

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Effect of spiritual care based on Sound Heart Model on spiritual needs and spiritual Dryness of patients with cancer

#### Protocol summary

##### Study aim

The effect of spiritual care is determined based on Sound Heart Model on spiritual needs and spiritual Dryness of patients with cancer

##### Design

Sampling method available Sample size: 104 patient  
Shift block randomization with a volume of four units in each block will be done.

##### Settings and conduct

This study is a randomized clinical trial. The study population includes all cancer patients (diagnosed by a doctor) undergoing treatment (chemotherapy, radiation therapy) who refer to Ayatollah Khansari Hospital in Arak in 1399.

##### Participants/Inclusion and exclusion criteria

Cancer patients Inclusion criteria: All patients with definitive diagnosis of cancer, access and ability to use social network by the patient, the patient's desire to participate in the study Exclusion criteria: Mental illness, inability to read and write (illiterate), lack of smart phone, age over 70 years

##### Intervention groups

Spiritual care Spiritual care based on Sound Heart Model in the intervention group is performed on three dependent variables: spiritual health, spiritual need, and spiritual Dryness through 2 months of virtual intervention. The control group receives routine care.

##### Main outcome variables

Spiritual needs mental health spiritual Dryness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201231049896N1**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

##### Registration date

2021-11-23, 1400/09/02

##### Registrant information

###### Name

sobhan ebrahimpour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3313 6055

###### Email address

sobhan.ebrahimpour.110@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-23, 1400/08/01

##### Expected recruitment end date

2022-01-05, 1400/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of spiritual care based on Sound Heart Model on spiritual needs and spiritual Dryness of patients with cancer

##### Public title

Effect of spiritual care on patients with cancer

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

All patients are diagnosed with a definitive diagnosis of cancer Patient access and the ability to use social network The patient 's willingness to participate in the study

**Exclusion criteria:**

Mental illness Inability to read and write (illiterate) Lack of smart phone Age over 70 years

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling is done when patients go to the hospital for chemotherapy. The samples will then be randomly divided into two groups of 52 with random allocation in block in intervention (A) and control (B) groups. First, the four blocks are defined as follows: ABAB, BBAA, BABA, BAAB, AABB, ABBA, etc., and individuals according to A and B will be divided into two groups of intervention and control. Patient A was in the supportive educational intervention group through Soroush virtual social network and patient B was in the control group.

**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**

No. 23, Kowsar One St., 12 meters from Motahhari., Kohanz., Shahriar., Tehran

**City**

tehran

**Province**

Tehran

**Postal code**

۳۳۵۱۸۵۶۶۳۹

**Approval date**

2021-04-28, 1400/02/08

**Ethics committee reference number**

IR.ARAKMU.REC.1400.012

**Health conditions studied**

1

**Description of health condition studied**

بیماران مبتلا به سرطان

**ICD-10 code**

D49

**ICD-10 code description**

Neoplasms of unspecified behavior

**Primary outcomes**

1

**Description**

Spiritual needs score in the Spiritual Needs Questionnaire (SpNQ)

**Timepoint**

Before the intervention, immediately after the intervention, one month after the end of the intervention

**Method of measurement**

Spiritual Needs Questionnaire (SpNQ)

2

**Description**

Spiritual Dryness score in the spiritual Dryness Scale (SDS)

**Timepoint**

Before the intervention, immediately after the intervention, one month after the end of the intervention

**Method of measurement**

Spiritual Dryness Scale (SDS)

3

**Description**

Spiritual health score in the spiritual health questionnaire

**Timepoint**

Before the intervention, immediately after the intervention, one month after the end of the intervention

**Method of measurement**

spiritual health of Palutzin and Ellison Questionnaires

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Spiritual care intervention based on the model of sound heart, model of sound heart based on Islamic teachings is the paradigm of the Abrahamic religions that has been registered worldwide. The intervention is 8 virtual sessions over 2 months.

Sequence of sessions including: 1. Familiarity and examination of the patient's feelings and attitude to the disease 2. Attention to the positive aspects of the disease on the axis of dualism, expressing the concept of divine testing 3. The effect of different dimensions of health on each other and spiritual self-awareness 4. Development of social relations 5 Exploitation of creation 6. Motivation and values 7. Development of relationship with God as a factor of creating hope, courage, optimism, endurance 8. Coping and adaptation. In addition to the above sessions, individuals receive a daily message and must send the word {read ر} to the researcher in a virtual application.

**Category**

Other

**2****Description**

Control group: They receive only routine hospital care (including training provided by physicians and nurses and hospital training pamphlets). Immediately after the intervention, participants in both groups complete three questionnaires again and are compared to evaluate the effectiveness of the educational and supportive intervention. One month after the end of the intervention, the questionnaires are completed again in order to follow up the intervention.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ayatollah Khansari tertiary referral hospital

**Full name of responsible person**

Sobhan Ebrahimpour

**Street address**

End of Daneshgah Street., Ayatollah Khansari Hospital., Arak

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arak

**Province**

Markazi

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**Phone**

+98 86 3336 7501

**Email**

www.pr\_khansari@arakmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

DR Alireza kamali

**Street address**

Third Floor., Imam Musa Kazem Building., University Complex of the Great Prophet (PBUH)., Basij Square., Sardasht

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Arak

**Province**

Markazi

**Postal code**

3848176341

**Phone**

+98 86 3417 3639

**Email**

research@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**

Sobhan Ebrahimpour

**Position**

Master of nursing student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 23, Kowsar One St., 12 meters from Motahhari., Kohanz., Shahriar., Tehran

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**Province**

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**Postal code**

3351856639

**Phone**

+98 21 6522 8400

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sobhan.ebrahimpour.110@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Nazi Nejat

**Position**

Consultant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Third floor., School of Nursing Arak University of Medical Sciences., Sardasht., Arak

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after unidentified individuals.

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions will be available

**Under which criteria data/document could be used**

The use of data is allowed by mentioning the source.

**From where data/document is obtainable**

Nazi Nejat Arak - Sardasht - Arak University of Medical Sciences 3319693345 nazinejat@gmail.com sobhan ebrahimpour No. 23, Kowsar One St., 12 meters from Motahhari., Kohanz., Shahriar., Tehran 3351856639 sobhan.ebrahimpoor.110@gmail.com

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

The applicant must first register his / her request through the mentioned communication channels, and after reviewing the request for information, the information will be provided on condition of confidentiality and without identity information. This process will take a minimum of one month and a maximum of 2 months.

**Comments**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Sobhan

**Position**

Master of nursing student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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