

Telephone intervention for anxiety management in oncology patients: a randomized clinical trial

Intervenção telefônica para manejo da ansiedade de pacientes oncológicos: ensaio clínico randomizado
Intervención telefónica en manejo de la ansiedad de pacientes oncológicos: ensayo clínico randomizado

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Keywords

Telephone; Anxiety; Clinical trial; Neoplasms; Nursing

Descritores

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Descriptorios

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Abstract

Objective: Assess the efficacy of the telephone intervention by nurses to reduce the anxiety scores of patients under radiotherapy treatment.

Methods: Randomized clinical trial undertaken at a radiotherapy outpatient clinic with 15-day monitoring. The sample consisted of 39 patients under radiotherapy treatment (20 in Intervention Group and 19 in Control Group). The interventions were performed by means of two telephone contacts. To collect the data, a questionnaire with sociodemographic and clinical questions and the State-Trait Anxiety Inventory were used. The data were analyzed in the Statistical Package for Social Sciences. Student's t-test for paired samples was used to compare the pre and post-intervention times.

Results: A significant reduction in the anxiety scores was found after the telephone calls ($p < 0.027$) for the patients in the Intervention Group.

Conclusion: The use of the telephone during the 15-day monitoring showed to be an effective strategy to reduce the radiotherapy patients' anxiety scores.

Resumo

Objetivo: Avaliar a eficácia da intervenção telefônica realizada por enfermeira na diminuição dos escores de ansiedade de pacientes em tratamento radioterápico.

Métodos: Ensaio clínico randomizado realizado em ambulatório de radioterapia com seguimento de 15 dias. A amostra foi composta por 39 pacientes em tratamento radioterápico (20 no Grupo Intervenção e 19 no Grupo Controle). As intervenções foram realizadas por meio de dois contatos telefônicos. Para coleta de dados, utilizaram-se questionário com questões sociodemográficas e clínicas, e Inventário de Ansiedade Traço-Estado. Os dados foram analisados pelo pacote estatístico *Statistical Package for Social Sciences*. O teste *t* de Student para amostras pareadas foi utilizado para comparar os momentos pré e pós-intervenção.

Resultados: Houve redução significativa dos escores de ansiedade após as ligações telefônicas ($p < 0,027$) para os pacientes do Grupo Intervenção.

Conclusão: O uso do telefone durante seguimento de 15 dias mostrou-se estratégia eficaz para a diminuição dos escores de ansiedade de pacientes em tratamento radioterápico.

Resumen

Objetivo: Evaluar la eficacia de intervenciones telefónicas de enfermeras en el descenso de los puntajes de ansiedad de pacientes en tratamiento radioterápico.

Métodos: Ensayo clínico randomizado realizado en servicio de radioterapia con seguimento de 15 días. Muestra de 39 pacientes en tratamiento radioterápico (20 en Grupo Intervención, 19 en Grupo Control). Intervenciones realizadas por contacto telefónico. Datos recolectados utilizando cuestionario con preguntas sociodemográficas y clínicas, e Inventario de Ansiedad Estado-Rasgo. Fueron analizados con el paquete estadístico *Statistical Package for Social Sciences*. Se utilizó el test *t* de Student para muestras pareadas en la comparación de momentos previo y posterior a la intervención.

Resultados: Hubo reducción significativa de los puntajes de ansiedad luego de las llamadas telefónicas ($p < 0,027$) en los pacientes del Grupo Intervención.

Conclusión: El uso del teléfono durante el seguimento de 15 días se mostró eficaz en la disminución de los puntajes de ansiedad de pacientes en tratamiento radioterápico.

