Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Virtual Reality on Anxiety, Stress, and Hemodynamic parameters among Primiparous Women During Cesarean Section: A Randomized controlled Clinical Trial

Protocol summary

Study aim

This study aims to: investigates the effect of virtual reality on anxiety, stress, and hemodynamic parameters among primiparous women during cesarean section.

Design

parallel, group, Non blind, Randomized controlled clinical trial

Settings and conduct

operating theater / Maternal and Children Hospital in Najran city.

Participants/Inclusion and exclusion criteria

Inclusion criteria were parturient with normal vision and hearing abilities, no history of generalized anxiety disorder or mental illness, free from serious obstetrics complications (according to the obstetrician evaluation), no increased intraoperative risk (e.g., placental disturbance) that identified in the preoperative period and accept to participate on the study. Any woman developed intraoperative complication will be excluded from the study.

Intervention groups

For the intervention group, the virtual reality glass (VR) will be applied after regional anesthesia; then, hemodynamic parameters were assessed before intervention, immediately after anesthesia, skin incision, delivery, skin suture, and two hours after surgery. Anxiety will be reassessed at siting on surgery table, after completing skin suturing, and recovery time (2 hours postoperative). Stress will be reassessed after completing skin suture and two hours post-operative. Women is also asked about her satisfaction about the care provided.

Main outcome variables

Anxiety, Stress, and Hemodynamic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050192N2**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date

2021-08-06, 1400/05/15

Registrant information

Name
Wafaa Elgzar
Name of organization / entity
Damanhour University
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Egypt
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+20 13 2265261
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-12-30, 1400/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Virtual Reality on Anxiety, Stress, and Hemodynamic parameters among Primiparous Women During Cesarean Section: A Randomized controlled Clinical Trial

Public title

The Effect of Virtual Reality on Anxiety, Stress, and Hemodynamic parameters among Primiparous Women During Cesarean Section: A Randomized controlled Clinical Trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Parturient with normal vision Parturient with normal hearing No history of generalized anxiety disorder No history of mental illness Free from serious obstetrics complications (according to the obstetrician evaluation) No increased intraoperative risk (e.g., placental disturbance) that identified in the preoperative period Accept to participate on the study.

Exclusion criteria:

Any woman developed intraoperative complication will be excluded from the study.

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: **350**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be randomly assigned to intervention or control group through randomization block technique. Six steps were followed to carryout participants' assignment using randomization block technique. First, the investigators will write a list contains numbers from 1 to 350. Second; the investigators will prepare small pieces of papers that comprise numbers from 1 to 350. Third; the investigators will fold each piece of papers to hide the written number, then it will be collected in a large bowl. Fourth; the researchers divided the 350 pieces of papers into 35 blocks in a random and blind manner. Each block contains 10. Fifth; from each block, five pieces of papers will be selected randomly and blindly to the intervention group and the remaining 5 pieces of papers will be assigned to the control group. A total of 175 numbers will be assigned to each group. Sixth; the classification of cases will be recorded in the pre-prepared list (the word intervention or control will be recorded in front of each number) to be considered at the time of data collection. The intervention group (G1) included 175 participants and the control group (G2) involved 175 patients who will be submitted to routine care.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Najran University ethics committee

Street address

Elmashalia Najran University campus

City

Najran

Postal code

55461

Approval date

2021-04-25, 1400/02/05

Ethics committee reference number

25-04-2021-3NEC

Health conditions studied

1

Description of health condition studied

Caesarian section

ICD-10 code

O34.21

ICD-10 code description

Maternal care for scar from previous cesarean delivery

Primary outcomes

1

Description

Stress

Timepoint

Stress will be reassessed after completing skin suture and two hours post-operative. Women is also asked about her satisfaction about the care provided.

Method of measurement

Part III: Emotional preoperative stress (B-MEPS)Caumo (2016) first developed this scale, it will be developed to measure the emotional preoperative stress. It composed of 15 items, 3 of them rated on 4-point Likert scale, 11 of them rated on 3-point Likert scale and one of the have two answers. The high score indicates high stress.

2

Description
Anxiety
Timepoint
Anxiety will be reassessed at siting on surgery table, after completing skin suturing, and recovery time (2 hours postoperative).
Method of measurement
Part: IV: A novel visual facial anxiety scale for assessing preoperative anxiety Cao et al, 2017 developed this scale. This Self-reported scale to measure anxiety during clinical practices. It composed of six faces that asses different degrees of anxiety from none (1), mild (2), mild-moderate (3), moderate (4), moderate-high (5) and highest (6). The highest score indicates high degree of anxiety.

3

Description
Hemodynamic parameters and fetal APGR score
Timepoint
hemodynamic parameters were assessed before intervention, immediately after anesthesia, skin incision, delivery, skin suture, and two hours after surgery.
Method of measurement
Part II: Maternal hemodynamic parameters and newborn APGAR assessment sheet:The researchers developed this part after reviewing the current literature. This part will be used to register the maternal pulse, systolic, diastolic and mean blood pressure, respiratory rate and o2 saturation at patient admission, skin incision, delivery, skin suture and two hours after surgery. This part also contained questions about the incidence of nausea and drowsiness or vomiting. At the end of this part fetal APGAR sheet is present to asses at 1 and 5 minutes.

Secondary outcomes

empty

Intervention groups

1

Description
For the intervention group, the virtual reality glass (VR) will be applied after regional anesthesia; then, hemodynamic parameters were assessed before intervention, immediately after anesthesia, skin incision, delivery, skin suture, and two hours after surgery. Anxiety will be reassessed at siting on surgery table, after completing skin suturing, and recovery time (2 hours postoperative). Stress will be reassessed after completing skin suture and two hours post-operative. Women is also asked about her satisfaction about the care provided.
Category
Treatment - Other

2

Description
For the control group, they were left for routine hospital care. The same measurement timing for stress, anxiety, hemodynamic parameters neonatal APGAR score and maternal satisfaction about care provided were followed.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Maternal and Children Hospital in Najran city
Full name of responsible person
Heba Abdine
Street address
Elmashalia Najran University campus
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55461
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+966 17 542 8888
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wafaa.elgzar@nur.dmu.edu.eg

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Najran University
Full name of responsible person
Wafaa Taha Elgzar
Street address
Elmashalia Najran University campus
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Postal code
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+966 17 542 8888
Email
wafaa.elgzar@nur.dmu.edu.eg
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Najran University
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
Najran University
Full name of responsible person
Wafaa Taha Elgzar
Position
Associate professor
Latest degree
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Person responsible for updating data

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Other areas of specialty/work
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Postal code
66241
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+966 17 542 8888
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wafaa.elgzar@nur.dmu.edu.eg

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
published research report that contains all the study findings
When the data will become available and for how long
within one year and will be available long life
To whom data/document is available
public
Under which criteria data/document could be used
for scientific use and public education
From where data/document is obtainable
non
What processes are involved for a request to access data/document
non
Comments
non