Trial Protocol

The BEAD Feasibility Study: Baby Head Elevation device at full dilatation caesarean section

Registration: ACTRN12623000758606

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The BEAD Feasibility Study: Baby head elevation device at fully dilated caesarean section

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List of abbreviations

AE	Adverse event
BMI	Body mass index
CRF	Case report form
CS	Caesarean section
CSFD	Caesarean section at full dilatation
DRG	Diagnosis related group
DSMC	Data and safety monitoring committee
EBL	Estimated blood loss
HDEC	Health Disability Ethics Committees
HIE	Hypoxic ischaemic encephalopathy
HTN	Hypertension
ICU	Intensive care unit
IFH	Impact Fetal Head
LOS	Length of stay
LMC	Lead maternity carer
LSCS	Lower segment caesarean section
MAS	Meconium aspiration syndrome
NICU	Neonatal intensive care unit
NZ	New Zealand
PPH	Postpartum haemorrhage
RCT	Randomised controlled trial
SAE	Serious adverse event
SMO	Senior medical officer (consultant)
TMG	Trial management group
VBAC	Vaginal birth after caesarean

Trial Management Group

This will include:

All investigators listed on this protocol

Project manager

1. LAY SUMMARY

Each year in New Zealand (NZ) around 1500-2000 babies are born by an emergency caesarean section in the second stage of labour (10 cm dilated or cervix fully open). This accounts for around 3% of all births. A caesarean section at this time carries increased risks of injury for mother and baby as the baby's head is often deep in the pelvis. Potential injuries include tears of the uterus (sometimes into the vagina) and injury to nearby organs (example the bladder or ureter) with subsequent increased bleeding, operating time, and risk of preterm birth in subsequent pregnancies. Difficulty in delivering the baby can lead to neonatal injury and admission to baby intensive care unit.

Techniques to deliver babies where there is an impacted fetal head have been reviewed in the literature. The Fetal Pillow® (CooperSurgical), is a disposable inflatable medical device, placed in the vagina at the time of caesarean section and already used widely across New Zealand. Limited research suggests this may be beneficial in aiding safe delivery for mother and baby, but the findings of studies to date are not consistent or reliable. The BEAD (Baby head ElevAtion Device) Feasibility Study will take place at two maternity units over a 12 month period to inform the recruitment strategy and trial processes of a planned, larger BEAD Trial. We anticipate that clinical outcomes of the BEAD Feasibility Study will contribute to the BEAD Trial.

The BEAD Trial will be an investigator-led, two-centre, placebo-controlled, double (or triple) blinded, randomised trial in Auckland New Zealand. It will assess the effect of inflating the Fetal Pillow® at a fully dilated caesarean section to improve outcomes for the mother and baby.

2. BACKGROUND

Caesarean section performed in the second stage of labour is a challenging procedure with increased morbidity for both the mother and baby[1]. International, and local data from Te Toka Tumai Auckland, report that caesarean at full dilation (CSFD) currently occurs in 2-3% of all term cephalic singleton births, or which equates to 1,500 births per year across New Zealand (NZ)[2-7]. The fetal head may be low and fixed in the pelvis, following a prolonged labour, related to malposition or macrosomia (large baby), oxytocin augmentation or after an unsuccessful instrumental delivery[8,9]. Impacted fetal head (IFH), although without a universally agreed definition, is reportedly encountered in 16-30% of Caesarean Sections at Full Dilatation (CSFD)[9-11]. Attempts to disimpact the head can be difficult and lead to fetal trauma such as skull fracture, nerve palsy, intracranial haemorrhage or neonatal intensive care unit (NICU) admission[9-13].

Direct maternal trauma is commonly reported at CSFD including uterine incision extension, occurring in up to 20-40% of cases[8,14,15]. This complication can be difficult to repair and lead to significant blood loss, need for blood transfusion, increased operating time and longer hospital stay[8-11]. Risk factors for uterine incision extension include labour arrest, macrosomia, previous caesarean section, CSFD and failed instrumental delivery, with the latter two potentially related to presence of an impacted fetal head[8,14-17]. **In addition, there is mounting evidence that CSFD is associated with an increased risk of preterm birth in subsequent pregnancies.** Uterine incision extensions, resulting in damage or impaired healing of the cervix may be responsible for this risk[18,19].

A deeply impacted fetal head at Caesarean is an obstetric emergency, and a safe technique for delivery is important for doctors, parents and families. However, unlike other emergencies (such as

shoulder dystocia), there is a lack of both structured skills teaching and procedural drills, as well as a lack of evidence around which techniques are safest or most effective[20].

1.1 Rationale for study

More recently, a medical device - The Fetal Pillow® (CooperSurgical) has been developed. The pillow is a disposable silicone balloon that is inserted vaginally immediately before a CSFD and inflated with 180mL of water to elevate the fetal head prior to delivery[21]. This device costs approximately NZ$580 per unit and has been assertively marketed as making birth easier and less traumatic[21]. This device has been introduced in almost all maternity hospitals in NZ (along with many in Australia, and some in North America and the United Kingdom). Introduction of the device appears to occur on the recommendation of colleagues or after adverse event review, even though the published literature on its effectiveness is limited and/or of poor quality.

High quality evidence to support the use of the pillow is lacking. There are three published randomised controlled trials (RCTs) on the Fetal Pillow® to date. The first non-blinded RCT from India (Seal et al) included 240 women and reported a substantial reduction in major uterine surgical incision extension (32.5% control vs 5% in the pillow group)[22]. However, due to significant concerns with the conduct of this study, and the integrity of the data, the journal has issued a retraction[23]. We would add to these concerns that the rate of major uterine incision extension in the control group at 32.5% is vastly inflated, given a rate of major extension in our own local retrospective studies of 6 - 7% among cases before the introduction of the Fetal Pillow® device into local practice.

A second, well designed randomised trial from USA (Lassey et al), reported after recruiting only 60 women, well short of the target enrolment of 200. In this study the time from uterine incision to delivery was reduced in the pillow group by 23 seconds[24]. This outcome was chosen as a surrogate for delivery difficulty. However the study was underpowered to report on the impact of the pillow on either maternal or neonatal morbidity but observed a reduction in uterine incision extensions from 43% to 20%. There are also other inconsistencies around eligibility and timing of consent and randomisation between the trial registration and published paper in this study. Both of these trials were industry funded. A third small RCT also from India (Dutta et al) has also been published comparing the Fetal Pillow® to Patwardhan's technique. This study has major flaws, including reporting statistically significant differences where such differences are not possible, based on the data supplied in the manuscript, and published in a predatory journal[25].