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Introduction

Cancer treatment influences the patients' emotional, mental and physical aspects, making anxiety symptomatic of the need to discharge the energy of constant concerns. Anxiety is a complex reaction of the individual in situations and stimuli that are potentially dangerous/damaging or subjectively perceived as permeated by danger, even if only due to an uncertain circumstance. Its symptoms include physical, psychological and behavioral components.⁽¹⁾

Radiation therapy may have negative effects on the patient, which may entail physical effects, such as pain and decreased physical capacity, and emotional effects, such as anxiety.⁽²⁾ Side effects of radiation therapy may interfere with the patient's emotional balance and belief in the therapy.⁽³⁾ In this perspective, anxiety symptoms need to be assessed before and in the course of radiotherapy, as they tend to increase and have negative consequences, such as lack of treatment compliance, lower survival and decrease of patients' quality of life.^(2,3)

In an international systematic review, the psychological functioning of cancer patients was described, showing that about 10% to 20% present anxiety before radiotherapy.⁽⁴⁾ In Brazil, an estimated 31.33% of anxiety was identified in cancer patients undergoing treatment.⁽⁵⁾ The psychosocial distress of oncology patients, primarily anxiety, can be minimized by providing accurate, up-to-date and personalized information about the disease and its causes, treatment options, procedures and side effects of therapy.⁽⁶⁾ Considering the anxiety as a symptom present in the radiotherapy treatment, studies focused on providing relief for this symptom permeate the daily care challenges, with a view to supporting specific actions directed at the patients who experience this situation.

The use of the telephone is one of these strategies and figures as an important means of communication between nurse and patient. Technologies such as telephone do not only present potential as a therapeutic modality, but also contribute to reduce some gaps in health services, such as a reduced number of professionals, inappropriate physical facilities

and reduced resources; in the follow-up of patients; and in improved access.⁽⁶⁾ The telephone has been used in some Brazilian initiatives for patient monitoring and health education.⁽⁷⁻⁹⁾ Furthermore, in the international scenario, it serves as a resource for anxiety management in cancer patients undergoing treatment.^(10,11)

Considering the gap in the Brazilian literature on the use of telephone for anxiety management of cancer patients, this study is relevant by presenting it as a tool for comprehensive care and as a possible advance for nursing care, favoring the continuity and the longitudinality of health actions. Appropriate and innovative interventions, performed at the appropriate time in radiotherapy, can be beneficial to the quality of life of the patients and their families, being more effective with regard to the cost of the disease, as they can contribute to mitigate symptoms that may arise due to the illness. Thus, there is a clear need to test interventions aimed at reducing the anxiety of patients undergoing radiotherapy, enhancing the care directed at this population group through the development of nursing intervention strategies.

The objective of this study was to evaluate the effectiveness of a telephone intervention performed by a nurse in reducing the anxiety scores of patients undergoing radiotherapy. The hypothesis to be tested was that "the telephone intervention decreases the anxiety scores of patients undergoing radiotherapy treatment".

Methods

Randomized, controlled clinical trial conducted in a radiotherapy outpatient clinic of a university hospital in the central region of the State of Rio Grande do Sul, a reference in oncological treatment that receives people from all regions of the State. Data were collected from April to July 2014.

Study participants were patients undergoing radiotherapy. Patients aged 18 years or older were included; under radiotherapy treatment due to a diag-

nosis of cancer; and who had a telephone. Being in no clinical, cognitive and/or communicative conditions was established as an exclusion criterion of the study. The reasons for the loss of follow-up were the impossibility of telephone contact, suspension of treatment due to clinical and health problems and deaths.

As a routine of the hospital, when patients start treatment at the oncology service, a nursing consultation (with evaluation, verification of vital signs, anthropometric measures, guidelines on the beginning of radiotherapy sessions, time and duration of treatment) is performed, including information on the times and appointments. In the course of treatment, other consultations occur only in case of any problem/change.

The sample was calculated according to the sampling technique for finite populations, with 80% power, significance level of 5%, accuracy level 5% and total population of 120, based on the monthly average of patients who started radiotherapy in the year prior to the survey. According to this method, at least 46 patients should be included. After the participants' eligibility, the randomization was performed using the randomization method in blocks of 20.⁽¹²⁾ In an opaque envelope, ten mini envelopes were placed containing a "Group 1" card (referring to the Intervention Group), and ten identical mini envelopes containing a "Group 2" card (referring to the Control Group). The patient randomly drew a mini envelope, selecting the allocation group, but without being informed about which group (s)he would belong to.

At the time of data collection, 83 patients started treatment at the radiotherapy outpatient clinic. Of these, 31 did not meet the inclusion criteria and six refused to participate in the study. There were two follow-up losses in the Intervention Group: one due to the patient being in no clinical conditions to complete the participation in the research and one case of death; in the Control Group, four patients had no telephones available for the second contact and there was one death. At the end of the research, 39 participants received the telephone calls, being 19 in the Control and 20 in the Intervention Group.

