

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

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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

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Province

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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

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2

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

Shahid Chamran Heart Educational

Full name of responsible person

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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

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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

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

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

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Position

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Bachelor

Other areas of specialty/work

Nursery

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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

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Other areas of specialty/work

Nursery

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Fax**Email**

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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

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