

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Investigating the effect of the Generalized Anxiety Disorder training package based on the solution-focused therapy on meta-worry, psychological capital and marital intimacy in couples referring to medical centers: a clinical trial based on a comparison and control group

Protocol summary

Study aim

A clinical trial of an educational intervention package, for generalized anxiety disorder based on the solution-focused therapy on meta-worry, psychological capital and marital intimacy in couples referring to medical centers.

Design

This study is a clinical trial with a pre-test and post-test design in the control and intervention groups. The groups are parallel and for randomization two series of codes are used for each group of 15

Settings and conduct

In this study, the treatment package developed by the researcher for generalized anxiety is examined on meta-Worry, psychological capital and marital intimacy. The number of 30 people who refer to the medical centers of Mahabad city who are diagnosed with generalized anxiety disorder and will be selected through available sampling and then will be randomly replaced in 2 groups of 15. The test group will undergo intervention and during this period the control group will not receive any training.

Participants/Inclusion and exclusion criteria

having symptoms of generalized anxiety disorder as diagnosed by the center's psychiatrist or psychologist, being married and reading and writing at least until the end of middle school, age range of 25-50 years, couple's commitment and desire to regularly and consistently attend meetings, not having addictions and not having severe mental disorder according to the psychiatric file and not receiving individual counseling and psychological services during the participation in therapy sessions and a high score in the general anxiety questionnaire

Intervention groups

The test group includes 15 samples that will be subjected to the comprehensive anxiety intervention training

package, the control group includes 15 samples that will not be subjected to any intervention.

Main outcome variables

score of meta worry, psychological capital , marital intimacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220203053930N1**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

Registration date

2022-09-05, 1401/06/14

Registrant information

Name

Aziz Lachini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4224 3132

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the Generalized Anxiety Disorder training package based on the solution-focused therapy on meta-worry, psychological capital and marital intimacy in couples referring to medical centers: a clinical trial based on a comparison and control group

Public title

Clinical trial of an educational package, an intervention of Generalized Anxiety Disorder on meta-worry, psychological capital and marital intimacy in couples.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having symptoms of generalized anxiety disorder as diagnosed by the center's psychiatrist or psychologist being married Reading and writing literacy at least until the end of middle school Age range 25-50 years The commitment and desire of the couple to attend regular and consecutive meetings High score in generalized anxiety Disorder questionnaire

Exclusion criteria:

Having an addiction according to the psychiatric file and the person's own statement Severe mental disorder according to psychiatric records Using counseling and individual psychological services during participation in therapy sessions

AgeFrom **25 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

For randomization, the participating couples will first be given two-digit codes from 01 to 30. Then, using the website www.Randomization.com, two series of codes will be selected for each group, the first series will be in the intervention group and the second series will be in the control group.

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**

Islamic Azad University Roodhen

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Postal code

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Approval date

2021-12-08, 1400/09/17

Ethics committee reference number

IR.IAU.R.REC.1401.014

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

Generalized anxiety Disorder

ICD-10 code

F41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is "free-floating"). The dominant symptoms are variable but include complaints of persistent nervousne

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

Meta-worry

Timepoint

Before the intervention / the end of the intervention / 1 month after the end of the intervention

Method of measurement

Wells meta- worry Questionnaire

2**Description**

Psychological Capital

Timepoint

Before the intervention / the end of the intervention / 1 month after the end of the intervention

Method of measurement

Psychological Capital Questionnaire

3

Description

Marital intimacy

Timepoint

Before the intervention / the end of the intervention / 1 month after the end of the intervention

Method of measurement

Marital Satisfaction Questionnaire

Secondary outcomes

1

Description

Reduce pervasive anxiety disorder

Timepoint

Before the intervention / the end of the intervention / 1 month after the end of the intervention

Method of measurement

Generalized Anxiety Disorder Questionnaire

Intervention groups

1

Description

Intervention group: 15 people are subjected to the package intervention of diffuse anxiety based on the solution-focused therapy approach

Category

Treatment - Other

2

Description

Control group: For 15 people will not receive any counseling.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hima Psychological Counseling and Services Center

Full name of responsible person

Aziz Lachini

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Salahuddin Doctors Building, Three Ways of Wafaith

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Dr. mina mojtabaie

Position

Associate Professor and Faculty of the University

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

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

Yes - There is 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

Title and more details about the data/document

The researchers decided to share the main findings of the study and use individual data if necessary

When the data will become available and for how long

Any documentation will be published 3 months after the intervention

To whom data/document is available

Academic and medical centers prioritize access to content and protocols

Under which criteria data/document could be used

Documents will be provided if they are intended for use in future supplementary studies

From where data/document is obtainable

Correspond directly with the original author's email

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

If the applicant's explanations regarding the use of evidence or documents are sufficiently convincing, especially if they are for educational purposes, the material will be provided in a short period of time.

Comments