

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison the effect of using multimedia and pamphlet on anxiety, side effects and self care behaviors of patients undergoing radiotherapy

Protocol summary

Summary

This study is a randomized trial single blind, with two groups. The aim of study is Comparison the effects of using multimedia and pamphlet on anxiety, side effects and self-care behaviors of patients undergoing radiotherapy. The study population included patients with head and neck radiotherapy. Main Inclusion criteria include having no chemotherapy in last three months, radiotherapy for the first time, ability to read and write in patient or main caregivers, having acceptable visual and hearing ability for receiving education. The main Exclusion criteria include Unwillingness to continue cooperation, unstable situation in patient that making impossible to continue participate, receiving information from the other sources apart from intervention during the program and do not use of provided educational content until the first session of treatment. The total sample size is 33 patients per group, so 66 patients in both group were considered. In both group one individual educational session will be held on a day in which patient visits and the physician diagnoses the need of radiotherapy for him. One group will receive the provided pamphlets and the other group will receive multimedia. The patients will be asked to use educational contents at least one time before the first session of treatment. Pamphlets and multimedia educational content will be the same in both groups and they have information about how radiotherapy is don, possible side effect and recommendation for managing the side effects. Outcomes of this study are self-care behaviors, anxiety and side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010520559N1**

Registration date: **2015-06-03, 1394/03/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-03, 1394/03/13

Registrant information

Name

Atefeh Behboodifar

Name of organization / entity

Mashhad University Of Medical Science- Nursing And Midwifery University

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical science

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of using multimedia and pamphlet on anxiety, side effects and self care behaviors of patients undergoing radiotherapy

Public title

Education of self care behaviors in patients undergoing radiotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:1-Age between 18 and 65 2-Patient that Singed Consent Knowingly 3-Decisive diagnose for needing radiotherapy by physician 4-Have no chemotherapy in last three months 5-Radiotherapy for the first time 6-Head and neck radiotherapy 7-Patient or close family not to be in health group 8-Ability to read and write in patient or main caregivers 9-Enough ability for receiving education 10-Having acceptable visual and hearing ability for receiving education Exclusion criteria: 1- Unwillingness to continue cooperation 2-Stressful events during intervention such as divorce, death in close family and losing job 3-Unstable situation in patient that making impossible to continue participate 4- Receiving information from the other sources apart from intervention during the program(for example participate in other education program or classes) 5-Do not use of provided educational content until the first session of treatment.

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University Of Medical Science

Street address

Ghoraishy Building, University"St". Mashhad

City

Mshhad

Postal code

9177899191

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

930947/1/407

Health conditions studied

1

Description of health condition studied

head and neck cancers

ICD-10 code

c00-c14

ICD-10 code description

Malignant neoplasms of lip, oral cavity and pharynx

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and almost 2 weeks after intervention depending on the time of starting treatment

Method of measurement

Spielberger STAI

2

Description

Radiotherapy Side Effects

Timepoint

First, third and fifth week after intervention

Method of measurement

Nail's Self Care Diary

3

Description

Self-care behaviors

Timepoint

First, third and fifth week after intervention

Method of measurement

Nail's Self Care Diary

Secondary outcomes

1

Description

Severity of side effects of radiotherapy

Timepoint

First, third and fifth week after interventin

Method of measurement

Nail's Self Care Dairy

Intervention groups

1

Description

After a one individual session for the 20 minutes about radiotherapy, local and systematic side effects, the 20 minutes Multimedia will be delivered to the patients or transfer to their mobiles as they want. The patients will be asked to use it before the first session of treatment. This file contents several parts. The first part contents general information about disease and treatments. The second part contents information about radiotherapy and treatment environment. The third part contents information about possible side effects (sleep disorders, loss of appetite, fatigue and mouth dryness), management of these side effects and necessary cares for them. Final part contents an exam with 5 questions about delivered subjects that after specified time for answering ,the responses will be displayed. Most of the designed file containing sounds and images and in some parts texts is used.

Category

Other

2**Description**

In pamphlet group after individual training session, three pamphlets that have same content with multimedia include general information about radiotherapy and treatment environment, possible side effects (such as sleep disorders, loss of appetite, fatigue and mouth dryness), management of these side effects and necessary cares for them will be delivered to the patients and asked them to read the pamphlets before the first session of treatment.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Omid Hospital

Full name of responsible person

Fatemeh Kavousi

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2**Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Mojhgan Ghiyassi

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3**Recruitment center****Name of recruitment center**

Reza center of radiotherapy

Full name of responsible person

Dr. Mozafari

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Fallahi 2, Ghasem abad "Blvd". Mashhad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University Of Medical Science

Full name of responsible person

Dr. Mohsen Tafaghodi

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Ghoraishy Building, University"St". Mashhad

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Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mashhad University Of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University Of Medical Sciences

Full name of responsible person

Atefeh Behboodifar

Position

Nursing Graduate Student

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty