OptiBreech Care Group Allocation Information Sheet

This sheet contains information about your group allocation. The information should be read in conjunction with the OptiBreech Care Participant Information Sheet, v 1.2, dated 20-Jun-2022 and the OptiBreech Care Consent Form, v 1.2, dated 20-June-2022.

Description

Optibreech care is a new care pathway. That means care starts when your baby has first been diagnosed as breech after 36 weeks and follows you through to your birth, whether you choose to try to turn your baby head-down, plan a vaginal breech birth or plan a caesarean section. The most important difference in this potential new care pathway is that care for vaginal breech births, for those who choose this, is delivered by a proficient team, all of which have had enhanced training in physiological breech birth.

If you choose to accept this care pathway, you will have the opportunity to discuss your options with an experienced specialist. They will offer you 3 options:

1. Planning a vaginal breech birth with OptiBreech care in labour
2. Trying to turn the baby head-down (external cephalic version, or ECV)
3. Planning a caesarean section birth at 39 weeks

The choice of what to do is entirely yours, just as it would be in standard care. The only change is that you are being offered counselling by a specialist who is experienced in vaginal breech birth and can offer you that option right from the start.

Study settings

Some hospitals participating in this study all participated in another study first, to determine whether they could provide experienced staff to care for women planning a vaginal breech birth, called OptiBreech 1. The results so far are presented below, alongside the results from the largest UK study of results after turning the baby.

No service can offer you an absolute guarantee that experienced staff will be available for a vaginal breech birth, due to the unpredictability of birth in general. Nor can we guarantee a good outcome no matter which option you choose. But in the OptiBreech 1 study, over 90% of births were attended by professionals who had completed the enhanced training.

Do I have to take part?

Participation is completely voluntary. You can decline OptiBreech care if you prefer, and you will be referred to the standard care pathway within your hospital. Choosing not to take part will not disadvantage you in anyway. You are able to choose whether you would like to attempt turning your baby down and/or how you would like to give birth, whether you receive specialist counselling or not.

Previous research related to the OptiBreech care pathway

OptiBreech 1 results, data received to 09/05/22

Outcome	**OptiBreech 1** *68 planned vaginal breech births following or without ECV attempt*	**Melo et al 2019 ECV study** *gold standard UK ECV pathway*
Parity	First baby 57.4% (39/68)	First baby 62.4% (1632/2614)
Total vaginal births	54.4% (37/68)	43.6% (1141/2614)
Spontaneous vaginal birth	51.5% (35/68)	33.1% (866/2614)
Instrumental birth *(forceps or suction cup)*	2.9% (2/68)	10.5% (275/2614)
Pre-labour caesarean birth	17.6% (12/68)	36.6% (957/2614)
In-labour caesarean birth	27.9% (19/68)	18.5% (484/2614)
Baby turned head-down prior to labour following failed ECV	2.9% (2/68)	4% (57/1334)
Admission to NICU / SCBU* *National average @ term = 5.4%*	4.4% (3/68)	3.6% (95/2614)
Stillbirth or neonatal death (within 28 days of birth) *	0	0.19% (5/2614)
Someone present who had completed physiological breech birth training	91.4% (32/35)	*Not reported*
Someone present who met all proficiency criteria	74.3% (26/35)	*Not reported*
Less than 5 minutes elapsed between the birth of the pelvis and the birth of the head	88.6% (31/35)	*Not reported*
Maternal birth position	Upright – 74.3% (26/35) Supine (back) – 25.7% (9/35)	*Not reported*

* The OptiBreech 1 study has not collected enough data to make a realistic comparison on these outcomes, but we would expect results to be similar, based on the RCOG Guidance described below.

Physiological breech birth training

Results of vaginal breech births only. Conducted in 6 hospitals across the UK. No attempt was made to quantify the experience/proficiency of attendant, only their completion of training package.

Total = 90	**PBB trainee at the birth** (n=21)		**No PBB trainee at the birth** (n=69)	
Birth Position				
upright	17/21	**81%**	22/69	**32%**
supine	4/21	**19%**	47/69	**68%**
Maternal Severe Adverse Outcomes	0/21		5/69	**7%**
PPH > 1500 mL	0/21		3/69	**4%**
3rd/4th degree tear	0/21		2/69	**2%**
Perineum				
Intact	11/21	**52%**	27/69	**39%**
Episiotomy	1/21	**5%**	15/69	**22%**
Neonatal Severe Adverse Outcomes	0/21		5/69	**7%**
5 min APGAR < 4	0/21		4/69	**6%**
NICU > 4 days	0/21		1/69	**1%**

PBB trainee at the birth = Someone present at the birth who participated in Physiological Breech Birth training
PPH = postpartum haemorrhage (heavy bleeding after birth); NICU = neonatal intensive care unit; APGAR = assessment of baby's condition after birth, on a scale of 1-10

Note: These results could be due to chance. Much larger numbers are needed to draw conclusions about the relative safety of PBB training. But they encourage us to feel that continuing to conduct this research is safe and ethical, with strict monitoring of outcomes in place. That is the current study.

What are the possible benefits of taking part?

The attendance of a skilled and experienced professional is the only factor associated with a reduction in perinatal mortality in previous, high-quality research. However, very few hospitals offer a plan to increase the likelihood of attendance by a skilled and experienced professional. ***Your OptiBreech team cannot offer you an absolute guarantee due to the unpredictable nature of labour,*** but by participating in this study, they are agreeing to try their best. Also, although the RCOG guideline supports the use of both supine and upright birthing positions, not all professionals have had fully evaluated training to support upright breech births. All members of your hospital's breech team will have had this training.

