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## **Effect of pretreatment education on anxiety in patients undergoing radiation therapy for the first time: a randomized clinical trial**

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**Public interest statement:** Any program that enables patients to prepare for treatment could also help reduce their anxiety levels. Educational interventions proposed to be used before radiotherapy include face-to-face education provided by a radiotherapist, as well as group or individual education via visual tools, such as brochures and booklets, PowerPoint presentations, videotapes, e-Learning, and printed materials supplemented with phone calls by a nurse. Comparative studies concerning the efficacy of multimedia tools in relation to written educational materials have revealed conflicting evidence. This study indicated that written materials instead of multimedia presentation appear to be more effective.

**About the author:** Fatemeh Heshmati Nabavi is an Assistant Professor in the Department of Nursing Management (MUMS), School of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran. Her main areas of research are medical education, nursing management, and qualitative study. She is also interested in studying patients with cancer, examining the causes of anxiety, and the ways of reducing such emotion. The latest articles published by her are: "Investigating the relationship between anxiety of school age children

undergoing surgery and parental state-trait anxiety”, “Effect of a preoperative preparation program on anxiety in school-age children undergoing surgery using a factorial design”, and “Directed qualitative content analysis: the description and elaboration of its underpinning methods and data analysis process”.

## **Abstract**

**Background:** Pre-treatment anxiety is one of the most common problems in patients undergoing radiotherapy, especially for the first time. There are limited and contradictory studies on the effect of multimedia as compared with common education methods. This study was intended to evaluate the effect of pretreatment multimedia on patient anxiety in the head and neck cancer radiotherapy setting.

**Methods:** In a randomized clinical trial, 66 patients who resided in eastern Iran were recruited from three cancer treatment centers. The experimental group (n=33) received a 20-minute multimedia presentation, while its print version of the same content was applied in the control group (n=33). The study measure was evaluated by the Spielberger State-Trait Anxiety Inventory (STAI), which was answered by the participants at baseline after the visit by a cancer specialist deciding on radiotherapy and 2 weeks later prior to the starting of the treatment.

**Results:** The findings indicated that statistically significant differences were observed in anxiety scores between the groups with multimedia as compared to the control (p=0.009). Pamphlet-associated education led to a notably larger mean difference in anxiety score between the baseline score and two-week post-treatment score in the controls than multimedia version in the experimental group (p<0.001). However, adjustment for covariates showed no significant reduction in anxiety between them (p=0.115).

**Conclusion:** Developing educational materials in written format can successfully reduce radiotherapy-associated anxiety in cancer patients. It may be ascribed to the nature of the media that deals with more detail and facilitates the flow of information.

**Keywords:** anxiety; multimedia; education; radiotherapy; head and neck cancer

## **Introduction**

Radiotherapy, either alone or in combination with chemotherapy and surgery, is found as an effective treatment for a variety of malignant cancers, where nearly half of all cancer patients undergo radiotherapy (Jones et al., 2006; Martin & Hodgson, 2006). The terms “cancer”, “cancer treatment”, and particularly “radiotherapy” elicit negative emotional responses in people (Kaur, Pathak, Kaur, & Patel, 2014). Anxiety, for instance, is one of the most common

psychological responses to the experience of cancer (Kaur et al., 2014) and the preparation for radiotherapy (Schofield et al., 2008). Efforts to regulate emotions are more likely to decrease their potentially adverse influences on physical and psychological well-being. Today, informing cancer patients of their condition is a common task in many western countries however physicians avoid informing patients of their diagnosis and there is a lack of clarity with respect to their current performance in Iran akin to a number of eastern countries (Conley, Bishop, & Andersen, 2016; Khalil, 2013). Of note, patients' families also may disagree with medical team to disclose the diagnosis to the patient (Khalil, 2013; Ozdogan et al., 2006). What is more, some patients prefer to receive less information or instead, want their family to be involved regarding their medical condition in order to decrease their anxiety (Zeguers et al., 2012).

