Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Digital Childbirth Storytelling on Childbirth Self-Efficacy and Psychosocial Adaptation to Pregnancy among Nulliparous Pregnant Women : A Randomized Controlled Trial

Protocol summary

Study aim
To determine the effect of digital childbirth storytelling on childbirth self-efficacy and psychosocial adaptation to pregnancy in nulliparous pregnant women.

Design
Cluster randomized controlled trial with parallel groups and a control group; eight comprehensive health centers as clusters; four centers allocated to intervention and four to control using a random number table; sample size 80 (40 per group); single-blind only for the statistical analyst; non-pharmacological phase.

Settings and conduct
.Cluster randomized trial with pretest-posttest and a control group at comprehensive health centers in Shahrekord; recruitment of nulliparous women at 24–28 weeks of gestation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: providing informed consent; nulliparity; singleton pregnancy; gestational age of 24–28 weeks; age 18–49 years; ability to use digital devices and access the internet; attendance at childbirth preparation classes; no history of infertility or psychiatric disorders and no use of psychiatric medications. Exclusion criteria: lack of informed consent; multiparity or multiple gestation; gestational age outside 24–28 weeks; age outside 18–49 years; inability to use digital devices or lack of internet access; non-attendance at childbirth preparation classes; history of infertility or psychiatric disorders or use of psychiatric medications.

Intervention groups
Intervention: online digital childbirth storytelling package (six educational-narrative animations, two narrated PowerPoints, and educational infographics) over six weeks; Control: usual prenatal care and childbirth preparation classes without the package.

Main outcome variables
Childbirth self-efficacy; psychosocial adaptation to pregnancy.

General information

Reason for update

Acronym
DCST-PSA Trial

IRCT registration information
IRCT registration number: **IRCT20260906070943N1**
Registration date: **2026-10-22, 1405/07/30**
Registration timing: **prospective**

Last update: **2026-10-22, 1405/07/30**
Update count: **0**

Registration date
2026-10-22, 1405/07/30

Registrant information

Name
Ehteram Hashemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-11-06, 1405/08/15

Expected recruitment end date
2027-03-06, 1405/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Digital Childbirth Storytelling on Childbirth Self-Efficacy and Psychosocial Adaptation to Pregnancy among Nulliparous Pregnant Women : A Randomized Controlled Trial

Public title

Effectiveness of Digital Childbirth Storytelling on Childbirth Self-Efficacy and Psychosocial Adaptation to Pregnancy among Nulliparous Pregnant Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study and provide informed consent Gestational age of 24 to 28 weeks Being nulliparous No history of diagnosed psychiatric disorders or use of psychiatric medications based on the health record or participant self-report Ability to use digital devices such as a mobile phone or computer Access to the internet Participation in childbirth preparation classes Singleton pregnancy No history of infertility Age 18 to 49 years

Exclusion criteria:

Presence of a medical or obstetric complication requiring specialized care that makes participation in the study inappropriate Presence of a documented psychiatric or psychological disorder that may substantially affect the assessment of childbirth self-efficacy or psychosocial adaptation. History of childbirth or a previous pregnancy reaching the stage of fetal viability. A confirmed indication for planned cesarean delivery at the time of enrollment. Concurrent participation in a structured childbirth education program or a similar psychological intervention Lack of access to the digital device required to receive the digital childbirth storytelling intervention. Inability to use the digital platform required to receive the intervention. Inability to understand the study information or complete the study questionnaires due to cognitive or language limitations. Unwillingness to provide informed consent before randomization.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eight centers providing childbirth preparation classes will be considered as study clusters. Four centers will be allocated to the intervention group and four centers to the control group using a random number table. Subsequently, the list of nulliparous pregnant women at 24–28 weeks of gestation will be obtained from the SIB health information system of each center. After screening for the eligibility criteria, eligible participants will be selected from each center using simple random sampling according to the predetermined allocation quota for that center. A total of 80 pregnant women will be included in the study, with 40 participants in the intervention group and 40 in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this clinical trial, single-blinding will be used. Blinding will be applied to the statistical analyst; the analyst will not be informed about the content of the intervention received by the groups, and the raw data file will be provided to the analyst under the labels Intervention A and Intervention B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahrekord and Borujen Schools of Nursing and Midwifery and School of

Street address

Research and Technology Deputy, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2026-08-17, 1405/05/26

Ethics committee reference number

IR.SKUMS.NUMHE.REC.1405.057

Health conditions studied

1

Description of health condition studied

Nulliparous pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Childbirth Self-Efficacy
Timepoint
Before the intervention, immediately after the intervention, and 4 weeks after the intervention
Method of measurement
Total score of the Iranian short form of the Childbirth Self-Efficacy Inventory (CBSEI-C32)

Secondary outcomes

1

Description
Psychosocial Adaptation to Pregnancy
Timepoint
Before the intervention, immediately after the intervention, and 4 weeks after the intervention
Method of measurement
Total score of the Prenatal Self-Evaluation Questionnaire (PSEQ)

Intervention groups

1

Description
Digital childbirth storytelling package including six educational-narrative animations, two narrated PowerPoint presentations, and educational infographics, delivered online over six weeks
Category
Behavior

2

Description
Usual prenatal care and childbirth preparation classes, without receiving the digital childbirth storytelling package
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord County Health Center
Full name of responsible person
Ehteram Hashemi
Street address
Next to Mosalla, Shahid Bahonar Street.
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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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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Faranak Safdari
Position
Assistant Professor, Head of the Midwifery Department
Latest degree
Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available