

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of a web-based Benson relaxation training program on the sleep quality and pain intensity of cancer patients referred to the Chemotherapy Center of Jahrom University of Medical Sciences.

Protocol summary

Study aim

The effect of Benson's relaxation technique on pain intensity and sleep quality in cancer patients

Design

This clinical trial design has a control group, with parallel, one-sided blind, randomized groups, 52 patients were selected by available sampling method.

Settings and conduct

This clinical trial study will be conducted on 52 cancer patients receiving chemotherapy aged 20-80 years old, who will be selected by the available sampling method and will be randomly assigned to control and intervention groups using a computer. It was a blind strain that only the researcher knows about the type of intervention

Participants/Inclusion and exclusion criteria

Entry requirements: • Willingness to participate in research • Being literate in reading and writing • Having a smart mobile phone • Definitive diagnosis of cancer by an oncologist and receiving chemotherapy Exit conditions: • Any psychological disorders • Regular sports activity • Having concomitant diseases such as heart attack or stroke in the previous three months • Use of sleeping pills and painkillers.

Intervention groups

Educational program for 25 participants of the intervention group in the form of virtual training in ETA or Soroush software in four virtual sessions that include familiarization with types of cancers, symptoms and diagnostic methods - treatment and care - nutrition and exercise - ways to cope with the disease and improve the quality of life virtually will be executed. After this file is voiced and Benson's relaxation training is uploaded to the group twice a day for eight weeks. The day after uploading the educational file, the researchers follow up with patients by phone and SMS to ensure that all patients have viewed and read the sent file. During the

research period, educational intervention is not carried out in the control group.

Main outcome variables

Pain intensity and sleep quality

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20211121053137N2**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **prospective**

Last update: **2023-12-20, 1402/09/29**

Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

Afrooz Rahmanian

Name of organization / entity

The university of Shiraz

Country

Iran (Islamic Republic of)

Phone

+98 71 5427 6232

Email address

rahmaniannurse1395@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2023-12-25, 1402/10/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of a web-based Benson relaxation training program on the sleep quality and pain intensity of cancer patients referred to the Chemotherapy Center of Jahrom University of Medical Sciences.

Public title
Benson's relaxation training program on sleep quality and pain intensity in cancer patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:

- Desire to participate in research
- Being literate in reading and writing
- Having a smart phone
- Definitive diagnosis of cancer by an oncologist and receiving chemotherapy

Exclusion criteria:

- Any psychological disorders
- Regular sports activity
- Having concomitant diseases such as heart attack or stroke in the previous three months
- Use of sleeping pills and painkillers

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
52 participants were selected by available sampling method. Then they were randomly divided into intervention and control groups. The intervention and control groups were named A and B, and then 52 random numbers were selected using a computer. Numbers from 0 to 4 or those with 0-4 as their first digit were assigned to group A, while numbers 5 to 9 or those with 5-9 as their first digit were assigned to group B.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants who were in the intervention and control groups and the data analysts, were blinded and were not in progress

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics Committee of Jahrom University of Medical Sciences
Street address
Motahari Blvd., Farhangtown
City
Jahrom
Province
Fars
Postal code
7414845794
Approval date
2023-10-28, 1402/08/06
Ethics committee reference number
IR.JUMS.REC.1402.081

Health conditions studied

1
Description of health condition studied
Cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Sleep quality score
Timepoint
The beginning of the study (before the start of the intervention) and the end of the study and two months after the end of the study
Method of measurement
Petersburg Sleep Quality Questionnaire

2
Description
Pain intensity score
Timepoint
The beginning of the study (before the start of the intervention) and the end of the study and two months after the end of the study
Method of measurement
NRS pain intensity scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training program is sent as a training file in four sessions in the virtual training group in Ita or Soroush for 26 people, and the training content of these four sessions includes: getting to know the types of cancers - diagnostic methods - treatment and care - nutrition, exercise - ways to deal with the disease and Improving the quality of life. Then, the voiced file of Benson's relaxation and its method is loaded twice a day in the group for up to eight weeks.

Category

Lifestyle

2

Description

Control group: During the research period, the control group receives their previous treatments and training.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Chemotherapy ward, Peymanieh hospital

Full name of responsible person

Rahmanian Afrooz

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Valiasr Square, Peymaniye Hospital

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Research Assistant of the University of Medical

Sciences

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Web page address

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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

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Badiyepaymaie Jahromi Zohreh

Position

Associate professo

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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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

Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Rahmanian Afrooz

Position

Nurse

Latest degree

Master