

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison effectiveness of web-based unified transdiagnostic treatment versus diagnosis-specific internet psychotherapies for improvement of psychological distress in women with threatened abortion

Protocol summary

Study aim

To compare the effect of two types of psychotherapies on the anxiety of women with threatened abortion

Design

A non-inferiority, non-blind clinical trial with two parallel groups of 116 patients. Random assignment is a block method in which a list of random sequences is generated through the site and provided to a person outside the research team for concealment.

Settings and conduct

This study will be conducted on 116 pregnant women with threatened abortion referring to hospitals affiliated with Babol University of Medical Sciences and Obstetrics private offices. Women under the threat of abortion are randomly divided into two groups. 58 individuals will receive web-based unified transdiagnostic treatment and 58 individuals will receive web-based disorder-specific treatment. All patients will complete the Edinburgh Depression postnatal Edinburgh Scale (EPDS), BSI-18, Yale-Brown Obsession, and Gasnfsky Emotion Regulation Questionnaire before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with threatened abortion, gestational age 5-12 weeks, Educational level above primary school, access to the internet, having been diagnosed as one of the mental disorders including depression, anxiety, or obsession compulsion. Exclusion criteria: vaginal bleeding except for the threat of abortion like inevitable abortion, pregnancy through assisted reproductive technology, patients without Baseline ultrasound, diagnosis of severe mental disorder at risk of suicide, receiving other psychotherapy, lack of informed consent.

Intervention groups

Intervention group 1: Participants will receive web-based unified transdiagnostic treatment. Intervention group 2:

Participants will receive diagnosis-specific internet psychotherapies. The duration of the treatment in both groups is 8 internet sessions of 45 minutes.

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110228005931N13**

Registration date: **2023-04-13, 1402/01/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-13, 1402/01/24**

Update count: **0**

Registration date

2023-04-13, 1402/01/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effectiveness of web-based unified transdiagnostic treatment versus diagnosis-specific internet psychotherapies for improvement of psychological distress in women with threatened abortion

Public title
Comparing the effectiveness of web-based unified transdiagnostic treatment with specific diagnosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Education above elementary Vaginal bleeding related to pregnancy between 5 and 12 weeks Taking progesterone due to the threat of abortion Internet access Having diagnostic criteria for disorders, including depression (MDD, depression NOS), anxiety disorders (Panic disorder, Generalized anxiety disorder, Agoraphobia, Specific phobia, Social phobia, and anxiety NOS) and Obsessive-compulsive disorders based on the DSM-5 Clinical Structured Interview
Exclusion criteria:
Patients with vaginal bleeding for reasons other than threatened abortion Patients who became pregnant through assisted reproductive technology Patients diagnosed as missed abortion or inevitable miscarriage and ectopic pregnancy on admission Patients without baseline ultrasound Severe psychiatric disorders and suicidal ideation Receiving other psychotherapy at the same time as this study Lack of informed consent

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **116**

Randomization (investigator's opinion)
Randomized

Randomization description
One hundred sixteen eligible participants will allocate randomly two groups (58 individuals) by permuted block randomization method. Group A (unified transdiagnostic treatment) and group B (diagnosis-specific) including three subgroups of depression, anxiety, and obsession will be received. The size of each block will be considered 12 using the statistical program on (seadenvelope.com). In each block, 6 times group A and 6 times group B (2 repetitions of each disorder) will be considered and

produce a total of 116 sequences. In order to comply with the concealment sequence, the random list is given to a hospital staff member outside the research team who sends the codes to the principal investigator.

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

Ethic Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Babol, Iran.

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Approval date

2023-01-09, 1401/10/19

Ethics committee reference number

IR.MUBABOL.REC.1401.158

Health conditions studied

1

Description of health condition studied

Depression Disorders

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Anxiety Disorders

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Obsession Compulsive Disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression

Timepoint

Before intervention, after intervention (8 weeks after beginning), follow-up of 3 month after end of intervention

Method of measurement

Edinburgh Postnatal Depression Inventor

Secondary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, after intervention (8 weeks after beginning), follow-up of 3 months after the end of the intervention

Method of measurement

Brief Symptoms Inventory (BSI-18)

2

Description

Obsession- compulsion

Timepoint

Before the intervention, after intervention (8 weeks after beginning), follow-up of 3 months after the end of the intervention

Method of measurement

Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)

3

Description

Emotion regulation

Timepoint

Before intervention, after intervention (8 weeks after beginning), follow-up of 3 month after end of intervention

Method of measurement

Cognitive emotion regulation questionnaire (CERQ)

Intervention groups

1

Description

Intervention group 1: Participants will receive web-based unified transdiagnostic treatment with a duration of 8 weeks, each session 45 minutes. The Unified protocol for transdiagnostic treatment of the emotional disorder(UP) is an emotion-focused cognitive-behavioral intervention that consists of five modules or "core" components based on elements of cognitive behavioral therapy (CBT) with proven effectiveness that address negative emotions and reactivity. It targets the negative aspects of emotions, which include learning to observe emotional experience; cognitive evaluation in creating and

maintaining emotional responses, identifying behaviors affected by emotion, awareness of internal and external triggers of emotion, and learning how to prepare a hierarchy of fear and avoidance.

Category

Treatment - Other

2

Description

Intervention group 2: Participants will receive web-based diagnosis-specific internet psychotherapies including Internet-based cognitive behavior therapy for three disorders (depression, anxiety, and obsession-compulsion disorders) with a duration of 8 weeks, each session of 45 minutes. Specific strategies used in the protocols include the specific strategies used in the protocols included specific treatment of obsessions (types of obsessions, change of mind, confrontation and response prevention, hierarchy of anxiety, and prevention of relapse), depression: (identification and cognitive re-evaluation, negative automatic thoughts and basic beliefs, exercises to test negative beliefs, identifying schemas and changing them) and anxiety (identification and cognitive re-evaluation, cognitive errors, effective and ineffective coping strategies, behavior change, relaxation sessions).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani Educational and Medical Center

Full name of responsible person

Dr. Shahnaz Barat

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

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Grant name

Thesis in PhD degree

Grant code / Reference number

724134501

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol 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

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Mahbobeh Faramarzi

Position

Professor

Latest degree

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Other areas of specialty/work

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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