

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

A comparative study on the effect of expressive writing on the fear of childbirth in nulliparous and primiparous/multiparous pregnant women

Protocol summary

Study aim

Comparison of the effect of expressive writing on the fear of childbirth in nulliparous and primiparous/multiparous pregnant women referring to the health services centers in Isfahan in 2021

Design

Controlled clinical trial with two intervention groups (N=45) and two control groups of (nulliparous and primiparous/multiparous) in parallel groups by block randomization on 180 participants.

Settings and conduct

Out of all pregnant women referring to two comprehensive health services centers of Ebn-e-Sina and Amir-Hamzeh, the score of child birth fear will be determined with Wijma-questionnaire among the ones having study inclusion criteria and willing to participation. Achieving score 28 or more will be included. The fear of childbirth will be measured and compared before and after intervention in two intervention groups and two control groups.

Participants/Inclusion and exclusion criteria

Iranian nationality and Persian language; Gestational age 36 weeks; Ability of reading and writing; Score 28< from Wijma questionnaire of fear of childbirth; No cesarean indications; No psychological disorders; No use of artificial reproductive technology; No history of abortion among nulliparous women; No history of infertility; Mother's tendency and consent to participation

Intervention groups

Intervention group: expressive writing will be done for 7 days at least 15 minutes daily; as, the mother will write down on a piece of paper her deepest thoughts, emotions, and concerns about giving birth and the causes of her fear as well as concerns about behaviors of the personnel of delivery ward and ... Control group: neutral writing will be done for 7 days at least 15 minutes daily about ordinary daily affairs such as cooking, cleaning, ... They will be asked to write honestly about the matters that arouse no negative/positive emotion.

Main outcome variables

Fear of childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091001002531N4**

Registration date: **2021-11-01, 1400/08/10**

Registration timing: **retrospective**

Last update: **2021-11-01, 1400/08/10**

Update count: **0**

Registration date

2021-11-01, 1400/08/10

Registrant information

Name

Tahmineh Dadkhahtehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7596

Email address

dadkhahtehrani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-20, 1400/03/30

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of expressive writing on the fear of childbirth in nulliparous and primiparous/multiparous pregnant women

Public title

"The effect of expressive writing on the fear of childbirth"

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The mothers with Iranian nationality and Persian language Pregnant mothers with gestational age 36 weeks (252 days) or more based on sonographic evidences and self declaration Having ability of reading and writing Achieving score 28 or more from Wijma questionnaire of fear of childbirth Mother's tendency and consent to participation in the study

Exclusion criteria:

Use of artificial reproductive technology for becoming pregnant History of abortion among nulliparous women History of infertility History of known psychological disorders(based on self declaration and information of SIB software) Having obstetrical indications of cesarean(multiple pregnancy, placenta previa, history of surgery on uterus, skeletal malformation, and other indication of cesarean based on country protocol)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **198**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation was conducted through permuted blocked randomization (block size=4 including 2 controls and two interventions). First, using the following website(<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) the blocks were determined for nulliparous women then the blocks were determined for prim parous /multiparous women. So, this website was applied twice. A= intervention B= control Block size: 4

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In present study; there are two categories of pregnant mothers (nulliparous and primiparous/multiparous) and each category includes two groups of control and

intervention; so totally four groups will be assessed.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Faculty of Nursing & Midwifery, Isfahan University of Medical Science, Hezarjerib Street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2021-05-24, 1400/03/03

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.011

Health conditions studied**1****Description of health condition studied**

fear of childbirth

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Score of "Fear of childbirth" based on Wijma questionnaire

Timepoint

"Measurement of fear of childbirth before expressive writing and after a period of 7- day expressive writing"

Method of measurement

Wijma questionnaire of fear of childbirth

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: expressive writing in nulliparous pregnant women for 7 days, at least 15 minutes daily about their deepest thoughts, emotions and concerns

about childbirth and the reasons for fear of childbirth, worries about the fetus during delivery, the concerns of the maternity ward staff, and any other concerns related to natural childbirth. They are also advised to discover their deepest feelings and thoughts when writing, and to put it down on paper with simple details and colloquial literature and the same words that are in their minds, and not to be concerned about the correctness of grammar or politeness of the expressions or their logical.

Category

Other

2

Description

First control group: neutral writing in nulliparous pregnant women for 7 days at least 15 minutes daily about ordinary daily affairs such as cooking, cleaning, cloths washing, shopping of foodstuff ,... .They will be asked to write honestly about the matters that arouse no negative/positive emotion.

Category

Other

3

Description

Second intervention group: expressive writing in primiparous/multiparous pregnant women for 7 days, at least 15 minutes daily about their deepest thoughts, emotions and concerns about childbirth and the reasons for fear of childbirth, worries about the fetus during delivery, the concerns of the maternity ward staff, and any other concerns related to natural childbirth. They are also advised to discover their deepest feelings and thoughts when writing, and to put it down on paper with simple details and colloquial literature and the same words that are in their minds, and not to be concerned about the correctness of grammar or politeness of the expressions or their logical.

Category

Treatment - Other

4

Description

Second control group: neutral writing in primiparous/multiparous pregnant women for 7 days at least 15 minutes daily about ordinary daily affairs such as cooking, cleaning, cloths washing, shopping of foodstuff ..They will be asked to write honestly about the matters that arouse no negative/positive emotion.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Hamzeh Comprehensive Health Service Center

Full name of responsible person

Maryam KHalili

Street address

In front of the housing bank and the bazaarst, st. Fourth, Amir Hamzeh town, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81486-53374

Phone

+98 31 3775 7509

Email

maryamkhalili68@yahoo.com

2

Recruitment center

Name of recruitment center

Ibn Sina Comprehensive Health Service Center

Full name of responsible person

Maryam KHalili

Street address

Ebn-e-Sina Comprehensive Health Services center. Ebn-E-Sina Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81486-53374

Phone

+98 31 3445 9147

Email

maryamkhalili68@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

Street address

The deputy of research and technology, bulding 4, Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Fax

Email

sh_haghjoo@med.mui.ac.ir

Web page address

<https://research.mui.ac.ir/fa/dr.haghjoo>

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Tahmineh Dadkhah Tehrani
Position
Instructor of Midwifery, Faculty member
Latest degree
Master
Other areas of specialty/work
Postpartum rehabilitation
Street address
Faculty of Nursing & Midwifery, Isfahan University of Medical Science, Hezarjerib Street, Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73465
Phone
+98 31 3792 7596
Email
tdtahmineh@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Tahmineh Dadkhah Tehrani
Position
Instructor of Midwifery, Faculty member
Latest degree
Master
Other areas of specialty/work
Postpartum rehabilitation
Street address

Faculty of Nursing & Midwifery, Isfahan University of Medical Science, Hezarjerib Street, Isfahan

City
Isfahan
Province
Isfahan
Postal code
81746-73465
Phone
+98 31 3792 7596
Email
tdtahmineh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Tahmineh Dadkhah Tehrani
Position
Instructor of Midwifery, Faculty member
Latest degree
Master
Other areas of specialty/work
Postpartum rehabilitation
Street address
Faculty of Nursing & Midwifery, Isfahan University of Medical Science, Hezarjerib Street, Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73465
Phone
+98 31 3792 7596
Email
tdtahmineh@gmail.com

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