

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparing The Effectiveness of Group training Based on Acceptance and Commitment with Transactional Analysis on Mother-Fetus Attachment, Ego Strength and Fear of Childbirth in Pregnant Women

#### Protocol summary

##### Study aim

Comparing The Effectiveness of Group training Based on Acceptance and Commitment with Transactional Analysis on Mother-Fetus Attachment, Ego Strength and Fear of Childbirth in Pregnant Women

##### Design

This research will be of the type of semi-experimental research (pre-test, post-test and follow-up test design with control group and parallel groups, unidirectional and without phase) and 45 participants will be randomly selected based on random allocation software. They will be placed in two experimental groups and one control group

##### Settings and conduct

The statistical population of the current study will include all women with their first pregnancy in the last quarter of the year 2023 , 1st district of Tehran, who will refer to the pregnancy care clinics and will be willing to participate in the research.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparous women, Iranian nationality, literacy at least diploma, age 18 to 45 years, pregnancy age 12 weeks to 25 weeks, normal pregnancy, no psychological and personality diseases, no addiction. Exclusion criteria: participation in other educational and counseling programs Individual or drug therapy

##### Intervention groups

The first experimental group training based on commitment and acceptance, the second experimental group, training based on transactional analysis, and the control group will remain in the waiting list. The intervention protocol will be 8 weekly 90s sessions

##### Main outcome variables

Mother's attachment to the fetus, ego strength, fear of childbirth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230725058924N1**

Registration date: **2023-09-24, 1402/07/02**

Registration timing: **prospective**

Last update: **2023-09-24, 1402/07/02**

Update count: **0**

##### Registration date

2023-09-24, 1402/07/02

##### Registrant information

##### Name

Sara Langroudian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2612 6417

##### Email address

s.langroudian@iau-tnb.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2023-12-21, 1402/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparing The Effectiveness of Group training Based on Acceptance and Commitment with Transactional Analysis on Mother-Fetus Attachment, Ego Strength and Fear of Childbirth in Pregnant Women

## Public title

Comparing The Effectiveness of Group training Based on Acceptance and Commitment with Transactional Analysis on Mother-Fetus Attachment, Ego Strength and Fear of Childbirth in Pregnant Women

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Primiparous women Gestation age 12 to 25 weeks  
Having a literacy level of at least a diploma Age 18 to 45 years  
The normality of pregnancy Iranian nationality

### Exclusion criteria:

Previous diagnosis of psychological and personality diseases  
Taking psychotropic drugs Participation in other psychology training programs  
Individual counseling Psychotherapeutic drugs

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **45**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The purpose-based sampling will be done based on the entry criteria and with random assignment based on the random allocation software, so that first the samples are selected based on the entry criteria and each sample will be given a number, and then the number and groups will be assigned to the software. is given and the software gives us a page that has randomly assigned each person in the corresponding group

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this research, the researcher is aware of the methods and interventions, but the subjects are not aware of the difference between interventions and work methods.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University, North Tehran branch

##### Street address

Unit 111, No. 7, The third ally, Shahid Sabari St., corner of Koche Som East

##### City

Tehran

##### Province

Tehran

##### Postal code

1957843434

#### Approval date

2023-07-16, 1402/04/25

#### Ethics committee reference number

IR.IAU.TNB.REC.1402.051

## Health conditions studied

### 1

#### Description of health condition studied

Comparing the effectiveness of group training based on commitment and acceptance with transactional analysis on mother-child attachment, ego strength and fear of childbirth in pregnant women.

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Mother\_fetus Attachment

#### Timepoint

before the start of the interventions, after the end of the interventions and three months after the end of the interventions

#### Method of measurement

Cranley Maternal Attachment Questionnaire (1981)

### 2

#### Description

Ego Strength

#### Timepoint

before the start of the interventions, after the end of the interventions and three months after the end of the interventions

#### Method of measurement

Markstrom's Strength Questionnaire (1997)

### 3

#### Description

Fear of childbirth

### Timepoint

before the start of the interventions, after the end of the interventions and three months after the end of the interventions

### Method of measurement

Harman Fear of Childbirth Questionnaire (1993)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The protocol of training sessions based on the acceptability and commitment for 90-minute on 8 sessions will be held during 8 weeks.

#### Category

Lifestyle

### 2

#### Description

Transactional analysis (TA): In this study, group training of Transactional analysis will be held during 8 sessions of 90 minutes and on a weekly

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic Didgaaheno

##### Full name of responsible person

Maryam Janfada

##### Street address

Unit 12, 3rd floor, plate 36, Chizer Square, Qaytarieh

##### City

Tehran

##### Province

Tehran

##### Postal code

1938963394

##### Phone

+98 21 2221 5352

##### Email

janfada@didgaaheno

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Saied Malmasi

##### Street address

Shahid Babaei Highway, shahid Abbaspor, Shahid Sadoqi, North Tehran Branch, Islamic Azad University

##### City

Tehran

##### Province

Tehran

##### Postal code

1651153511

##### Phone

+98 21 7700 9848

##### Email

ravabet-omomi@iau-tnb.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Islamic Azad University

##### 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

Islamic Azad University

##### Full name of responsible person

Sara Langroudian

##### Position

Consultant

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

##### Street address

Unit 11, No. 7, 3rd East Alley, Shahid Sabari St

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##### Email

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

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## **Person responsible for updating data**

### **Contact**

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Islamic Azad University

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### **Phone**

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### **Email**

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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