# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## The Impact of Digital Storytelling by Experienced Mothers on Level of Fear of Childbirth and Choosing the Mood of Delivery in Nulliparous Pregnant Women

## Protocol summary


**Study aim**

To investigate the effect of digital storytelling by experienced mothers on childbirth fear and delivery mode choice in Nullipara pregnant women.

**Design**

A randomized controlled clinical trial with parallel groups, single-blind (data analyst blinded), using block randomization, conducted on 66 nulliparous pregnant women. Randomization was performed using the Sealedenvelope website.

**Settings and conduct**

The study will be conducted in healthcare centers in eastern Ahvaz. After screening and consent procedures, participants will be randomized into two groups. The W-DEQ-A questionnaire will be administered at all three time points, and delivery mode will be recorded.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: Primiparous women aged 18-45 with singleton, low-risk pregnancy at 28-32 weeks gestation, possessing literacy skills, a childbirth fear score above 65 on the W-DEQ-A questionnaire, mobile phone proficiency, and providing informed consent. Exclusion Criteria: Depression (Beck score >13), psychiatric disorders, systemic diseases, high-risk pregnancy, fetal abnormalities, infertility history, substance use, sensory impairments, concurrent trial participation, or non-compliance.

**Intervention groups**

Intervention group: Receives 8 digital storytelling podcasts over 4 weeks via a secure blog Control group: Receives routine prenatal care (podcasts provided after study completion)

**Main outcome variables**

Childbirth fear score (W-DEQ-A) Delivery mode selection (vaginal delivery or cesarean section) at follow-up


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250915067264N1**
Registration date: **2025-11-29, 1404/09/08**
Registration timing: **prospective**

Last update: **2025-11-29, 1404/09/08**
Update count: **0**

**Registration date**

2025-11-29, 1404/09/08

**Registrant information**


**Name**

Mahboobeh Zilaei

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-12-22, 1404/10/01

**Expected recruitment end date**

2026-06-22, 1405/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
The Impact of Digital Storytelling by Experienced Mothers on Level of Fear of Childbirth and Choosing the Mood of Delivery in Nulliparous Pregnant Women

**Public title**
The impact of digital storytelling on the fear of childbirth and the choice of delivery method.

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Provision of written informed consent to participate in the study. Age between 18 and 45 years. Primiparity (first-time pregnancy). Singleton pregnancy. Low-risk pregnancy based on medical history and patient file documentation. A Fear of Childbirth (FOC) score greater than 65 on the W-DEQ-A questionnaire. Basic literacy or higher (ability to read and write). Gestational age between 28 and 32 weeks, confirmed by the first day of the last menstrual period or an ultrasound performed before 12 weeks of gestation. Ability to communicate and use a mobile phone, tablet, or computer to receive the interventions.

**Exclusion criteria:**
Presence of clinical depression or a psychological disorder, defined as a total score above 13 on the Beck Depression Inventory. A history of, or current use of, psychotropic medications or active psychiatric illnesses based on participant report or medical records. Concurrent participation in other clinical trials. Presence of maternal systemic diseases such as diabetes, cardiovascular diseases, hypertension, and other chronic conditions. The pregnancy becoming high-risk for medical reasons during the study period. Diagnosis of fetal abnormalities by ultrasound. A history of infertility. Pregnancy achieved through assisted reproductive technologies. Use of tobacco, alcohol, or illicit drugs. Presence of sensory impairments (visual or hearing). Previous experience with digital storytelling.

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

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **66**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
For the random allocation of participants to the intervention and control groups, Permuted Block Randomization will be used. In this method, the order of participant allocation within each block is determined randomly to maintain a balance in the number of individuals in each group throughout the study and to prevent an excessive accumulation of participants in one group during any time interval. After the completion of each block, the number of individuals in the two groups will be approximately equal. The allocation sequence generation will be carried out using the reputable website sealedenvelope.com. To maintain allocation concealment, each allocation code will be placed in sequentially numbered, sealed, opaque envelopes. These envelopes will be opened according to the participants' order of entry into the study. This process prevents the investigator from having prior access to each individual's group assignment and reduces the potential for bias.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
Due to the nature of the intervention (delivery of digital stories by experienced mothers), it will not be possible to blind the participants or the intervention facilitators. However, the data analyst will be blinded to group allocation in order to reduce the potential for bias in the analysis of the results.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Ahvaz University of Medical Sciences

**Street address**
Golestan Blvd., Golestan District

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
۶۱۳۵۷۱۵۷۹۴

**Approval date**
2025-10-18, 1404/07/26

**Ethics committee reference number**
IR.AJUMS.REC.1404.340

## Health conditions studied

### 1

**Description of health condition studied**
Fear of childbirth, Digital storytelling, Nulliparous pregnant women, Mode of delivery, Tokophobia, Vaginal delivery, Cesarean section, Maternal anxiety

**ICD-10 code**
094-099

**ICD-10 code description**
Pregnancy, childbirth and the puerperium

## Primary outcomes

**1**

**Description**
Change in the fear of childbirth score measured by the Wijma Delivery Expectancy Questionnaire (W-DEQ-A) before and after the intervention
**Timepoint**
Baseline: Before the interventionPost-intervention: At the end of the 4-week interventionFollow-up: 4 weeks after completion of the interventionAt delivery: Recording the mode of delivery
**Method of measurement**
Fear of childbirth will be measured using the standard Wijma Delivery Expectancy Questionnaire – Version A (W-DEQ-A), a 33-item Likert-scale instrument.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Receives 8 digital storytelling podcasts over 4 weeks via a secure blog
**Category**
Other

**2**

**Description**
Control group: Receives routine prenatal care (podcasts provided after study completion)
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
healthcare centers in eastern Ahvaz
**Full name of responsible person**
Somaye Makvandi
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Between Ghanovati St. and Rastegari St., Gandomi Neighborhood, East Imam Khomeini St., East Ahvaz Health Center
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Web page address**
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Ahvaz 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**
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**Position**
Associate professor
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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