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

Main outcome variables
Psychological well-being, anxiety

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

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
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
Public title
Comparison of the effect of two educational methods on
psychological well-being and anxiety of graduate
students of midwifery before the final clinical
examination
Purpose
Education/Guidance
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.)
Age
No age limit
Gender
Female
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: 27
Randomization (investigator's opinion)
Randomized
Randomization description
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.
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
Ethics Committee of Isfahan University of Medical
Sciences
Street address
Hezar Jarib street
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Approval date
2020-03-13, 1398/12/23
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.823
Health conditions studied
1
Description of health condition studied
Psychological well-being
ICD-10 code
ICD-10 code description
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
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

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

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

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Sponsors / Funding sources

1

Sponsor

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Person responsible for general inquiries

Contact

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Position

Associate Professor, Isfahan University of Medical Sciences

Latest degree

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Other areas of specialty/work

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Full name of responsible person

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Person responsible for updating data

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Full name of responsible person
Dr Mahnaz Noroozi
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Associate Professor, Isfahan University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
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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
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