Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of schema training and emotional coaching on fear of childbirth, emotional regulation and self-compassion among pregnant women

Protocol summary

Study aim

1.To determine the effectiveness of schema-based training and emotion coaching on fear of childbirth, emotion regulation, and self-compassion in pregnant women. 2.Compare schema-based training and emotion coaching in reducing fear of childbirth. 3.Compare their effects on improving emotion regulation. 4.Compare their impact on enhancing self-compassion.

Design

This phase 2 randomized, double-blind, parallel-group trial includes 90 participants equally assigned to schema-based training, emotion coaching, or control groups using blocked randomization via Excel.

Settings and conduct

This single-blind trial examines the impact of schema-based training and emotion-focused coaching on childbirth fear, emotion regulation, and self-compassion in pregnant women, with 90 participants randomly assigned to three groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women with at least a high school diploma Willingness to participate and commitment to the rules of psychological group training Clinical diagnosis of fear of childbirth In the third trimester of pregnancy No previous childbirth experience Exclusion Criteria: Absence from more than two training sessions Pregnancy poisoning (preeclampsia) Gestational hypertension Placenta previa History of psychotic and chronic psychiatric disorders Gestational diabetes Polyhydramnios (excess amniotic fluid)

Intervention groups

The Schema Education Group receives ten weekly sessions targeting maladaptive schemas related to pregnancy. The Emotion Coaching Group attends ten sessions to improve emotional awareness, regulation, and self-compassion. The Control Group receives routine prenatal care, with optional access to educational content after the study.

Main outcome variables

Fear of childbirth Emotion regulation Self-compassion

General information

Reason for update

Acronym

Fear of Chidbirth (FoC)

IRCT registration information

IRCT registration number: **IRCT20241212064031N1**
Registration date: **2025-08-07, 1404/05/16**
Registration timing: **retrospective**

Last update: **2025-08-07, 1404/05/16**
Update count: **0**

Registration date

2025-08-07, 1404/05/16

Registrant information

Name

Zahra Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3267 0726

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z.97asghari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-06, 1404/04/15

Expected recruitment end date

2025-08-06, 1404/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of schema training and emotional coaching on fear of childbirth, emotional regulation and self-compassion among pregnant women

Public title

the effect of psychological training on maternal mental health during pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum education of high school diploma for pregnant women Willingness to participate in the study and group mental education program Psychological dignosis of fear of childbirth (FOC) Women in their third trimester of pregnancy No previous experience of labor

Exclusion criteria:

Absence from more than two sessions during the training phase Preeclampsia Gestational hypertension Placenta previa A prior diagnosis of psychotic disorders and chronic mental illnesses Gestational diabetes Polyhydramnios

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomization:Participants are randomly assigned to three groups — control, schema therapy training, and emotion coaching training — using blocked randomization with a fixed block size of 20.

Blinding (investigator's opinion)

Single blinded

Blinding description

The pregnant mothers were unaware of the group to which they were assigned (control, schema therapy training, or emotion coaching), but the researchers and intervention facilitators were aware of the group allocations.

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, Shiraz Branch

Street address

Ladbaestan Building, opposite Dr. Farvardin Eye Clinic, between Mollasadra St. and Baghshah St., Ma’adal Gharbi St., Shiraz, Iran.

City

Shiraz

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7134686499

Approval date

2024-12-11, 1403/09/21

Ethics committee reference number

IR.IAU.SHIRAZ.REC.1403.227

Health conditions studied

1

Description of health condition studied

Fear of childbirth Emotion dysregulation Low self-compassion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Score of childbirth fear in Wijma Delivery Expectancy Questionnaire (W-DEQ Version A)Childbirth fear is assessed using the W-DEQ Version A (33 items, six-point Likert scale).

Timepoint

Childbirth fear score: Measured at two time points: before the intervention begins and immediately after the completion of the training program.

Method of measurement

Wijma Delivery Expectancy Questionnaire Version A, consisting of 33 items with a six-point Likert scale.

2

Description

Score of emotion regulation strategies in Cognitive Emotion Regulation Questionnaire (CERQ)Cognitive emotion regulation is measured using the CERQ (18 items, nine subscales, five-point Likert scale).

