

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The Effect of Cognitive- Behavior Therapy on the prevention of depression in nursing students

Protocol summary

Study aim

Determining the Effect of Cognitive-Behavioral Intervention on Prevention of Depression in Nursing Students in the First semester of Nursing and Midwifery Faculty

Design

Clinical trial with control group, pre-test and post-test, simple randomization using random numbers table

Settings and conduct

The study is an intervention group with control group. Participants in the intervention group are included in six sessions of cognitive-behavioral education. Group-based education will be implemented. The place of the study is the School of Nursing, Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Entry criteria: Nursing students who are first semester, The desire to attend the study; Exit criteria: The presence of any psychiatric disorder

Intervention groups

Intervention group: The intervention group will participate in 6 sessions of cognitive-behavioral therapy, focusing on social skills Control group: The control group will only participate in free discussion sessions

Main outcome variables

Depression Score in Beck Depression Inventory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160404027216N7**
Registration date: **2018-12-08, 1397/09/17**
Registration timing: **retrospective**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name

Fatemeh Vizeshfar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4258

Email address

vizeshfarf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-07-01, 1397/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive- Behavior Therapy on the prevention of depression in nursing students

Public title

Effect of Cognitive-Behavior Therapy on the prevention of depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

First term nursing student Tend to participate in the

study

Exclusion criteria:

Use of any antidepressant medication

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

All positions of the two groups in the blocks of 4 were numbered from 1 to 6. Then numbers 1-6 were selected randomly and by placement. By selecting each number, the procedure for locating individuals using letters A and B was shown in a table. This was repeated so that the order of the two groups in the table was reached to 36

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 Shiraz University of Medical Sciences

Street address

Namazi Square, Faculty of Nursing and Midwifery of Hazrat Fatemeh

City

Shiraz

Province

Fars

Postal code

13119-71936

Approval date

2018-03-11, 1396/12/20

Ethics committee reference number

IR.SUMS.REC.1396.158

Health conditions studied

1

Description of health condition studied

Mild Depression

ICD-10 code

F32.0

ICD-10 code description

Mild depressive episode

2

Description of health condition studied

Moderate depressive episode

ICD-10 code

F32.1

ICD-10 code description

Moderate depressive episode

3

Description of health condition studied

Severe depressive episode without psychotic symptoms

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

Depression Score in Beck Depression Inventory

Timepoint

Before and after the intervention

Method of measurement

Beck depression inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will participate in six sessions of cognitive-behavioral group therapy focused on social skills. Which includes the description of depression disorder, assertiveness training, problem-solving skills training, anger control skill training, familiarity with depressive cognitive errors, and how to replace effective thoughts with ineffective thoughts, The participants will be divided into two groups of 8 and 9 persons

Category

Prevention

2

Description

Control group: The control group will participate in free-

group sessions
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Nursing and Midwifery of Fatemeh Shiraz
Full name of responsible person
Zakiye Ghelbash
Street address
Namazi Square, Faculty of Nursing, Hazrat Fatemeh
City
Shiraz
Province
Fars
Postal code
7132145321
Phone
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Email
nurs_midwif@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Basir Hashemi
Street address
Imam Hossein Square, Shiraz University of Medical Sciences
City
Shiraz
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Postal code
23247532543
Phone
+98 71 3213 4456
Email
nurs_midwif@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Zakiye Ghelbash
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Assistant Professor
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+98 71 3245 6765
Email
vizeshfar@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fateme Vizeshfar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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3435674334

Phone

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Email

vizeshfar@sums.ac.ir

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

Yes - There is 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

Title and more details about the data/document

General data

When the data will become available and for how long

Six months after printing results

To whom data/document is available

Governmental and Research Organizations

Under which criteria data/document could be used

Submit a request to the research officer

From where data/document is obtainable

Deputy of Research of Shiraz University of Medical Sciences

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

Submit a request and consent letter

Comments