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VERSION DATE: *30/12/25*

UNIVERSITY OF MALAYA MEDICAL CENTRE

RESEARCH PROTOCOL

1. Particulars of Researcher

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TITLE OF RESEARCH PROPOSAL

POSTOPERATIVE SATISFACTION AND ACCPETABILITY FOLLOWING CESAREAN DELIVERY: A RANDOMIZED CONTROLLED TRIAL COMPARING ABDOMINAL BINDER TO NON PRESSURE BINDER USE

KEY WORDS

Abdominal binder, caesarean delivery

BACKGROUND/ JUSTIFICATION

Caesarean delivery according to World Health Organization (WHO), continues to rise globally, accounting to 1 in 5 (21%) of all childbirths. This number is set to rise over the coming decade, with nearly a third (29%) of all births likely to take place by caesarean section by 2030. According to the data from the Malaysian National Obstetrics Registry, about 1 in 5 deliveries in Malaysia are caesarean deliveries.

Caesarean delivery (CD) is generally considered a safe surgical procedure, however still carry negative outcome including postoperative pain, infection, venous thromboembolism (1). Recovering from a caesarean section requires special attention to abdominal area. Surgical site infection occurred in 3%–15% (2). It is multifactorial, influenced by a combination of patient, procedure, and/or healthcare facility-related factors, yet it can be prevented.

Pain being the most common, experience during wound healing, particularly in the initial inflammatory phase, but unresolved or excessive pain can hinder the healing process and negatively impact a patient's quality of life. Managing wound-related pain effectively is crucial for promoting healing and ensuring patient well-being (3).

Abdominal binder (AB) is a non-pharmacological method of pain relieve after surgical procedures. It acts by minimizing stress on the wound, promoting support thus reducing abdominal muscle activity during ambulation, improving overall mobility, and promote deep breathing (4). By improving mobility and potentially reducing the risk of wound dehiscence (separation of the incision) or other complications, the binder may indirectly lower the overall risk of infection. In addition, it might speed up involution of uterus and surrounding organs to their pre-pregnancy positions by compressing the abdomen, improve blood circulation and tissue repair (5).

The aim of abdominal binder is to protect incision and reduce postoperative complication but their adverse impact on intra- abdominal pressure should also be considered. Lasithiotakis et al analysed one case of spontaneous non traumatic trans diaphragmatic intercostal hernia and reported that high intra-abdominal pressure caused by a long term AB wear can cause slimming and loosening of the diaphragm and intercostal muscle thus weakening their resistance to the rapidly increased pressure of the thoracic intra-abdominal cavity (6). However, this is a very rare side effect of the abdominal binder. A study by Arici et al in 2023 showed there was no statistically significant relationship between abdominal binder use and the development of incisional hernia 3 years after the abdominal surgery (7)

More common but less serious side effects include skin irritation and discomfort or pain. The use of ABs should be avoided in patients with intra-abdominal hypertension or risk factors for intra-abdominal hypertension, and if a binder must be used, the application time should be minimal (8). Current studies on binders after CD is mixed, small scale mostly limited to pain.

Enhanced Recovery After Surgery (ERAS) protocols emphasize early ambulation, reduced opioid use, and functional recovery postoperatively. The potential of abdominal binders to contribute to these ERAS goals remains under-explored in high-quality studies.

A 2019 systematic review by Seo et al. further highlighted the role of patient acceptability and perception of therapeutic interventions as a key dimension of postoperative care quality. However, few studies have objectively evaluated maternal acceptability and pre-intervention anxiety in relation to abdominal binder use.

This study aims to fill the gaps by determining patient acceptability on AB use through patients reported outcome. This links directly to ERAS core outcomes and adds body image domains which are essential to improve maternal well-being, mental health and confidence.

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OBJECTIVES & EXPECTED OUTCOMES

Objectives:

- To determine the impact of post-Caesarean application of abdominal binder based on patient reported outcome measure of acceptability, satisfaction and confidence.