Such concerns are not limited only to the diagnosis of cancer, new experiences of its treatment can also cause further stress and anxiety in patients, family, and caregivers (Canil, Cashell, Papadakos, Abdelmutti, & Friedman, 2012; Hauffman et al., 2017). Moreover, several factors, including distrust in treatment, novelty of treatment experience, length of treatment, lack of familiarity with a typical radiation therapy environment, equipment and intangible outcomes, and long waiting times prior to treatment, can affect levels of anxiety caused by radiotherapy, especially its first session. Indeed, 40-62% of patients receiving radiotherapy have reported anxiety before its commencement (Jones et al., 2006; Martin & Hodgson, 2006; Waller, Forshaw, Bryant, & Mair, 2014). A lack of sufficient knowledge and information also plays a pivotal role and culminates in a misunderstanding about the severity of its symptoms and the resulting anxiety, which can mitigate patients' ability to perform daily tasks and exacerbate their quality of life (Canil et al., 2012; Schofield et al., 2008; K. Williams, Blencowe, Ind, & Willis, 2017).

Although the level of anxiety decreases with the progress of treatment in later sessions, the patient's first visit to the oncology center appears very stressful (Kaur et al., 2014). On the other hand, radiotherapy can be conducted on an outpatient basis, which, in turn, may have short length of treatment, poor mental and physical condition of patient, and care providers' insufficient time for interaction with patient that subsequently pose challenges for patient training and education (Ghavam-Nasiri et al., 2012; S. A. Williams & Schreier, 2005). The use of educational media can be a viable approach to pre-treatment education because its correct implementation not only saves time and improves learners' motivation, but also deepens their learning (Bastable, 2003; Garcia, 2014). In this case, two common groups of instructional tools for patients are written materials and multimedia. Printed educational

materials, especially pamphlets, are considered as the cheapest and most accessible educational tool that can be utilized at crowded health centers while needing no equipment. Nevertheless, they also have some drawbacks, such as heavy reliance on reading skills of patients or family members and lack of animation (Dunn, Steginga, Rose, Scott, & Allison, 2004; Friedman, Cosby, Boyko, Hatton-Bauer, & Turnbull, 2011; Wilson et al., 2012). Multimedia typically refers to "the use of a computer to present and combine text, graphics, audio and video with links and tools that allow the user to navigate, interact, create, and communicate". Therefore, multimedia-based instruction is a new method in which information and educational materials are conveyed more easily and attractively to a broader audience through a combination of text, audio, and video. Furthermore, the educational materials can be repeatedly viewed, engage visual and auditory sensations, thus acting as a more effective alternative for patients with low literacy skills (Bastable, 2003; Wilson et al., 2012).

Despite a body of literature on the effectiveness and comparison of educational materials (i.e., written materials and multimedia) on anxiety in different medical conditions, few attempts have been made to use the same content. Therefore, this study aimed at evaluating the effect of pretreatment education through written materials and multimedia with the same content on the anxiety of patients who underwent radiotherapy for head and neck cancers. To the best of our knowledge, this study was the first one examining two education models issue among radiation therapy patients in Iranian population.

### **Methods**

This was a randomized clinical trial using a pretest–post-test design and approved by the Regional Ethics Committee affiliated to Mashhad University of Medical Science, Mashhad, Iran (IR.MUMS.REC.1393). We also registered the research design in the Iranian Registry of Clinical Trials (IRCT2015010520559N1). All participants filled out an informed consent form before entering to the study. Further, they were allowed to quit the study at any time without any negative influence on their treatment plan.

### **Participants**

Based on Williams and Schreier's study (S. A. Williams & Schreier, 2005), a sample of convenience including 66 patients scheduled for radiotherapy were recruited from cancer treatment centers in eastern Iran. Inclusion criteria for participation were as follows: being diagnosed with head and neck cancers, being aged between 18 and 65 years, being fluent in Persian, having the ability to understand the given instruction, having no history of diagnosed psychiatric disorder, having no history of using psychiatric medicines, and having no history

of chemotherapy within the last three months until the study started and a history of radiotherapy. The following factors were taken into account as exclusion criteria: failure to read/view the educational content before the first session of treatment, and occurrence of stressful events (except for the cancer diagnosis) during the last 6 months prior to the study such as, death of loved ones, marital separation and being fired from work. There were three radiation therapy centers in 2016 across Mashhad, the second largest city of Iran and the only main referral center offering medical services in eastern Iran. These centers were government general hospitals with same physicians working in. To prevent data transfer and sharing of media between the study groups, the radiotherapy centers were divided into two groups based on the total number of patients admitted. Then, the centers were randomly assigned into two groups receiving written material (control) or multimedia (experimental) for intervention.

