

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Effect of Spiritual Consultation on The Spiritual Health Of Women With Cancer

#### Protocol summary

##### Summary

This study is a clinical trial that randomly assigned to two groups from October to December 1394 martyr Beheshti Hospital of Hamedan on 40 female patients with cancer who were referred to this center. The number of samples in each of 15 groups was determined that the risk of loss or lack of satisfaction in the study, 20 patients in each group were considered. Inclusion criteria included: age 18-65 years, and Shiite Muslim, passing at least 4 months of diagnosis, consent to participate in research, the ability to talk and get on the stage of the End Stage . The study tools were completed by interviewing patients and patients randomly using a table of random numbers in both groups were 21 people intervention and control. Individual spiritual counseling intervention group and 2 times a week and consisted of 8 sessions of 45 minutes in the morning or the evening was. At the end of the intervention and control groups were examined again by the tool The data in this study through spiritual health assessment questionnaire (Paloutzian & Ellison), and demographic information was gathered Demographic information including age, education, social class and income level, number of family members, the company was in religious ceremonies and rites.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015112225187N1**  
Registration date: **2015-12-23, 1394/10/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-23, 1394/10/02

#### Registrant information

##### Name

Naemeh Niazi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3829 0270

##### Email address

dr.sajadei@arakmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Arak University of Medical Sciences

#### Expected recruitment start date

2015-09-23, 1394/07/01

#### Expected recruitment end date

2015-11-22, 1394/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Spiritual Consultation on The Spiritual Health Of Women With Cancer

#### Public title

Effect of Spiritual Consultation on The Spiritual Health Of Women With Cancer

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria included: age 18-65 years old and Shia Muslim; passing at least 4 months of diagnosis; consent to participate in research; the ability to talk and get on the stage of the end stage. Exclusion criteria: lack of

consent to continue to participate in research and patient non-compliance in a timely manner to carry out assignments and participation in conferences.

#### **Age**

From **18 years** old to **80 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **42**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Hamedan University of Medical Sciences

##### **Street address**

Hamedan,Pajuhesh Crossroads, Hamedan University of Medical Sciences

##### **City**

Hamedan

##### **Postal code**

6517838678

#### **Approval date**

2015-07-25, 1394/05/03

#### **Ethics committee reference number**

IR.UMSHA.RCE.1394.240

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Cancer

#### **ICD-10 code**

C80.0

#### **ICD-10 code description**

Malignant neoplasm, primary site unknown, so stated

## **Primary outcomes**

### 1

#### **Description**

Spiritual Health

#### **Timepoint**

Before the intervention and after the intervention

#### **Method of measurement**

Spiritual Health Questionnaire paloutzian & Ellison

## **Secondary outcomes**

### 1

#### **Description**

Age, educational level, social class, income level, number of family members, the participation in religious ceremonies and rites

#### **Timepoint**

Before the intervention

#### **Method of measurement**

Demographic questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention for spiritual counseling with Islamic approach individual whose 8 sessions for 45 to 60 minutes was performed at the patient's bedside.

#### **Category**

Other

### 2

#### **Description**

The control group received only care nurse at the hospital and did not receive counseling

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Beheshti Hospital

##### **Full name of responsible person**

Educational Assistant Shahid Beheshti Hospital

##### **Street address**

Hamedan, Ghaem sqr, Shahid Beheshti Hospita.

##### **City**

Hamedan

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mahbobeh Sajadi

**Street address**

Arak University of Medical Sciences

**City**

Arak

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Naemeh Niazi

**Position**

MSc Student of Nursing

**Other areas of specialty/work**

**Street address**

Arak, Arak University of Medical Sciences

**City**

Arak

**Postal code**

6517817953

**Phone**

+98 81 3821 1670

**Fax**

**Email**

naemehniazi@yahoo.com

**Web page address**

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Naemeh Niazi

**Position**

MSc Student of Nursing

**Other areas of specialty/work**

**Street address**

Arak University of Medical Sciences

**City**

Arak

**Postal code**

6517817953

**Phone**

+98 81 3821 1670

**Fax**

**Email**

naemehniazi@yahoo.com

**Web page address**

### Person responsible for updating data

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Naemeh Niazi

**Position**

MSc Student of Nursing

**Other areas of specialty/work**

**Street address**

Arak University of Medical Sciences

**City**

Arak

**Postal code**

6517817953

**Phone**

+98 81 3821 1670

**Fax**

**Email**

naemehniazi@yahoo.com

**Web page address**

### Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*