Even if you decide to try to turn your baby or plan a caesarean section, you will receive unrushed, experienced counselling about your options.

What are the possible disadvantages and risks of taking part?

According to the Royal College of Obstetricians and Gynaecologists guideline (RCOG, Impey et al 2017), planning a caesarean section leads to a small reduction in the risk of perinatal mortality (baby's death) compared with vaginal breech birth. The risk of perinatal mortality is approximately 0.5/1000 with caesarean section after 39+0 weeks of pregnancy; and approximately 2/1000 with planned vaginal breech birth. This compares to 1/1000 with planned head-first birth.

Current guidelines also recommend trying to turn the baby head-down because it reduces the risk of having a caesarean birth compared to standard care. We do not know yet whether OptiBreech care also reduces this risk, and therefore not attempting to turn the baby head-down may result in a higher risk of caesarean birth.

We are carefully studying OptiBreech care because we believe it may improve these outcomes for women planning a vaginal breech birth. However, it could introduce risks that we are not aware of yet. You should carefully consider your mode of childbirth with a breech baby at term, and your team will support you regardless of your choice. The study sponsor has also identified a Trial Steering Committee with experienced health care professionals who will consider all of the outcomes of the study and recommend stopping if risks for women participating appear to be increased.

Consent

You have already consented to participation in this research study, and you should have received a copy of that consent form. We do not require you to sign an additional consent form because you are able to choose elements of your care, just as you would under standard care. You are able to seek a second opinion, or decline any element of this care, just as you would under standard care. If you wish to withdraw from the study entirely, you can do that at any time, but we will retain information we have collected about you up until that point.

What if I have further questions?

You are welcome to contact the research team:

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Your counselling should include:

Topic	Date	Signature
What are her priorities, values and hopes for this birth?		
Skilled intrapartum care and the absence of additional risk factors may allow planned vaginal breech birth to be nearly as safe as planned vaginal head-down birth. • Explain OptiBreech plan for providing skilled intrapartum care • Results of pilot study achieved >90% OptiBreech team intrapartum attendance in the sites participating in this study, but this cannot be guaranteed due to the unpredictability of labour		
Turning the baby head-down (external cephalic version, ECV) • Success ≈ 50% • Reduces CS rate from 40% (planned VBB) to 20% • 1:200 emergency CS at time of procedure • Neither improves nor worsens outcomes for the baby		
Any additional information/advice re: turning the baby head-down		
Planned caesarean section leads to a small reduction in perinatal mortality compared with planned vaginal breech birth. The reduced risk is due to 3 factors: • The avoidance of stillbirth after 39 weeks • The avoidance of intrapartum risks • The risks of vaginal breech birth Only the last is unique to a breech baby		
When planning birth for a breech baby, the chance of perinatal mortality is approximately 0.5/1000 with caesarean section after 39 weeks of gestation, and approximately 2/1000 with planned vaginal breech birth. This compares to approximately 1/1000 with planned head-down birth.		
Planned vaginal breech birth increases the chance of low Apgar scores (poor condition at birth) and serious short-term complications (such as admission to the neonatal unit), but this has **not** been shown to increase the chance of long term morbidity. Planned caesarean birth does **not** reduce the risk of death or neurodevelopmental delay in children at 2 years of age.		
Planned caesarean birth for breech presentation at term carries a **small** increase in immediate complications for the mother compared to planned vaginal birth Infection / thrombosis / pain / injury to bladder / bowel / bleeding		
Caesarean section increases the chance of complications in **future pregnancies** for both mother and future children. This may include scar dehiscence (1:200 with a planned vaginal birth afer CS), increased complications at an elective repeat caesarean section and the chance of an abnormally invasive placenta. A vaginal birth after CS is usually supported, but also has a 25-28% chance of EMCS.		
Caesarean section has been associated with a **small** increase in the chance of stillbirth for subsequent babies although this may not be causal.		
Factors affecting safety of planned vaginal breech birth The RCOG guidelines cite increased risk if:		

• Hyperextended neck on ultrasound • High estimated fetal weight (more than 3.8 kg) – increased risk of EMCS • Low estimated fetal weight (less than 10th centile) • Standing/footling presentation (discuss all presentations / cord events) If your baby is in a position that makes it likely the foot will drop down before the bottom during the birth (flexed/standing/footling), there is a 20% (1:5) chance the cord will drop down as well. Although this may require an emergency CS, this risk has not been associated with an increase in adverse outcomes for these babies, compared to other types of breech birth. The OptiBreech protocol, developed in consultantion with OptiBreech leads across our participating sites, does not recommend an emergency CS solely because a foot is lower than a bottom during the birth. This is a common situation in flexed breech babies. However, this differs from standard practice, and there is currently no evidence to guide decision-making in this situation. If your baby is in a flexed position, you are planning a VBB and you have a preference for management in labour, please discuss this with your team.		
Additional discussion points • Continuous monitoring may lead to improved neonatal outcomes • Choice of pain relief • Maternal positioning for labour and birth		
Individualised assessment based on individual risk profile and reproductive intentions		

References and Sources of Further Information

Impey, L., Murphy, D., Griffiths, M., Penna, L., & on behalf of the Royal College of Obstetricians and Gynaecologists. (2017). Management of Breech Presentation. *BJOG: An International Journal of Obstetrics & Gynaecology*, *124*(7), e151–e177. https://doi.org/10.1111/1471-0528.14465

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Melo, P., Georgiou, E. X., Hedditch, A., Ellaway, P., & Impey, L. (2019). External cephalic version at term: a cohort study of 18 years' experience. *BJOG: An International Journal of Obstetrics and Gynaecology*, *126*(4), 493–499. https://doi.org/10.1111/1471-0528.15475