A systematic review published in 2021 includes two of these studies as well as case series, cohorts and a conference poster with mixed results on the effectiveness of the Fetal Pillow®[26]. No studies were excluded due to low quality even though a number of these data arise from case series without comparison groups, and the retrospective nature of most of the included studies. Therefore, this review has a high risk of bias and results should be interpreted with caution. In summary, **there is inadequate evidence to demonstrate the Fetal Pillow® is effective at reducing complications associated with CSFD.**

In November 2022 the National Institute for Clinical Excellence (NICE) updated their guidance in IPG744, "Advice on Balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour"[36]. They concluded that the Fetal Pillow® was safe and effective to be used by maternity staff trained in managing impacted babies' heads during an emergency caesarean birth provided that standard arrangements are in place for clinical governance, consent and audit. The process of developing this guidance involved a "rapid literature review" and does not provide a critical review of any of the literature such as the considerable concerns around the RCTs, lack of quality review of the observational data, and was published prior to the expression of concern (January 2023)

around the largest of the clinical trials[23]. We are aware that a request for review of the NICE guidance has recently been sent to NICE.

Table 1: Summary of published Fetal Pillow® data (RCT=randomised controlled trial)
Those in bold are included in the published systematic review[31].

Observational studies	**Pillow N=**	**No Pillow N=**	**Pillow – incision extension (%)**	**No Pillow – incision extension (%)**	**Pillow superior?**
2022 Chooi[32]	53	48	21%	25%	N
2020 Sacre[33]	170	221	22%	21%	N
2020 Hanley[34]	114	60	17%	25%	Y
2018 Sarkar[35]	39	-	33%	NA	NA
2017 Hepburn[36]	26	-	Major* 8%	NA	NA
2014 Seal[37]	50	124	Major^ 4%	Major 15%	Y
2016 Safa[38]	91	69	20%	35% (IFH = hand push)	Y
2013 Mufti[39]	16	18	31%	33%	N
2009 Papanikolaou[40]	28	-	14%	NA	NA
RCTs			**Pillow**	**No Pillow/Sham**	
2016 Seal[27] (retracted)	120	120	10% (Major^ 5%)	36% (Major 33%)	Y
2019 Dutta[28]	25	25 (Patwardhan)	8% (n=2)	24% (n=6)	Y
2020 Lassey[29]	30	30	20%	43%	Y
SUMMARY			8% - 31%	21% - 43%	
2021 Systematic Review[31]			17%	28%	Y

*Major uterine extension not defined
^Major uterine extension defined as grade 2 = increased operating time and/or blood loss or grade 3 = involved one or both uterine arteries, cervix, vagina or bladder (Of note: grade 1 = minor extensions that did not increase operating time or blood loss)

Local data suggests purported benefits of the Fetal Pillow® may be overstated. Our recently completed observational study of outcomes of the Fetal Pillow® at CSFD across two sites (Te Toka Tumai Auckland and Te Whatu Ora Counties Manukau including 1,703 women (375 women who had a CSFD with Fetal Pillow® and 1328 who had a CSFD without Fetal Pillow®)(*in preparation for publication*). For most patients, complications including uterine incision extension, major uterine incision extension, need for blood transfusion, and a composite of neonatal morbidity did not change with use of Fetal Pillow®. Although this is the largest observational study to date, it is still retrospective observational data with inherent concerns of bias. The data suggest that the benefits of the Fetal Pillow® may be overstated, **however a randomised placebo-controlled trial, with sufficient power to determine whether the Fetal Pillow® in Caesarean section at full dilatation reduces maternal morbidity** (measured by uterine incision extension) is needed.

Our observational local data has been presented to multidisciplinary maternity care providers at two tertiary level hospitals (Te Whatu Ora Counties Manukau and Te Toka Tumai Auckland), which together oversee 14,000 births a year. At both hospitals, there has been support from staff and clinical

leads for a randomised study. Furthermore, support appears to extend nationwide. Members of our group have conducted a national survey of obstetricians and obstetric trainees on techniques to deliver which has found that many already use the Fetal Pillow®. The Fetal Pillow® was usually introduced on the advice of colleagues not in response to consideration of the evidence. Despite the widespread usage of the pillow, the majority of respondents supported a clinical trial, and indicated that they would change their practice in response to trial findings.

There are particular aspects of a randomised trial investigating the management of impacted head at CSFD that will be challenging. Examples of the challenges anticipated include:

1) CSFD is reasonably infrequent, and unpredictable in its occurrence.
2) Recruitment to the study will be intrapartum, which means the process of informed consent will be more complicated to navigate.
3) Randomisation, intervention and control (sham inflation of the balloon) will depend on multiple individuals from different specialties, working together as a team, to ensure blinding is adequate.

We have calculated that we would need to recruit 424 patients to a definitive trial of the Fetal Pillow® at CSFD in order to be adequately powered for maternal morbidity. It is vital that we determine whether a trial this size is feasible. We therefore propose first the **BEAD Feasibility study which will determine feasibility to optimise the processes around engagement, recruitment, randomisation, and practical aspects of the trial.**

3. TRIAL HYPOTHESIS & AIMS

3.1 Hypothesis

Patients will be willing to take part in an intrapartum trial using the Fetal Pillow® device at fully dilated caesarean section

3.2 Aims

Primary Aim:

To identify how many patients are offered and willing to participate in a randomised controlled trial of Fetal Pillow® use at fully dilated caesarean section (recruitment)

Secondary Aims:

1. To identify how many patients are offered and willing to participate in the longer-term outcome (gestation at subsequent birth) sub-study, assessing impact of uterine incision extension on rates of preterm birth
2. To identify whether equitable recruitment by ethnicity is achievable
3. To identify barriers and enablers to participation in such a trial (patients/clinicians) and to modify these as they become apparent during the feasibility study including exploring patient and clinician experience of intrapartum consent
4. To assess the quality of resources developed to aid in recruitment, education for clinicians (around use of Fetal Pillow® and delivery of an impacted fetal head)
5. To assess the usability of the BEAD Study template form
6. To contribute outcome data to The BEAD Trial

4. TRIAL AND DEVICE SAFETY

There have been no adverse events (maternal or neonatal) from use of the Fetal Pillow® reported in the international literature to date.

This device is already widely used around New Zealand, including at Te Whatu Ora Counties Manukau.