Hypothesis:

- Women who use an abdominal binder after Caesarean delivery will report **higher acceptability, satisfaction, and body confidence** at **24 hours** compared with women assigned to sham binder

METHODOLOGY

Study design

Randomized Controlled Trial

Place of Study: The trial will be conducted at the Department of Obstetrics and Gynaecology, University Malaya Medical Centre (UMMC).

Population of Study: The study population will consist of eligible and consented patient undergoing caesarean delivery

Inclusion criteria

- Planned including category 3&4 caesarean delivery (CD)
- Age > 18 years old
- Gestational age > 36weeks gestation

Exclusion criteria

- General anaesthesia
- Blood loss > 1L
- Use of abdominal drain or additional surgical procedures
- Patient with underlying chronic pelvic pain
- Unable to fit the abdominal binder
- Unable to come physically to clinic follow up

Study flow

Patients undergoing planned or category 3 or 4 CD will be approached, recruited based on inclusion and exclusion criteria. They will be divided into sham group and intervention group after randomization

Pre operatively, both study groups acceptability toward abdominal binder use will be assessed using Likert scale (very uneasy, very comfortable, or unsure)

Intervention: Eligible participants will be fitted with appropriately sized abdominal binder (elastic, breathable, latex free binder size S/ M/L/XL) after transfer out from OT. For application of the appropriate abdominal binder according to the abdominal circumference, the abdomen will be measured by a standard measuring tape, Participants will be instructed to wear the binder **continuously for the first 24 hours**, only removing for hygiene or clinical indication; nursing staff will check binder fit and ask for symptoms of irritation or discomfort and document any removals

Control/ Sham group: Participants allocated to the control group will receive a **sham binder** (tension-free binder). Binders will be pre-marked, and patients will be instructed to fasten the binder only up to the marked site to prevent tension application. The type and quality of the binder will be identical to the intervention group.

Standard care: Both groups will continue to receive routine postoperative care and standard analgesia according to hospital protocols.

Compliance to abdominal binder will be monitored and time off use of abdominal binder will be recorded. Any skin changes while on abdominal binder will be assessed and recorded.

Outcome Assessments

- **Primary outcome (24h):**
    - **Patient acceptability of binder use using 3 point Likert's scale**
    - **Patient satisfaction** with binder use assessed using a **VNRS 0–10** (0 = not satisfied at all, 10 = very satisfied).
    - **Body confidence** assessed using **2-item questionnaire**:
        1. "How well supported does your abdomen feel when you move around?"
        2. "How confident do you feel about using your body (standing, walking, and sitting) since surgery?"
           (Rated on a 5-point Likert scale: 1 = Not at all, 5 = completely).

- **Secondary outcome:**

- **Pain at first ambulation and 24 hours:** assessed using VNRS 0–10.
- **Time to first ambulation:** recorded in EMR.
- **Day 7:** Continued use of binder and wound assessment (REEDA).
  Follow-up conducted at postnatal clinic
- **Reason for early discontinuation (before 24 hours/ after discharge)**

Safety Monitoring
Skin changes and wound condition will be assessed prior to discharge and Day 7 using the **REEDA scale** (redness, edema, ecchymosis, discharge, approximation). Patients reporting significant irritation or skin issues will be managed according to standard care and, if necessary, discontinue binder use. A pamphlet outlining our study—including instructions on applying the abdominal binder, red flag signs to watch for (any discomfort which may be increasing in nature, numbness, tingling, or loss of sensation, skin redness that does not fade, blisters, rash, or sores, difficulty breathing, worsening abdominal pain, nausea or vomiting), and contact information in case any issues arise—will be provided to participants together with patient information sheet.

Randomization:
Randomization will be conducted using a computerized sequence generator to ensure unbiased allocation. The sequence will be generated in random blocks of 4 or 8 (1:1 ratio) via https://www.sealedenvelope.com/simple-randomiser/v1/lists by a co-investigator not involved in trial recruitment. Participants will be assigned to one of two trial arms by opening a numbered, sealed, opaque envelope, with the lowest numbered envelope available assigned to the latest recruit.

