Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Country
Iran (Islamic Republic of)
Phone
+98 31 3420 0651
Email address
ebrahimiyan127@gmail.com

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

Street address
Asian Roadside Border

City
Gonabad

Province
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
Street address
Asian Road Rim, Gonabad University of Medical Sciences
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 31 3420 0651
Email
ebrahimiyan127@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Sajjadi
Street address
Asian Road Rim, Gonabad University of Medical Sciences
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Email
sajjadi@gmu.ac.ir
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
Atefeh Ebrahimiyan

Position
Master Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Asian Road Rim, Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3028

Email
ebrahimiyan127@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Dr. Roghaieh Rahmani

Position
Associate

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Asian Road Rim, Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
۹۶۹۱۷۹۳۷۱۸

Phone
+98 51 5722 3028

Email
roghaiehrahmany@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Atefeh Ebrahimiyan

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Asian Road Rim, Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3028

Email
ebrahimiyan127@gmail.com

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