

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Effectiveness of Meditation as a Meta- Cognitive Therapy in Reducing Anxiety in Pregnant Women in the Last Trimester of Pregnancy

Protocol summary

Study aim

Objective for this research is to compare the effectiveness of meditation meta-cognitive therapy in reducing anxiety in pregnant women in the last trimester of pregnancy.

Design

two experimental group, target sampling, peer based on age, job and education, not blinded

Settings and conduct

pregnancy woman took part in individually meta-cognitive therapy (MCT) and meditation sessions in a private counseling clinic. The score of anxiety in the pre-test anxiety in pregnancy, during therapy sessions (second, fourth, sixth and eighth), end of therapy sessions and follow-up phase (40 days after the end of therapy sessions) were assessed.

Participants/Inclusion and exclusion criteria

Inclusion: satisfaction and high pregnancy anxiety score in pregnant women in the last trimester. exclusion: serious physical disease and mental disorder

Intervention groups

The first group of intervention group took part in individually meta-cognitive therapy (MCT) in 8 sessions and second group of intervention group took part in individually meditation in 7 sessions.

Main outcome variables

anxiety in pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040042N1**

Registration date: **2018-06-27, 1397/04/06**

Registration timing: **retrospective**

Last update: **2018-06-27, 1397/04/06**

Update count: **0**

Registration date

2018-06-27, 1397/04/06

Registrant information

Name

Azra Zebardast

Name of organization / entity

University of Guilan

Country

Iran (Islamic Republic of)

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zebardast@guilan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

2015-03-21, 1394/01/01

Actual recruitment end date

2016-03-19, 1394/12/29

Trial completion date

empty

Scientific title

Effectiveness of Meditation as a Meta- Cognitive Therapy in Reducing Anxiety in Pregnant Women in the Last Trimester of Pregnancy

Public title

Effectiveness of Meditation as a Meta- Cognitive Therapy in Reducing Anxiety in Pregnant Women in the Last Trimester of Pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant Women in the Last Trimester of Pregnancy
Pregnancy anxiety Minimum Education Is Graduated of High School Voluntarily and Satisfaction

Exclusion criteria:

Mental Disorders other than pregnancy anxiety Serious Physical Illness

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: **8**

Actual sample size reached: **8**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Islamic Azad University, Rasht Branch

Street address

Islamic Azad University, Rasht Branch, Darvazeh Lakan Street, Rasht

City

Rasht

Province

Guilan

Postal code

4147654919

Approval date

2013-03-13, 1391/12/23

Ethics committee reference number

17-335/6114

Health conditions studied

1

Description of health condition studied

Pregnancy Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Score of Pregnancy Anxiety in pregnancy anxiety scale (PRAQ)-Van den Bergh

Timepoint

Participants anxiety in pregnancy measured in the pre-test, during therapy sessions (for metacognition therapy group: end of second, forth, sixth and eighth therapy session and for mediation therapy group: end of second, forth and sixth session) and follow-up phase (40 days after the end of therapy sessions).

Method of measurement

pregnancy anxiety scale (PRAQ)-Van den Bergh

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group took part in individually meditation in 7 sessions and every session was held for 45 minutes. first session was about practical relaxation, second session was about Diaphragmatic breathing, third session was about reviewing home work, forth session was about controlling of thought about past and future, fifth session was about ignoring of sadness, sixth session was about monitoring of thought, sensation and emotion and seventh session was about reviewing of all learned skills.

Category

Treatment - Other

2

Description

Intervention group: second group took part in individually meta-cognitive therapy (MCT) in 8 sessions and every session was held for 45 minutes. MCT was so that: 1- case conceptualization; 2- preparation for therapy; 3- Induction of induction of meta- cognition; 4- challenging with meta cognitive believes about Uncontrollably; 5- challenging with meta cognitive believes about worry; 6- challenging with meta cognitive positive believes about worry; 7- Reinforcing of new processing about worry; 8- to prevent of relapse.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic Obstetricians

Full name of responsible person

Roya Fraji

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facing the Revolutionary mosque, Hajiabad Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

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

University of Guilan

Full name of responsible person

Azra Zebardast

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable