

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effectiveness of psychological intervention(CBT) in the treatment of patients with tocophobia in Imam Khomeini Hospital in 2022

Protocol summary

Study aim

Determining the effectiveness of psychological interventions in the treatment of patients with tocophobia in Imam Khomeini hospital in 2022

Design

This clinical trial has a parallel, non-randomized intervention and control group with a sample size of 30 patients.

Settings and conduct

The duration of the study will be 12 months and the study environment will be Imam Khomeini Hospital. The target group of the study is pregnant women referring to the obstetrics and gynecology clinic of Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnant women 20-40 years old; tocophobia. Exclusion criteria: accompanying physical or psychiatric illness; unwillingness to participation

Intervention groups

The intervention includes cognitive-behavioral psychotherapy sessions and is performed for the control group of other prenatal care

Main outcome variables

Tokophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220411054496N1**

Registration date: **2022-05-16, 1401/02/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-16, 1401/02/26**

Update count: **0**

Registration date

2022-05-16, 1401/02/26

Registrant information

Name

Sahar Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2421

Email address

sansari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-24, 1401/02/04

Expected recruitment end date

2023-04-24, 1402/02/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of psychological intervention(CBT) in the treatment of patients with tocophobia in Imam Khomeini Hospital in 2022

Public title

Effectiveness of psychological intervention(CBT) in the treatment of patients with tocophobi

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant, gestational age 6-12 weeks Existence of tokophobia based on screening with WDEQ-A (Wijma Delivery Questionnaire) by trained midwife and positive evaluation score. Primary tokophobia

Exclusion criteria:

Comorbidity with another psychiatric disorder

Comorbidity with another physical disorder

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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 Imam Khomeini Hospital, Tehran
University of Medical Sciences

Street address

Keshavarz Boulevard, Imam Khomeini hospital

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.496

Health conditions studied**1****Description of health condition studied**

Tokophobia

ICD-10 code

F40.9

ICD-10 code description

Phobic anxiety disorder, unspecified

Primary outcomes**1****Description**

Tokophobia

Timepoint

Before and at the end of intervention and at the gestational age of 35 weeks

Method of measurement

Interview and Questionnaire (Wijma)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Cognitive-behavioral psychotherapy intervention will be performed in this group.

Interventions will be performed face to face or virtually, once a week for 10 sessions of 2 hours.

Category

Treatment - Other

2**Description**

Control group: This group will receive routine pregnancy care.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Obstetrics and Gynecology Clinic, Imam Khomeini hospitals complex

Full name of responsible person

Dr Sahar Ansari

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Keshavarz Blvd

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Sponsors / Funding sources

Sponsor

Name of organization / entity
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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

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr Sahar Ansari

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

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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

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

Data Dictionary

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