

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of spiritual counseling on the care burden of elderly cancer caregivers.

Protocol summary

Study aim

Determining the effect of spiritual counseling on the care burden of caregivers of the elderly with cancer

Design

Clinical trial with control group, randomized, phase 3 on 66 patients. Matlab software was used for randomization.

Settings and conduct

The sampling location is Khansari Hospital, Arak city, and each group includes 33 patients, who will be divided into control group and intervention group by simple randomization method, and each patient will be given a code. Zarit 4 care burden questionnaire will be completed in two pre-test and post-test stages for both intervention group and control group before the implementation of the intervention. For i.g, the spiritual counseling protocol of Baljani and colleagues will be implemented, and then, the questionnaires of the post-test phase will be implemented and the analysis process will be performed.

Participants/Inclusion and exclusion criteria

Entry requirements include consent to participate in the study Age above 18 years Literacy for reading and writing The conditions of non-entry include lack of consent of the patient or companion in the study Cancer patients with multiple chronic diseases, such as cancer with mental illness, diabetes, etc

Intervention groups

The intervention group of caregivers of the elderly with cancer who receive intervention The control group of caregivers of the elderly with cancer who do not receive intervention

Main outcome variables

Carers' burden of care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230319057757N1**

Registration date: **2023-04-29, 1402/02/09**

Registration timing: **prospective**

Last update: **2023-04-29, 1402/02/09**

Update count: **0**

Registration date

2023-04-29, 1402/02/09

Registrant information

Name

Saeid Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3435 2823

Email address

nu.saeidmaleki1995@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual counseling on the care burden of elderly cancer caregivers.

Public title

"Investigating the effect of spiritual counseling on care

giving burden"

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study
Age above 18 years
Literacy for reading and writing
Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **33**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher will assign a back code to each volunteer, which divides the volunteers into two intervention groups (A) and control group (B) using the block randomization method using Matlab software, which was done by a statistician.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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
A'lam Al Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2023-02-19, 1401/11/30
Ethics committee reference number
IR.ARAKMU.REC.1401.339

Health conditions studied

1

Description of health condition studied
caregivers of the cancer patients

ICD-10 code
XXI

ICD-10 code description
Factors influencing health status and contact with health services

Primary outcomes

1

Description
Reducing the care burden of caregivers of elderly patients with cancer

Timepoint
Before the intervention and 10 sessions after the intervention.

Method of measurement
Zarit et al. care burden questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Caregivers of the elderly with cancer will receive 10 sessions of spiritual counseling in a month and a half, two 60-minute sessions a week on Sundays and Tuesdays.

Category
N/A

2

Description
Control group: Caregivers of the elderly with cancer for whom no intervention will be implemented

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Khansari Specialized Educational and Therapeutic Center
Full name of responsible person
Parsa Rostami
Street address
The end of university street, Arak.
City

Arak
Province
Markazi
Postal code
3818649433
Phone
+98 86 3336 7500
Email
info_khansari@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Arak University of Medical Sciences
Street address
Alam El Hadi St., Shahid Shiroudi St.
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3313 6055
Email
info@arakmu.ac.ir

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

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Saeid Maleki
Position
Nursing master student
Latest degree
Bachelor
Other areas of specialty/work

Nursery

Street address

No 3 Javadieh Alley, Javadieh Township, Shahid Mousavi St., Qaim Maqam St.

City

Arak

Province

Markazi

Postal code

3816996797

Phone

+98 86 3435 2823

Email

nu.saeidmaleki1995@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ameneh Yaghoobzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Basij Square, Markazi Province,

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3526

Email

A.yaghoobzadeh@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Saeid Maleki

Position

Nursing master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 3 Javadieh Alley, Javadieh Township, Shahid Mousavi St., Qaim Maqam St.

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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