chi-square tests were utilised to test for baseline differences between the intervention and control groups on the demographic and dependent variables. The amount of missing data was low (<5%).

Linear Generalized Estimating Equations (GEE) models were used to examine intervention effects on the following scales: the HADS, the RT Concerns Scale, Knowledge of RT Scale and single items relating to preparedness and understanding. The models incorporated a time by group interaction to determine whether the intervention and control groups differed at the two post-intervention measurements.

GEE analyses were utilised to account for the dependency in the repeated observations from each subject and maximise the use of the observations. The covariance matrices formed by the item and scale scores were assumed to be exchangeable. Model assumptions such as normality assumptions, were tested in each instance and found to hold. Potential confounders, i.e. demographic variables and whether chemotherapy was being received, were tested for and included in the models as required to control for their effects. The nominal 5% level of significance was used for all tests.

Results

Recruitment rates

Patients were recruited between July 2009 and January 2011. Overall, 288 patients were screened for eligibility (Figure 2) and 151 were deemed eligible. 101 patients were not eligible because there was not enough time to recruit them and complete the baseline questionnaire between the appointment with their radiation oncologist and their radiation planning appointment (some patients see their radiation oncologist weeks or months before their radiation planning appointment, while others might not meet their radiation oncologist until the day of radiation planning). 151 patients were approached and 122 consented and completed baseline measures (response rate =81%). The main reason participants declined was because they felt it would take too much time. At Follow up 1, 114 participants completed questionnaires (retention = 93%) and at Follow up 2 102 participants completed questionnaires (retention = 89%).

Drop-outs occurred between baseline and follow up time points due to patients not completing surveys (n=5), being excluded due to the study protocol (n=15), patient compliance (n=2), one patient withdrew from the study and one patient did not commence radiotherapy. Patients were excluded if the surveys were administered at the wrong time point/not completed within the specified time frames. Patient compliance referred to patients in the intervention group not attending at the correct time and therefore they were not provided with the intervention.

Patient characteristics and success of randomisation

Demographic details are provided in Table 1. There were no significant differences between the intervention and usual care groups for demographic characteristics (all $p>0.05$). However, a significantly higher proportion of intervention (69%) than usual

care (50%) patients had received or were receiving concurrent chemotherapy (p=0.035) in comparison to those who received no chemotherapy.

At baseline there were no significant differences between the intervention and control groups for anxiety, depression, concerns, knowledge, preparedness and understanding (all p>0.05).

Intervention Fidelity

Tape recordings of the intervention delivery demonstrated that RTs were able to deliver the intervention successfully. Completion of the checklist items relating to the radiation planning consultation elements ranged from 51% to 88% (mean=70%, standard deviation = 11) with one significant degradation of intervention RT performance (poor performance with intervention content missing) over the duration of the study. Completion of the pre treatment consultation elements ranged from 58% to 88% (mean = 71%, standard deviation = 9.4) with one significant degradation of intervention RT performance over the duration of the study. There was no diffusion into usual care as assessed by the audiotapes.

Time taken to deliver the intervention

The mean duration of the consultations prior to radiation planning was 25.4 minutes (SD= 5.8, min=16, max=37.6) and prior to treatment was 24.4 minutes (SD=8.6, min = 8.4 and max = 38.4). The overall mean time to deliver the consultations was 24.9 minutes (SD=7.2).

Effect of the Intervention

The results of the GEE models testing for intervention effects on the main outcome measures are presented in Table 2. Significant differences were found between the intervention and usual care groups for all, but one of the five main outcome measures at the first follow-up (Time 2), but no differences were found at the second follow-up (Time 3) (Table 2).

The regression coefficients reflect the differences between the intervention and control patients' mean changes in the outcome measures from baseline to each of the Time 2 and Time 3 measurements respectively. For example, at Time 2, after receiving the first

consultation, patient anxiety levels dropped by 0.15 points more on average in the intervention group than the usual care group (range 0-3). The changes over time in anxiety and depression in the two groups are illustrated in Figure 3.There were no differences between the groups in changes in anxiety from baseline (Time 1) to the second follow-up (Time 3) and no differences for depression for either follow-up time point (Table 2 and Figure 3).

