Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 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 slamic Azad University, North Tehran branch

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

City
Tehran

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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
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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
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1651153511
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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
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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