Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 21 6119 2421

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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

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Akbar Fotouhi

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1418653761

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afotouhi@tums.ac.ir

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