Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effectiveness of Transdiagnostic based Emotional efficacy on the Faulty Cognitive-affective system, Psychological syndrome and Sleep Quality of Nurses with Anxiety Signs

Protocol summary

Study aim

determination effectiveness of Transdiagnostic based Emotional efficacy on the Faulty Cognitive-affective system, Psychological syndrome and Sleep Quality of Nurses with Anxiety Signs

Design

Selection of 140 nurses with inclusion criteria based on purposive sampling, those with an anxiety score above 16 based on Beck Anxiety form were divided into two groups of 25 with quota sampling method,The treatment group will receive eight 90-minute sessions and a two-month follow-up.

Settings and conduct

The nurses in Chamran and Versaul hospitals who have an anxiety score above 16 are divided into intervention and control groups of 25 persons, which the intervention group receives treatment after two months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 25-45 years; Minimum2 years nursing experience; Minimum bachelor's degree; Working in clinical shift nurses; Satisfaction Exclusion criteria: Psychiatric drug use; experiencing stressors ... History of receiving similar intervention; incomplete response to questionnaires; severe mood disorder such as severe depression

Intervention groups

Emotional efficacy-based therapy, is a combination of acceptance and commitment therapy, dialectical behavior therapy, and cognitive behavioral therapy On defective cognitive system (emotional schema, distress tolerance, uncertainty intolerance, experiential avoidance), psychological syndrome (anxiety, stress, depression, health anxiety, nursing stress) and sleep quality of nursesIn this studywith Anxiety Signs.

Main outcome variables

Outcome variables included psychological symptoms (depression, stress anxiety, health anxiety, nursing stress), impaired cognitive emotional system (experience avoidance, distress tolerance, uncertainty intolerance, emotional schemas), sleep quality, emotional efficacy،anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191014045096N1**
Registration date: **2019-11-28, 1398/09/07**
Registration timing: **prospective**

Last update: **2019-11-28, 1398/09/07**
Update count: **0**

Registration date

2019-11-28, 1398/09/07

Registrant information

Name

Masoumeh Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-04-29, 1399/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Transdiagnostic based Emotional efficacy on the Faulty Cognitive-affective system, Psychological syndrome and Sleep Quality of Nurses with Anxiety Signs

Public title

Effect of treatment based Emotional efficacy on the Faulty Cognitive-affective system, Psychological syndrome and Sleep Quality of Nurses with Anxiety Signs

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

At least 2 years of nursing experience Minimum bachelor's degree Clinical staff(Nurses with shifts in circulation) Study consent Age 25-45 years

Exclusion criteria:

Psychiatric drug use Experience stressors(Deceased first class relatives, accidental, divorce)And.. History of receiving similar intervention Incomplete response to questionnaires Physical complications such as limb fractures,Chronic diseases affecting behavior such as tuberculosis Affecting mood disorderSuch as thyroid, diabetes Severe mood disorder, such as severe depression, controlled by medication use

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, among the nurses working in Ferdowsi hospitals, 140 people who meet the inclusion criteria will be selected by purposeful sampling. Then among them, 50 nurses with moderate to severe anxiety (receiving a score above 16 based on Beck's anxiety form) will be enrolled in the available method and will be randomly divided into two groups of 25, using random cards, The experimental group received the intervention (Emotionally Effective Therapy) during eight 90-minute sessions a week for two months and two months post-treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Two-way curve In terms of group breakdown statistics, (participants, researcher, outcome assessor), both participants and researchers or outcome assessors were unaware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Technology Research, Birjand University of Medical Sciences, Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

IR.BUMS.REC.1398.224

Health conditions studied

1

Description of health condition studied

Anxiety Syndrome, Defective Affective Cognitive System, Anxiety Symptoms

ICD-10 code

F41.8

ICD-10 code description

Other specified anxiety disorders

Primary outcomes

1

Description

Anxiety score above 16 based on Beck Anxiety Inventory

Timepoint

At the beginning of the study before intervention

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

1

Description
Depression, Anxiety, Stress
Timepoint
Before the intervention, after the end of the intervention and two months follow up
Method of measurement
Depression, Anxiety and Stress Questionnaire DASS-21

2

Description
Health anxiety
Timepoint
Before intervention, after intervention and two months follow up
Method of measurement
Health Anxiety Questionnaire

3

Description
Nursing Stress
Timepoint
Before intervention, after intervention (after eight weeks), two-month follow-up
Method of measurement
Nursing Stress Questionnaire

4

Description
sleep quality
Timepoint
Before the intervention, after the end of the intervention (after eight weeks), two months follow-up
Method of measurement
Pittsburgh Sleep Quality Questionnaire

5

Description
Experience Avoiding
Timepoint
Before intervention, after intervention and two months follow up
Method of measurement
Acceptance and Practice Questionnaire

6

Description
Intolerance of uncertainty
Timepoint
Before intervention, after intervention and 2 months follow up
Method of measurement
Uncertainty Intolerance Questionnaire

7

Description
Distress Tolerance
Timepoint
Before intervention, after intervention, two-month follow-up
Method of measurement
Emotional distress tolerance questionnaire

8

Description
Emotional Schemas
Timepoint
Before intervention, after intervention, two-month follow-up
Method of measurement
Emotional Schema Questionnaire

9

Description
Emotional efficiency
Timepoint
Before intervention, after intervention, two-month follow-up
Method of measurement
Emotional Efficacy Questionnaire

Intervention groups

1

Description
The intervention group will receive emotional efficacy-based metacognitive therapy within two months, consisting of eight weekly sessions of a 90-minute session conducted by a doctor of psychology, followed by a follow-up follow-up of 2 months.
Category
Behavior

2

Description
Control group: The control group does not receive any treatment (inadequate) but after a follow-up follow up a training session will be held.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Mohsen Imantbaleh
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2

Recruitment center

Name of recruitment center
Hazrat Rasoul Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Tuba Kazemi

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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
Birjand 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
Islamic Azad University

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Position
PhD student

Latest degree
Master

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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