

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effectiveness of Acceptance and Commitment Therapy (ACT) on Perceived stress , Psychological Hardiness and Emotional Regulation in nurses

#### Protocol summary

##### Study aim

Determining the effectiveness of treatment based on acceptance and commitment on perceived stress, psychological toughness, emotional regulation of nurses

##### Design

Two groups of subjects, including an experimental group and a control group with 20 people for each group, both experimental and control groups, are measured twice (pre-test-post-test) by questionnaires. Clinical trial with control group, blinded, randomized and without study phase on 40 nurses

##### Settings and conduct

The experimental groups will be treated with Act; But the control group does not receive any intervention. Both the experimental group and the control group are measured twice (pre-test-post-test) separately. The statistical population will be all the nurses of the gynecological department of public hospitals in Semnan city. It will be implemented virtually on the Literary platform of Connect, and every week two to three intervention sessions and one introduction session will be held face-to-face with the nurses of the sample group before the implementation of the research.

##### Participants/Inclusion and exclusion criteria

The age of the participants should be between 25 and 50 years old and they should not have completed the ACT treatment course and should not have an acute or chronic physical or mental illness that disrupts the work process.

##### Intervention groups

including 40 nurses (20 in both experimental and control groups) Then, people will be assigned in two experimental and control groups by simple random sampling method.

##### Main outcome variables

Acceptance and commitment therapy: independent distance Perceived stress: a continuous interval

Psychological hardiness: a distance variable Emotion regulation: continuous interval

#### General information

##### Reason for update

##### Acronym

Act

##### IRCT registration information

IRCT registration number: **IRCT20220707055405N1**

Registration date: **2022-08-10, 1401/05/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-08-10, 1401/05/19**

Update count: **0**

##### Registration date

2022-08-10, 1401/05/19

##### Registrant information

##### Name

Niusha Rastegar kafshgari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4225 9899

##### Email address

rastegarniusha@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-01, 1401/05/10

##### Expected recruitment end date

2022-09-01, 1401/06/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of Acceptance and Commitment Therapy (ACT) on Perceived stress , Psychological Hardiness and Emotional Regulation in nurses

**Public title**

The effectiveness of Acceptance and Commitment Therapy on Perceived stress , Psychological Hardiness and Emotional Regulation in nurses

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

nurses should work in public hospitals in semnan their age should be between 25 and 50

**Exclusion criteria:**

Failure to complete the course of treatment based on acceptance and commitment

**Age**

From **25 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, 40 people are selected according to similar research, in the available way. Then random replacement is done by lottery method (one number will be assigned to each of the sampled people). We write down the numbers on paper, fold them and put them in a container. We mix and stir the papers completely. Then we take out the papers one by one and put one number in the first group and one number in the second group. Then random application will be done. In this way, one group is known as "control group" and the other group is known as "intervention group". The lottery will be done by putting the two groups obtained from the previous step (random replacement step) into two separate envelopes and placing them in a container. Then we randomly take one envelope out of the container and assign it to the "intervention group" and the other envelope to the "control group". Research data are analyzed using SPSS version 21 statistical package software in social sciences Simple randomization

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University, Semnan branch

**Street address**

University campus, Islamic Azad University, Semnan branch

**City**

Semnan

**Province**

Semnan

**Postal code**

3513137111

**Approval date**

2022-07-27, 1401/05/05

**Ethics committee reference number**

IR.IAU.SEMNAN.REC.1401.024

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

The effectiveness of Acceptance and commitment therapy on perceived stress, psychological hardiness and emotional regulation in nurses

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

"Determining the effectiveness of treatment based on acceptance and commitment on perceived stress" depression score in Cohen's perceived stress questionnaire

**Timepoint**

The first measurement is by performing a pre-test at the beginning of the study and the second measurement is by performing a post-test after the study

**Method of measurement**

Cohen's Perceived Stress Questionnaire (1983)

**2****Description**

"Determining the effectiveness of treatment based on acceptance and commitment on the psychological toughness of nurses" psychological toughness score in Kubasa psychological toughness questionnaire

### **Timepoint**

The first measurement is by performing a pre-test at the beginning of the study and the second measurement is by performing a post-test after the study

### **Method of measurement**

Kubasa Psychological Toughness Questionnaire (1979)

## **3**

### **Description**

"Determining the effectiveness of treatment based on acceptance and commitment on the emotional regulation of nurses" emotional regulation score in Garnevsy's emotional regulation questionnaire

### **Timepoint**

The first measurement is by performing a pre-test at the beginning of the study and the second measurement is by performing a post-test after the study

### **Method of measurement**

Garnevsy emotion regulation questionnaire (2001)

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: an educational-therapeutic course that includes 8 treatment sessions and two to three sessions a week, each session lasting one and a half hours on the subjects of the experimental group based on a certain schedule in the sessions determined according to the package headings. Treatment training is based on acceptance and commitment

#### **Category**

Treatment - Other

### **2**

#### **Description**

Control group: It does not receive any intervention

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Shefa hospital

##### **Full name of responsible person**

Rastegarkafshgari Niusha

##### **Street address**

Semnan Province, Semnan, Shahid Noroozi Blvd, Shafa Hospital

##### **City**

Semnan

##### **Province**

Semnan

##### **Postal code**

3514895171

##### **Phone**

+98 23 3342 3312

##### **Email**

shefa.hos@tamin.ir

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Amiralmomenin hospital

##### **Full name of responsible person**

Rastegarkafshgari Niusha

##### **Street address**

No 9771, Imam Hossein Square, Shahid Mostafa Khomeini Blvd

##### **City**

Semnan

##### **Province**

Semnan

##### **Postal code**

3473135197

##### **Phone**

+98 23 3346 0055

##### **Email**

amir.hospital@semums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Semnan University of Medical Sciences

##### **Full name of responsible person**

Beidokhti hengame

##### **Street address**

University campus, Islamic Azad University, Semnan branch

##### **City**

Semnan

##### **Province**

Semnan

##### **Postal code**

3513137111

##### **Phone**

+98 23 3365 4040

##### **Email**

akram4453@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Rastegarkafshgari Niusha

**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Shahid Beheshti Street, 24 Adalat Alley, 2 Gholinejad Alley, Pasargad Building, 2nd floor

**City**

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**Province**

Mazandaran

**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

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University student

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

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**Full name of responsible person**

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**Email**

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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 further 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