On the first day of treatment and after the end of the nursing consultation, the research proposal was presented to the patients, who were invited to participate. The data collection procedure was performed individually in the nurse's office at the radiotherapy outpatient clinic.

Participants in the Control and Intervention Groups answered a sociodemographic questionnaire and the State-Trait Anxiety Inventory (STAI)⁽¹³⁾ in person, during the first contact with the researcher (pre-intervention), and again answered the STAI on the final day of radiotherapy (post-intervention). The interview to apply the questionnaires took approximately 45 minutes for each participant.

The sociodemographic questionnaire applied contained questions related to: age, sex, income and clinical conditions, sociodemographic and health questions (for example, about medication use, smoking and/or alcohol consumption habits).

The primary outcome was the reduction of anxiety scores. To measure it, the STAI was applied.⁽¹³⁾ This scale is composed of two distinct parallel scales (Trait and State) for self-evaluation. In this study, the State-Anxiety scores were presented, which refers to the transient emotional state, or a condition marked by feelings of tension and apprehension, constituted by 20 assertions, whose response intensity ranges from 1 to 4 points. The sum classifies the individuals according to their anxiety score, as follows: low (from 20 to 34 points), moderate (35 to 49), high (50 to 64) and very high (65 to 80).⁽¹³⁾

The intervention was developed through two telephone calls, carried out on the 7th and 15th day of radiotherapy treatment, previously agreed upon between the researcher and the participants in the Control and Intervention Groups, at scheduled days and times. In cases where the calls were not answered on the scheduled day and time, three other contact attempts were made, at different times or the day after the scheduled call. The phone calls made were recorded with the Auto Call Recorder, an application for Android®, which allows for the recording of phone calls.

The content addressed during the calls, as well as the length, was different depending on the group. In the Control Group, each call lasted approximately three minutes, during which the date of the next appointment at the radiotherapy outpatient clinic was confirmed and instructions were given on the correct amount of fluid intake; and in the Intervention Group, the duration of the call was approximately 15 minutes, when specific and objective information on radiotherapy was provided. For the Intervention Group, the first call followed the following script: the first three minutes were intended to ask how the participant was feeling about radiotherapy; during the next seven minutes, information on radiotherapy (what radiotherapy is and what the benefits are) was offered; in the last five minutes of the call, the participant could ask questions about the telephone intervention itself or solve any doubts about the treatment; the call was terminated by scheduling the date and time for the next telephone contact. The second call followed the same structure as the first, with the difference that the guidelines provided more specifically concerned the possible effects of radiotherapy and the ways of proceeding if these effects occurred.

Information on the content and period to have the telephone contacts was sought in other primary studies that had used telephone interventions for cancer patients^(14,15) and in the guidelines of the National Cancer Institute.⁽¹⁶⁾ In radiotherapy, the effects usually manifest as of the third week of application, tend to extend according to the patient's physiological condition and treatment dose, and disappear within a few weeks after the completion of therapy.⁽¹⁷⁾ An international study identified that side effects during radiotherapy were identified as one of the main concerns of patients.⁽¹⁸⁾

Data were analyzed in the Statistical Package for Social Sciences Inc. (SPSS), Chicago, IL, version 20.0, and expressed as mean and standard deviation. To evaluate the normality, the Shapiro-Wilk test was used and parametric analysis was applied. For the comparison between the pre- and post-intervention moments by telephone, Student's t-test

for paired samples was used. The level of significance adopted in all tests was $p < 0.05$.

The study was previously registered in the Brazil Platform under Certificate of Presentation for Ethical Appreciation (CAEE) 28050514.7.0000.5346 and approved by the Research Ethics Committee at the Federal University of Santa Maria (CEP-UFSM), under No. 554.423. Participants signed the Free and Informed Consent Form (TCLE) and the study complied with the Brazilian and international standards of research ethics involving human beings, according to resolution 466/12. This randomized clinical trial was enrolled in the Brazilian Registry of Clinical Trials under number RBR-8wn8ck.