### **Instruments**

Two instruments were used in the study to collect demographic information and measure of anxiety. The eligible participants initially filled out the demographic information sheet covering both their demographics (i.e., age, gender, marital status, occupation, financial status, education level) and medical health conditions (e.g., treatment location on the body and history of chemotherapy). The second questionnaire was the state version of STAI (1983) composed of 20 questions, which asked about the patients' current feelings in Likert scale (range: 1 [very mild] to 4 [very severe]). Overall, the total score of STAI could be between 20 and 80. Given the original inventory, the score ranges of 20 to 31, 32 to 53, 54 to 64, 65 to 72, and 73 to 88 respectively correspond with mild, moderate, relatively severe, severe, and very severe anxiety. The validity and reliability of the Spielberger STAI in Iranian population were previously confirmed by Mahram (Mahram, 1993). In this study, the reliability of STAI was 0.83 using Cronbach's alpha coefficient.

### **Intervention**

A 20-minute multimedia presentation was developed by Camtasia software while containing general information about the medical condition, method of radiotherapy, preparation of patients for treatment, experience in radiotherapy, and essential tips during a treatment session in the form of photos, music, sounds and videos. This was employed in the experimental group, whereas the control group was exposed to instructional pamphlets with equivalent content. Training of patients with written tools is a routine method in radiotherapy centers of our country. In this study, they were prepared as pamphlets with the same content to multimedia for the control group. Noteworthy, the term 'cancer' was substituted by the other relevant terms, such as 'mass' or 'disease' in both educational tools. Also, direct

presentation of side effects was avoided by means of images. The content in both media was reviewed and verified by several experts, including oncologists and medical education experts. At baseline after the visit by a cancer specialist deciding on radiotherapy, all participants were asked to complete the demographic form and STAI questionnaire. In this way, we could gain data about the patient's anxiety at time when they generally did not have any knowledge about radiotherapy. Thereafter, a 20-minute face-to-face session was held for both groups and their caregivers to briefly explain the disease and treatment. The multimedia CD was then provided to the participants in the experimental group. The subjects in the control group received the printed educational materials. They were asked to implement (read or watch) their given education at home up until the first session of the treatment, which was usually two weeks later. These two weeks were required to prepare the patient's treatment plan and device.

### **Data analysis**

Data were collected and then were analyzed using SPSS version 11.5 software. Descriptive statistics, such as frequency, percentage, mean, and standard deviation were used to describe the characteristics of the participants. The chi-square test was performed to determine if there were differences between the groups for categorical variables. Paired t-test was carried out to find significant differences in anxiety measures before and after intervention (within-group comparison) and independent samples t-test for differences in anxiety between the experimental and control groups (between-group comparison). Also, ANCOVA was used to adjust the possible impact of the baseline variables with a significant difference between the two groups (i.e., education level, financial status, and history of chemotherapy before the last 3 months) on these findings. A two-sample t-test power analysis was also performed applying PASS software (PASS 13. NCSS, LLC. Kaysville, Utah, USA). A value of  $P \leq 0.05$  was considered statistically significant.

### **Results**

This study included patients with head and neck cancers from three major medical centers, Mashhad, Iran. The recruitment was conducted from December 2015 to February 2016. After a series of interviews, only 66 were verified to be at least 18 years, to have the ability to understand the given instruction, and to not experience previous chemotherapy within the last three months until the study started and a history of radiotherapy hitherto. Of these subjects, a half served as the experimental group. There were no significant differences between the study groups, except for education level, financial status, and history of chemotherapy before the last 3 months (Table 1).