It is registered with MEDSAFE (Wand reference: 210421-WAND-6WPRBA).

5. STUDY DESIGN

The BEAD Feasibility Study is a two-site, double-blinded, randomised placebo-controlled trial.

This is investigator-led and grant supported research, and CooperSurgical have no role in the design, funding, or undertaking of the study.

5.1 Trial Setting

This study will be conducted at two maternity units: Te Toka Tumai|Auckland and Te Whatu Ora Counties Manukau. Te Toka Tumai|Auckland is a large 'research-active' tertiary unit with experience in recruiting patients and babies into multi-centre randomised trials, including labour trials. The investigators in the trial have experience running labour trials (LS, MH). The Fetal Pillow® device is not currently in use at this site. Te Whatu Ora Counties Manukau is a tertiary maternity unit with an ethnically diverse maternity population. Clinicians at Te Whatu Ora Counties Manukau have been using the Fetal Pillow® device for the last 5 years and have modest engagement in perinatal clinical trials, supported by this trial's investigators (CO, KO, RC).

5.2 Trial Co-ordination

The trial will be coordinated by staff at The University of Auckland and Te Whatu Ora Auckland. One investigator will be undertaking this trial as part of a PhD (JW), and one is currently employed on an HRC Clinical Research Fellowship (LS). Research assistants (providing project management, midwifery, and nursing skills) will be employed at both sites. Education for clinicians on standardised use of the Fetal Pillow will be provided by the manufacturer, and simulation-based education on techniques for delivery of the impacted fetal head will be provided by co-investigators, obstetric leads and/or labour ward clinicians at both sites. These education sessions will be provided repeatedly during the life of the studies to ensure engagement and standardisation across all, including new, staff.

6. STUDY POPULATION – Inclusion & Exclusion Criteria

Patients who require an emergency CS in the second stage of labour at Te Toka Tumai|Auckland and Te Whatu Ora Counties Manukau.

6.1 Inclusion criteria

- Age ≥ 16 years
- Singleton pregnancy
- Gestational age ≥37 weeks
- Cephalic presentation
- Confirmed 10cm cervical dilatation

Patients can be included if they have had an unsuccessful assisted vaginal delivery (forceps or ventouse) and if they have previously had a caesarean section.

6.2 Exclusion criteria

- Unable to or don't give consent
- Major congenital anomalies requiring NICU admission or palliative care
- Known stillbirth at decision for caesarean section
- Urgency of caesarean section (as determined by operating surgeon) leading to inadequate time to randomise and place the device

Patients enrolled in other labour RCTs (such as ARM trial at Te Toka Tumai|Auckland) are potential candidates for our study**.**

6.3 Withdrawal of Participants

Participants may withdraw their consent from the study for any reason at any time without prejudice. All participants will receive on-going medical care according to clinical need.

7. PARTICIPANT RECRUITMENT AND CONSENT

We acknowledge that gaining consent for clinical research for labouring women presents ethical difficulties and requires researchers to balance the wellbeing of trial participants whilst ensuring quality research improves intrapartum care[37]. In accordance with the 'Charter for Ethical research in Maternity Care' we plan to ensure women receive information well in advance of being asked to participate (during pregnancy) and will seek informed consent as close to randomisation/treatment as possible[38]. We have undertaken consultation with local consumer groups including Māori and Pacific stakeholders to ensure this process is culturally appropriate.

The information and consent pathway proposed aims to ensure that women have the opportunity to become fully informed, however it is also important to consider whether those who have not received adequate information antenatally (due to choice or lack of access) should be automatically excluded[38]. The risk or concern about coercion can be reduced by separating the roles of researchers and clinicians[38].

1. Information on the trial will be widely disseminated in hospitals and community-antenatal clinics, to Lead Maternity Carers (LMCs), antenatal education classes and online (at Te Toka Tumai|Auckland and Te Whatu Ora Counties Manukau websites and Facebook pages) through a variety of methods including poster, brochure and videos.
2. As recruitment is required during acute care, successful enrolment in this study will require the support of, and education for, birthing unit staff, obstetricians, registrars, and LMCs prior to commencement. Education will include the purpose of the study, and the consent process. We plan to contact as many LMCs as possible before the start of the study, to present to the majority of birthing, maternity, and anaesthetic staff across all shifts, and provide written resources, video resources, and a device for demonstration purposes.
3. Due to the relative infrequency of full dilatation CS (2-3% of all births), participants will only be approached to participate once a decision for caesarean at full dilatation (or trial of instrumental birth and/or caesarean section) has been made. This is in keeping with other research recommendations on rarer intrapartum interventions/trials with event frequency <20%, as well as local consumer advice[43]. The Fetal Pillow® is already used at half of CSFD at one of the trial sites and there is no evidence to suggest the device causes harm. We will be presenting clinicians with the findings of our retrospective study to reconsider their stance on equipoise in the usefulness of the device.
4. All patients requiring an emergency caesarean section at full dilatation from 37+0 weeks at the two recruiting sites will be assessed for eligibility by clinicians providing care (based on the inclusion and exclusion criteria). We anticipate the LMC or midwife providing labour cares to be aware of the study, and trial participation will be discussed with the midwife present.

5. Further information about the trial will be provided to potential participants and consent obtained by the obstetric/clinical team involved. We requested from HDEC that we undertake an abbreviated consent prior to CS, along with usual surgical consent for caesarean section (or trial of instrumental +/- caesarean section), using a standardised script. The standardised script outlines key information about the Fetal Pillow® device, placement at time of caesarean section and randomisation to inflation or sham-inflation. Clinicians can use their clinical judgement on a case-by-case basis (as per the exclusion criteria) if they feel time spent discussing the study, obtaining consent, randomising and/or placing the Fetal Pillow® would cause any potential concerns about the wellbeing of the mother or baby.
6. After birth, written confirmation of consent will be obtained by the research staff from the patient for the woman's data, their baby's data and for collection of data (from the Manatū Hauora Ministry of Health) around subsequent pregnancies for the longer-term outcomes part of the study. This will occur within 3 days of birth. This is required pursuant to section 36 of the Care of Children Act and the Ethics Approval of this study.

Patients will be approached by the midwives and doctors attending the birth. This will be done verbally (using a standardised script) and a written information sheet will be provided. A short (3 minute) video in Te Reo or English summarising the trial will also be offered if acceptable to the patient. The clinician obtaining consent (usually the operating surgeon) will be responsible for discussing the trial and obtaining written abbreviated consent. A photo or model of the device will be available to show patients and whanau.

