

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Investigating the impact and evaluation of educational intervention based on gamification in childbirth preparation classes on the dimensions of maternal adaptation in pregnant women covered by comprehensive health service centers

Protocol summary

Maternal adjustment, evaluation, reaction (satisfaction), learning

Study aim

-Determining the effect of educational intervention based on gamification in childbirth preparation classes on the dimensions of maternal adaptation during pregnancy in pregnant women covered by comprehensive health service centers in Shahr Gonabad in 1402 - Determining the effectiveness of gamification-based training in childbirth preparation classes based on the first and second levels of the Kirkpatrick evaluation model in pregnant women covered by comprehensive health service centers in Shahr Gonabad in 1402

Design

Clinical trial with control group, with parallel groups, not blinded, randomized on 80 pregnant mothers.

Settings and conduct

in the city of Gonabad Random distribution of pregnant mothers Completing the questionnaire (PSEQ and demographics) and a 10-question test in two groups Separate training in the form of routine training and gamification training Re-completion of the questionnaire (PSEQ and Kirkpatrick) and test Re-completion of questionnaire (PSEQ) and test after one month

Participants/Inclusion and exclusion criteria

Inclusion criteria • Age range of 18-45 years • Literacy for reading and writing • Gestational age 20 to 28 weeks • No medical problems • Absence of pregnancy with special care • No addiction • No intense family conflict • The mother (pregnant woman's mother) must be alive. Exit criteria: • The event of a stressful event • Absence of more than one meeting • Withdrawal from the study • Using virtual training

Intervention groups

Training pregnant mothers in the intervention group in the form of routine and gamification Routine training of pregnant mothers in the control group

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230510058147N1**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

Registration date

2023-06-12, 1402/03/22

Registrant information

Name

Tahere Tavasoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5725 9344

Email address

tavasoli.t@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the impact and evaluation of educational intervention based on gamification in childbirth preparation classes on the dimensions of maternal adaptation in pregnant women covered by comprehensive health service centers

Public title
Investigating the impact and evaluation of the educational intervention based on gamification in childbirth preparation classes on the dimensions of maternal adaptation in pregnant women.

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Willingness to participate in the study
Age range of 18-45 years Literacy for reading and writing
Gestational age 20 to 28 weeks No medical problems (such as diabetes and blood pressure, mental illnesses, multiple births and heart and respiratory diseases)
Absence of pregnancy with special care (history of bleeding in the same pregnancy, placenta previa, cerclage, pregnancy with assisted reproduction methods)
No addiction No intense family conflict The mother (pregnant woman's mother) must be alive.

Exclusion criteria:

The event of a stressful event (divorce, death of close relatives,...) Absence of more than one meeting
Withdrawal from the study Using virtual training

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by simple random; In this way, a list of all pregnant women participating in childbirth preparation classes has been prepared, then people will be randomly selected from the desired list and will be included in the study if they meet the entry criteria; Otherwise, another person will be replaced. Allocation of people to test and control groups will be done using the method of two and four permutation blocks. This list is prepared by the statistical consultant.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used
Assignment
Parallel
Other design features
In this study, a type of game called Mamano is used for education; which was made by the researcher.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

No. 18, Shahid Shurideh 29

City

Gonabad

Province

Razavi Khorasan

Postal code

9691963745

Approval date

2023-05-10, 1402/02/20

Ethics committee reference number

IR.GMU.REC.1402.027

Health conditions studied

1

Description of health condition studied

Education of pregnant mothers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average scores of maternal adaptation

Timepoint

The beginning of the study, immediately after completion and one month after the study

Method of measurement

PSEQ questionnaire

2

Description

Average reaction

Timepoint

Immediately after completing the study

Method of measurement

Kirkpatrick questionnaire

3

Description

Average learning scores

Timepoint

The beginning of the study, immediately after completion and one month after the study

Method of measurement

A 10-question test made by the researcher

Secondary outcomes

1

Description

Maternal adjustment score

Timepoint

First, immediately and one month after the study

Method of measurement

PSEQ questionnaire

2

Description

Educational intervention evaluation score

Timepoint

First, immediately and one month after the study

Method of measurement

Kirkpatrick questionnaire

Intervention groups

1

Description

In 8 sessions, pregnant mothers are trained by gamification and routine for 90 minutes (once a week). The question and answer part of the class is done using a game, and mothers will answer the questions in two groups of 5 people, and for each correct answer, they will receive a bonus card. Questionnaires will be completed by mothers at the beginning of the study, immediately after completion and one month after completion. The teaching content of the book is pregnancy training and preparation for childbirth. The game used was made by the researcher and is made from a number of cards that are placed on a device and the device has a pen, voice and score counter.

Category

Behavior

2

Description

Control group: pregnant mothers who only receive routine training. The content of the training and the number of sessions and its duration are not different from the intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Fayaz Bakhsh comprehensive health service center

Full name of responsible person

Mrs. Dr. Munira Danyai

Street address

Ghadir Square, next to the Blood Transfusion Organization

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Gonabad

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monire.donyaei@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Amin Momeni Moghadam

Street address

On the side of Asian Road, Gonabad University of Medical Sciences

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Aminmomeni90@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Tahere Tavasoli
Position
Midwifery graduate student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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No. 18, 29 Shahid Shourideh St
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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data are pregnant mothers and can be shared after de-identifying the names of all individuals.

When the data will become available and for how long

The access period starts after the results are printed

To whom data/document is available

Researchers in the field of midwifery training and other medical science groups

Under which criteria data/document could be used

Researchers can use the work method, the type of participants by mentioning the name of the main researcher and the relevant university.0

From where data/document is obtainable

Tahere Tavasoli, tahere.tavasoli.55@gmail.com, mobile number 09157271241 Dr. Fariba Askari faribaaskari10@yahoo.com, mobile number 09151778676

What processes are involved for a request to access data/document

In case of a request, the request will be answered within a week after the review.

Comments