Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Country
Iran (Islamic Republic of)
Phone
+98 51 3859 1511
Email address
behboudifara1@mums.ac.ir

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

Street address

Alandasht"Sq". Kuhsangi "St". Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Mojhgan Ghiyassi

Street address

Ebne sina "Ave". Mashhad

City

Mashhad

3

Recruitment center

Name of recruitment center

Reza center of radiotherapy

Full name of responsible person

Dr. Mozafari

Street address

Fallahi 2, Ghasem abad "Blvd". Mashhad

City

Mashhad

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

Street address

Ghoraishy Building, University"St". Mashhad

City

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

Other areas of specialty/work

Street address

Number82, Modaress 11"St". Vakil abad "Blvd". Mashhad

City

Mashhad

Postal code

Phone
+98 51 3609 5512
Fax
Email
behboudifara1@mums.ac.irAtefehbehboodifar@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashad University Of Medical Scienses
Full name of responsible person
Fateme Heshmati Nabavi
Position
PHD in Nursing
Other areas of specialty/work
Street address
Faculty of Nursing and Midwifery, Doctora Crossroads, Mashhad
City
Mashhad
Postal code
Phone
+98 51 3859 1511
Fax
Email
heshmatinf@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University Of Medical Sciences
Full name of responsible person
Atefeh Behboodifar
Position
Nursing graduate student
Other areas of specialty/work
Street address
Number82.Modaress 11"St". Vakil abad "Blvd". Mashhad
City
Mashhad
Postal code
9188885536
Phone
+98 51 3609 5512
Fax
Email
behboudifara1@mums.ac.irAtefehbehboodifar@gmail.com
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