If patients decline to participate in the BEAD Feasibility Study, their caesarean section care will continue to the same standard as for all women undergoing emergency caesarean section. The Fetal Pillow® device is not currently available at Te Toka Tumai|Auckland site, and therefore use of the device at this site is not available outside the clinical trial. Use of the Fetal Pillow® at the Te Whatu Ora Counties Manukau site will be monitored outside use in the trial to ensure that this is not a default option. While this is a risk, at this stage, the unit consultants, including the Director of Women's Health and the Labour Unit Clinical Lead, are supportive of this trial.

All eligible patients will be approached during their postpartum inpatient stay and be asked if they consent to complete a short anonymous questionnaire on barriers and enablers to inclusion in a labour trial and their experience of being approached about a trial during labour.

7.1 Additional approval

We have received approval from HDEC to request access, without consent, to the details for all women who did or might have had a fully dilated caesarean section in our study period to determine the numbers and demographic characteristics of potentially eligible persons. These data will be requested from the Health Information Service at both hospitals. See separate data management plan for further details.

8. TREATMENT GROUPS AND STUDY DEVICE

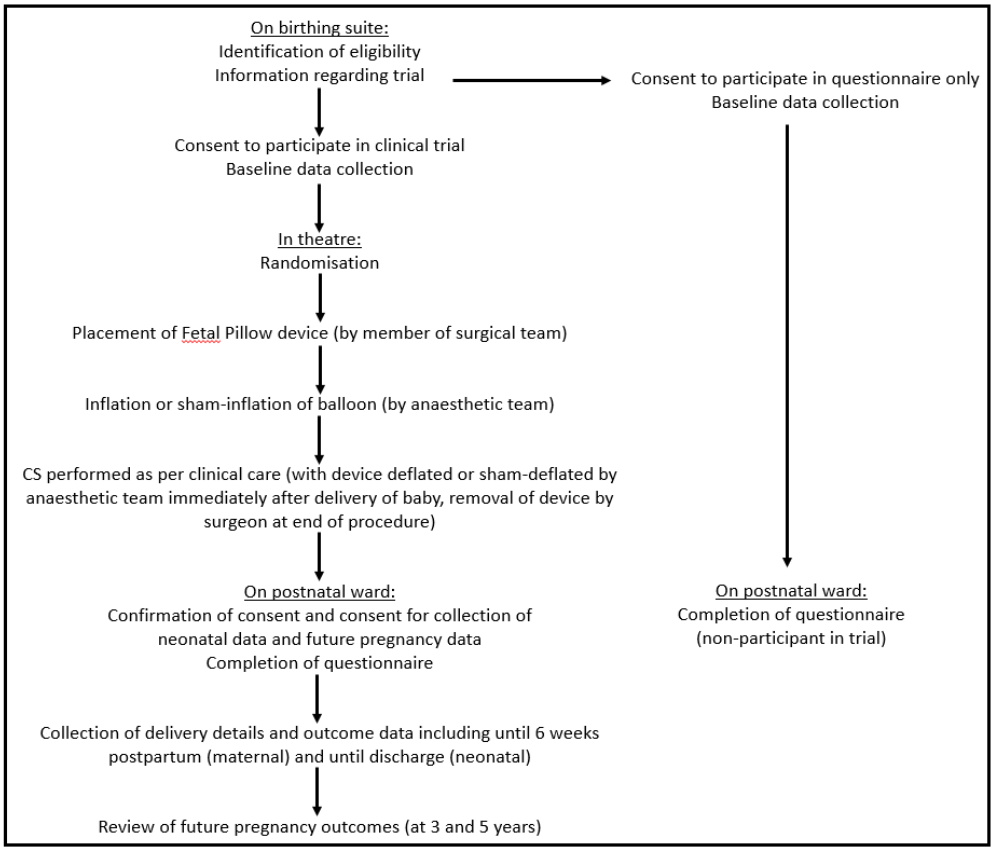
Patients will be invited to take part in one or both of the following:

1. **Randomised Clinical Trial:** randomised controlled trial with inflation or sham-inflation of the Fetal Pillow® (including the BEAD Feasibility Study questionnaire and longer-term outcomes sub-study).
2. **BEAD Feasibility Study questionnaire:** a study-specific (anonymous) questionnaire about their decision to take part in, or not take part in, the clinical trial component. This will include questions about the effectiveness and appropriateness of any information about the trial they

were exposed to prior to labour, and any resources given to them before, during and after labour.

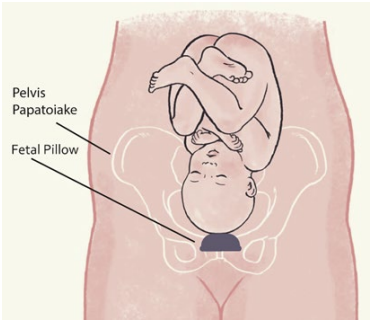
8.1 Participant schedule

The study procedures for participants are summarised in the flow chart below.



Note: Tasks of 'randomisation' and 'inflation or sham-inflation' may be undertaken by another member of the theatre team after adequate education and training (other than anaesthetist) as determined by each recruitment site. The underlying principle is to ensure that the persons undertaking the operation (the surgeon) and persons providing or completing any outcome data (e.g. the BEAD Study Template or clinical notes), or extracting outcome data (e.g. research midwife) are blinded to the allocation.

8.2 Study device (The Fetal Pillow®)



The baby head elevation device "Fetal Pillow®" to be used in this trial is a soft silicone balloon device that is inserted into the vagina and placed beneath the fetal head and then inflated with 180mL of water (via a syringe, 3-way tap, and tube at the head of the bed) to help lift the head from the pelvis[40]. The flat surface of the device is against the maternal vaginal tissue. The inflatable balloon is against the baby's head. In inflating the balloon with water, this will aid in elevating the baby's head (disimpacting the head from the pelvis) to make it easier for the surgeon the deliver the baby. Adequate length of tubing is required to easily extend to the head of the bed for easy anaesthetic access.

The devices will be stored in theatre. The lead investigator at each site is responsible for the study device inventory and accountability throughout the trial.

