Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 between30-60 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
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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 between30-60 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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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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