Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 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
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Iran (Islamic Republic of)
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+98 44 4224 3132
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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
Age
From **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
Street address
Islamic Azad University, University Complex, Ayatollah Khamenei Blvd, Roodehen
City
Rudehen
Province
Tehran
Postal code
3973188981
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
Street address
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
Dr. Malek Mirhashemi
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Islamic Azad University, University Complex, Ayatollah Khamenei Blvd, Roodehen
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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
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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
f 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