

# 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**

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**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

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**2**

**Recruitment center**

**Name of recruitment center**

Ibn Sina Comprehensive Health Service Center

**Full name of responsible person**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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**Full name of responsible person**

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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**  
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Postpartum rehabilitation  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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