Table 2 summarizes the mean scores of anxiety in both groups prior to and following the intervention. It was indicated that anxiety significantly reduced in both groups as compared to the mean scores at baseline ( $p < 0.001$ ). The power analysis showed that this study had more than 99% power in a paired t-test. Moreover, there were no differences in anxiety between the two groups at baseline ( $p = 0.145$ ). Afterwards, exposure to educational materials did considerably change this finding; that is, a statistically significant disparity was found between the two ( $37.9 \pm 3.3$  vs.  $40.0 \pm 3.07$  in the control and experimental groups, in order;  $p = 0.009$ ). The power analysis revealed that this study had 0.84% power in an independent-sample t-test. As for the results of ANCOVA, there was not a statistically considerable difference in the mean score of anxiety [ $F(1, 50) = 2.577, p = 0.115$ , partial  $\eta^2 = 0.049$ ] between the two educational models, while adjusting for the education level, history of chemotherapy, and financial status. Therefore, the education level, history of chemotherapy, and financial status had no significant effects on the patients' level of anxiety.

### **Discussion**

The findings of this study showed that written instruction in the form of pamphlets before radiotherapy significantly reduced anxiety of the patients as opposed to multimedia, which was corroborated by Kaur et al., whose study evaluated the impact of an orientation program on patient anxiety when exposed to radiotherapy for the first time and concluded that educational interventions carried a lowering influence on the levels of anxiety, with visual aids (i.e., booklet and PowerPoint presentation) showing more strength than routine care (Kaur et al., 2014). In contrast with our results, Thomas et al. found that pre-treatment education via videotapes could mitigate anxiety more than routine oncology practice in patients undergoing radiotherapy and chemotherapy (Thomas, Daly, Perryman, & Stockton, 2000). This may be justified by the different settings, namely measurement tool for anxiety (Hospital Anxiety and Depression) and interventional practices (video-directed information, routine consultation and booklet education). Conversely, Wang et al. indicated that multimedia was able to attenuate anxiety in gynecologic laparotomy patients more than pamphlets (Wang, Lin, Lee, Kan, & Lee, 2013). Follow-up schedule in their study (one hour after nursing intervention) was different from that of ours (two weeks after the intervention). There has been conflicting evidence concerning the effects of multimedia and written materials. On one hand, some reported no significant difference between them in ameliorating anxiety; put differently, both methods improved anxiety to the same extent. For example, applying educational videotapes for patients with breast, head, and neck cancers



undergoing radiotherapy positively contributed to a decrease in anxiety. This effect was comparable to that of booklet. Both methods covered the same educational content, namely a description for the radiotherapy procedure and clarification of some misconceptions related to this treatment, with no explanation for side effects (Dunn et al., 2004). Another study by Huber et al. found similarity between reduced scores of anxiety following instruction with written and multimedia materials in patients undergoing prostatectomy. Of note, the educational content included adverse effects in addition to a description for the procedures used (Huber et al., 2013). On the other hand, some studies have documented the negative impact of multimedia on anxiety of patients, implying that the clarity and detail of educational content can afford to induce anxiety. Indeed, the behavioral response of patients to such material may depend on some factors, including stepwise flow of information, as well as clarity and transparency of training (Heshmati Nabavi, Behboudifar, Pouresmail, & Shafiee, 2016). For example, Tipotsch-Maca et al. presented that exposure to educational materials, particularly multimedia, elevated anxiety among cataract surgery patients. In the planned materials, they explained the disease, method of diagnosis, necessary postoperative care, surgical procedure, and method of cataract removal (Tipotsch-Maca, Varsits, Ginzl, & Vecsei-Marlovits, 2016). It is more likely that more details on the surgical procedure augment patient anxiety. In another setting using patients undergoing open-heart surgery, it was exhibited that preoperative education by means of a demonstration dealing with breathing exercises, physical exercise, pain management, possible side effects of surgery, and a tour of the cardiac unit did not increase anxiety, but rather was much less effective than routine education (Deyirmenjian, Karam, & Salameh, 2006). Likewise, Harrison et al. reported that patients with cancers of the head and neck or prostate and bladder scheduled for radiotherapy developed more anxiety about hair loss after viewing videotapes than their peers exposed to written education. However, there were no significant inter-group differences in terms of feeling sick, lying under machines, and feeling tense about treatment (Harrison et al., 2001).

