Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 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
Street address
Valiasr Square, Peymaniye Hospital
City
Jahrom
Province
Fars
Postal code
Phone
+98 71 5412 0010
Fax
Email
Rahmaniannurse1395@gmail.com
Web page address
http://www.jums.ac.ir

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
Street address
, University of Medical Sciences, Ostad Motahari St.
City
Jahrom
Province
Fars
Postal code
74148-46199
Phone
+98 71 5434 0405
Fax
Email
Rahmaniannurse1395@gmail.com
Web page address
http://www.jums.ac.ir/
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
Badiyepeymaie Jahromi Zohreh
Position
Associate professo
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Motahari Blvd., Nursing Faculty
City
Jahrom
Province
Fars
Postal code
7414785318
Phone
+98 71 5437 2000
Email
rahmaniannurse1395@gmail.com
Web page address
http://www.jahromu.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Badiyepeymaie Jahromi Zohreh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Motahari Blvd., Nursing Faculty

City
Jahrom

Province
Fars

Postal code
7414785318

Phone
+98 71 5437 2000

Email
z.badiyepeyma@gmail.com

Web page address
http://www.jahromu.ac.ir

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

Other areas of specialty/work
Nursery

Street address
Paymaneh hospital

City
Jahrom

Province
Fars

Postal code
۷۴۱۹۸۸۶۶۸۸

Phone
009871541230010

Fax

Email
Rahmaniannurse1395@gmail.com

Web page address
http://www.jahromu.ac.ir

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