



RESEARCH PROTOCOL

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TITLE OF RESEARCH PROPOSAL
MECHANICAL MASSAGE WITH AN ELECTRIC MASSAGE CHAIR AND PREOPERATIVE ANXIETY IN PLANNED CAESAREAN SECTION: A RANDOMISED CONTROL TRIAL
KEY WORDS
BACKGROUND/ JUSTIFICATION
Childbirth represents a major milestone in a woman's life and is frequently associated with intense emotional reactions, particularly anxiety. This form of anxiety involves a heightened state of tension and concern about possible negative outcomes. [1] Anxiety can be broadly categorized into two types: state anxiety and trait anxiety. State anxiety refers to a temporary emotional response to specific situations that typically fades once the triggering factor is removed. In contrast, trait anxiety reflects a more enduring personality characteristic that persists over time. [2] Globally, the rate of caesarean deliveries has risen significantly, especially over the last 30 years, with projections suggesting that nearly 29% of births will occur via caesarean section by 2030. [10] Among women undergoing caesarean delivery, preoperative anxiety is highly prevalent, affecting up to 63% of patients. [3] Elevated anxiety levels before surgery have been linked to various complications, including greater postoperative pain, increased use of pain medication, higher incidences of nausea and vomiting, delayed recovery, heightened risk of infection, and generally poorer surgical outcomes and patient satisfaction. [4] Addressing preoperative anxiety is, therefore, essential for improving recovery, minimizing hospital stay, and enhancing overall patient wellbeing. [5] To assess preoperative anxiety more effectively, the Perioperative Anxiety Scale-7 (PAS-7) has been developed. [6] We have decided to use this tool compared to anxiety scales such as the State-Trait Anxiety Inventory (STAI), the Hamilton Anxiety Scale (HAMA) and Generalised Anxiety Disorder 7 (GAD-7) for its higher sensitivity and focus on perioperative anxiety. By incorporating somatic symptoms, the PAS-7 offers a more comprehensive evaluation of a patient's anxiety status. Given the high incidence and negative impact of preoperative anxiety, its management has become a clinical priority. [7] Current approaches are divided into pharmacological and non-pharmacological treatments. Medications such as sedatives and anxiolytics are commonly used, though they carry risks including drowsiness, respiratory issues, and potential interference with anaesthetic agents. Consequently, non-drug alternatives are gaining traction in clinical settings. Massage therapy, for instance, is believed to influence the sympathetic nervous system and improve the hypothalamic-pituitary-adrenal axis function. It also enhances circulation, potentially benefiting vascular health. [8] While manual massage requires skilled personnel and is resource-intensive, mechanical massage using electric chairs offers a more practical alternative. These devices deliver consistent, targeted massage, are reusable, and may be more cost-effective in healthcare environments. [9] A 2024 proof of concept study conducted at UMMC found that mechanical massage using an electric chair was both safe and effective in reducing labor pain. [9] However, its potential in reducing anxiety, particularly in obstetric patients, remains underexplored.

This study aims to investigate whether mechanical massage using an electric chair on admission for planned caesarean section delivery can acutely reduce preoperative anxiety. To evaluate this, we have designed a randomized-controlled trial as a preliminary investigation into this hypothesis.

OBJECTIVES & EXPECTED OUTCOMES

Objectives:

The primary objective of this study is to evaluate the impact of mechanical massage with an electric massage chair on anxiety at planned caesarean.

The secondary objectives include maternal and neonatal outcomes for evaluating effectiveness and safety of the intervention.

Expected outcomes: We hypothesise that mechanical massage with an electric massage chair will acutely reduce the pre caesarean anxiety.

METHODOLOGY

Study design

A randomised control trial. All agreeable potential participants will be asked to complete the PAS-7 questionnaire as screening before recruitment. Patient screened positive for preop anxiety and fulfilling other study criteria as per the eligibility assessment form (EAF) will be invited to participate.

The patient information sheet (PIS) will be provided and queries about the study are invited. All queries will be responded by the recruiting provider. Written informed consent will be obtained, and their relevant details and characteristics transcribed onto the Case Report Form (CRF).

Intervention 1: Sitting comfortably for 30minutes on the electric massage chair with a massage programme as selected by participants activated in two separate sessions at least 12hours apart. The second session will be within 4 hours of the planned caesarean.

Intervention 2: Sitting comfortably for 30minutes on the electric massage chair with programme not activated in two separate sessions at least 12hours apart. The second session will be within 4hours of the planned caesarean.

