

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Sep 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

Name of organization / entity

Allameh Tabatabaei 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

Tehran

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

Sponsor

Name of organization / entity
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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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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