Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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
Name of organization / entity
Allameh Tabatabei University
Country
Iran (Islamic Republic of)
Phone
+98 71 4252 4840
Email address
z.simin00@yahoo.com

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

Street address

Rahesevom Counselling Offices, Kazeroun, Fars, Iran.

City

Kazeroun

Province
Fars
Postal code
7131723559
Email
z.simin62@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Researcher
Full name of responsible person
Zahra Simi
Street address
Social Welfare Bureau, Street rally
City
kazroun
Province
Fars
Postal code
7131723559
Phone
+98 71 2221 9990
Email
sadrahm2014@gmail.com
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
Name of organization / entity
Allameh Tabatabaei university.
Full name of responsible person
Zahra Simi
Position
M. Sc
Latest degree
Master
Other areas of specialty/work
Street address
Kazerun branch of Payame Noor university, Kazeroun, Fars, Iran.
City
Kazeroun
Province
Fars
Postal code
7351737966
Phone
+98 71 4253 0986
Fax
Email
z.simin00@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Allameh Tabatabaei University.
Full name of responsible person
Zahra Simi
Position
M. Sc.
Latest degree
Master
Other areas of specialty/work
Street address
Kazerun branch of Payame Noor university, Kazeroun, Fars, Iran.
City
Kazeroun
Province
Fars
Postal code
7351737966
Phone
+98 71 4252 4840
Fax
Email
z.simin00@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Islamc Azadi university Arak.
Full name of responsible person
Mohsen Makhlough
Position
M.A
Latest degree
Master
Other areas of specialty/work
Street address
Amirkabir complex, 3km Khomin road, Arak, Markazi, Iran.
City
Arak
Province
Markazi
Postal code

3836119131

Phone

+98 912 553 6963

Fax

Email

PsychoRavan@yahoo.com

Web page address

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