

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of benson muscle relaxation on cancer patients's quality of sleep & anorexia: a randomized clinical trial

Protocol summary

Study aim

Effects of benson's muscle relaxation on quality of sleep and anorexia of cancer patients

Design

Clinical trial with control group, with parallel groups, without blindness, randomized

Settings and conduct

In this study will be selected 80 patients suffering from cancer hospitalized in the hematology and oncology departments of Ayatollah Khansari hospital in arak city and with random blocks will be divided to two groups of experimental and control. Benson muscle relaxation for five days and every day for 20 minutes will be performed by the intervention group, control group during this period only will receive their routine cares and cures.

Participants/Inclusion and 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. Exclusion criteria: a) Lack of Literacy; b) Non-treatable cancer.

Intervention groups

Intervention group: In this group benson muscle relaxation for five days and every day for 20 minutes will be performed by the patients. Control group: This group only will receive their routine cares and cures.

Main outcome variables

Sleep quality; Anorexia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N5**

Registration date: **2019-01-31, 1397/11/11**

Registration timing: **prospective**

Last update: **2019-08-25, 1398/06/03**

Update count: **1**

Registration date

2019-01-31, 1397/11/11

Registrant information

Name

Mehdi Harorani

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of benson muscle relaxation on cancer patients's quality of sleep & anorexia: a randomized clinical trial

Public title

The effect of benson muscle relaxation on quality of sleep & anorexia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 30-60 years old
Experience of at least one period of chemotherapy
Absence of psychologic or known cognitive disease
Stages 2,3 & 4 of cancer

Exclusion criteria:

Lack of literacy
Non-treatable cancer

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to allocate the patients randomly into two groups of treatment and control, at first 8 blocks of 10 with C and T letters (The letters indicate the intervention and control groups) are created in each 5 patients are belonged to the intervention group and 5 patients are belonged to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 80 letters. Each letter will be placed in a sealed packet according to the obtained sequence.

Blinding (investigator's opinion)

Not 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 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

Province

Markazi

Postal code

38481-76941

Approval date

2018-12-16, 1397/09/25

Ethics committee reference number

IR.ARAKMU.REC.1397.247

Health conditions studied**1****Description of health condition studied**

Cancer

ICD-10 code

C80.0

ICD-10 code description

Disseminated malignant neoplasm, unspecified

Primary outcomes**1****Description**

Sleep Quality

Timepoint

Before and 5 days after the intervention

Method of measurement

SMHSQ Sleep Quality Questionnaire

2**Description**

Anorexia

Timepoint

30 minute before chemotherapy, Immediately after chemotherapy, 24 hour after intervention, 48 hour after intervention.

Method of measurement

Anorexia questionnaire with Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Benson muscle relaxation for five days and every day for 20 minutes will be performed by the intervention group

Category

N/A

2**Description**

Control group: This group only will receive their routine cares and cures.

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

Khansari hospital, Arak
Full name of responsible person
Mehdi Harorani
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mehdi Harorani
Position
Academic Instructor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available