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Can using an electric massage chair reduce anxiety before a planned caesarean section?

Submission date
08/05/2026

Recruitment status
Recruiting

Registration date
14/05/2026

Overall study status
Ongoing

Last Edited
13/05/2026

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many women feel anxious before a planned caesarean section, which is an operation to deliver a baby through a cut in the abdomen and womb. High anxiety before surgery can affect both physical and emotional wellbeing. This study aims to find out whether using an electric massage chair can help reduce anxiety before a planned caesarean section.

Who can participate?
Women aged 18 years or older who are pregnant with one baby at 37 weeks of pregnancy or later, are planned to have a caesarean section, and are experiencing anxiety before their operation can take part. Participants must be able to give consent and communicate in English or Bahasa Melayu.

What does the study involve?
Participants will be randomly placed into one of two groups. One group will receive massage using an electric massage chair, while the other group will sit in the same chair but without the massage function switched on. Those in the massage group will receive two sessions lasting 30 minutes each. One session will take place the day before surgery, and the other will take place within four hours before surgery. Researchers will measure anxiety levels before and after the sessions using a simple questionnaire.

What are the possible benefits and risks of participating?
Participants may benefit if the massage helps to reduce their anxiety before surgery. The study is considered low risk because it does not involve medication and uses a gentle massage setting. Some participants may experience mild discomfort from sitting in the chair or from the massage itself.

Where is the study run from?
The study is run from Universiti Malaya Medical Centre in Malaysia.

When is the study starting and how long is it expected to run for?
May 2026 to April 2027.

Who is funding the study?
This study is investigator initiated and funded.

Who is the main contact?
Dr Dhivya Dharshini Subramaniam at Universiti Malaya Medical Centre in Malaysia
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Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title
Mechanical massage with an electric massage chair and preoperative anxiety in planned caesarean section: a randomised control trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/05/2026, Medical Research Ethics Committee, University of Malaya Medical Centre (Pusat Perubatan Universiti Malaya (ppum) Jalan Profesor Diraja Ungku Aziz Seksyen 13, Petaling Jaya, 50603, Malaysia; +60 37949 3209/2251; ummc-mrec@ummc.edu.my), ref: 2025123-15958

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Anxiety at planned caesarean

Interventions
This study is a prospective, single-centre, parallel-group, assessor-blinded randomized controlled interventional trial evaluating the effect of mechanical massage using an electric massage chair on preoperative anxiety in women undergoing planned caesarean section. Eligible participants are pregnant women aged ≥18 years with singleton pregnancies at ≥37 weeks' gestation and clinically significant preoperative anxiety (Perioperative Anxiety Scale-7 [PAS-7] score ≥8). Participants will be randomized in a 1:1 ratio using computer-generated random allocation with sequentially numbered opaque envelopes into either the intervention arm (ON-MASSAGE) or control arm (OFF-MASSAGE).

Participants in the ON-MASSAGE arm will receive two 30-minute sessions of seated mechanical massage using the Zero Healthcare uShine Massage Chair. The massage programme will be standardized to a preset "relax/gentle" mode at fixed low intensity (approximately level 2/5). Sessions will be conducted one day prior to surgery and within four hours before the planned caesarean section. Participants will remain in a semi-reclined position during the intervention to minimise aortocaval compression. Reduction in massage intensity is permitted for comfort; however, participants will not be allowed to increase intensity or alter programme mode.

Participants in the OFF-MASSAGE control arm will sit in the identical massage chair for the same duration and positioning, but with the massage function deactivated (inactive sham-device seated control). This control is intended to account for environmental exposure, resting effects, and staff interaction. Baseline maternal vital signs, fetal heart rate (as per routine obstetric care), and symptom screening will be performed prior to each session. Outcome assessors and data analysts will remain blinded to group allocation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Zero Healthcare uShine Massage Chair

Primary outcome(s)
1. Preoperative measured using Perioperative Anxiety Scale-7 (PAS-7) at baseline to 30 minutes after completion of the second intervention session

Key secondary outcome(s)

Completion date
08/04/2027

Eligibility

Key inclusion criteria
1. PAS-7 score ≥ 8 out of a maximum score of 28, indicating preoperative anxiety
2. Planned caesarean section
3. Singleton pregnancy
4. Term pregnancy (gestational age ≥ 37 weeks)
5. Adult (age ≥ 18 years)
6. Reassuring fetal status (based on CTG monitoring as part of standard care)
7. Able to give consent
8. Able to communicate in English or Bahasa Melayu

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Known psychiatric illnesses (e.g., depression, bipolar disorder, schizophrenia, etc.) requiring current medications or other treatment.
2. Gross fetal anomalies
3. Placenta praevia
4. Morbidly adherent placenta spectrum
5. Major maternal medical disorders (Eg: cardiac disease, renal failure, etc)

Date of first enrolment
25/05/2026

Date of final enrolment
08/04/2027

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Malaya Medical Centre
Malaysia

Sponsor information

Organisation
Universiti Malaya Medical Centre

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Case report form version 1	18/07/2025	08/05/2026	No	No
Participant information sheet	version 1	18/07/2025	08/05/2026	No	Yes
Protocol file	version 1	18/07/2025	08/05/2026	No	No