Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of the Self determination theory based training program on social adjustment and self-efficacy in clinical performance of nursing students

Protocol summary

Study aim

Determining the effect of the educational program based on self-determination theory on social adaptation and self-efficacy of clinical performance of nursing students of Isfahan University of Medical Sciences in 2023

Design

a clinical trial with a control group,A blind strain and it is performed on 92 samples. Randomization in this study is done using a table of random numbers

Settings and conduct

environment is Al-Zahra, Chamran, Amin and Kashani hospitals in Isfahan. The sample of our study will be nursing internship students in these centers. The sessions of the program based on the theory of self-determination will be conducted in 6 45-minute sessions in the form of groups of eight to ten students for the intervention group and twice a week, by a master's student and with the supervision and accompaniment of the supervisor in the classroom of the department.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nursing interns who passed the pre-internship test at the end of the 6th semester and had acceptable results, the student was interested in participating in the study and gave consent. More than 1 month has passed since the start of the internship; Exclusion criteria: No previous history of physician-diagnosed psychiatric problems that led to drug use. Students are not concurrently or previously enrolled in similar educational programs. The student has not experienced significant stress, such as the death of a loved one, in the past 6 months.

Intervention groups

Program sessions based on the theory of self-determination will be conducted in 6 sessions of 45 minutes for the intervention group and twice a week in the department's classroom. Control group:They will not receive any training program and at the end, the content of the sessions will be provided to the members of the control group

Main outcome variables

Social adjustment, Social self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039321N3**
Registration date: **2023-05-16, 1402/02/26**
Registration timing: **prospective**

Last update: **2023-05-16, 1402/02/26**
Update count: **0**

Registration date

2023-05-16, 1402/02/26

Registrant information

Name

sima ghezelbash

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7607

Email address

ghezelbash@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the Self determination theory based training program on social adjustment and self-efficacy in clinical performance of nursing students

Public title

Investigating the effect of the Self determination theory based training program on social adjustment and self-efficacy in clinical performance of nursing students

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

A nursing internship student who has managed to get a passing score in the pre-internship test at the end of the 6th semester. The student is interested to collaboration in the study. At least 1 month has passed since the student entered the internship.

Exclusion criteria:

A history of psychiatric disorders that led to drug use Participate in similar training programs Experiencing severe stress such as the death of loved ones during the last six months

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

According to simple randomization, Numbers are assigned to the names of the students based on the list of internship divisions for each hospital, and half of them are divided according to the even numbers as the control group and the odd numbers as the test group, and the people are randomly assigned an odd number or an even number. they choose and enter the desired group accordingly

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants are in two control and test groups. Informed consent is obtained from both groups. To avoid errors, we first give the questionnaires to the control group and then start the intervention program with the test group and do not talk to them about the control group so that bias does not occur.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences., Hazar Jarib St., Isfahan., Iran

City

Isfahan

Province

Isfehan

Postal code

۸۱۷۴۶۷۳۴۶۵

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.003

Health conditions studied

1

Description of health condition studied

Social adjustment

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Self determination

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Social adjustment score

Timepoint

At the beginning of the study (before the start of the intervention), immediately after the intervention and one month after the intervention

Method of measurement

Bell Social Adjustment Questionnaire

Secondary outcomes

1

Description
Clinical self-efficacy score
Timepoint
At the beginning of the study (before the start of the intervention), immediately after the intervention and one month after the intervention
Method of measurement
Cheraghi clinical self-efficacy questionnaire

Intervention groups

1

Description
Intervention group: Intervention sessions based on self-determination theory are conducted in a hospital classroom by investigators in groups of 8 to 10 students in 6 sessions of 45 minutes twice a week. The educational content of the sessions will be based on existing texts and Deci and Ryan's theory of self-determination. Session titles include introduction and problem definition, goal selection and problem-solving skills, self-awareness and self-regulation, communication and empathy, self-efficacy and self-actualization, and internalization. These sessions are based on the Student Self-Empowerment Theory Book. The course runs for 3 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra University Hospital
Full name of responsible person
Donya Hafezi nia
Street address
Isfahan University of Medical Sciences., Hazar Jarib St., Isfahan., Iran
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
internal@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Donya Hafezi nia
Street address
Kashani st,. Isfahan., Iran
City
isfahan
Province
Isfehan
Postal code
81839 83434
Phone
+98 31 3233 0091
Email
internal@med.mui.ac.ir

3

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
Donya Hafezi nia
Street address
Ebn e Sina St., Isfahan., Iran
City
isfahan
Province
Isfehan
Postal code
53141 81486
Phone
+98 31 3445 5051
Email
internal@med.mui.ac.ir

4

Recruitment center
Name of recruitment center
Shahid Chamran Heart Educational
Full name of responsible person
Donya hafezi nia
Street address
Salman Farsi St., Isfahan., Iran
City
Isfahan
Province
Isfehan
Postal code
73414 81661
Phone
+98 31 3260 0961
Email
internal@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari

Street address
Nursing and Midwifery Faculty., Isfahan University of Medical Sciences., Hezerjerib Ave., Isfahan., Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 7898
Email
research@mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Sima Ghezelbash
Position
member of nursing faculty
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Isfahan University Of Medical Sciences, Hezar-Jerib Ave., Isfahan., Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3465 4661
Fax
Email
ghezelbash@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Donya Hafezi nia
Position
Master's student in psychiatry
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Isfahan University Of Medical Sciences, Hezar-Jerib Ave., Isfahan., Iran.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3465 4661
Fax
Email
Donya_hafezi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Sima Ghezelbash
Position
Faculty member- instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Isfahan University Of Medical Sciences, Hezar-Jerib Ave., Isfahan., Iran.
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۵
Phone
+98 31 3792 7607
Fax
Email
ghezelbash@nm.mui.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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable