Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of internet-based stress inoculation therapy (ISIT) counseling approach on quality of life and stress related to infertility of women undergoing assisted reproductive treatment (ICSI).

Protocol summary

Study aim
Determining the effect of internet-based self-care counseling using a stress inoculation approach on the quality of life and infertility-related stress in women undergoing assisted reproductive technology (ICSI) treatment.

Design
A randomized, open-label, parallel-group clinical trial involving 90 women undergoing ICSI treatment. Group allocation is performed using Random Allocation Software with block randomization (block size of 6) and allocation concealment via opaque envelopes.

Settings and conduct
The present study is a randomized clinical trial conducted on 90 female volunteers undergoing ICSI treatment. Participants are assigned to either the intervention group (n=45) or the control group (n=45) using a block randomization method (block size of 6) and allocation concealment via numbered (1–90) opaque envelopes. The intervention group receives five virtual sessions of Stress Inoculation Training (ISIT) over five consecutive weeks prior to the oocyte retrieval procedure.

Participants/Inclusion and exclusion criteria
Infertile women under the age of 45 are candidates for infertility treatment via ICSI.Exclusion criteria: Receiving psychological support and having experienced a stressful event within the last three months.

Intervention groups
The intervention will be conducted via the "Zehn-e Aram" website as individual counseling sessions based on the Internet-based Stress Inoculation Training (ISIT) approach, consisting of five 30-to-45-minute sessions over five consecutive weeks. Links to the counseling sessions will be sent to intervention group participants on a weekly basis via SMS or the Eitaa messaging app. Participants in the control group will receive standard care and counseling through the Fertility and Infertility Center's counseling unit.

Main outcome variables
Quality of life and infertility; infertility-related stress

General information

Reason for update

Acronym
ICSI

IRCT registration information
IRCT registration number: **IRCT20110326006108N2**
Registration date: **2026-10-08, 1405/07/16**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-08, 1405/07/16**
Update count: **0**

Registration date
2026-10-08, 1405/07/16

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
2199592-0111

Email address
h.pasha@mubabol.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-06, 1405/07/14

Expected recruitment end date
2027-02-03, 1405/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of internet-based stress inoculation therapy (ISIT) counseling approach on quality of life and stress related to infertility of women undergoing assisted reproductive treatment (ICSI).

Public title

The Effectiveness of "SIT" Counseling for Infertile Individuals

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the study Infertility as defined by the World Health Organization (WHO) Physician-confirmed primary infertility Iranian nationality Age under 45 years Basic literacy (ability to read and write) Availability of spouse Permanent marriage Monogamous marriage (not in a polygamous relationship) No adopted children Women deemed candidates for assisted reproductive technology (ICSI) by a physician Ownership of a smartphone Familiarity with, and successful installation and setup of, the "Eitaa" messaging app on the smartphone No history or current diagnosis of severe mental disorders (based on self-report or medical records), such as major depression, bipolar disorder, psychosis, or substance abuse Not currently taking psychiatric medication Not currently receiving counseling interventions

Exclusion criteria:

Receipt of psychological support (participation in psychotherapy sessions, relaxation techniques, yoga) within the last 3 months Experience of a stressful event in the last three months (death or acute illness of a close relative, major change in living circumstances)

Age

To **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Random Allocation software, participants are randomly assigned to the intervention group (A) and the control group (B) via block randomization with a block size of 6.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

In the intervention group, counseling sessions based on the internet-delivered stress inoculation approach will be conducted as individual online counseling (ISIT). Participants in the control group will receive routine care and counseling through the fertility and infertility center's counseling unit.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj-Afrouz Street, Babol

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2026-08-16, 1405/05/25

Ethics committee reference number

IR.MUBABOL.HRI.REC.1405.212

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

infertility

Primary outcomes

1

Description

Quality of life in infertility

Timepoint

Before the intervention, immediately after, and 2 months after the end of the intervention.

Method of measurement

The fertility quality of life tool (FertiQoL)

2

Description
Infertility-related stress
Timepoint
Immediately and 2 months after the intervention
Method of measurement
Fertility Problem Inventory (FPI)

Secondary outcomes

1

Description
Anxiety and Depression Associated with Infertility
Timepoint
Before the intervention, immediately after, and 2 months after the end of the intervention.
Method of measurement
Hospital Anxiety and Depressin Scale (HADS)

Intervention groups

1

Description
Intervention group: For this group, the internet-based stress inoculation counseling sessions will be conducted as individual online consultations (ISIT) via the "Zehn-e Aram" website, consisting of five 30-to-45-minute sessions over five consecutive weeks. Links to the counseling sessions will be sent weekly to intervention group members via SMS or the Eitaa messaging app. A student researcher will follow up by phone to ensure participants access the session links and complete the assigned exercises and tasks. All five sessions will be provided to the participants prior to the egg retrieval procedure.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Infertility Treatment Center, Babol
Full name of responsible person
Hajar Pasha
Street address
Babol, past the Mohammad Hassan Khan Bridge (on the old Amol-Babol road): Fatemeh Al-Zahra Specialized Fertility and Infertility Treatment Center.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
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Mazandaran
Postal code
4717647745
Phone
+98 11 3219 9592
Fax
+98 11 3219 0181
Email
info@mubabol.ac.i
Web page address
https://www.mubabol.ac.ir/
Grant name
Grant code / Reference number
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
Dr. Hajar Pasha
Position
Associate Professor
Latest degree
Ph.D.

Other areas of specialty/work
Midwifery
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Ph.D.
Other areas of specialty/work
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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