# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The effectiveness of cognitive-behavioral training based on immunization against stress on increasing coping skills and quality of life in maladjusted couples

## Protocol summary

**Study aim**
To determine the effectiveness of cognitive-behavioral training based on immunization against stress on increasing coping skills and quality of life in maladjusted couples

**Design**
In this study, 24 maladjusted couples who had referred to counseling centers were selected and randomly assigned to two experimental and control groups

**Settings and conduct**
This study was conducted in Kazeroun

**Participants/Inclusion and exclusion criteria**
Participants were selected based on perceived stress and marital adjustment

**Intervention groups**
The experimental group consisted of 12 couples who received anti-stress immunization training. The control group also included 12 couples who did not receive any intervention.

**Main outcome variables**
Immunization intervention is effective in improving quality of life in couples and increases their problem-oriented coping style.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160721029019N2**
Registration date: **2018-06-17, 1397/03/27**
Registration timing: **retrospective**

Last update: **2018-06-17, 1397/03/27**
Update count: **0**

**Registration date**
2018-06-17, 1397/03/27

**Registrant information**
**Name**
Zahra Simi
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Allameh Tabatabei University
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**Recruitment status**
**Recruitment complete**

**Funding source**
investigator

**Expected recruitment start date**
2016-08-22, 1395/06/01

**Expected recruitment end date**
2016-09-22, 1395/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effectiveness of cognitive-behavioral training based on immunization against stress on increasing coping skills and quality of life in maladjusted couples

**Public title**
The effectiveness of cognitive behavioral training based on immunization against stress

**Purpose**
Prevention

**Inclusion/Exclusion criteria**
**Inclusion criteria:**

Having a standard deviation higher than the mean in perceived stress Having a score below 101 in marital adjustment

**Exclusion criteria:**

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Twenty-four couples were selected and randomly divided into two experimental and control groups

**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**

Allameh Tabatabaei University.

**Street address**

Olympic Village, Hemmat Exp way, Tehran, Iran

**City**

Tehran

**Province**

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**Postal code**

7351737966

**Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

2048197

## Health conditions studied

### 1

**Description of health condition studied**

The effectiveness of cognitive behavioral training based on immunization against stress on creasing coping skills and life quality in maladjusted couples

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Quality of life

**Timepoint**

Pre, post test and follow up

**Method of measurement**

Questionnaire

## Secondary outcomes

### 1

**Description**

Coping skills

**Timepoint**

Pre post & follow up

**Method of measurement**

Questionnaire

## Intervention groups

### 1

**Description**

The control group received no training but after completing the research period, the members of the control group received practical training packages based on stress-management immunization training.

**Category**

Behavior

### 2

**Description**

The experimental group received 10 sessions of interventions and then received an independent variable in the stress-safety approach for 60 minutes. Data were collected by the Coping Styles Questionnaire of Endler & Parker, Cohen's Perceived Stress, and Quality of Life SF-36 in two stages: pre-test and post-test

**Category**

Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Counselling Offices

**Full name of responsible person**

Zahra Simi

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## Sponsors / Funding sources

### 1

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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Researcher
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Persons

## Person responsible for general inquiries

**Contact**
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M. Sc
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## Person responsible for updating data

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

because of full report of data analysis in the article

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available