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UNIVERSITY OF MALAYA MEDICAL CENTRE

RESEARCH PROTOCOL

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TITLE OF RESEARCH PROPOSAL

Impact of Advance Provision of an Evidence-Based Information Leaflet on Women's Decision Regarding Elective Induction of Labour at 39 Weeks Among Low-Risk Nulliparous Women: A Randomized Controlled Trial

KEY WORDS

Induction of labor, nulliparous women, shared-decision making, decision aid, birth experiences, satisfaction

BACKGROUND/ JUSTIFICATION

Elective induction of labour (IOL) at 39 weeks has gained increasing attention following the ARRIVE trial (Grobman et al., 2018), which demonstrated a lower rate of caesarean birth without increasing adverse maternal or neonatal outcomes compared with expectant management. Current guidelines recommend that women should receive balanced, evidence-based information about both options to support informed, shared decision-making.

However, many women report that discussions about IOL occur late in pregnancy, leaving insufficient time to consider their options, discuss them with their partner or family, or prepare questions before making a decision (Falk et al., 2019; Henderson & Redshaw, 2013). Although decision aids have been shown to improve knowledge and decision quality, there is limited evidence on whether providing information earlier in pregnancy influences women's actual decision regarding elective induction of labour.

This study will evaluate whether advance provision of a bilingual, evidence-based information leaflet at 34–36+6 weeks influences women's decision regarding elective induction of labour at 39 weeks compared with providing the same information at the time of routine counselling. Secondary outcomes include decision quality, maternal satisfaction with labour and birth, and maternal and neonatal outcomes.

OBJECTIVES & EXPECTED OUTCOMES

Primary Objective

To determine whether advance provision of an evidence-based information leaflet influences women's acceptance of an appointment for elective induction of labour at 39 weeks following routine counselling.

Secondary Objectives

1. To compare decision quality between study groups using:
    - Knowledge adequacy
    - Perceived time pressure
    - Control over decision-making

2. To compare maternal satisfaction with labour and birth experience between study groups.
3. To compare actual labour management received between study groups.
4. To compare maternal outcomes between study groups.
5. To compare neonatal outcomes between study groups.

METHODOLOGY

Study design

Single-centre, randomized controlled trial

Inclusion Criteria

1. Age ≥18 years.
2. Nulliparous woman (no previous pregnancy beyond 22 weeks' gestation).
3. Singleton pregnancy.
4. Gestational age between **34+0 and 36+6 weeks** at recruitment.
5. Cephalic presentation.
6. Intact membranes.
7. Low-risk pregnancy without known maternal, fetal, or obstetric complications requiring planned delivery before 39 weeks.
8. Able to read and understand English or Malay.
9. Able and willing to provide written informed consent.

Exclusion Criteria

1. Previous caesarean delivery or previous uterine surgery contraindicating labour.
2. Contraindication to vaginal birth (e.g., placenta praevia, major uterine anomaly).
3. Current indication for immediate induction of labour or emergency delivery.
4. Planned elective induction of labour or caesarean delivery for maternal or fetal indications.
5. Major congenital fetal anomaly.
6. Non-reassuring fetal status, including suspected fetal growth restriction (FGR), severe small-for-gestational-age (SGA) fetus requiring planned delivery, abnormal fetal surveillance (e.g., abnormal umbilical artery Doppler or cardiotocography), or other fetal conditions requiring obstetric intervention.
7. Regular uterine contractions suggestive of established labour.
8. Maternal medical disorders requiring intervention or planned delivery (e.g., pre-existing diabetes mellitus, gestational diabetes requiring medication, chronic hypertension, gestational hypertension, pre-eclampsia).
9. Inability to read or understand English or Malay.

Methods

Eligible women will be recruited between **34+0 and 36+6 weeks' gestation** and randomized (1:1) to either the intervention or control group. Participants in the intervention group will receive an evidence-based information leaflet regarding elective induction of labour at 39 weeks at recruitment, while the control group will receive routine antenatal care.

At the routine follow-up visit (37+0–38+6 weeks' gestation), eligibility will be reassessed. Before routine counselling, participants will be asked whether they had already formed a decision regarding elective induction of labour at 39 weeks. Both groups will then receive the same evidence-based information leaflet followed by standardized counselling regarding elective induction of labour and expectant management. Participants will be given sufficient time (approximately 10–15 minutes) to read or review the information leaflet before standardized counselling.

Immediately after counselling, participants will complete the study questionnaire, after which the participant's decision to accept or decline an appointment for elective induction of labour at 39 weeks will be recorded as the primary outcome. Obstetric management will subsequently proceed according to the participant's decision and any clinical indications arising during the remainder of pregnancy.