Overall, it can be claimed that although multimedia have an advantage in the conveying of education, providing pre-treatment education containing general information instead of detailed images of procedures is more effective in reducing the anxiety of patients in eastern Iran.

### **Limitations**

The first limitation of the present study regards its sample size. Owing to the small sample size, the generalization of these findings needs a larger one. Also, the evidence of the present

study is drawn from patients with moderate levels of anxiety. It is worth investigating if these findings can be generalized to other levels of anxiety. The effectiveness of an educational tool in a society does not necessarily reflect its desirable results in other societies. Indeed, the effect of an instructional media should be investigated in the cultural context of the society where it is to be implemented. Hence, it would be in the interest of the study to investigate the effect of such media in a different culture. Also, the main limitation was not having a control group without intervention, which warrants further consideration due to violation of patient's rights. Noteworthy, although this study ruled out the participation of those patients with any history of major stressful events, it would be of interest to investigate the effect of psychiatric disorders (e.g. depression) or stressful events (e.g. divorce) on the healthcare delivery services.

### **Conclusion**

The use of educational materials in the form of written pamphlets can reduce the pre-treatment anxiety of these patients more than multimedia presentation. In this study, written materials were found to be more successful than multimedia ones in decreasing anxiety.

### **Acknowledgement**

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### **Conflict of Interest**

The authors declare that there is no conflict of interest regarding the publication of this paper.

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## Tables

Table 1: Demographic characteristics of the study groups

<b>Variable</b>	<b>Experimental group (n= 33)</b>	<b>Control group (n= 33)</b>	<b>X<sup>2</sup></b>	<b>p-value</b>
Age, years (Mean ± SD)	52.66±14.6	50.51±13.8	-1.115*	0.265*
Males (%)	17 (51.5)	24 (72.7)	3.155	0.076
<b>Education level (%)</b>				
primary or lower	10 (30.3)	24 (72.7)		
Junior high school	3 (9.1)	2 (6.1)	3.472	0.001
Senior high school	12 (36.4)	5 (15.2)		
College and above	8 (24.2)	2 (6.1)		
<b>Marital status (%)</b>				
Single	2 (6.1)	2 (6.1)		
Married	30 (90.9)	29 (87.9)	0.350	0.839
Widowed	1 (3.0)	2 (6.1)		
Divorced	0 (0.0)	0 (0.0)		
<b>Economic status (%)</b>				
Poor income (less than 540\$)	9 (27.3)	22 (66.7)		
Fair income (540 \$ to 1100 \$)	22 (66.7)	11 (33.3)	11.11	0.004
Good income(more than 540 \$)	2 (6.1)	0 (0.0)		
<b>Insurance (%)</b>	32 (97.0)	31 (93.9)	0.349	0.555
<b>History of chemotherapy before the last 3 months</b>	1 (3.0)	18 (54.5)	21.359	<0.001
<b>Place of treatment (%)</b>			4.978	0.083
Neck	19 (57.6)	26 (78.8)		
Mouth	13 (39.4)	5 (15.2)		
Face	1 (3.0)	2 (6.1)		

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\* Z in the Mann-Whitney U test

ACCEPTED MANUSCRIPT

Table 2: The STAI total scores at baseline and two weeks (Mean± SD)

<b>Anxiety score</b>	<b>Written material</b>	<b>Multimedia</b>	<b>p-value</b>	<b>t</b>	<b>df</b>
At baseline	45.4± 2.9	46.6±2.4	0.145 <sup>a</sup>	-2.2	64
Two weeks	37.9± 3.3	40.0± 3.1	0.009 <sup>a</sup>	-3.9	64
Difference	7.5± 3.8	6.6±3.5	<0.001 <sup>b</sup>	10.7	32

a, independent samples t-test; b, paired samples t-test

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