Randomisation

Randomisation sequence will be generated using <https://www.sealedenvelope.com/simple-randomiser/v1/lists>, in blocks of 4 or 8, in 1 to 1 ratio, by a co-investigator who will not be involved in the recruitment process. Allocation will be sealed within a numbered opaque envelope. Randomisation will be implemented using strict sequential opening of the lowest-numbered remaining sealed envelopes for the latest recruit.

Intervention

The intervention will take place twice. First, 1 day prior to the operation and second time on the day of scheduled elective caesarean date. The outcome will then be assessed using PAS – 7 questionnaire 30min post second session of intervention.

Massage Chair Intervention (ON-MASSAGE): Participants will be instructed on how to recline and control the massage chair programmes. Participants are asked to adjust the massage chair reclined position to their own comfort. An automated massage programme of the participants own choosing will be activated

for 30minutes. Participants may change the massage programme or stop the session on their own volition. We will be recommending using relaxing or spa massage mode which has the least intensity to the participants, but they may change the programme on their own volition. Participants will vacate the chair after the 30-minute session and return to their usual inpatient activity.

Control Intervention (OFF-MASSAGE): Participants will be instructed on how to recline and control the massage chair programmes. Participants are asked to adjust the massage chair reclined position to their own comfort. The participant is instructed not to activate any massage programme. The participant sits passively and comfortably for 30minutes. Participants may adjust the recline position or stop the session on their own volition. Participants will vacate the chair after the 30-minute session and return to their usual inpatient activity.

Blinding

Due to the obvious nature of the interventions and the instructions given to the participants, blinding is not considered feasible.

Stopping rule

Given the nature of the interventions (30minutes reclined comfortably on an electric massage chair) and the main objective is preop anxiety using PAS- 7 scale, we have not constituted the stopping rule. However in the unlikely event of major harm occurring that is related to the study intervention, the study will be paused for the department's safety committee and Ethics committee to consider the issue.

Inclusion criteria

- PAS-7 Score more than equals to 8 out of max score of 28 (Denoting state of preoperative anxiety)
- Planned caesarean section
- Singleton pregnancy
- TERM (Gestational age $\geq$ 37 weeks)
- ADULT (Age $\geq$ 18 years)
- Reassuring fetal status (CTG monitoring as part of standard care)
- Able to consent
- Able communicate in English/ Bahasa Melayu

Exclusion criteria

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

Sample size

A pretrial survey on 100 patients admitted for planned caesarean using the pas-7 questionnaire identified that 66/100 (66%) had pre caesarean anxiety.

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Assuming that following control sham massage chair session, the pre caesarean anxiety rate will reduce to 80%, and following active massage chair session the rate will reduce to 60%, using OpenEpi online sample size calculator <https://www.openepi.com/SampleSize/SSMean.htm>, inputting alpha 0.05, beta 0.2, and a 1:1 ratio, 84 are required in each arm. Factoring in a dropout rate of 20%, $84 / 0.8 = 105$ participants are needed 105 in each arm for a powered study (total 210).

Data Analysis

Data will be entered into a statistical software package SPSS (Version 26, IBM, SPSS Statistics). The Student t test was used to analyse means of continuous data that is normally distributed, the Mann-Whitney U test for non-normally distributed data or ordinal data, and Chi-square test for categorical data. Two-sided P values will be reported and $p < 0.05$ taken as the level of significance. Analysis will be on intention to treat basis.

RESEARCH DATA

Where will the data be kept? (Please provide details)

- Manual records: stored in filing cabinets in UMMC
- Digital records" password-protected computers accessible only to researchers

Who will have access to the research data?

- Principle investigator and approved co-investigators

How long will the data be kept? (suggestion: at least 7 years)

- Minimum of 7 years after completion of the study

BUDGET / FINANCIAL SUPPORT (IF APPLICABLE):

No	Budget Detail	Amount (RM)
1.		
2.		
3.		
Grand Total		

GANTT CHART

YEAR/ MONTH	2 0 2 5	2026												2027				
		1 2	1	2	3	4	5	6	7	8	9	1 0	1 1	1 2	1	2	3	4
ACTIVITIES																		
1. Ethics application & approval																		
2. Data collection																		
3. Data entry																		
4. Data analysis																		
5. Manuscript writing																		
6. Submission for publication																		
7. Research progress report & presentation																		

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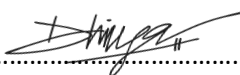
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POTENTIAL IMPACT

3. Please state whether you have submitted this research proposal for funding, now or before
- ☐ Yes: If Yes, which grant? _____
- ☒ No

This proposal will be kept strictly private and confidential. It will not be shared with anyone without your prior approval.

Name of Researcher (CAPITAL): DHIVYA DHARSHINI A/P SUBRAMANIAM

Signature of Researcher: 

Date: 18/7/2025