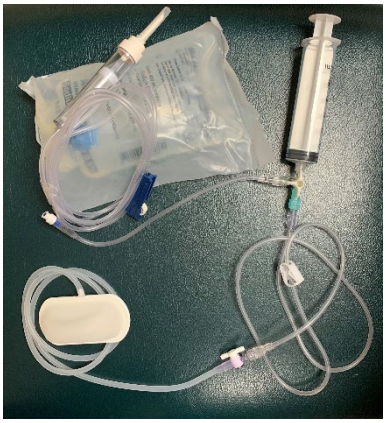
8.3 Treatment groups

Participants will be randomised to one of two groups.

For both groups the Fetal Pillow® device will be placed, after catheterisation of the bladder and vaginal preparation, by the operating surgeon or a member of the surgical team as per manufacturer's instructions and the patient's legs laid flat[40]. The tubing leading to the pillow will be passed up alongside the patient to the head of the table to the anaesthetist.

1. *Inflation group (intervention)*

   The anaesthetist or theatre staff inflates the Fetal Pillow® with 3x60mL syringes sterile water from a 500mL bag of water, using a syringe attached to the pillow tubing, via a 3-way tap while the surgeon is outside the operating theatre. The bag is placed under the operating table out of sight of the operating team. The theatre team deflates the Fetal Pillow® after birth of the baby, reversing the above to return the fluid to the 500mL bag. The deflated Fetal Pillow® device is removed by the surgeon at the end of the procedure.



   OR

2. *Sham-inflation group (control)*

   Sham-inflation group (control) A member of the theatre team sham inflates the balloon with 180mL sterile water, while actually removing and returning 3x60mL syringes of sterile water out of and then back into a 500mL bag, via the 3-way tap, thus creating the appearance of inflation to any observer (sham-inflation). The bag is placed beneath the operating table out of sight of the surgical team. The process is reversed after birth of the baby to mimic deflation. The Fetal Pillow® device is removed by the surgeon at the end of the procedure.

All aspects of the caesarean are unaffected by trial participation. The surgeon may use other standard techniques for assisting delivery of an impacted fetal head in either arm of the trial. If vaginal disimpaction is required/requested during the surgery, deflation and removal of the balloon is performed, as is currently advised with use of the Fetal Pillow® outside of the trial setting.

Participants, maternity clinicians caring for women, and trial investigators, will remain blinded to treatment allocation throughout the study. This method of blinding the surgeon was described and shown to be effective in the Boston RCT[24].

9. CLINICIAN ROLES AND EDUCATION

9.1 Role of the lead maternity carer

Mode of birth is discussed between all patients and their lead maternity carer (LMC) during the antenatal course. This provides an opportunity for the study to be introduced well in advance of labour, and for patients to consider whether they would like to be involved and to gather more information about the study. Many patients are also referred to hospital antenatal clinics, for a variety of reasons during their pregnancy, where study information will be posted, and clinicians will be in a position to discuss the study.

To facilitate and empower LMCs and clinicians we will be holding education sessions around the study, creating a video to explain how the study works and providing written information so that they feel confident advocating for their patients and answering questions. One of the roles of our research assistants will be to ensure there is widespread korero about the study. LMCs will be able to direct patients to our website through a QR code and we will have available posters and brochures for patients and whanau to take away and read.

Once patients are identified as being eligible for the trial during their labour course, the LMC will be involved in the discussion around suitability for the trial and will be present to advocate for their patients during the consent process.

9.2 Role of the surgeon

Written (abbreviated) consent for participation in the study will be obtained at the time of consent for CSFD, by the operating surgeon. The surgeon will discuss the trial verbally (using a standardised script) and a written information sheet will be provided to all patients. A short (up to 2 minute) video summarising the trial will also be offered if acceptable to the patient as well as a photo and/or model of the Fetal Pillow®.

The operating surgeon (or member of the surgical team) is also responsible for placing the Fetal Pillow® immediately prior to the caesarean section and removing the device at the end of the procedure. All obstetricians and obstetric trainees will be provided standardised education on placement of the Fetal Pillow®. The operating surgeon will also be asked to complete a simple form in addition to their operation note (*BEAD Study template).* We plan to do a pilot with the template tool in advance of the study.

CooperSurgical will be providing education to all clinicians (at both recruitment sites) involved in the study around the correct placement (as per manufacturers instructions) of the Fetal Pillow® using simulation models. This is to ensure that those who have never used the pillow before are clear on how it is to be used and placement is standardised amongst those who use it already. This education will take place prior to the trial commencing and will be repeated as required if new clinicians become involved (for example – new trainees coming to a recruitment site).

Education and resources around the trial itself will also be available (as described in 9.1) to ensure all clinicians are comfortable discussing the trial with patients both antenatally and in labour.

In addition we will be providing education sessions and simulation exercises specifically around delivery of an impacted head which will include other recognised techniques other than the Fetal Pillow® such as reverse breech extraction so that all clinicians are equipped to deal with this if encountered. This is of particular relevance for those clinicians at Te Whatu Ora Counties Manukau who may currently rely on the Fetal Pillow® at CSFD. This also is important in the longer term if the study demonstrates no benefit with use of the Fetal Pillow®.

9.3 Role of the anaesthetist

The anaesthetist will be involved in the randomisation using the online REDCap database. The randomisation will occur in theatre once eligibility is confirmed by the operating surgeon. As described in section 8.3, the anaesthetist will either inflate the Fetal Pillow® with 180mLs water (inflation group) or perform a sham-inflation (control group), whilst the surgeon is scrubbing

(outside the theatre). Once the baby is delivered, the anaesthetist will deflate the balloon or sham-deflate the balloon.

Education around the trial and simulation of the relevant trial processes including use of the REDCap database will take place in advance of the trial, with the support from the research assistants. It can be repeated as required throughout the study. We have been in discussion with the anaesthetic leads at both recruitment sites who are supportive of the trial.

The process of randomisation and sham inflation by the anaesthetic team was described in the Boston (Lassey) trial and in that trial sham was found to be adequate with 97% in the inflation, and 73% in the sham inflation, group agreeing they would use the device again and recommend it to others[24].

9.4 Role of the theatre staff

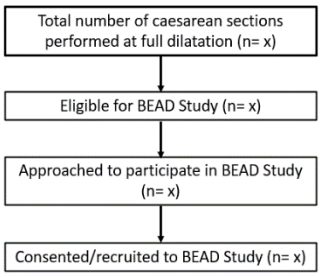
One of the circulating nurses in the theatre will be required to use a stopwatch to record the uterine incision (uterotomy) to delivery interval in seconds and record this on the BEAD Study template. The stopwatch will be provided in theatres and education around the trial itself (via posters and face-to-face sessions) and this role will be provided to all staff.

