Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

A clinical trial for determination of the effect of Benson’s relaxation technique on depression, anxiety, and quality of life of caregivers of patients with cancer

Protocol summary

Study aim

The effect of Benson’s relaxation technique on depression, anxiety and quality of life of caregivers of patients with cancer

Design

A non-blind controlled randomized trial with a parallel design will be conducted on two groups of 25 subjects.

Settings and conduct

Among caregivers of patients with cancer referring to Kashan’s Shahid Beheshti Hospital, 50 eligible ones will be assigned into two groups of 25 subjects. The intervention group will perform Benson's relaxation technique, once a day for six weeks. The Beck’s Depression, and the Spielberger's Anxiety Inventories, and the Quality of Life of Cancer Caregivers Questionnaire will be used to evaluate the depression, anxiety, and quality of life at the beginning of the study, at the end of the sixth week, and four weeks after the end of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Caring for a patient with cancer, age of 20 to 59 years, fluency in the Persian language, signing the informed consent form, not receiving antidepressants and anxiolytics, having a mild or higher degree of anxiety and depression, having no known cognitive impairments. Exclusion criteria: Getting any acute illness requiring medical attention, the occurrence of a critical condition for the caregiver which affect the quality of life, death of a caregiver, and doing the intervention for less than 5 sessions in a week, and decision to withdraw.

Intervention groups

After the participants were trained about the relaxation technique, they will be required to do it for 6 weeks, once daily, for 20 min each time. The subjects must take a comfortable position, close their eyes, breathe deeply and regularly through nostrils, loosen all their muscles from feet to the face, and at the same time whisper some calming words. The control group does not perform the technique.

Main outcome variables

Depression, anxiety, and quality of life.

General information

Reason for update

An error has occurred in the recruitment dates.

Acronym

IRCT registration information

IRCT registration number: **IRCT20100403003618N7**
Registration date: **2019-07-04, 1398/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-26, 1399/02/07**
Update count: **1**

Registration date

2019-07-04, 1398/04/13

Registrant information

Name
Mohsen Adib-Hajbaghery
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial for determination of the effect of Benson's relaxation technique on depression, anxiety, and quality of life of caregivers of patients with cancer

Public title

The effect of Benson's relaxation technique on depression, anxiety, and quality of life of caregivers

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Caring for a patient with cancer at the time of the study (i.e. a spouse, a child, a father, or a mother). Age between 20 and less than 60 years. Fluency and ability to read and write in Persian language. Willingness to participate in the study and signing the informed consent form. Not receiving antidepressants and anxiolytic medications at the beginning of the study. Having mild or higher anxiety and depression based on Beck's depression and the Spielberger State-Trait Anxiety Inventories. Having no known cognitive impairment (to this end, the individual, and the patient will be questioned if any physician made him/her a medical diagnosis of mental disorders such as amnesia and Alzheimer disease?)

Exclusion criteria:

A caregiver's decision to withdraw from the study. Getting any acute illness or conditions requiring medical attention during the study. The occurrence of a critical condition for the caregiver (such as getting an acute illness, being hospitalized, being divorced) so that his/her quality of life is affected. Doing the recommended intervention for less than 5 sessions in a week. Death of a caregiver.

Age

From **20 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The permuted blocked randomization method will be used via an online randomizer, to randomly assign 50 caregivers into 12 four-subject and one two subjects blocks to create two groups of 25 subjects.

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

Kashan University of Medical Sciences

Street address

Ravand Street, Kashan

City

Kashan

Province

Isfehan

Postal code

8715981151

Approval date

2019-06-10, 1398/03/20

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1398.013

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

3

Description of health condition studied

Quality of life

ICD-10 code

C80

ICD-10 code description

Malignant neoplasm without specification of site

Primary outcomes

1

Description
Depression
Timepoint
Before the intervention, the end of the sixth week of intervention, and also four weeks after the end of the intervention.
Method of measurement
The Beck Depression Inventory

2

Description
Anxiety
Timepoint
Before the intervention, the end of the sixth week of intervention, and also four weeks after the end of the intervention.
Method of measurement
The Spilberger Inventory

Secondary outcomes

1

Description
Quality of life
Timepoint
Before the intervention, the end of the sixth week of intervention, and also four weeks after the end of the intervention.
Method of measurement
The Caregiver Quality Of Life index-Cancer scale

Intervention groups

1

Description
Intervention group: Benson's relaxation technique will be performed once a day (20 minutes) for six weeks.
Category
Behavior

2

Description
Control group: The control group will not receive intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Mohammad Reza Fazel
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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
Kashan 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
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Bahareh Ebrahimi
Position
Master of Science Student in Medical-Surgical Nursing
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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
Yes - There is 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
Not applicable
Title and more details about the data/document
Not decided yet.
When the data will become available and for how long
Not decided yet.

To whom data/document is available

Not decided yet.

Under which criteria data/document could be used

It has not been decided yet.

From where data/document is obtainable

Not decided yet.

What processes are involved for a request to access data/document

Not decided yet.

Comments