Knowledge scores for planning increased by 3.5 points (range 0-10) more on average between the baseline and first follow-up in the intervention versus the usual care group. As can be seen from Figure 4, the intervention group answered more questions correctly at the first follow-up compared to baseline while there was no improvement in the usual care group's knowledge between these two time points. Knowledge scores for treatment increased by 5.3 points (range 0-20) more on average in the intervention versus the usual care group in the same period (Figure 4). Patient RT related concerns dropped by 0.9 points more on average in the intervention group than the usual care group (Figure 5).

The results of the GEE models testing for single item index questions are presented in Table 3. Significant intervention effects were obtained for the following questions: "How prepared do you currently feel for the treatment planning procedure that you are about to undergo?" (Time 2); "I know what is going to happen during the treatment planning appointment" (Time 2); "How much understanding do you currently have of radiation therapy?" (Time 2 and Time 3); "How prepared do you currently feel to receive radiation therapy?" (Time 2 and Time 3); and "I know what is going to happen during my treatment" (Time 2). In each instance, patients in the intervention group reported more positive outcomes e.g. greater increases in preparedness and understanding.

Discussion

The primary hypothesis that patients receiving the intervention would report decreased anxiety was supported following delivery of the first consultation prior to radiation planning. However, patient depression levels were not significantly changed. The intervention was also effective in reducing patient concerns about radiotherapy, and increased patient knowledge and preparation prior to treatment planning. However, the

effects of the intervention were only short term with this small sample and significant differences were not found for anxiety, patient related RT concerns and knowledge between the two groups on the patient's first day of treatment. Further testing is required to determine whether these differences at the first consultation prior to treatment planning can be achieved with a larger sample size and within multiple sites and whether with a larger sample we can achieve a significant difference at the latter time of the first day of treatment. Because the intervention may also take potentially longer than usual care future studies also need to assess the cost benefit of the intervention.

Information delivery about radiotherapy needs to be staggered over time [11]. Previous studies involving testing informational resources for patients who require radiotherapy [26-29] have failed to show significant differences in reducing patient anxiety prior to treatment commencement. We have found that delivery of a face-to-face consultation is likely to be effective prior to treatment planning. To fully assess the benefit of these face-to-face consultations it is necessary to assess the full impact of the intervention on workflow and the cost of providing the intervention.

The intervention was developed using Level I evidence for preparing patients for threatening medical procedures [19-22]. Statistically significant differences for anxiety, preparation and treatment related concerns suggests that the approach used for intervention was appropriate to be used for patients receiving radiotherapy. In order to deliver the intervention it is essential that RTs receive training relating to both delivering information about radiotherapy and eliciting and responding to patients' emotional cues.

Although the intervention appears superior to usual care, the study had several limitations. First, the sample size used for this pilot study was relatively small (n=122). Second, the stratification of patients in the chemotherapy group failed due to the randomisation of patients in blocks of 50. However, this error was accounted for in all GEE analysis where it was identified to have an effect. Third, the single item index used to measure patient preparedness and understanding has not been tested for reliability and validity. At the time of this study no scales existed for measuring patient preparation. However, the Cancer Treatment Scale [35] has subsequently been tested to

assess patient preparation and will be used in future studies. Fourth, the study was undertaken at a single hospital and studied a limited patient population. Further research is now being conducted to determine whether similar results can be obtained in multiple institutions.

Conclusion

This pilot study demonstrated that a tailored psycho-educational intervention delivered by RTs prior to radiation planning and treatment may be effective in reducing breast cancer patients' anxiety prior to radiation planning. Additionally, such an intervention may result in further positive outcomes for patients such as increased knowledge of and preparedness for as well as reduced concerns about their radiation treatment. Further testing is required to see whether this intervention can be implemented at multiple sites, is cost effective and significantly reduces patient anxiety and depression prior to treatment commencement.