10. OUTCOME MEASURES

10.1 Primary Outcome

Total number of women recruited in the second six months of the Feasibility Study

- Number of patients recruited in the second 6 months of the Feasibility study. Our power calculation for the full BEAD trial suggests that 424 women to determine whether use of the Fetal Pillow® significantly reduces maternal uterine extensions. To support this, we need to be able to recruit 40-50 women in the second 6 months of the Feasibility Study across the two sites.



10.2 Secondary outcomes

- Recruitment rate by ethnicity and recruitment site
- Proportion who provide full consent for study participation following intrapartum consent
- Proportion who consent for collection of maternal, neonatal and future pregnancy follow-up
- Barriers and enablers to trial participation identified by patients
- Barriers and enablers to trial participation identified by clinicians/medical professionals and recruitment site
- Assessment of quality of resources including written and video developed for patients
- Assessment of quality of resources including written and video developed for clinicians
- Assessment of adequacy of clinician training for involvement in the study
- Proportion of template reporting tool completed
- Qualitative analysis of intrapartum consent experiences of patients
- Qualitative analysis of intrapartum consent experiences of clinicians

10.3 BEAD Trial Outcomes

Data from the BEAD Feasibility Study will contribute to the BEAD Trial outcomes:

***Primary outcome*:** any extension of the uterine incision.

This includes any extension of the initial uterotomy. The uterotomy is the intentional, usually sharp incision into the uterus, which is followed by lateral or cephalo-caudal blunt extension generated by traction with two fingers pulling in opposite directions. Extension includes sharp, and inadvertent extension. In sharp extension, the uterotomy is enlarged by sharp incision into a T, a J or U shape or laterally and undertaken after difficulty delivering the head is encountered. Inadvertent extension may occur laterally or inferiorly and may involve the uterine arteries, broad ligament, lower segment, cervix, vagina, bladder, or ureter. Inclusion of any of these structures (including caused by sharp incision) will be included as part of the primary outcome.

This primary outcome was chosen because it is the maternal trauma which leads to blood loss and prolonged surgery, is objectively measurable, and is the probable cause of future preterm birth in people who had had previous Caesarean. It was the most frequently chosen primary outcome by obstetrician respondents to an NZ survey.

Secondary outcomes:

Maternal

- Major uterine extensions – defined as into surrounding structures (uterine arteries, broad ligament, cervix, vagina, bladder, or ureter)
- Incision-to-delivery interval (secs)
- Birth to end of surgery (mins)
- Total length of surgery (mins)
- Estimated blood loss (EBL) (ml)
- RBC transfusion
- ICU admission
- Maternal length of stay (LOS) post-partum (hours)
- Readmission within 6 weeks
- Maternal death

Neonatal

- Perinatal death (within 28 days of delivery and before primary hospital discharge; including intrapartum stillbirth and neonatal death)
- Moderate to severe hypoxic ischaemic encephalopathy (Sarnat stage 2 or 3) or treatment with therapeutic hypothermia
- Seizures treated with anticonvulsants
- Significant neonatal birth injury
    - Any fracture, intracranial haemorrhage, nerve palsy, spinal injury
- Hypoxia at birth (any of)
    - APGAR <7 at 5 mins
    - Received cardiac massage
- NICU admission ≥ 24 hours

Composite neonatal outcome (any of perinatal death (intrapartum stillbirth or neonatal death before primary discharge), moderate to severe HIE or treatment with therapeutic hypothermia,

seizures treated by an anticonvulsants, significant birth injury (any fracture or nerve palsy or intracranial haemorrhage or spinal injury), or NICU admission >=24 hours).

Other neonatal secondary outcomes, not included in composite neonatal outcome above:

- Cord pH and lactates
- Apgar<7 at 5 minutes,
- Resuscitation with cardiac massage
- Phototherapy for hyperbilirubinaemia
- Breastfeeding at primary hospital discharge (fully or exclusively)
- NICU length of stay (LOS) in days
- Meconium aspiration syndrome (MAS)

Other outcomes

- Manoeuvrers required for impacted fetal head and frequency of these
- Perceived degree of difficulty of delivery by surgeon (4 point Likert scale)
- Cost effectiveness (using hospital coding) from public health system perspective
- Preterm birth in subsequent pregnancy within 5 years

11. DATA COLLECTION

11.1 Recruitment rate and baseline data collection

Demographic data on the eligible population, to assess recruitment rate, will be requested at the end of the feasibility study from the Business Intelligence units, from the maternity database (BadgerNet).

Data will be collected on maternal demographics including age, ethnicity, height and weight (booking, to calculate BMI), past obstetric history (parity, previous CS) and current pregnancy (gestation at delivery and indication for caesarean section).

11.2 BEAD Feasibility Study Questionnaires

Patients may consent to complete the anonymous BEAD Feasibility Study Questionnaire without also agreeing to take part in the randomised clinical trial to capture barriers and enablers that may have influenced their decision as well as information about adequacy of resources and their intrapartum consent experience. Consent for the questionnaire will be obtained on the postnatal ward. Patients will be approached prior to discharge from hospital to complete the questionnaire.

11.3 Trial Participation: clinicians and trial sites

We will aim to explore barriers and enablers to trial participation including but not limited to: site set-up, clinician and consumer engagement including intrapartum consent, trial conduct processes including randomisation and completion of BEAD Study template as per protocol. This will be done via face-to-face interviews with research staff and medical professionals involved in intrapartum care and recruiting sites.

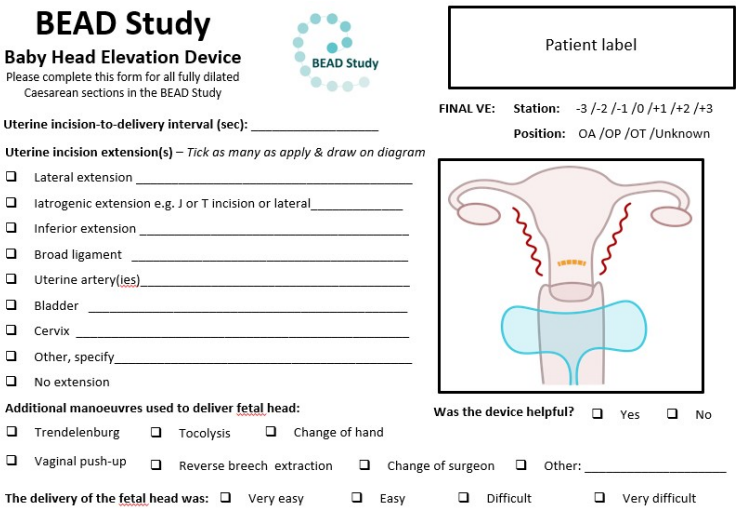
For participants who consent to RCT component the following data will be collected.

