Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
tow 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 privet counseling clinic. The score of anxiety in the pre-test anxiety in pregnancy, during therapy sessions(second, forth, 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)

Phone
+98 13 3358 5097

Email address
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 anixety 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 Anixty

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

Street address
facing the Revolutionary mosque, Hajiabad Street ,Rasht, Guilan.

City
Rasht

Province
Guilan

Postal code
41367119779

Phone
+98 13 3322 7020

Email
royafaraji@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Alireza Seidavy

Street address
Deputy of research and technology, Islamic Azad university, Berench of Rasht, Lkan Street, Rasht

City
Rasht

Province
Guilan

Postal code
4147654919

Phone
+98 13 3242 4079

Email
alirezaseidavi@iaurasht.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
University of Guilan

Full name of responsible person
Azra Zebardast

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Department of Psychology, Faculty of Literature and Humanity sciences, University of Guilan, Rasht, Guilan.

City
Rasht

Province
Guilan

Postal code
4199613776

Phone
+98 13 3358 5097

Fax

Email
zebardast@guilan.ac.ir

Person responsible for scientific 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

Street address
Department of Psychology, Faculty of Literature and Humanity sciences, University of Guilan, Rasht, Guilan.

City
Rasht

Province
Guilan

Postal code
4199613776

Phone
+98 13 3358 5097

Fax

Email
zebardast@guilan.ac.ir

Person responsible for updating data

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

Street address
Department of Psychology, Faculty of Literature and Humanity sciences, University of Guilan, Rasht, Guilan.

City
Rasht

Province
Guilan

Postal code
4199613776

Phone
+98 13 3358 5097

Fax

Email
zebardast@guilan.ac.ir

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