Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Microbiome-Focused Nutritional Education with the Trans-Theoretical Model on Anxiety and retrieved oocyte count in women undergoing IVF: A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of microbiome-based nutrition education using the trans-theoretical model on anxiety and the number of retrieved oocytes in women undergoing IVF treatment

Design

The study will include 60 participants, who will be allocated to either the intervention or control group by a person not involved in sampling, using stratified random block allocation based on infertility type and treatment cycle, employing the RAS with blocks of 4 and 6 at a 1:1 ratio.

Settings and conduct

Sampling will be conducted among women undergoing IVF or ICSI treatment who are referred to the infertility clinic of Alzahra Hospital in Tabriz. After reviewing the main inclusion criteria, the researcher will provide an explanation regarding the objectives and procedures of the study.

Participants/Inclusion and exclusion criteria

Women undergoing IVF or ICSI treatment, aged 15 to 49 years, in the precontemplation and contemplation stages of dietary behavior change, with an anxiety score between 32 and 53; those who have used antibiotics at the time of sampling or within the preceding month will be excluded.

Intervention groups

For the intervention group, a coordinated face-to-face session will be held in groups of 4 to 6 participants, during which nutritional education, an explanation of the intervention method, and an educational pamphlet will be provided. The educational content will be delivered as messages via a virtual channel to participants in the intervention group twice a week. The intervention will be delivered for 8 weeks prior to the initiation of treatment. The control group will receive no intervention.

Main outcome variables

Comparison of the mean anxiety score; and the mean number of retrieved oocytes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N17**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date

2026-09-28, 1405/07/06

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0649

Email address

mehrabie@tbzmed.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-07, 1405/07/15

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Microbiome-Focused Nutritional Education with the Trans-Theoretical Model on Anxiety and retrieved oocyte count in women undergoing IVF: A Randomized Controlled Trial

Public title
The effect of Microbiome-Focused Nutritional Education with the Trans-Theoretical Model on Anxiety and retrieved oocyte count in women undergoing IVF
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1. Married women aged 15 to 49 years2. Undergoing infertility treatment (IVF/ICSI) for the first or second time3. No concurrent use of probiotic or prebiotic supplements within the past month4. State anxiety score between 32 and 535. Precontemplation and contemplation stages of behaviour change6. Possession of a smartphone7. Minimum literacy level of lower secondary education8. Verbal and auditory communication ability and ability to use mobile applications
Exclusion criteria:
1. History of underlying chronic diseases such as diabetes, hypertension, or heart disease based on the patient's medical record2. Antibiotic use at the time of sampling and within the preceding month3. Adherence to a specific dietary regimen4. Psychiatric illness or use of psychiatric medications based on patient self-report5. Current participation in related educational programs
Age
From **15 years** old to **49 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The study will include 60 participants (calculated based on two primary variables: mean anxiety score and mean number of retrieved oocytes), who will be allocated to either the intervention or control group by a person not involved in sampling, using stratified random block allocation based on infertility type (primary or secondary) and treatment cycle (first or second), employing the Random Allocation Software (RAS) with blocks of 4 and 6 at a 1:1 ratio. The allocation will be written on paper and placed in sequentially numbered opaque envelopes (allocation concealment). The envelopes will be opened in the order of participants' entry into the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor and data analyst in this study will be blinded to the allocation of participants to the groups. The initial outcome assessment before randomization will be conducted by the principal investigator (who administers the intervention). However, the outcome evaluation and data analysis will be performed by other individuals not involved in participant allocation, sampling, or intervention administration.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Central Building, Tabriz University of Medical Sciences, Golgasht St., Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947-977
Approval date
2026-09-23, 1405/07/01
Ethics committee reference number
IR.TBZMED.REC.1405.431

Health conditions studied

1

Description of health condition studied
infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description

Anxiety score

Timepoint

Before the intervention and immediately after the completion of the intervention

Method of measurement

Spielberger State Anxiety Inventory (Form 1)

2

Description

Number of retrieved oocytes

Timepoint

Two weeks after the completion of the intervention and the initiation of treatment

Method of measurement

Laboratory record / Embryology data registration checklist

Secondary outcomes

1

Description

Retrieved oocyte quality

Timepoint

Two weeks after the completion of the intervention and the initiation of treatment

Method of measurement

Laboratory record / Embryology data registration checklist

2

Description

Frequency of pregnancy

Timepoint

four weeks after the completion of the intervention and the initiation of treatment