11.4.1 Adequacy of the BEAD Study Template

Study investigators will review the completed templates (without knowing treatment groups) to assess for completeness and adequacy for documentation.

11.4.2 Outcome data collection (related to RCT)

Detailed data will be collected regarding delivery, maternal and neonatal outcomes from the
maternal and neonatal records. Completion of the BEAD Study template will be done by the operating surgeon immediately following caesarean section. This will capture information about uterine extensions, uterine incision to delivery interval and feedback on Fetal Pillow® use and difficulty of delivery. Review of maternal and neonatal notes at 6 weeks postpartum will be used to assess for readmission to hospital and to extract neonatal outcomes.



BEAD Study

Baby Head Elevation Device

Please complete this form for all fully dilated Caesarean sections in the BEAD Study

BEAD Study

Patient label

Uterine incision-to-delivery interval (sec): _____

FINAL VE: **Station:** -3 /-2 /-1 /0 /+1 /+2 /+3

Position: OA /OP /OT /Unknown

Uterine incision extension(s) – *Tick as many as apply & draw on diagram*

- ❑ Lateral extension _____
- ❑ Iatrogenic extension e.g. J or T incision or lateral_____
- ❑ Inferior extension _____
- ❑ Broad ligament _____
- ❑ Uterine artery(ies)_____
- ❑ Bladder _____
- ❑ Cervix _____
- ❑ Other, specify_____
- ❑ No extension

Additional manoeuvres used to deliver fetal head:

❑ Trendelenburg ❑ Tocolysis ❑ Change of hand

❑ Vaginal push-up ❑ Reverse breech extraction ❑ Change of surgeon ❑ Other: _____

Was the device helpful? ❑ Yes ❑ No

The delivery of the fetal head was: ❑ Very easy ❑ Easy ❑ Difficult ❑ Very difficult

Hospital coding data, including diagnostic reporting group (DRG) and costing data, will be requested from the Business Intelligence units for the outcome of cost effectiveness.

We plan to apply to Te Manatū Hauora at 5 years following the index birth to determine gestation at any subsequent birth, and to determine whether any birth <37 weeks (preterm) was spontaneous or medically indicated (defined as onset of birth with labour or preterm rupture of membranes compared to onset of birth following induction of labour or elective Caesarean section).

12. STUDY NUMBERS AND POWER CALCULATION

12.1 BEAD Trial Feasibility Study

The number of participants recruited in the second six months of the Feasibility Study is the primary outcome. There are approximately 400 CSFD across the two planned recruitment sites annually, based on recent retrospective data. Our aim for the BEAD study is to recruit 40-50 women across the two sites in the second 6 months of the Feasibility Study, to make the larger BEAD Trial feasible. We hope this is a conservative estimate of recruitment.

12.2 Feasibility of Recruitment

Site participation: We have consulted with obstetricians and anaesthetists at Te Toka Tumai|Auckland and Te Whatu Ora Counties Manukau about participation and support for a trial. We undertook the observational study at Te Whatu Ora Counties Manukau and Te Toka Tumai|Auckland to establish the use of the Fetal Pillow®, the incidence rate of uterine incision extensions at CSFD, and to determine whether there was evidence to support a further trial.

We surveyed NZ obstetricians to understand their CSFD practices, and received 137 responses. The survey queried their perception of the need for, and willingness to participate in, a trial, and to understand what might lead them to practice change. The survey found limited awareness among obstetricians and trainees of the incidence of uterine incision extensions, and mixed beliefs of the usefulness of the device. While many were aware that their use may not be based on good

understanding of the evidence, many believed anecdotally that to the device was effective at reducing morbidity.

One third (33%) of respondents "didn't know" and 30% disagreed with the statement "there is adequate research demonstrating effectiveness for maternal outcomes." Most (84%) were interested in participating in a trial and would encourage women's participation (73%). Respondents thought the most important primary outcome for a trial was uterine incision extension (36%), uterotomy to birth interval (26%) or neonatal morbidity (12%). More respondents said they would start using the device in response to a trial (88%) than agreed would stop (55%).

76% of respondents who use the Fetal Pillow® stated they do not specifically mention the device in gaining consent for trial in theatre or CSFD. Only 21% thought that consent should be gained for use of the Fetal Pillow®.

Concept development workshop: We presented the draft trial protocol at the ON-TRACK Research Development workshop (2021) which included feedback from Māori health advisors, consumers and healthcare providers. Since this time we have continued to work on the protocol and to gather evidence to support a trial, including undertaking an observational study looking at frequency of Fetal Pillow® use and obstetric outcomes, and a national survey of clinicians use of the Fetal Pillow®.

Consumer participation: A small survey (n=20) was conducted through the vaginal birth after caesarean (VBAC) clinic at Te Toka Tumai|Auckland . Wāhine Māori who had a caesarean section in a prior pregnancy were asked about timing of consent (intrapartum), with feedback indicating consent for participation in the trial at the time of consent for emergency caesarean section in labour is acceptable to them.

13. INTERIM ANALYSIS AND STOPPING GUIDELINES

13.1 Interim analysis

Interim analysis is planned after the first 6 months to assess trial recruitment, however we will use feedback from patient and clinician surveys on barriers and enablers to fine tune the approach to patients and trial processes throughout the Feasibility study.

13.2 Treatment duration

This study involves a one-off intrapartum intervention for participants with a follow-up consent for access to neonatal and subsequent pregnancy data. Although we intend to gain consent to assess outcome of future pregnancies, there are no additional appointments or tests required of participants.

14. RANDOMISATION

Eligible women who have provided written, informed (abbreviated) consent to participate will be randomised to true or sham-inflation of the Fetal Pillow® by a member of the anaesthetic team. Randomisation will be completed immediately prior to Caesarean by the anaesthetist using the web-based REDCap platform. Only data required to identify the woman and to confirm eligibility will be entered into the database.

Women will be randomly assigned to the inflation or sham-inflation group with a 1:1 ratio. The randomisation will be stratified by parity (nulliparous v multiparous) and recruitment site.

The randomisation process assigns each participant a unique study ID number. The online randomisation service provides 24 hour access, 7 days a week.

