Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

Protocol summary

Study aim
Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

Design
A randomized controlled clinical trial with parallel groups, Randomized block, sample size 45 (15 persons per group)

Settings and conduct
Prior to the start of the sessions and obtaining a license, all three groups completed the Anxiety Questionnaire, Psychological Welfare, and Marital Satisfaction. Then, the experimental group A (mindfulness-based stress reduction) and experimental group B (cognitive-behavioral therapy) were grouped weekly among women in the Tehran Health Center. The control group did not intervene. The study is being held at the Tehran Health Center.

Participants/Inclusion and exclusion criteria
Inclusion Criteria were being Iranian, age 35-20 years, being primitive, literacy, no history of miscarriage or intrauterine death and infertility, no pregnancy problems (blood pressure, bleeding, diabetes, thyroid disease, Congenital anomalies, fetal anomalies), no adverse events over the past 6 months, no addiction, and no treatment for psychiatric disorders. Exclusion Criteria were lack of cooperation of the sample group in each stage of research and having physical and physical problems and a history of psychiatric problems.

Intervention groups
For the first Mindfulness-based stress reduction, for the second group cognitive behavior therapy, and in the third group, no intervention will be performed.

Main outcome variables
Anxiety, psychological well-being, marital satisfaction and maternal consequences

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200514047449N1**
Registration date: **2020-06-28, 1399/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-28, 1399/04/08**
Update count: **0**

Registration date
2020-06-28, 1399/04/08

Registrant information

Name
Elahe Shahtaheri
Name of organization / entity
Islamic azad university kish,iran
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-11, 1398/09/20

Expected recruitment end date
2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

Public title

Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Age range 20 to 35 years Being primitive Have literacy No history of miscarriage or intrauterine death and infertility Absence of pregnancy problems (blood pressure, bleeding, diabetes, thyroid disease, placenta previa, fetal anomalies) No accidents during the last 6 months Not addicted and not being treated for psychiatric disorders

Exclusion criteria:

No cooperation of the sample group at each stage of the study Having physical and physical problems and a history of psychiatric problems

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the block randomization method by the statistical consultant, the following randomization is done in 3 groups of cognitive behavior therapy (CBT), Mindfulness-based stress reduction (MBSR) and control: First, the list of names of qualified people is provided and coded. In block randomization, the number of participants in all groups will be very close, this is done by building blocks of sequences and intersections so that the same number of participants are allocated to study groups within each group. First, we encode the groups based on the Latin letters as follows: A =cognitive behavior therapy, B = Mindfulness-based stress reduction and C control group In this study, with three groups A, B and C, we create the following six groups and assign the numbers 1 to 6 to each: ABC-ACB-BAC-BCA-CAB-CBA Then, using the table of random numbers, we contract that if the numbers 1, 2, 3, 4, 5, 6, and 6 appear in order, one of these blocks will be selected, and if another number appears, we will assume it to be null and void and move on to the next selection. In fact, we have obtained a random sequence of numbers with a table of random numbers, which we consider the order of the assigned allocation for each number. In this way, the number of people in the groups will be almost equal.

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 Hormozgan University of Medical Sciences

Street address

No. 64, Janbazan Ave., North Karegar Street

City

Kish

Province

Hormozgan

Postal code

1437697419

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.HUMS.REC.1398.337

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Beck Anxiety Inventory

2

Description
Psychological well-being
Timepoint
Measurement will be done in pre-test, post-test and follow-up three months after post-test
Method of measurement
Psychological well-being Questionnaire

3

Description
Marital satisfaction
Timepoint
Measurement will be done in pre-test, post-test and follow-up three months after post-test
Method of measurement
Marital satisfaction Questionnaire

4

Description
Infant Maternal Consequences
Timepoint
Measurement will be done in pre-test, post-test and follow-up three months after post-test
Method of measurement
Checklist of Infant Maternal Consequences

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention Group: MBSR-based stress reduction training was conducted for 8 weekly sessions (120 minutes each session) for the experimental group. The regular routine of each session included reviewing the homework of the previous session, feedback on existing questions and problems, teaching the intended materials and techniques, meditation skills, discussing stress and coping techniques, and presenting homework.
Category
Treatment - Other

2

Description
Second Intervention Group: Cognitive Behavioral Therapy refers to the training that is performed once a week for 10 sessions and for 45 minutes each session for mothers. Familiarity with the process of childbirth is marital satisfaction.
Category
Treatment - Other

3

Description
Control group: No Intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Health Center
Full name of responsible person
Elahe Shahtaheri
Street address
No. 11, West Azerbaijan Ave., Valiasr Blvd.
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2578695784
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Email
elishah1348@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Alireza Roosta
Street address
Kish Island, Sana'i Boulevard, Free Zone Organization Square, Islamic Azad University of Kish International Branch.
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Kish
Province
Hormozgan
Postal code
7941775883
Phone
+98 76 4442 2720
Email
Info@laukishint.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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

Islamic Azad University

Full name of responsible person

Elahe Shahtaheri

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Nombr 26, #4 Alley Ali hosseini ST, Niazzadeh ST, Zaferanieh AVE, valieasr, Tehran

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any type of analysis on the data delivered is permitted

From where data/document is obtainable

Elahe Shahtaheri Adress: No. 11, West Azerbaijan Ave., Valiasr Blvd. Tel: +98 21 8457 9643

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

The request will be sent by email to:

elishah1348@gmail.com

Comments