Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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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+98 916 393 7309

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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
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Abdollah Rafiei
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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
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Somaye Makvandi
Position
Associate professor
Latest degree
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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