

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigation the effect of benson's relaxation on care burden and coping strategies among caregivers of cancer patients

Protocol summary

Study aim

Determining the effect of Benson relaxation on the care burden and coping strategies of cancer caregivers

Design

The study is a clinical trial with a control group, with a parallel design that was randomly divided into two equal groups with a sample size of 124 caregivers.

Settings and conduct

Using convenience sampling, we collect samples from all caregivers of patients who refer to the chemotherapy and radiotherapy wards of Sabzevar Vasei Hospital. Samples are randomly divided into experimental and control groups based on permutation blocks. Sealed and numbered envelopes are used for concealment. Demographic characteristics questionnaire, care pressure and coping strategies are completed by both groups before and after four weeks of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least six months of care work Age between 18 to 67 years Do not take professional care Not participating in other research Greater total caregiver burden score equal to 36 Exclusion criteria: Neuromuscular disorders Acute disease or special conditions Severe mental disorder and the use of sedatives Occurrence of stressful events

Intervention groups

The test group is taught the Benson relaxation technique, then a CD is given to the research units to perform twice a day for four weeks at home. During the study, the intervention group will be followed up by telephone for relaxation and the control group will not receive any intervention, and only due to stressful events and not attending a class or effective stress program based on the times mentioned in The above will be reviewed and caregiver questionnaires and coping strategies will be completed before the study and after four weeks by both groups. Also, the researcher is available to the participants by phone during the study.

Main outcome variables

caregiver burden: coping strategies

General information

Reason for update

Correction of the care burden score in the inclusion criteria and recording the date of onset of the sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051849N1**

Registration date: **2021-07-13, 1400/04/22**

Registration timing: **prospective**

Last update: **2023-10-08, 1402/07/16**

Update count: **2**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Hamid Barghbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4501 3452

Email address

hamidbarghbani75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-18, 1400/04/27

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation the effect of benson's relaxation on care burden and coping strategies among caregivers of cancer patients

Public title
the effect of benson's relaxation on care burden and coping strategies

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Caring for a cancer patient during the study Have at least six months of care for a cancer patient Age of care between 18 to 67 years Not to be a professional caregiver (not being employed as a health care worker) Willingness to participate in the study Have the ability to read and write Access to the phone to follow the training program The caregiver obtains the total care pressure score of $X \geq 48$ based on the score obtained from the questionnaire
Exclusion criteria:
 Neuromuscular disorders Having an acute illness or special condition that requires medical attention Severe mental disorder and the use of sedatives Occurrence of stressful events such as the death of a first-degree relative, separation or divorce, and legal disputes in the past six months and during the course of study hearing and vision disorders (deaf and dumb) participate in other research by the caregiver during the last 3 months receive a fee for care Participate in any classes or programs that affect stress such as relaxation, yoga and meditation

Age
From **18 years** old to **67 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be selected by available method and will be placed in intervention and control groups using random allocation permutation blocks. R software will be used to obtain the blocks. In this way, the control group is marked with the letter a and the intervention group with the letter b, and the size of each block is 4 people, the number of blocks is 31 and the number of possible permutations is 6. Then, from the table of random numbers, 31 random numbers are selected. And we fill 31 blocks of scenarios. For example, if block 1 is baba, from the left, the first person will enter the intervention group, the second person will enter the control group,

the third person will enter the intervention group, and finally the fourth person will enter the control group.

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
 Research Ethics Committee of Sabzevar University of Medical Sciences
Street address
 Nuclear Martyrs Boulevard, above the Memorial of the Unknown Martyrs, Campus of the University of Medical Sciences, Vice Chancellor for Research and Technology
City
 Sabzevar
Province
 Razavi Khorasan
Postal code
 9617913112
Approval date
 2021-05-10, 1400/02/20
Ethics committee reference number
 IR.MEDSAB.REC.1400.058

Health conditions studied
1
Description of health condition studied
 cancer
ICD-10 code
 C80.0
ICD-10 code description
 Malignant neoplasm, without specification of site

Primary outcomes
1
Description
 Care burden of caregivers
Timepoint
 Before and four weeks after the intervention
Method of measurement
 Novak and Guest Caregiver burden Questionnaire

2

Description

Caregiver coping strategies

Timepoint

Before and four weeks after the intervention

Method of measurement

Endler and Parker Short Form Coping Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Benson Relaxation is taught to caregivers as an intervention in a special room in the chemotherapy and radiotherapy wards to fully learn, then a CD is given to them to do benson relaxation in home twice a day in the morning and evening with at least two hours interval for 20 minutes and continue for four weeks. During the study, three days after the training, the members of the intervention group will be followed up by telephone to ask questions about relaxation and to evaluate stressful events during the study, and it will be repeated every seven days. Then, after four weeks, the care burden questionnaires and coping strategies will be completed again .Benson relaxation is done by asking people to lie down in a quiet environment and in a comfortable position, or to sit on a chair and close their eyes, then slowly relax their muscles from the legs to the face. And at the same time breathe in through the nose and be aware of their breathing, and then say the word "one" silently when exhaling. People are advised not to worry if they do not reach a deep level of relaxation and to allow the relaxation to happen at its own pace, to ignore disturbing thoughts and to focus on saying one exhale at a time. When finished, open your eyes and sit for a few minutes, then stand still (they may open their eyes to check for time while relaxing, without using an alarm).

Category

Rehabilitation

2

Description

Control group: The control group will not receive any intervention and will be reviewed solely for the occurrence of stressful events and failure to attend a class or program affecting stress based on the times mentioned above.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei educational and medical center

Full name of responsible person

Batool Keykhosravi

Street address

Sabzevar, Tohidshahr Boulevard, Vasei Hospital

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hamidbarghbani75@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

mohammad hossein saghi

Street address

Nuclear Martyrs Boulevard, above the Memorial of the Unknown Martyrs, Campus of the University of Medical Sciences, Vice Chancellor for Research and Technology

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vc.Research@medsab.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Hamid Barghbani

Position

Master student of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nuclear Martyrs Boulevard, above the Memorial of the Unknown Martyrs, Campus of the University of Medical Sciences, School of Nursing and Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

hamidbarghbani

Position

Master student of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mojgan Ansari

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information security of participants

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available