Results

The sociodemographic characteristics of the group participants are described in table 1. The groups were homogeneous in terms of the sociodemographic characteristics, except for the income. Most participants were female (56.4%), aged 50-69 years (51.2%), lived with their husband or partner (46.1%) and gained up to two minimum wages (41.0%).

During the research, all participants answered the calls according to the attempts and appointments with the researcher.

The predominant type of cancer among the patients was head and neck cancer (Intervention Group: 30.0%; and Control Group: 31.5%); the overall time of diagnosis was less than six months (Intervention Group: 55.0%; and Control Group: 57.9%); and the number of radiation therapy sessions ranged between 25 and 30 (Intervention Group: 55.0%; and Control Group: 36.8%).

The anxiety scores of the patients in the Intervention and Control Groups were assessed at the pre and post-intervention times. A statistically significant difference was found in the State-Anxiety scores ($p=0.027$) in the Intervention Group patients at pre and post-intervention, according to figure 1.

Table 1. Distribution of sociodemographic variables for patients in radiotherapy treatment from Intervention Group (IG) and Control Group (CG)

Variables/Allocation group	IG (n=20) n(%)	CG (n=19) n(%)	p-value*
Age, years			0.31
Mean	62.2 (±11.8)	63(±10.3)	
30-49	2(10.0)	3(15.8)	
50-69	11(55.0)	9(47.4)	
70-89	7(35.0)	7(36.8)	
Sex			0.84
Female	11(55.0)	11(57.9)	
Male	9(45.0)	8(42.1)	
Marital situation			0.20
Married	10(50.0)	14(73.6)	
Not married	10(50.0)	5(26.4)	
Education level			0.50
Illiterate	-(-)	4(21.1)	
Unfinished Primary Education	3(15.0)	4(21.1)	
Unfinished Secondary Education	14(70.0)	8(42.1)	
Finished Secondary Education	-(-)	2(10.5)	
Unfinished Higher Education	2(10.0)	-(-)	
Finished Higher Education	1(5.0)	1(5.3)	
Lives			0.50
Alone	4(20.0)	1(5.3)	
With husband or partner	10(50.0)	8(42.1)	
With child	1(5.0)	1(5.3)	
Other†	5(25.0)	9(47.4)	
Number of children			0.14
0-2	10(50.0)	8(42.1)	
3-5	8(40.0)	9(47.4)	
6 or more	2(10.0)	2(10.5)	
Income, minimum wage			0.05*
No income	1(5.0)	-(-)	
Up to 1	10(50.0)	4(21.1)	
Up to 2	6(30.0)	10(52.6)	
Up to 3	3(15.0)	3(15.8)	
≥ 4	-(-)	2(10.5)	

* Chi-squared; †lived with other relatives, such as siblings, brothers/sisters-in-law, sons/daughters-in-law and/or friends

Discussion

Among the limitations of the study, we highlight the inclusion of patients with different types of cancer, which made it difficult to provide guidelines during telephone contacts and which may be associated with the anxiety scores - each type of cancer requires a treatment protocol, as well as nursing and specific health care. Due to the characteristics of the radiotherapy service where the study was performed, however, the composition of a homogeneous sample by type of cancer would require another study design. Another limitation relates to the duration of the intervention, which was 15 days on average. This did not permit reliable monitoring of