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Conflict of interest statement: None to declare.

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Tables and Figures

Figure 1: Structure of the intervention (*=radiation therapist)

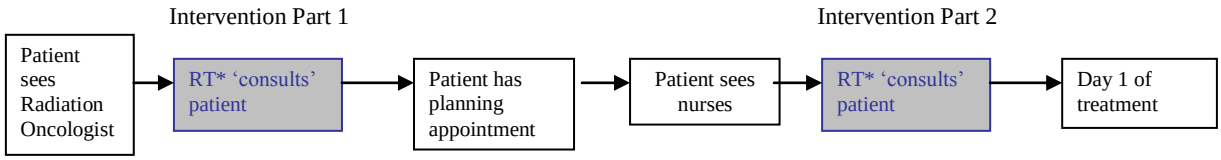


Figure 2 – CONSORT flow diagram

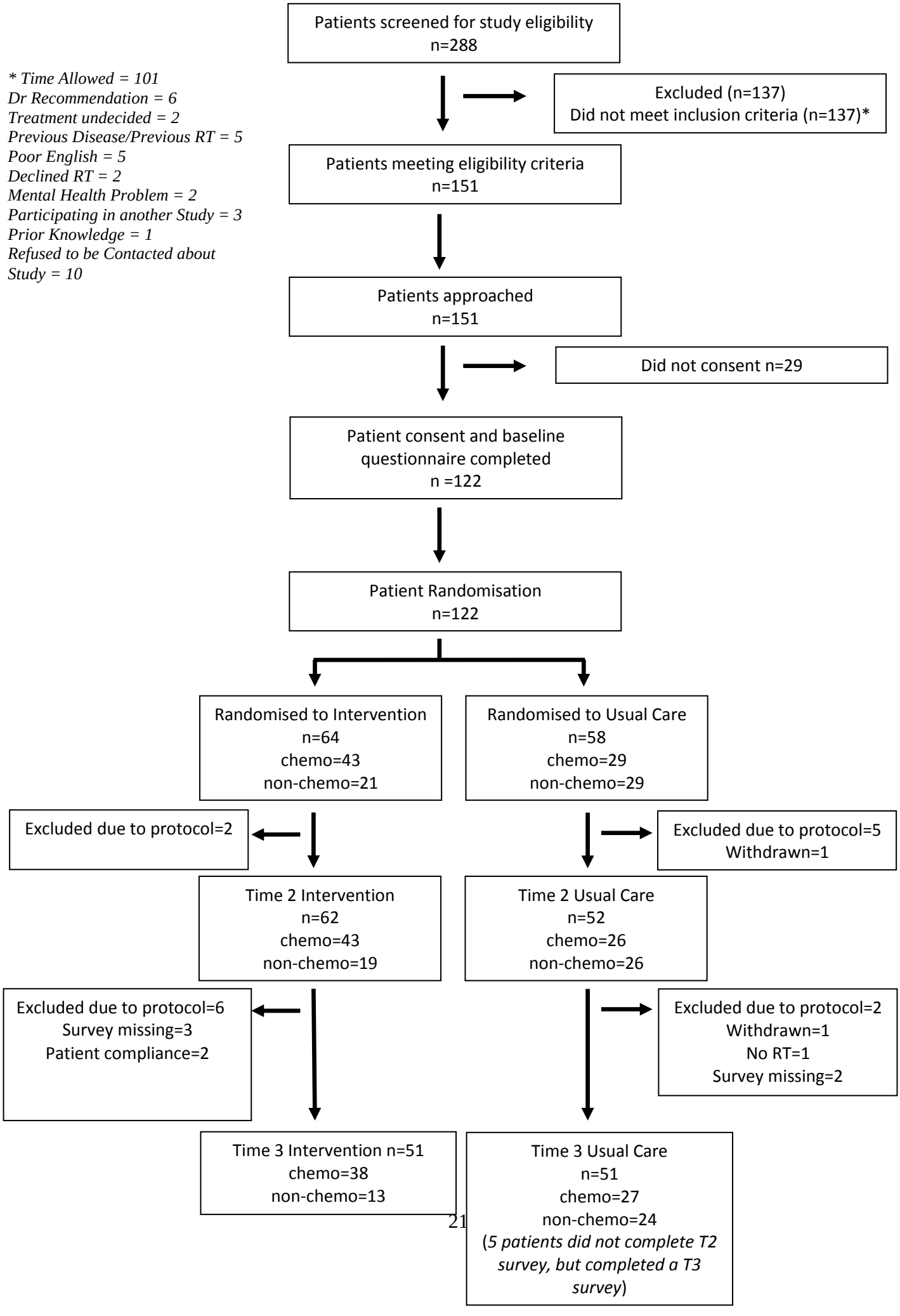
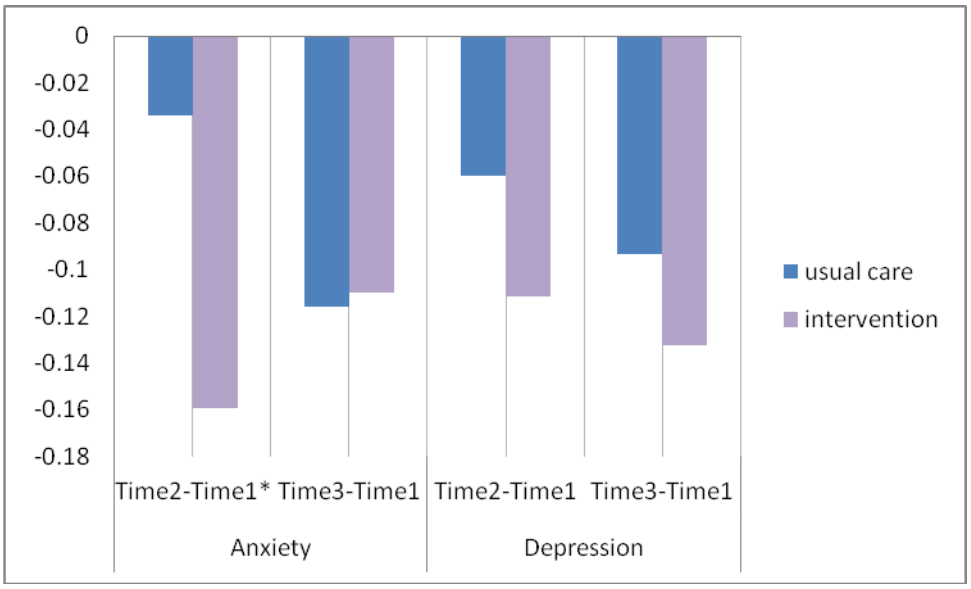
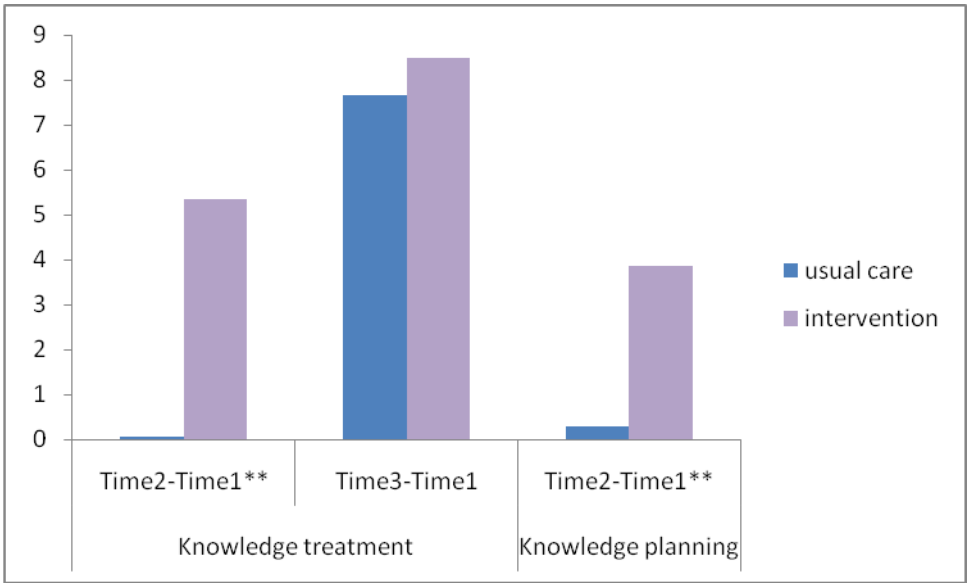