Method of measurement

Patient record

3

Description

Embryos obtained

Timepoint

four weeks after the completion of the intervention and the initiation of treatment

Method of measurement

Laboratory record / Embryology data registration checklist

4

Description

Quality of obtained embryos

Timepoint

four weeks after the completion of the intervention and the initiation of treatment

Method of measurement

Laboratory record / Embryology data registration checklist

5

Description

Frequency of continuation of pregnancy up to the first trimester

Timepoint

Four months after the completion of the intervention and the initiation of treatment

Method of measurement

Patient record

6

Description

Women's depression score

Timepoint

Before the intervention and immediately after the completion of the intervention

Method of measurement

BDI-II questionnaire

7

Description

Frequency of stages of behavioral change for dietary pattern

Timepoint

Before the intervention and immediately after the completion of the intervention

Method of measurement

Behavioral Change Stages Checklist

8

Description

Fertilized oocytes

Timepoint

four weeks after the completion of the intervention and the initiation of treatment

Method of measurement

Laboratory record / Embryology data registration checklist

Intervention groups

1

Description

Intervention group: For the intervention group, during a coordinated in-person session held in groups of four to six participants, dietary education, an explanation of the intervention method, and an educational pamphlet will be provided. The content of the educational program (pamphlet, podcast, images containing educational messages, and short educational videos) is designed in relation to microbiome-based nutrition with the aim of improving gut and reproductive tract microbiome health, and includes topics such as appropriate nutrition for strengthening the microbiome (consumption of fiber, fermented foods, and probiotics), reducing the intake of processed foods and simple sugars, and avoiding the excessive use of antibiotics. The content validity of the educational materials will be reviewed by the research

team and ten faculty members from the Departments of Midwifery, Obstetrics and Gynecology, and Nutrition. Ultimately, the content will be delivered as messages in a virtual channel and made available to participants in the intervention group twice a week. To enhance understanding of the importance of nutrition in treatment outcomes and adherence to the recommended diet, the messages will contain simple and comprehensible information to address informational and practical barriers. In addition, short daily messages will be sent to invite participants to take practical action and to remind them to perform the recommended actions. The intervention will be delivered for 8 weeks before the initiation of treatment, twice a week. On the first occasion, immediately after uploading the materials, participants will be informed about the upload and encouraged to study the content. Participants will be requested to provide feedback by sending a private message with a 'like' symbol to the researcher once they have reviewed the materials, and if they have any questions about the materials posted in the channel, they will receive the necessary guidance. In case of no feedback from the participant until 24 hours after uploading the materials, a second reminder SMS will be sent. In case of no feedback again until 48 hours, a phone call will be made to the participant.

Category
Lifestyle

2

Description
Control group: The control group will not receive any intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Infertility Clinic of Alzahra Hospital, Tabriz

Full name of responsible person
Aylar Abdzadeh

Street address
South Artesh Street, Baghshomal Intersection, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5138663134

Phone
+98 41 3553 9161

Fax
+98 41 3556 6449

Email
alzahrahospital@tbzmed.ac.ir

Web page address
https://alzahrahosp.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Khosro Adibkia

Street address
Central Building, Tabriz University of Medical Sciences, Golgasht St., Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Phone
+98 41 3335 7310

Fax
+98 41 3334 4280

Email
research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Aylar Abdzadeh

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
School of Nursing & Midwifery, South Shariati St.,Tabriz

City
Tabriz

Province

East Azarbaijan

Postal code
5138947977

Phone
+98 41 3740 8683

Email
aylar.abdzadeh11@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Esmat Mehrabi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
School of Nursing and Midwifery, South Shariati St., Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Phone
+98 41 3479 0364

Email
b.mehrabi62@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Esmat Mehrabi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
School of Nursing and Midwifery, South Shariati St., Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Phone
+98 41 3479 0364

Email
b.mehrabi62@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Part of the data related to the study outcomes will be available for sharing.

When the data will become available and for how long
Access period starts 6 months after the results are published.

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
De-identified data available for meta-analysis or replication studies, with approval from the principal investigator.

From where data/document is obtainable
By sending an email to the email address of Dr. Esmat Mehrabi: b.mehrabi62@gmail.com

What processes are involved for a request to access data/document
Emails sent by applicants to Dr. Esmat Mehrabi's email address (b.mehrabi62@gmail.com) will be responded to within one week.

Comments