Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness comparison of stress management skills training by 4A facilitation model with the mobile health self-help program on clinical stress, self-efficacy, and professional identity of nursing students

Protocol summary

Study aim
The effectiveness comparison of stress management skills training by 4A facilitation model with the mobile health self-help program on clinical stress, self-efficacy, and professional identity of nursing students

Design
A randomized clinical trial with a parallel control group (self-help intervention group).

Settings and conduct
Study setting will be the School of Nursing and Midwifery, Yazd, Iran. The implementation of the skill-training intervention in both groups will be carried out for five consecutive weeks by researchers and with the facilitation of a researcher. The content of mobile health self-help program group will be followed and carried out by researchers. 4A face-to-face facilitation sessions are weekly for up to five weeks. Content submission and follow-up for the mobile health self-help program group will be also continue for five weeks at the same time as the 4A facilitation group.

Participants/Inclusion and exclusion criteria
1. Willingness to participate in the study 2. Internet accessibility during the period of entering the research until termination 3. Having the physical and mental ability to complete the questionnaire 4. Passing at least two academic semesters and one internship unit

Intervention groups
This study is conducted with two main groups of the 4A facilitation model and the mobile health self-help program. The participants of group 4A are divided into 5 subgroups of 9 people. For face-to-face meetings, the Team Member Teaching Design Template (TMTD) method will be used. The purpose of these sessions is to teach theoretical educational content in a group and with a new approach. For the mobile health self-help program group: training content will be provided in the form of files and videos in the context of social media and a stress reduction application

Main outcome variables
Clinical stress, self-efficacy and professional identity of students

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221218056861N1**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**

Registration date
2023-01-18, 1401/10/28

Registrant information

Name
Fateme Bakhshi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3824 1751

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-07-01, 1402/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness comparison of stress management skills training by 4A facilitation model with the mobile health self-help program on clinical stress, self-efficacy, and professional identity of nursing students

Public title

Stress management skills training by 4A facilitation model and the mobile health self-help program in nursing students

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Internet accessibility during the research period Having the physical and mental ability to complete the questionnaire Passing at least two academic semesters and one internship unit

Exclusion criteria:

Occurrence of stressful events (such as death of family members, marriage or divorce) A history of neurological and mental diseases or acute mental problems during the last year Using psychiatric drugs Experiencing stressful event(s) at least 6 months before the study Participation in stress management skills training workshops

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the inclusion criteria, using the online software (using the website www.random.org/sequences/), students are randomly assigned to two groups, the 4A facilitation model and the mobile health self-help program (45 people in each group). For random assignment, a code is given to each student between 1 and 90, and their random assignment is done based on the output of the mentioned software and after completing the informed consent by the participants. Again, each group is divided into five subgroups of 9 people by a simple random method. In this way, the study is conducted with the two main groups of the 4A facilitation model and the mobile health self-help program. The participants of group 4A are divided into 5 subgroups of 9 people. Participants will be told that there is a 50% chance of falling into each of these groups.

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

Research Ethics Committees of Reproductive Sciences Institute - Shahid Sadoughi University of Medica

Street address

Safaiyeh, Bu Ali St., Yazd Infertility Research and Treatment Center

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Yazd

Province

Yazd

Postal code

8916635750

Approval date

2022-12-11, 1401/09/20

Ethics committee reference number

IR.SSU.RSI.REC.1401.014

Health conditions studied

1

Description of health condition studied

Clinical stress, self-efficacy and professional identity of students

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

Primary outcomes

1

Description

The clinical stress score of the students in Ebel's Clinical Stress Questionnaire

Timepoint

Measuring the clinical stress score at baseline and at the end of the ninth week of the study

Method of measurement

Ebel's Clinical Stress Questionnaire (1991) Clinical stress questionnaire: The clinical stress questionnaire was created by Abell (1991) and has 25 Items. This

questionnaire evaluates problems related to people's mental pressure. A higher score indicates more problems or higher severity. Habibi (2013) mentioned the content validity of the questionnaire as appropriate and obtained the reliability using Cronbach's alpha method of 0.88.