Sample size

The pilot study involving 30 low-risk nulliparous women demonstrated that approximately 69% of eligible women who reached the decision-making stage accepted elective induction of labour at 39 weeks. As the pilot study was not powered to estimate the true intervention effect, the sample size calculation was based on detecting a clinically meaningful absolute difference of 20% in the proportion of women accepting elective induction between the intervention and control groups (69% vs. 89%).

Sample size was calculated using **OpenEpi Version 3** based on the **Fleiss method with continuity correction** for comparing two independent proportions, assuming a two-sided significance level (α) of 0.05, 80% power, and equal allocation (1:1). A minimum of **74 participants per group (148 participants in total)** is required. To account for participants who may not contribute to the primary outcome analysis—including loss to follow-up, spontaneous labour before the routine counselling visit, or the development of medical or obstetric indications requiring delivery before primary endpoint assessment—the sample size was inflated by 20%. Therefore, a total of **186 participants (93 per group)** will be recruited.

Data Analysis

Statistical analyses will be performed using SPSS version 27.

Baseline characteristics will be summarized using descriptive statistics. Continuous variables will be presented as mean ± standard deviation or median (interquartile range) depending on data distribution. Categorical variables will be presented as frequencies and percentages.

Primary Analysis

The primary analysis will compare the proportion of women accepting an appointment for elective induction of labour at 39 weeks between the intervention and control groups using the Chi-square test or Fisher's exact test, as appropriate. Women who did not reach the decision-making time point because of medically indicated delivery before counselling will be excluded from the primary outcome analysis but reported in the CONSORT flow diagram.

Secondary Analyses

Decision quality scores and maternal satisfaction scores will be analysed using independent-samples t-tests or Mann–Whitney U tests depending on data distribution. Categorical maternal and neonatal outcomes will be analysed using Chi-square or Fisher's exact tests.

Multivariable logistic regression will be performed to identify independent factors associated with women's decision regarding labour management. Variables considered for inclusion will include study allocation, maternal age, ethnicity, educational level, body mass index, and other clinically relevant baseline characteristics.

RESEARCH DATA

Where will the data be kept?

- All study data will be kept securely within the research team at University Malaya Medical Centre (UMMC).
- - Electronic data (e.g., interventions, birth records and outcomes) will be stored in a password-protected, encrypted database accessible only to authorised members of the research team.
- - Paper-based documents (e.g., consent forms, questionnaires) will be kept in a locked cabinet in a secure research office within the Department of Obstetrics and Gynaecology, UMMC.
- - Each participant will be assigned a unique study ID number, and all identifying information will be removed or coded to maintain anonymity.

Who will have access to the research data?

Access to the research data will be strictly limited to the principal investigator and authorised members of the research team involved in data collection and analysis.

How long will the data be kept?

Data will be retained for at least 7 years after study completion, in accordance with UMMC research policy and Malaysian Good Clinical Practice (GCP) guidelines. After this period, data will be securely destroyed (electronic files deleted, paper forms shredded).

BUDGET / FINANCIAL SUPPORT (IF APPLICABLE):

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

GANTT CHART

Duration	June -Jul 2025	Oct 2025	Nov-Dec 2025	April 2026 to June 2026	June 2026	Jul 2026	Jul 2026 – Jan 2027	Feb 2027	Mar 2027	Apr 2027
Literature Review	■									
Proposal preparation and presentation	■									
Ethics Application		■								
Ethics amendments & Approval			■							
Initial recruitment (discontinued)				■						
Revision of protocol and materials					■					
Content and face validation					■					
Ethics amendment submission						■				
ISRCTN registration						■				
Participant recruitment and data collection							■			
Data analysis and writing								■		
Thesis Defence									■	
Thesis submission										■

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POTENTIAL IMPACT

This study will provide evidence on whether the advance provision of an evidence-based information leaflet influences women's decision-making regarding elective induction of labour at 39 weeks. The findings will contribute to the growing evidence on shared decision-making in maternity care by evaluating the impact of the **timing** of information provision, rather than the information itself.

If shown to be beneficial, the intervention could be incorporated into routine antenatal care by providing women with evidence-based information before the counselling appointment, allowing them sufficient time to review the information, discuss their options with their partner or family, and prepare questions before making a decision. This approach may support more informed, preference-sensitive decisions while preserving women's autonomy.

Please state whether you have submitted this research proposal for funding, now or before

- ☐ Yes: If Yes, which grant? _____
- ✓ No