



BEAD Feasibility Study: Baby head ElevAtion Device at Full Dilatation Caesarean Section

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Objectives

1. To assess the feasibility of undertaking an industry-independent, randomised trial of the impact of inflated versus non-inflated Fetal Pillow® on uterine incision extensions.
2. To gain feedback on abbreviated consent and trial processes from patients and clinicians.

Design

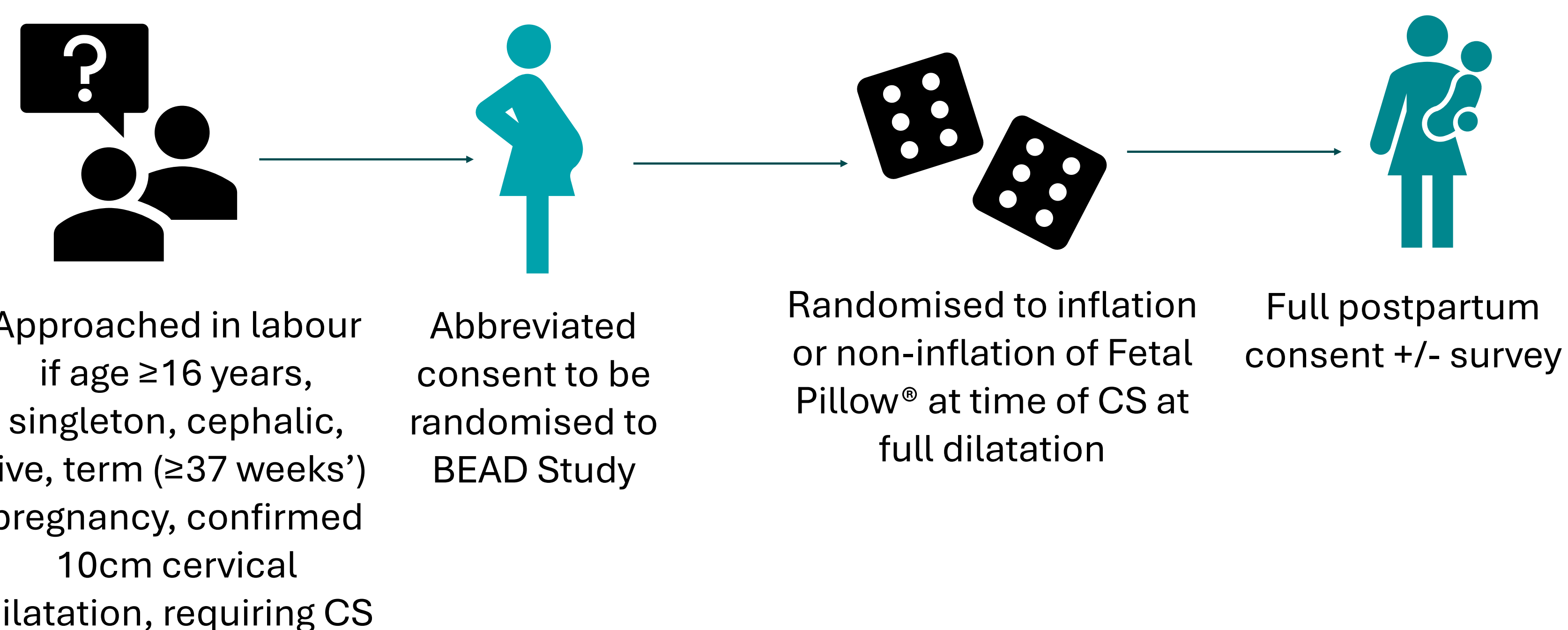
Double-blinded, randomised placebo-controlled feasibility study at two New Zealand hospitals.

Qualitative studies within the trial were used to understand patient and clinician experience.

Method

Mixed method survey with patients and semi-structured interviews with clinicians.

RCT process:



Key findings

Feasibility

- 60 patients recruited in second six months, exceeding progression criteria

- Randomisation was equitable by ethnicity

Patient feedback

- Most of those consenting (111/129, 86%) and declining the RCT (38/57, 67%) consented to postpartum survey

- Patients were supportive of the consenting approach although 33% of consenting, and 69% of declining, participants would have preferred more information pre-labour

Clinician feedback

Enablers to trial participation:

- 24/7 availability of research team
- Usefulness of study-specific resources such as script for intrapartum consent

Barriers:

- Lack of equipoise among some current device users
- Competing clinical demands

Clinicians were supportive of the 2-stage consent process (abbreviated intrapartum consent and full post-partum consent).

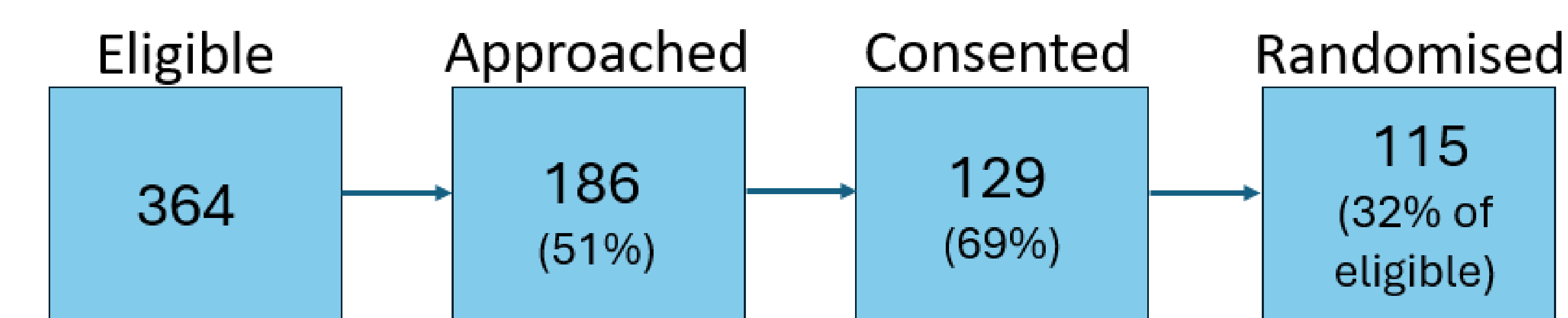


Figure 1: Recruitment to the BEAD Feasibility Study, August 2023 – August 2024



n= 149

Benefits in participation

Trust in Healthcare

Overwhelmed in the moment

Key themes regarding intrapartum consent:



n= 18

Communication and context

Two-stage process - ethical and flexible

Practical not premature
Early awareness, better prepared

Conclusion

- Recruitment for a larger trial (n=400) is feasible in this context.
- Abbreviated consent at decision for emergency CS is acceptable to patients and clinicians but providing information prior to labour may support broader patient participation.