Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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 labortion 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 Gasnefsky 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

Name

Mahbobeh Faramarzi

Name of organization / entity

Babol University of medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1329 4456

Email address

m.faramarzi@mubabol.ac.ir

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.

City

Babol

Province

Mazandaran

Postal code

47176-47745

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), fallow-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), fallow-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), fallow-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
Street address
Ayatollah Rouhani Hospital, Ganjafrouz Avenue, Babol, Mazandaran Province, Iran.
City
Babol
Province
Mazandaran
Postal code
47745-47176
Phone
+98 11 3219 9592
Email
dr.shahnazbarat@gmail.com

2

Recruitment center
Name of recruitment center
Yahya Nejad Educational and Medical Center
Full name of responsible person
Dr. Shahnaz Barat
Street address
Yahyanejad Hospital, Farhang Avenue, Babol,

Mazandaran Province, Iran.

City
Babol

Province
Mazandaran

Postal code
4713566547

Phone
+98 11 3222 3594

Email
dr.shahnazbarat@gmail.com

3

Recruitment center

Name of recruitment center
private office in Babol

Full name of responsible person
Dr. Shahnaz Barat

Street address
upper floor of Pasteur's laboratory, Farhang Avenue, Babol, Mazandaran Province, Iran

City
Babol

Province
Mazandaran

Postal code
4714766114

Phone
+98 11 3220 4550

Email
dr.shahnazbarat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr.Mehdi Rajabnia

Street address
Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47745-47176

Phone
+98 11 3219 9592

Email
ramazan@yahoo.com

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
Babol University of Medical Sciences

Full name of responsible person
Mahbobeh Faramarzi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47745-47176

Phone
+98 11 3219 9595

Email
Mahbob330@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Farzan kheirkhah

Position
professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47745-47176
Phone
+98 11 3219 9592
Email
drfarzankh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Seyedeh Mahboobeh Mirtabar
Position
PHD student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran City Babol Province Mazandaran
City
Babol
Province
Mazandaran
Postal code
47745-47176
Phone
+98 11 3223 8301
Email
seyedehm.mirtabar@gmail.com

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