Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efficacy of group metacognitive therapy on Patients with post-traumatic stress disorder due to earthquake in Kermanshah

Protocol summary

Study aim
The efficacy of group metacognitive therapy on Patients with post-traumatic stress disorder due to earthquake in Kermanshah

Design
Clinical trial with control group, Not blinded, Randomized

Settings and conduct
This study is conducted at the counseling Center of Kermanshah University of Medical Sciences. Patients receive 10 sessions of Group Metacognitive Therapy weekly. The duration of each session is 90 minutes. To evaluate the follow up period again three months after the end of the intervention the subjects are evaluated. In order to evaluate the effects of treatment subjects will be evaluated one week before, Mid-intervention, one week after and three months after the end of the intervention respectively. The intervention is done by an experienced psychologist and based on Wells Metacognitive Therapy treatmenl.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Suffering PTSD disorder with diagnosis of psychiatrist and clinical psychologist Exit criteria: current diagnosis of any mental disorder is consistent in Diagram 1 and 2 based on a psychologist's diagnostic interview, with the exception of PTSD disorder and emotional disorders including depression, anxiety

Intervention groups
Intervention group: 15 patients with ptsd disorder receive 10 sessions of Group Metacognitive Therapy Control group: 30 people and do not receive any special treatment.

Main outcome variables
Depression; anxiety; ptsd

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190724044326N1**
Registration date: **2019-09-05, 1398/06/14**
Registration timing: **prospective**

Last update: **2019-09-05, 1398/06/14**
Update count: **0**

Registration date
2019-09-05, 1398/06/14

Registrant information

Name
sasan amiri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3320 7884

Email address
sasanamiri2910@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-06, 1398/06/15

Expected recruitment end date
2019-10-07, 1398/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of group metacognitive therapy on Patients with post-traumatic stress disorder due to earthquake in Kermanshah

Public title

The assessment of group metacognitive therapy on Patients with post-traumatic stress disorde

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering PTSD disorder with diagnosis of psychiatrist and clinical psychologist the individual's ability to attend a therapeutic session The age range is between 50 to 18 years old Affliction of PTSD disorder and having emotional symptoms including depression, anxiety based on diagnostic interview by psychologist Motivation and satisfaction for participation during treatment Failure to receive psychological treatment in the past year Have at least a cycle of education Not having a history of sexual abuse Not having other chronic diseases such as severe liver disorder The lack of current diagnosis of any mental disorder is consistent in Diagram 1 and 2 based on a psychologist's diagnostic interview, with the exception of PTSD disorder and emotional disorders including depression, anxiety No obvious risk of suicide now There is no history of drug abuse or dependence at the current time and within one year before the start of treatment

Exclusion criteria:

Unwillingness to attend research meetings ot attending at least 50% of the sessions Creating severe physical problems so that it can not be present at meetings

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **3**

Using Beck Depression Inventory (BDI-II), Beck Anxiety Inventory and Post-traumatic Stress PTSD Checklist for assessing the level of participants' problems.

Randomization (investigator's opinion)

Randomized

Randomization description

For randomizing assignment, the Simple Random method is used. 45 cards with the same appearance are provided. On 15 of cards the number 1 and on 30 of them the number 2 is written which represent the intervention group and the control group respectively. Then, one card is given to each qualified individual randomly and his assignment to the group is recorded. This process is continues until all individuals are assigned. It should be noted that participants are unaware of the nature of the numbers and type of intervention.

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

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd, Kermanshah

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Kermanshah

Postal code

6715847141

Approval date

2019-08-17, 1398/05/26

Ethics committee reference number

IR.KUMS.REC.1398.547

Health conditions studied

1

Description of health condition studied

Post Traumatic Stress Disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

Post Traumatic Stress Disorder

Timepoint

A week before the intervention, Mid-intervention, one week after the intervention, Three months after the intervention

Method of measurement

Beck Depression Inventory (BDI-II), Beck Anxiety Inventory and Post-traumatic Stress PTSD Checklist

Secondary outcomes

1

Description

Depression

Timepoint

A week before the intervention, Mid-intervention, one week after the intervention, three months after the intervention

Method of measurement

Beck Depression Inventory (BDI-II)

2

Description

Anxiety

Timepoint

A week before the intervention, Mid-intervention, one week after the intervention, three months after the intervention

Method of measurement

Beck Anxiety Inventory

3

Description

Post-traumatic stress

Timepoint

A week before the intervention, Mid-intervention, one week after the intervention, three months after the intervention

Method of measurement

Post-traumatic Stress PTSD Checklist

Intervention groups

1

Description

Intervention group: In this study, Wells' metacognitive therapy for anxiety disorders will be used. .The sample size in this study is 45. They are randomly divided into two experimental and control groups, in which 15 subjects in the experimental group and 30 in the control group are placed and the treatment plan will be available in a group for 10 sessions.The contents of the group meta_cognitive therapy sessions are: The first session)Including referrals, Introducing ptsd disorder, Check ptsd symptoms second session) Introducing Metacognitive Therapy, Model introduction and preparation third session) Analysis of Metacognitive Positive and Negative Beliefs and Meta_cognitive Control Strategies fourth Session) Introduce Cognitive Attentional Syndrome to patients, a type of repetitive thinking that is a concern or rumination focused on threat and maladaptive behaviors (such as thought suppression, avoidance, substance use). Fifth Session) Technique of attention training, technique logic, technique validation Sixth Session) Applying Mindfulness Techniques to Breakthrough Seventh Session) Four of the ten mindfulness techniques were taught to the participants Eighth Session) Teaching the other three techniques of the ten mindfulness techniques Ninth Session) The remaining three techniques are taught to the participants Tenth Session) Prepare members for closure

Category

Behavior

2

Description

Control group: Control group: Control group: consists of 30 people who are waiting in the waiting list and do not receive treatment during the time of intervention. but after treatment, they will receive several sessions of meta_cognitive group therapy maintaining the ethics of the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

sasan amiri

Street address

Faculty of Medicine, Imam Reza Hospital, Shahid Shiroudi Blvd, Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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Grant name

Kermanshah University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

sasan amiri

Position

MSc

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

MSc

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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

There is no more information

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