

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Stress Inoculation Training on Existential Anxiety and Resilience of cancer patients

#### Protocol summary

##### Study aim

Investigation of the effectiveness of stress-immunization group training program on existential anxiety and resiliency of cancer patients

##### Design

This study is a nonblinded clinical trial. The research population will be included all patients with cancer who will refer to Imam Reza hospital in Kermanshah city. 30 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

##### Settings and conduct

This study, which will be conducted at Imam Reza Hospital in Kermanshah, is not blinded one. Before the study, immediately and one month after the end of the study, anxiety and resiliency questionnaire will be provided to the patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of cancer; lack of mental illness and use of psychotropic drugs; Absence of thyroid gland diseases Exclusion criteria: Physical disability due to the progression of illness and death; Absence more than two sessions in training sessions

##### Intervention groups

The intervention group will receive 90-minute training on immunization against stress (Maicon Baum model) each week 2 sessions, during eight sessions. The control group will receive the ward usual care.

##### Main outcome variables

Existential anxiety, Resiliency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N100**

Registration date: **2018-08-29, 1397/06/07**

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

Last update: **2018-08-29, 1397/06/07**

Update count: **0**

##### Registration date

2018-08-29, 1397/06/07

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-01, 1397/05/10

##### Expected recruitment end date

2018-10-02, 1397/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Stress Inoculation Training on Existential Anxiety and Resilience of cancer patients

##### Public title

The Effect of Stress Inoculation Training on Existential Anxiety and Resilience of cancer patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Definitive diagnosis of cancer The ability to understand and speak

**Exclusion criteria:**

Mental illness and the use of psychoactive drugs Patients with thyroid gland diseases

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomly Individually by random number table via code receipt

**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**

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2018-05-08, 1397/02/18

**Ethics committee reference number**

ir.kums.rec.1397.165

**Health conditions studied****1****Description of health condition studied**

Cancer

**ICD-10 code**

C80.0

**ICD-10 code description**

Disseminated malignant neoplasm, unspecified

**Primary outcomes****1****Description**

Existential anxiety

**Timepoint**

Before the study, immediately and one month after the end of the study

**Method of measurement**

Based on existential anxiety questionnaire

**2****Description**

Resiliency

**Timepoint**

Before the study, immediately and one month after the end of the study

**Method of measurement**

Base on Connor and Davidson Resiliency Questionnaire(CD-RIS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The intervention group will receive 90-minute training on immunization against stress (Maicon Baum model) each week 2 sessions, during eight sessions.

**Category**

Other

**2****Description**

The control group will receive the ward usual care.

**Category**

Other

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

Emam Reza Hospital

**Full name of responsible person**

Sara Ahmadi  
**Street address**  
Emam Reza Hospital, Parastar Boulevard  
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sa.Ah@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Dr. Farid Najafi  
**Street address**  
Vice Chancellor for Research Affairs, Kermanshah  
University of Medical Sciences, Building No.2, Shahid  
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fnajafi@kums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kermanshah 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**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**

Sara Amadi  
**Position**  
Master of Internal and Surgical Nursing  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
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Isar Square, Dolatabad Blvd, Faculty of Nursing and  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Master of Internal and Surgical Nursing  
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## Person responsible for updating data

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**Other areas of specialty/work**  
Nursery

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**City**

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**Province**

Kermanshah

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6715847141

**Phone**

+98 83 3826 6429

**Email**

sa.Ah@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**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

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

The main outcomes of the study will be shared.

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

6 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

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

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

**Comments**