Patients screened for study eligibility
n=288
Excluded (n=137)
Did not meet inclusion criteria (n=137)*
* Time Allowed = 101
Dr Recommendation = 6
Treatment undecided = 2
Previous Disease/Previous RT = 5
Poor English = 5
Declined RT = 2
Mental Health Problem = 2
Participating in another Study = 3
Prior Knowledge = 1
Refused to be Contacted about Study = 10
Patients meeting eligibility criteria
n=151
Patients approached
n=151
Did not consent n=29
Patient consent and baseline questionnaire completed
n =122
Patient Randomisation
n=122
Randomised to Intervention
n=64
chemo=43
non-chemo=21
Randomised to Usual Care
n=58
chemo=29
non-chemo=29
Excluded due to protocol=2
Excluded due to protocol=5
Withdrawn=1
Time 2 Intervention
n=62
chemo=43
non-chemo=19
Time 2 Usual Care
n=52
chemo=26
non-chemo=26
Excluded due to protocol=6
Survey missing=3
Patient compliance=2
Excluded due to protocol=2
Withdrawn=1
No RT=1
Survey missing=2
Time 3 Intervention n=51
chemo=38
non-chemo=13
Time 3 Usual Care
n=51
chemo=27
non-chemo=24
(5 patients did not complete T2 survey, but completed a T3 survey)

Figure 3 – Difference in mean Anxiety and Depression scores for intervention and usual care group



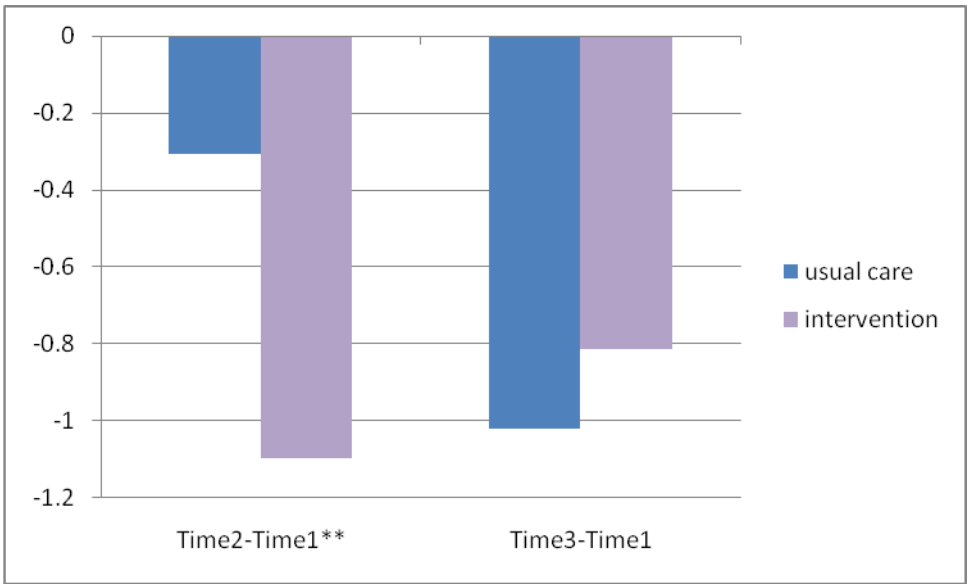
* significant at p<.05

Figure 4 – Difference in means for Knowledge Scores for intervention and usual care groups



** significant at <.01

Figure 5 – Difference in means for patient RT Related Concerns for intervention and usual care groups



** significant at <.01

Table 1. Patient Demographics.