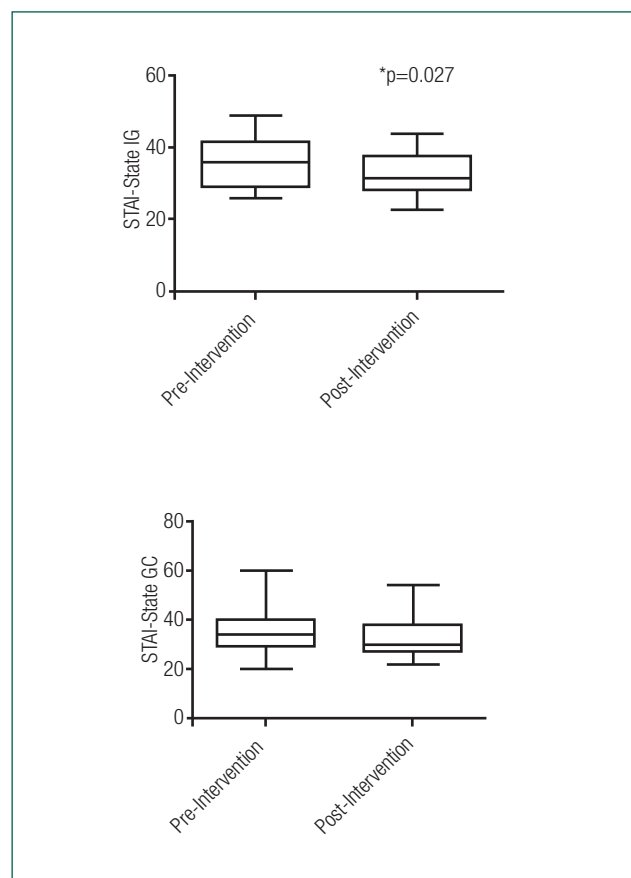


Figure 1. Comparison of patients' State-Anxiety at post-intervention. *p<0.05. STAI–State-Trait Anxiety Inventory; IG–Intervention Group; CG–Control Group (TRAD: Pre-Intervention / Post-Intervention / STAI-State)

the gradual process of radiotherapy, nor of the advances and difficulties the patients faced. This may have been related to the anxiety scores found in the study participants.

Studies that verified anxiety in cancer patients^(3,10,11,19-21) have shown that it tends to be higher at the beginning of the radiotherapy treatment. Regarding the State-Anxiety of the patients in this study, considering the interval between the initial time of the radiotherapy treatment (pre-intervention) and the end (post-intervention), a statistically significant difference was observed in the Intervention Group scores (p = 0.027) when compared to the Control Group.

The decrease in anxiety after telephone interventions is in agreement with results found in a controlled study carried out with 653 cancer patients, whose intervention involved the use of a sup-

port manual and instructions to people with cancer, through the telephone call, during a period of nine months. There was a reduction of the State-Anxiety scores in the intervention group when compared to the usual treatment group ($p < 0.01$).⁽²²⁾

The use of the telephone as a strategy to develop psychoeducational, monitoring and event control interventions has been tested in several situations in the field of nursing activities and has demonstrated favorable results. This study describes the process of developing a telephone nursing intervention program for family caregivers of people with chronic diseases in Colombia and Brazil, in which the intervention modality resulted in improvements in the tension of the caregiver role.⁽²³⁾ Improvements were also identified in the well-being and quality of life, as well as information provision, encouragement of the use of strategies to solve daily-life problems and skills development.

The positive impact of information and communication technologies on adherence to antiretroviral therapy in women with HIV has also been identified in the Brazilian literature.⁽⁸⁾ It is important to emphasize the importance of this strategy in the provision of specialized care services to complement routine care, with a view to the improvement of health monitoring.

The telephone can be a resource accessible to the majority of the population, with good adhesion rates, including the possibility of wide deployment in the health network. Research that analyzed the effect of the nursing intervention in the telephone guidelines for the elderly undergoing prostatectomy supports this assertion and guarantees that the post-operative telephone follow-up, already commonly used in other countries, can also be transposed to the reality of the health services in Brazil, especially because of its low cost.⁽²⁴⁾

In this perspective, the use of the telephone in this study reduced the anxiety scores of patients during the radiotherapy treatment, and the telephone intervention figures as a resource that extends the action limit of the health team, especially the nurse, with regard to attending to the needs that arise at every moment during the treatment, as is the case of anxiety relief. The research

entails implications for the teaching process, as it has contributed to the dissemination of nursing knowledge in oncology, arousing reflections about innovative care and assistance strategies to patients. The results also provide evidence to support the implementation of an innovative and easily accessible intervention with a view to expanding the health outcomes.

Conclusion

The use of the telephone as an anxiety management strategy during a 15-day follow-up for patients undergoing radiotherapy showed to be effective in decreasing anxiety scores, with a statistically significant difference. The results point to the use of the telephone as an alternative to complement nursing care for patients undergoing cancer treatment and suggest that knowing what to expect during the radiation therapy offers benefits.

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Collaborations

Stamm B, Girardon-Perlini NM, Pasqualoto AS, Beuter M and Magnano TSBS contributed to the design of the article, interpretation of the data, relevant critical review of the intellectual content and final approval of the version for publication.

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