2

Description

Professional identity score of students in Macleod Clark's professional identity questionnaire

Timepoint

Measuring the professional identity score at the baseline and at the end of the ninth week of the study

Method of measurement

Macleod Clark Professional Identity Questionnaire
Macleod Clark Professional Identity Questionnaire: This scale was developed based on the theory of social identity and includes 9 items under the subscales of professional dynamics, intra-group and professional communication, feeling of belonging to this profession and self-evaluation. The possible total score is between 9 and 54, which means the higher score, the higher the professional identity. Bakhshi et al. (2020) evaluated the psychometric validation of the original version of the McLeod Clark Professional Identity Questionnaire (MCPIS).

3

Description

Self-efficacy score of students in the clinical self-efficacy questionnaire

Timepoint

Measuring the self-efficacy score at the baseline and at the end of the ninth week of the study

Method of measurement

Clinical Performance Self-Efficacy Scale: This scale was designed and psychometrically evaluated by Cheraghi et al (2010). In this questionnaire, self-efficacy means the judgment of nursing students in the ability to organize and administer nursing care independently and based on the nursing process in the bedside. The minimum and maximum total scores are 37 to 148 respectively.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: implementation of the intervention in the 4A facilitation model group: after completing the questionnaires upon arrival (baseline), the people of this group will be offered five consecutive weeks of stress management skills training with the 4A model with the presence of a facilitator. During the training of this method, in the first step (asking), the student asks himself whether the stress he feels is a sign of distress caused by a clinical problem or is it a common annoyance? The purpose of this stage is to know the source of stress in nursing students. In the second stage (Affirmation), by sharing his feelings with others, the student is sure of the existence of stress and its cause, and initial efforts to manage and reduce it begin. In the third stage (Assess), the student identifies the source of discomfort and stress, which is personal or environmental, estimates the intensity of his stress and prepares himself for the action stage. In the last stage (act), the student tries to reduce stress both personally and professionally and uses strategies to achieve this goal. It is not uncommon for a person to go back to previous stages. The important thing is that the person tries to maintain his individual integrity after entering the action stage. Daily follow-up by sending text messages to keep the participants active and continue to practice the skills learned in the classes from the beginning of the study until one month after the end of the fifth week (the end of the ninth week).

Category

Other

2

Description

Control group: Control group: implementation of the intervention in the self-help health program group: in order to keep the control group active during the study, training with the same content for five weeks at the same time as group 4A classes, in the form of textual content, photos, videos or audio files in This group is at the discretion of the students. In addition to the presented content, a stress reduction software (usable on IOS and Android operating systems) is introduced to students. The software is installed on the student's mobile phone participating in this group. The description of how to use the software is explained step by step through a video file. The person is requested to complete all the information requested in the stress reduction software daily. Daily follow-up by sending text messages to keep the participants active and completing the software daily from the beginning of the study until one month after the end of the fifth week (the end of the ninth week).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Śchool of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Full name of responsible person

Fatemeh Bakhshi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Office of Research and Technology of Shahid Sadoughi University of Medical Sciences, Yazd, Iran
Full name of responsible person
Alireza Moradi
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Central building of Office of Research and Technology, Shahid Sadougi University of Medical Sciences, Bahonar Sq.
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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
Office of Research and Technology of Shahid Sadoughi University of Medical Sciences, Yazd, Iran
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
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Bakhshi
Position
Assistant Professor of Nursing Education
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying individuals.

When the data will become available and for how long

Data accessibility will start 6 months after publication of the results.

To whom data/document is available

The data will be accessible to researchers working in academic and scientific institutions as well as people working in the industry.

Under which criteria data/document could be used

Regarding the need for data to perform meta-analysis, more data (if applicable) will be provided after communication with the responsible author and approval of the research team.

From where data/document is obtainable

Via an email request to the principle investigator and corresponding author: Dr. Fatemeh Bakhshi, Faculty member Research Center for Nursing and Midwifery Care, Shahid Sadoughi University of Medical Sciences, Yazd, Iran Safaeih, Buali St., Yazd 8916877443, Iran Email addresses: fateme.bakhshii@gmail.com; f.bakhshi@ssu.ac.ir

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

Ten days after receiving the email, data will be provided if approved by the research team

Comments