	Usual Care (n=57) N(%)	**Intervention (n=65) N(%)**	**P value**
Age	Mean =55.1 SD=12.25	Mean = 54.2 SD=12.22	p=0.693
Marital Status			
Married	46 (79%)	42(68%)	p=0.152
Not Married	12 (21%)	20 (32%)	
Employment Status			
Full-time	12 (21%)	19 (31%)	p=0.648
Part-time	16 (29%)	12 (20%)	
Unable to work	2 (4%)	5 (8%)	
Unemployed	5(9%)	4 (7%)	
Homemaker	7 (12.5%)	7(11.5%)	
Retired	14 (25%)	14(23%)	
Education			
Year 10 or below	19 (33%)	14(23%)	p=0.482
Year 11-12	13 (22%)	20(32%)	
University	13 (22%)	12(19%)	
Diploma/Certificate	13 (22%)	16(26%)	
Location			
Major City	48 (83%)	53 (85.5%)	p=0.625
Regional and Remote	10 (17%)	9 (14.5%)	
Chemotherapy			
Receiving Chemo	29 (50%)	44 (69%)	**p=0.035***
Not receiving Chemo	29 (50%)	20 (31%)	

Table 2. Results of the GEE models testing for intervention effects with main outcome measures.

Outcome (range)	b Coefficient[a]	Standard error	P value
HADs Anxiety[b] (0-3)			
Time 2	-0.145	0.056	**0.009***
Time 3	-0.033	0.080	0.683
HADs Depression[c,d] (0-3)			
Time 2	-0.068	0.052	0.194
Time 3	-0.085	0.061	0.162
Knowledge planning[c, e] (total correct score 1-10)			
Time 2	3.514	0.399	**<0.001***
Time 3	N/A		
Knowledge treatment[c] (total correct score 1-20)			
Time 2	5.280	0.594	**<0.001***
Time 3	0.974	0.704	0.167
RT concerns[c, f] (1-9)			
Time 2	-0.918	0.234	**<0.001***
Time 3	-0.048	0.232	0.835

[a]For each analysis the regression coefficient provides an estimate of the difference between the mean change scores of study arms. [b]Model adjusted for age. [c]Model adjusted for chemotherapy. [d]Model adjusted for marital status. [e]Model adjusted for employment status. [f]Model adjusted for education. N/A – scale not used for Time 3 because relates to radiation planning. *Statistically significant result p<=0.05.

Table 3. Results of the GEE models testing for intervention effects with single item index.

Outcome (range)	b Coefficient[a]	Standard error	P value
Prepared for treatment planning procedure[c] (1-9)			
Time 2	1.801	0.399	**<0.001***
Time 3	N/A		
Know what is going to happen during treatment planning[c] (1-9)			
Time 2	2.915	0.402	**<0.001***
Time 3	N/A		
Current understanding of radiation therapy[c] (1-9)			
Time 2	1.622	0.259	**<0.001***
Time 3	1.199	0.305	**<0.001***
Prepared to receive radiation therapy[c,f] (1-9)			
Time 2	2.076	0420	**<0.001***
Time 3	0.960	0.396	**0.015***
Know what is going to happen during treatment[f] (1-9)			
Time 2	2.027	0.366	**<0.001***
Time 3	0.674	0.436	0.123

[a]For each analysis the regression coefficient provides an estimate of the difference between the mean change scores of study arms. [c]Model adjusted for chemotherapy. [f]Model adjusted for education. N/A – scale not used for Time 3 because relates to radiation planning. *Statistically significant result p<=0.05.

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