

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation on the effectiveness relaxation methods on self-efficacy and self-esteem of cancer patients: a randomized clinical trial.

Protocol summary

Summary

Objectives: effects of relaxation methods on self-efficacy and self-esteem of cancer patients. Design: 80 of cancer patients will be selected for samples available and by using a randomized complete block will be divided in to intervention and control group. Setting and conduct: the patients with following criteria will be enrolled into the study; a) age between 30-60 years old; b) experience of at least one period of chemotherapy; c) absence of psychologic or known cognitive disease; d) stages 2,3 & 4 of cancer. Intervention 1: For the intervention group initially pre-test questionnaire will be completed. Then educational content will be presented during the two sessions of 30 minutes at a distance of a day of each other and the patients this technique will applied for 60 days. The curriculum includes providing a quiet environment and education tighten and relax muscles from head to toe or vice versa will be accompanied by deep breathing. The questionnaires after 60 days will be completed for this group, again. Intervention 2: For the control group initially pre-test questionnaire will be completed. While during this period control group only will receive their routine cares and cures, the questionnaires after 60 days will be completed for this group, again. Main outcome measures: Self-efficacy by strategies used by patients to promote health questionnaire and Self-esteem by cooper smith questionnaire will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070113110N2**

Registration date: **2015-09-08, 1394/06/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-08, 1394/06/17

Registrant information

Name

Mehdi Harorani

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Education and Research Arak University of Medical Sciences.

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on the effectiveness relaxation methods on self-efficacy and self-esteem of cancer patients: a randomized clinical trial.

Public title

Investigation on the effectiveness relaxation methods on self-efficacy and self-esteem of cancer patients.

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: a) age between 30-60 years old; b) being chemotherapy for at least one period; c) stages 2, 3 or 4 of cancer; d) absence of psychologic or known cognitive disease. Exclusion criteria: a) Lack of patient cooperation during the intervention for any reason; b) complete faulty of questionnaires.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be by using random blocks.

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City
Arak

Postal code
38481-76941

Approval date
2015-07-11, 1394/04/20

Ethics committee reference number
IR.ARAKMU.REC.1394,79

Health conditions studied

1

Description of health condition studied
Cancer

ICD-10 code
C80.9

ICD-10 code description
Malignant neoplasm, unspecified

Primary outcomes

1

Description
Self-Efficacy

Timepoint
Before and 60 days after the intervention.

Method of measurement
Self-Efficacy questionnaire Strategies Used by Patients to Promote Health

2

Description
Self-Esteem

Timepoint
Before and 60 days after the intervention.

Method of measurement
Self-Esteem questionnaire Cooper Smith

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention group: The cancer patient's self-efficacy scale and self-esteem questionnaire will be completed at the beginning of the study. The content of educational will be presented during the two sessions of 30 minutes at a distance of a day of each other. Then the patients this technique will applied for 60 days. The questionnaires after 60 days will be completed in this group, again.

Category
Treatment - Other

2

Description

Control group: The cancer patient's self-efficacy scale and self-esteem questionnaire will be completed at the beginning of the study. This group only will receive their routine cares and cures. The questionnaires after 60 days will be completed in this group, again.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khansari hospital, Arak

Full name of responsible person

Mehdi Harorani

Street address

Daneshgah Avenue

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor of Education and Research Arak
University of Medical Sciences

Full name of responsible person

Dr. Ali Ghazavi

Street address

Vice Chancellery For Research And Education, Pardis
Site Of University Of Medical Sciences, Basij Sq, Arak

City

Arak

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor of Education and Research Arak
University of Medical Sciences

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

Arak University of Medical Sciences

Full name of responsible person

Mehdi Harorani

Position

Master of Science in Nursing

Other areas of specialty/work

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Person responsible for updating data

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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