Subject withdrawal:
If a participant reports discomfort or any adverse effects while using the abdominal binder, the participant will be advised to temporarily stop using the binder. The research team will assess the nature and severity of the discomfort (**e.g., skin irritation, pain, breathing difficulty, spontaneous hernia).** Appropriate management will be provided, such as adjusting the binder size or fit, providing padding, or discontinuing use if necessary. Participants who choose to discontinue the binder will be allowed to withdraw from that aspect of the study without penalty. Their standard postnatal medical care will continue as usual, and the withdrawal will be documented.

Duration:
This study will be conducted over a period of 12-14 months starting as soon as approved by Ethical Committee Board

Data collection
Data collection started on the day before the patients underwent surgery, and finished on the seventh day after surgery if there is no complication (surgical site infection) and up to 14 days if there is any.

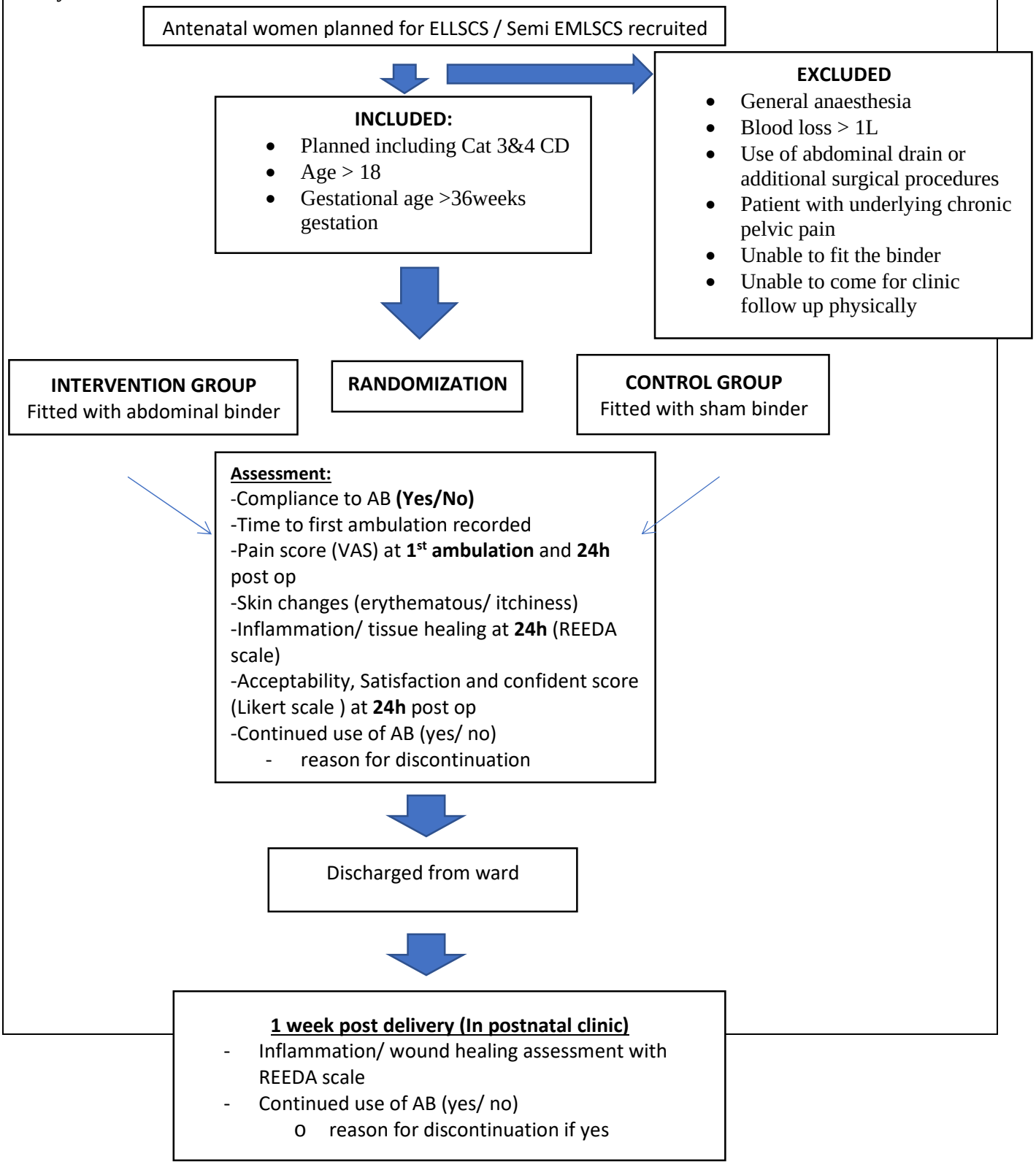
Sample size

Using Power and Sample Size program, assuming the response within each subject group distributed with standard deviation 1.5. If the true difference in the experimental and control means is 1, we will need to study 62 experimental subjects and 62 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The P value associated with this test of this null hypothesis is 0.005. Taking into consideration of 20% drop out rate, the total sample size that we have to take in this study is 150

Data Analysis

Data for the primary and secondary objective will be obtained from the case report form. Then it will be entered in the SPSS software and analysed.

Study Flow



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RESEARCH DATA

Where will the data be kept?
The hardcopy data will be kept in a secured locker with a lock in the Obstetrics and Gynaecology Department of UMMC. The keys to the lock will be kept by the primary investigator.

Who will have access to the research data?
The primary investigator (Khaulahradhiah Sahid), co- investigator (Dr Wan Nurul Ezyani) and supervisor (Dr Maherah Kamarudin)

How long will the data be kept?
Data will be kept at least until 2036

BUDGET / FINANCIAL SUPPORT (IF APPLICABLE):

No	Budget Detail	Amount (RM)
1.	Abdominal binder x 150.00 (RM 70 per piece)	**10500.00**
2.	Participant's compensation : RM 50x 150	**7500.00**
3.		
	Grand Total	**18000.00**

