Comparison of the effect of two educational methods of the mindfulness and cognitive emotion regulation strategies on psychological well-being and anxiety of graduate students of midwifery before the final clinical examination

Protocol summary

Study aim
Determining and comparing the effect of two educational methods of mindfulness and cognitive emotion regulation strategies on psychological well-being and anxiety of mid-term midwifery students before the final clinical exam

Design
A clinical field trial with two intervention and one control groups, parallel groups, randomized, on 27 final year midwifery students, a random number table will be used for randomization

Settings and conduct
This study will be performed in Isfahan University of Medical Sciences, School of Nursing and Midwifery. Eligible individuals with written consent to participate in the study, after explaining the objectives and methods of study and completing the questionnaires, will be divided into three groups using a table of random numbers. Then, the intended interventions will be performed on two intervention groups. At the end, all participants will complete the questionnaires again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Having written consent to participate in the study 2. Being in the last semester of midwifery 3. Do not take drugs that affect the psychological status 4. Lack of experience of an unfortunate, anxious or stressful events during the last 6 months 5. No medical disease (diabetes, hypertension, thyroid disease, cardiovascular disease, kidney disease, nervous disease, etc.) Exclusion criteria: 1. Failure to participate in more than 25% of educational programs 2. Reluctance to continue participating in the study

Intervention groups
Intervention group 1 = Education based on mindfulness
Intervention group 2 = Education based on cognitive emotion regulation strategies Control group = No intervention

Main outcome variables
Psychological well-being, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20160224026756N7
Registration date: 2020-08-26, 1399/06/05
Registration timing: registered_while_recruiting

Last update: 2020-08-26, 1399/06/05
Update count: 0

Registration date
2020-08-26, 1399/06/05

Registrant information
Name
Mahnaz Noroozi
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3441 1421
Email address
noroozi@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
Comparison of the effect of two educational methods of mindfulness and cognitive emotion regulation strategies on psychological well-being and anxiety of graduate students of midwifery before the final clinical examination

Comparison of the effect of two educational methods on psychological well-being and anxiety of graduate students of midwifery before the final clinical examination

Inclusion/Exclusion criteria

Inclusion criteria:
Being in the last semester of midwifery Having written consent to participate in the study

Exclusion criteria:
taking drugs that affect the psychological status Having experience of unfortunate, anxious or stressful events during the last 6 months Having Medical disease (diabetes, hypertension, thyroid disease, cardiovascular disease, kidney disease, nervous disease, etc.)

No age limit
Female

N/A

No information

Target sample size: 27

Randomization (investigator's opinion)

Randomized

For sampling random numbers table will be used. In this way, the samples included in the research will be numbered from 1 to n. Then, to select the samples from the table, we will randomly start from a table point (with closed eyes put fingers in a point) into direction of row and select the people in order for control, intervention 1 and intervention 2 groups.

Not blinded

Blinding (investigator's opinion)

Not used

Placebo

Not used

Assignment

Parallel

Secondary outcomes

empty

Primary outcomes

1

Description

Anxiety

Timepoint
At the beginning of the study, after the intervention

Method of measurement

Friedman Exam Anxiety Questionnaire

2

Description

Psychological well-being

Timepoint
At the beginning of the study, after the intervention

Method of measurement

Psychological Welfare Scale Questionnaire

Secondary outcomes

empty

Intervention groups
1
Description
Intervention 1 group: Education based on mindfulness. This educational program will be held in 8 sessions (twice a week) for 2 hours.
Category
Other

2
Description
Intervention 2 group: Education based on cognitive emotion regulation strategies. This educational program will be held in 8 sessions (twice a week) for 2 hours.
Category
Other

3
Description
Control group: No intervention
Category
Other

Recruitment centers

1
Recruitment center
Name of recruitment center
Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences
Full name of responsible person
Dr Fariba Taleghani
Street address
Hezar Jarib Street
City
Isfahan
Province
Isfehan
Postal code
84746-73461
Phone
+98 31 3792 7500
Email
taleghani@nm.mui.ac.ir

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Haghjouy Javanmard
Street address
Hezar Jarib Street
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 5149
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
Dr Mahnaz Noroozi
Position
Associate Professor, Isfahan University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Hezar Jarib Street
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3792 7570
Email
noroozi@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Mahnaz Noroozi
Position
Associate Professor, Isfahan University of Medical Sciences

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Mahnaz Noroozi
Position
Associate Professor, Isfahan University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Hezar Jarib Street
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3792 7570
Email
noroozi@nm.mui.ac.ir

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
Data of participants are privacy

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The results of clinical study will be published as an article.

When the data will become available and for how long
Immediately after publishing the results.

To whom data/document is available
Everyone

Under which criteria data/document could be used
Scientific using with citation to article.

From where data/document is obtainable
noroozi@nm.mui.ac.ir

What processes are involved for a request to access data/document
Request to receive the published file of the article containing research information

Comments