Timepoint

Emotion regulation score: Assessed at two time points: pre-intervention and immediately post-intervention.

Method of measurement

Cognitive Emotion Regulation Questionnaire, consisting of 18 items and 9 subscales with a five-point Likert scale.

3

Description

Score of self-compassion in Self-Compassion Scale (SCS)Self-compassion is evaluated through the SCS (26 items, six subscales, five-point Likert scale).

Timepoint

Self-compassion score: Evaluated at two time points: before the intervention and after the intervention ends.

Method of measurement

Self-Compassion Scale, consisting of 26 items and 6 components with a five-point Likert scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Schema-Based Training Number of sessions: 10 sessions, each one hour long, held weekly Educational content: Introduction to schemas, identification of maladaptive schemas, training on techniques for schema modification, and strengthening of healthy schemas Delivery method: Online sessionsTeaching methods: Theoretical instruction, practical exercises, and homework assignments

Category

Behavior

2

Description

Intervention group: Emotion-Focused Coaching Number of sessions: 10 sessions, each one hour long, held weeklyEducational content: Training on emotion regulation skills, recognition and acceptance of emotions, enhancing self-compassion, and providing coping strategiesDelivery method: Sessions conducted either online or in personTeaching method: A combination of theoretical instruction, practical exercises, and individual feedback

Category

Behavior

3

Description

Control group: This group does not receive any educational intervention and only receives routine care provided by the health centers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital, Shiraz

Full name of responsible person

Zahra Asghari

Street address

Chamran Boulevard,Hafez Medical Education and Treatment Center

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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3

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Name of recruitment center

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Full name of responsible person

Zahra Asghari

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
MohammadHashem HashemPour
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Zand Street, opposite Palestine Street, Central Building of Shiraz University of Medical Sciences
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Postal code
71348-14336
Phone
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Email
info@sums.ac.ir
Web page address
https://sums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Islamic Azad University
Full name of responsible person
Zahra Asghari
Position
Master's Student
Latest degree
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Other areas of specialty/work
Psychology
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After study completion, de-identified individual data, including demographic information and primary and secondary outcomes, will be uploaded to a secure data repository. Sharing may be limited to a subset of data if necessary. Access will be granted upon formal request and ethics committee approval, with strict confidentiality maintained.

When the data will become available and for how long

The data and documents will be made available in a public repository after the completion of the study, final analysis, and publication of primary results. They will remain accessible for at least five years following publication. Access requests within this timeframe require formal application and ethics committee approval.

To whom data/document is available

Access to the data and documents will be granted to qualified researchers who submit a formal request along with a research proposal and receive approval from the ethics committee. Access will be provided in compliance with confidentiality and ethical standards.

Under which criteria data/document could be used

De-identified individual participant data and related documents will be used solely for scientific research and knowledge advancement. Any commercial use, re-identification of participants, or unauthorized data sharing/publication is strictly prohibited. Conditions for Requesting and Using Data: Submission of a formal request and research proposal detailing the objectives and analysis methods Approval by the relevant ethics committee Guarantee of data confidentiality and security by the requester Respect for intellectual property rights and proper citation in any dissemination or publication Analyses limited to the approved objectives, with no use beyond without additional permission These measures are established to protect participant privacy and ensure ethical and responsible use of the data.

From where data/document is obtainable

Applicants wishing to obtain data and documents related to this study can do so through the following methods: Email contact: Official email of the principal investigator: z.97asghari@gmail.com (Please include the subject of your request, research purpose, and your contact information in the email.) Phone contact: Phone number: +98 913 294 1625 Availability: Saturday to Wednesday, 9 AM to 5 PM Contact person: Zahra Asghari Postal correspondence: Mailing address: Shiraz University of Medical Sciences Postal code: 7113613851 Shiraz, Iran

What processes are involved for a request to access data/document

The applicant must submit a formal request along with a research proposal. The request will be reviewed, and after approval by the ethics committee and signing a confidentiality agreement (if required), the de-identified data and documents will be prepared and sent. The entire process typically takes between 4 to 8 weeks.

Comments