GANTT CHART

ACTIVITIES \ YEAR	2025					2026								
	8	9	10	11	12	1	2	3	4	5	6	7	8	9
1. Ethics application & approval	■	■	■	■	■	■								
2. Questionnaire validation & Build up the open source online questionnaires			■	■	■	■								
3. Data collection						■	■	■	■	■	■			
4. Data entry & analysis									■	■	■			
5. Manuscript writing										■	■			
6. Submission for publication											■	■		
7. Research progress report & presentation												■	■	■

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APPENDIX

Pamphlet

Duration of Use

- The first 24 hours after your surgery till 1 week upon clinic review.

The study team will schedule a follow-up in 1 week in clinic

Emergency Contact (24/7)

If you experience any issues, have concerns, or need assistance, please contact:

+Dr Khaulah
+60188722389

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number:
03-7949 3209/2251

HOW TO APPLY


First place the belly band around the waist


Adjust to the proper position and securely fasten the wider ends

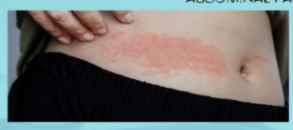

Grasp the thinner ends and tighten towards the abdomen


Adjust to your comfortable position and paste firmly

Red Flag Sign

Stop using the binder and contact the study team if you notice any of the following:

- Any discomfort which may be increasing in nature
- Numbness, tingling, or loss of sensation
- Skin redness that does not fade
- Blisters, rash, or sores
- Breathing or Abdominal Concerns
- Difficulty breathing
- Worsening abdominal pain
- Nausea or vomiting



General Warning Signs

- Dizziness or fainting
- Any new or unusual symptoms

What To Do?

1. **Check the Fit- You should be able to breathe comfortably.**
2. **The binder should not roll, pinch, or cause discomfort.**
3. **Remove periodically for hygiene and skin checks.**

*If wearing the binder becomes uncomfortable, you can stop using it at any time. This will not affect your care

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POTENTIAL IMPACT

Women who underwent caesarean section will not hesitate to use abdominal binder post-delivery as it is proven to be beneficial in terms of reducing pain, improve mobilisation, promote better healing and better nursing their children. They will be more confident in themselves after using abdominal binder.

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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):
KHAULAHRADHIAH BINTI SAHID

Signature of Researcher: ……..

Date: 30/12/25…….