Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of spiritual care based on Sound Heart Model on spirtual 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 spirtual 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.ebrahimpoor.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 spirtual 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 در 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

City

arak

Province

Markazi

Postal code

3818649433

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

City

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

City

tehran

Province

Tehran

Postal code

3351856639

Phone

+98 21 6522 8400

Email

sobhan.ebrahimpoor.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

City
arak

Province
Markazi

Postal code
3319693345

Phone
+98 86 3313 6055

Email
nazinejat@gmail.com

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

City
tehran

Province
Tehran

Postal code
3351856639

Phone
+98 21 6522 8400

Email
sobhan.ebrahimpoor.110@gmail.com

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