15. SAFETY ASSESSMENT AND MONITORING

15.1 Assessment of Adverse Events

Information will be collected by research staff regarding all adverse events (AE) that occur from time of randomisation until primary discharge from hospital (neonatal) and six-weeks postpartum (maternal).

15.2 Serious Adverse Events

Serious adverse events (SAEs) are defined as those which led to significant additional treatment, are life-threatening or have led to an unexpected death or major loss of function occurring to a participant during the study, related to any of the treatment arms. The adverse events may or may not be related to the intervention or to participation in the trial. The most common SAEs are likely to be major postpartum haemorrhage (PPH) (>2000mL) requiring red cell transfusion or peripartum hysterectomy for mother and Hypoxic Ischaemic Encephalopathy (HIE) for baby.

In this trial the following will be considered serious adverse events (SAE):

- Patient complaint about lack of intrapartum consent
- Maternal or neonatal death
- Persistent or significant maternal disability or incapacity (associated with the caesarean section) e.g. peripartum hysterectomy or uterine rupture
- Major PPH (≥2000mLs or requiring activation of the massive transfusion protocol)
- Hypoxic Ischaemic Encephalopathy (HIE) Sarnat stage 2 or 3
- Any neonatal fracture
- ICU admission thought to be related to a difficult caesarean section and not to other maternal co-morbidity
- Other medically important maternal or neonatal event considered to be an SAE by investigator
-

15.2 Investigator reviews of SAEs

All adverse events will be reviewed by the Principal Investigator, in consultation with co-investigators as required to determine whether the trial intervention was a causative and expected factor. SAEs will also be assessed for expectedness in the clinical setting based on underlying pregnancy, labour and/or neonatal factors. Serious Adverse Event reports will be created by the Principal Investigator and sent to the Data and Safety Monitoring Committee for review.

15.3 Procedures for SAE reporting

All serious adverse events should be reported within 72 hours to the Principal Investigator or Trial Manager. The REDCap database will include an electronic SAE data capture form, which will be completed by the trial manager or Principal Investigator, who will determine whether the trial intervention was a likely causative and expected factor. This is automatically sent to the DSMC once complete. The PI will ensure that a member or members of the DSMC have received and able to view the information within the required timeframe. A process for reporting adverse events (serious and not serious) will be provided to the participating site coordinator or manager. Research staff are encouraged to check whether an event should be regarded as serious by emailing the principal investigator if there is any uncertainty.

15.4 Data and Safety Monitoring

The BEAD study investigators have established an independent Data and Safety Monitoring Committee (DSMC) whom will meet before the start of the study to define terms of reference and a meeting schedule. The DSMC includes a senior obstetrician, a senior neonatologist, a biostatistician and an clinical academic with RCT experience. This committee will review any serious adverse events, trial safety, efficacy and conduct and report to the Trial Management Group (TMG). Interim analyses of this study are planned after six months.

16. CONFIDENTIALITY AND DATA MANAGEMENT

16.1 Confidentiality

All study-related information will be stored securely in password protected REDCap databases on either Hospital or University of Auckland servers. These databases will only be accessible to the research team. Data extracted for analysis will be de-identified (patient descriptors removed, and patients identified by study number only) and also retained only in University of Auckland password protected files and only available to research analytical staff. Only aggregate data will be reported so no persons will be identifiable in the reported data. No analyses will be presented which discriminate against any group or present any group in a deficit manner. All analyses of data for Māori whanau will be undertaken with support and advice from Māori co-investigators.

Identifiable data will not be reported or released to any third party.

Data storage – data will be stored for 26 years after the end of the trial consistent with ethical requirements for inclusion of children as participants.

All investigators and participants will remain blinded to treatment allocations until the study is complete and database lock has occurred. If a participant is un-blinded (although we cannot envisage that this will be necessary in this study) due to an urgent clinical need to reveal the study allocation the investigator is advised to limit the distribution of this information to other site staff or study personnel.

16.2 Access to Data and Data-Sharing

The Trial Management Group (TMG) will have access to the full dataset and oversee analysis, interpretation and reporting of results. Anonymised data on study allocation, primary and secondary outcomes may be made available for inclusion in individual patient meta-analyses on request to, and at the discretion of, the investigator team.

16.3 Data Management Plan

See separate data management plan for further details.

17. STATISTICAL ANALYSES

We will be assessing recruitment throughout, and reviewing feedback to surveys periodically to inform action research cycles (i.e. to resolve issues with information, recruitment, and process). We will formally review data on the primary and secondary outcomes of the feasibility study at six

months. All data will be analysed as single group, not by study treatment group. Descriptive statistics will be used for demographics and other baseline data. Recruitment will be calculated as number of participants recruited of the number of individuals identified as eligible and the number of individuals approached. This will be reported for the whole study population and by groups – ethnicity and recruitment site (Auckland Hospital and Middlemore).

Descriptive summary statistics will be used for all secondary outcomes. Qualitative methods such as Clarke and Braun thematic analysis will be used to assess enablers and barriers to trial participation and to explore intrapartum consent experiences[40].

The study data collected from patients randomised in the Feasibility Study will be included in the full BEAD Trial and will not be analysed prior to completion of that study.

18. STUDY TIMELINE

2022 – March 2023

Protocol preparation

Meetings with relevant clinicians (obstetric, midwifery, anaesthetic)

Meetings with consumers

Preparation of resources

2023

Ongoing meetings with relevant clinicians (obstetric, midwifery, anaesthetic)

Ongoing meetings with consumers

Ongoing preparation and revision of resources including education package for clinicians

HDEC ethics application

Locality approvals at Middlemore and Auckland Hospitals

Site engagement/local governance

Development of web-based data collection system and randomisation service

Recruitment of research midwives/project manager.

August 2023: Anticipate starting recruitment to the BEAD Feasibility Study (12 months)

2024

Analysis of the BEAD Feasibility Study, improvements to study protocol and assuming plan to proceed, secure funding and ethics approval for full trial

2024-2027

Contribution to the BEAD Trial (pending funding)

2027-2028

BEAD Trial data analysis and results publication

19. ETHICS AND REGULATORY

All participating sites have received ethics approval by NZ HDEC, and local hospital governance approval before commencing recruitment.

All staff will be allocated paid time to attend Good Clinical Practice training in line with ICH guidelines (provided by University of Auckland) and to be certified.

20. FUNDING

The Feasibility Study is funded by an Health Research Council of New Zealand (HRC) and the Mercia Barnes Trust.

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