

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of cognitive emotional intervention on post traumatic stress and growth, sleep quality and anxiety in hemodialysis patients

Protocol summary

Study aim

The effect of cognitive emotional intervention on post traumatic stress and growth, sleep quality and anxiety in hemodialysis patients

Design

Samples will be randomly assigned to the intervention and control groups.

Settings and conduct

Samples will be randomly assigned to the intervention and control groups. Both groups will be pre-tested by completing questionnaires on post-traumatic growth, post-traumatic stress, anxiety and sleep quality. The intervention group will receive 5 sessions of emotional cognitive training program in two sessions per week in groups of 4 to 8 people based on the specified content. After 12 weeks, the research questionnaires will be completed again as a post-test by going home or being in the ward. During this period, the control group will not receive any program other than the usual treatment program. Their case is also done.

Participants/Inclusion and exclusion criteria

Entrance: Lack of concurrent training program, Literacy for reading and writing
No Entrance: Do not attend or miss more than one session in the training program

Intervention groups

The intervention group will receive 5 sessions of emotional cognitive training program in two sessions per week in groups of 4 to 8 people based on the specified content. After 12 weeks, the research questionnaires will be completed again as a post-test by going home or being in the ward. During this period, the control group will not receive any program other than the usual treatment program. Their case is also done.

Main outcome variables

Emotional Cognition, Growth, Post Traumatic Stress, Sleep Quality, Hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150423021904N4**

Registration date: **2021-11-05, 1400/08/14**

Registration timing: **prospective**

Last update: **2021-11-05, 1400/08/14**

Update count: **0**

Registration date

2021-11-05, 1400/08/14

Registrant information

Name

Fatemeh Mahmoudi Kohani

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 854 3127

Email address

f.mahmodi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive emotional intervention on post traumatic stress and growth, sleep quality and anxiety in hemodialysis patients

Public title

Effect of cognitive emotional intervention on post traumatic stress and growth, sleep quality and anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Lack of concurrent training program Be literate

Exclusion criteria:

Absence or absence from more than one session in the training program Patient's critical condition

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects were randomly assigned to intervention and control groups. First, the total number of subjects enrolled in the envelope containing the study groups (A intervention and control B) was prepared and randomly sorted. Gradually, by identifying the eligible person, one of the envelopes was allocated to the selected individuals, respectively.

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 Bam University of Medical Sciences

Street address

Shahid Rajaie Blvd., Bam university Of Medical Sciences & Health Services

City

Bam

Province

Kerman

Postal code

7661771967

Approval date

2019-11-17, 1398/08/26

Ethics committee reference number

IR.MUBAM.REC.1398.093

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

Hemodialysis

ICD-10 code

F43.10

ICD-10 code description

Post-traumatic stress disorder, unspecified

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

Post traumatic stress

Timepoint

Assessing post traumatic stress before and after the intervention

Method of measurement

Post traumatic stress questionnaire

2**Description**

Post traumatic growth

Timepoint

Assessing post traumatic growth before and after the intervention

Method of measurement

Post traumatic growth questionnaire

3**Description**

Sleep quality

Timepoint

Assessing sleep quality before and after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

4**Description**

Anxiety

Timepoint

Assessing anxiety before and after the intervention

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 5 sessions of emotional cognitive training program in two sessions per week based on the specified content.

Category

Behavior

2

Description

Control group: They do not receive a plan other than the usual treatment plan.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bam Pastour Hospital

Full name of responsible person

Fatemeh Mahmoudi

Street address

Pastor Hospital., Persian Gulf Blvd., Bam-Baravtat Road., Bam

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76197745

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mahmodi2020@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bam University of Medical Sciences

Full name of responsible person

Dr Sajad Khosravi

Street address

Bam University of Medical Science., Shahid Rajaiee Blvd., Sardaran Shahid Square., Bam City

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mahmodi2020@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bam 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

Bam University of Medical Sciences

Full name of responsible person

Fatemeh Mahmoudikohani

Position

Bam University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available