# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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**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
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Emam Reza Hospital, Parastar Boulevard
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Dr. Farid Najafi
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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
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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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**