

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the Effectiveness of Virtual Reality and Chewing Gum on intensity of pain, Anxiety and Mothers Satisfaction from Labor Experience

Protocol summary

Study aim

Comparing the Effectiveness of virtual reality and Chewing Gum on the severity of Pain, Anxiety and satisfaction of Mothers with labor Experience

Design

Clinical trials with control group, three groups, with parallel groups, blind, randomized.

Settings and conduct

A total of 96 women will be referred to Allama Bhlol Gonabadi Hospital for delivery. First, a questionnaire on personal and reproductive characteristics is completed through a question from Zao and his case file. The pain ruler and the obstetric and demographic information checklist and the Spielberger Anxiety Inventory are completed before the intervention by the sample population. A pain reliever and the Spielberger anxiety questionnaire are completed immediately after each intervention, as well as the first 30 minutes after each intervention. The McKay Maternity Satisfaction Questionnaire is completed by the three groups after delivery.

Participants/Inclusion and exclusion criteria

Company satisfaction in research

Intervention groups

To chewing gum, one gram of chewing gum without ornamental mint sugar that is active at the beginning of the phase (dilatation 4 to 5 cm), and they are asked to go for at least 20 minutes. Also, for the second time in a dilatation of 7-8 cm, this group is given an orbit gum that lasts for 20 minutes. In the virtual reality group, virtual reality glasses are used twice, the first intervention at the beginning of the active phase and the second intervention in dilatation 7-8 cm. Each intervention is given for 20 minutes. For this study, distorted modes of view such as river, beach, waterfall, and lake have been used. In the control group, no intervention is performed, just as in the other two groups, the analgesia and the anxiety questionnaire are measured simultaneously with the intervention group.

Main outcome variables

Severity of labor pain; Satisfaction with delivery; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041963N1**

Registration date: **2018-12-27, 1397/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-27, 1397/10/06**

Update count: **0**

Registration date

2018-12-27, 1397/10/06

Registrant information

Name

Atefeh Ebrahimian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Virtual Reality and Chewing Gum on intensity of pain, Anxiety and Mothers Satisfaction from Labor Experience

Public title

Comparing the Effectiveness of Virtual Reality and Chewing Gum on intensity of pain, Anxiety and Mothers Satisfaction from Labor Experience

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Live Embryo Singetone Pregnancy Mother's age is between 18 and 35 years old The Gestational Age is 37-42 weeks (based on the first day of the last Menstruation or first trimester Sono) A Dilatation of 3-5 cm with regular Uterine contractions indicating active phase Satisfaction to Participate in the Research Without known medical conditions based on patient records (including history of or current infection to any systemic disease, such as Diabetes, High Blood Pressure, Heart Disease, Kidney, Nervous, Liver, Gastrointestinal, Respiratory, Thyroid) Not having an abnormal Embryo or limiting intrauterine growth Vertex Expansion Low risk pregnancy (lack of infertility, pre-eclampsia, Placenta Previa , Placental abruption) Decolmers are normal at the acceptance of normal fetal heart rate (no tachycardia with fetal heart rate greater than 160, bradycardia with pulmonary heart rate of less than 110, late dropout, and severe drop in heart rate) The embryonic curtains are healthy or less than 12 hours since they were torn Lack of history of mental illness No history of motion Sickness Not blind

Exclusion criteria:

Mother's unwillingness to cooperate Occurrence of Midwifery problems (Placental abruption during labor, fast delivery, fetal distress, intra uterine death, Thick meconium) Chewing Gum less than 20 minutes Less than 20 minutes of virtual reality movie viewing Use of Entonox and Spinal and Epidural Anesthetics

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

The division of people into each of the three groups (chewing gum, virtual reality, and control) will be done randomly, in this way, a number of cards to select a researcher (in line with sample size or more) as a

chewing gum group (card Green) and the same number of cards for the virtual reality group (red card) and the same number of cards for the control group (white card), then by merging the cards together (flipping) the cards inside A black box is poured. A sample card is issued by each individual and its allocation is recorded, and that card is returned to the other cards after it is exited. Then the cards are merged again and another card is removed. This process continues to reach a random sequence according to sample size

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are not aware of which group (chewing gum and intervention group, seeing virtual reality or control film) are not known (one-way blind). In the maternity research environment, each woman gives birth to her own room, so the research units do not deal with each other.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Gonabad University of Medical Sciences

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Asian Roadside Border

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Razavi Khorasan

Postal code

9691793718

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.GMU.REC.1397.088

Health conditions studied**1****Description of health condition studied**

Labor pain, Anxiety from childbirth, Satisfaction with delivery

ICD-10 code

080-084

ICD-10 code description

Delivery

Primary outcomes

1

Description

Labor pain

Timepoint

Before the intervention, immediately after the intervention and 30 minutes after the intervention

Method of measurement

Visual Analog Scale of Pain

2

Description

Anxiety

Timepoint

Before the intervention, immediately after the intervention and 30 minutes after the intervention

Method of measurement

Spielberger state questionnaire

3

Description

Childbirth satisfaction

Timepoint

Postpartum

Method of measurement

Mackey Childbirth Satisfaction Rating Scale

Secondary outcomes

1

Description

Duration of active phase of labor

Timepoint

After the intervention

Method of measurement

Kronometer

Intervention groups

1

Description

Intervention group: Group 1 Chewing gum 1 grams without sugarcane orbit for 20 minutes twice (dilation of 3-5 cm and 7-8 cm)

Category

Treatment - Other

2

Description

Intervention group: GRouh 2 Interventions of virtual reality films with special glasses for 20 minutes twice (dilatation of 3.5 cm and 7-8 cm) were used for this study of distorted modes of view such as the river, the beach, the waterfall, and the lake.

Category

Treatment - Other

3

Description

Control group: No intervention will take place.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlol Hospital Gonabad

Full name of responsible person

Atefeh Ebrahimiyan

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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?

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

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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

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