ORIGINAL ARTICLE

BIRTH ISSUES IN PERIMATAL CARE WILEY

Breech specialist midwives and clinics in the OptiBreech Trial feasibility study: An implementation process evaluation

Tisha Dasgupta MSc¹ | Sarah Hunter^{1,2} | Sharna Reid^{1,3} | Jane Sandall CBE PhD¹ Andrew Shennan OBE FRCOG¹ | Siân M. Davies MSc¹ Shawn Walker PhD^{1,4}

¹Department of Women & Children's Health, School of Life Course Sciences, Faculty of Life Sciences & Medicine, King's College London, London, UK

²Independent Lay Members of the Research Team, Peterborough, UK

³Independent Lay Members of the Research Team, London, UK

⁴Chelsea and Westminster Hospital NHS Foundation Trust, Women's and Children's Services, London, UK

Correspondence

Shawn Walker, PhD, Department of Women & Children's Health, School of Life Course Sciences, Faculty of Life Sciences & Medicine, King's College London, St Thomas' Hospital, 10th Floor North Wing, London SE1 7EH, UK.

Email: shawn.walker@kcl.ac.uk

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Abstract

Background: Attendance of skilled and experienced professionals at breech births has been associated with a reduction in adverse perinatal outcomes. We aimed to determine whether United Kingdom National Health Service (NHS) sites could reliably provide attendants with OptiBreech training and/or advanced proficiency (intervention feasibility) and consistent care (fidelity) that meets women's needs (acceptability), with low neonatal admission rates (safety) and recruitment adequate to support a clinical trial (trial feasibility).

Methods: Mixed methods implementation evaluation was used. Settings were 13 services in England and Wales. Participants were 82 women requesting support for a vaginal breech birth (VBB) at term. Outcomes were descriptively analyzed. Twenty-one women were interviewed, and transcripts were analyzed using the Theoretical Framework of Acceptability. Iterative analysis informed subsequent interviews and the ongoing process of implementation across sites.

Results: Although we initially suggested multidisciplinary teams, actively recruiting Trusts yielded services where VBB care was provided through a dedicated clinic, organized and delivered primarily by a lead midwife who functioned as a specialist. This model achieved 87.5% fidelity with the intervention's goal of ensuring the attendance of OptiBreech-trained professionals. Neonatal outcomes remained stable, with an admission rate of 5.5%. Women reported care from specialist midwives as highly acceptable, but the model is vulnerable without a strategic effort to develop additional proficient team members.

Conclusions: Dedicated clinics coordinated by specialist midwives appear to be an acceptable and feasible implementation strategy to test the safety and effectiveness of proficient team care for VBB in a clinical trial. Back-up arrangements should be maintained while additional members of the team develop proficiency.

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K E Y W O R D S

breech clinics, breech presentation, breech teams, feasibility, implementation, specialist midwives, vaginal breech delivery

1 | INTRODUCTION

"Physiological breech birth" is an approach to facilitating vaginal breech birth (VBB) centered on the optimization and restoration of normal physiological processes to achieve a safe outcome.¹ This includes upright maternal birth positions, such as kneeling, which promote active maternal movement and efficiency during expulsion.^{2,3} Interventions are performed in response to specific clinical indications based on evidence of what is considered "normal" breech birth physiology.^{4–6} Neither upright maternal positioning nor this approach has been tested in a clinical trial.

Before a trial can be conducted, the ability to reliably deliver the intervention needs to be established. The OptiBreech 1 study was designed to evaluate whether services could reasonably ensure professionals with OptiBreech training and/or proficiency were able to attend VBBs (intervention feasibility) and provide consistent care (fidelity), in a way that is acceptable to women and staff (acceptability), while maintaining low neonatal admission rates (safety). We also aimed to examine whether women would participate in such a study (trial feasibility).

The purpose of a process evaluation to inform trials of complex interventions is to understand the effects of implementing a new intervention and the mechanisms of these effects in new contexts.⁷⁻⁹ OptiBreech 1 was a noninterventional study, after women who requested a planned VBB at term under current guidelines. This study focuses on the analysis of data concerning the *models of service delivery* and their acceptability to care recipients.

2 | METHODS

We used a concurrent mixed methods design to evaluate the implementation of OptiBreech-trained birth attendants in these settings. Quantitative data were used to describe recruitment figures and outcomes. Qualitative data were used to understand how, why, and for whom the OptiBreech Care intervention was working. We integrated these insights to refine the program theory around service delivery in our complex VBB intervention.

2.1 | Ethics

The study was reviewed and approved by the East of England—Cambridgeshire and Hertfordshire Research Ethics Committee (20/EE/0287, IRAS 268668). Prospective consent was obtained from all participants, except when breech presentations were diagnosed in labor. In these cases, consent was obtained after the birth.

2.2 | Quantitative data and analysis

Quantitative data included recruitment figures, demographic data, fidelity criteria (Table 1), and neonatal admissions. Although all UK birth professionals have basic annual mandatory training in VBB, proficiency criteria were based on previously published research and assessed by local breech leads. We originally aimed for >90% of births attended by someone who fulfilled the proficiency criteria, but this was an unrealistic short-term goal given the low levels of baseline experience in most

TABLE 1 OptiBreech 1 fidelity and proficiency criteria

- Fidelity criteria for this portion of the study included:
- Attendance of someone who completed the OptiBreech training package;
- Attendance of someone who met the advanced proficiency criteria;
- Whether or not maternal movement and effort were used as a first intervention before hands-on assistance;
- Whether or not the birth was complete within 5 minutes of the birth of the fetal pelvis; and
- Maternal birthing position
- Proficiency criteria were based primarily on Standards for maternity care professionals attending planned upright vaginal breech births,⁴ Deliberate acquisition of competence in physiological breech birth: A grounded theory study,³² and Expertise in physiological breech birth: A mixed methods study.³¹

These included:

- Completion of the OptiBreech training package;
- Attendance of at least 10 VBBs including complications;
- Attendance of 3 VBBs within the past year;
- · Contributing to clinical teaching; and
- · Reflective reviews of births attended

centers. Following early discussion with sites, this was modified to >90% of births attended by someone who had completed the OptiBreech training, while continuing to also aim for proficient attendants. A detailed description of the training package has been published with previous evaluations.^{10,11} Participants were counseled according to their local guidelines based on the Royal College of Obstetricians and Gynaecologists guideline,¹² supplemented by a bespoke Participant Information Sheet (PIS). Quantitative data were obtained from individual Case Report Form (CRF) and Vaginal Breech Birth Pro Forma completed by local investigators and analyzed descriptively using IBM SPSS statistical software, Version 27.

The aim of this study was to determine the feasibility of ensuring OptiBreech trained and/or proficient care for VBBs. We collected only basic outcome data. For maternal outcomes, this was focused on the mode of birth. For neonatal outcomes, we collected only neonatal death (up to 28 days) or immediate admission to a neonatal intensive care unit. All neonatal admissions immediately after birth were considered serious adverse events (SAEs), reported to the CI, and reviewed carefully with the Study Steering Committee for oversight.

A copy of the CRF, Pro Forma, and PIS are included in Supporting Information.

2.3 | Qualitative data and analysis

Qualitative data included semi-structured interviews, lasting 37 minutes on average (range 15-52 minutes). A care recipient-specific interview guide, based on the Theoretical Framework of Acceptability (TFA), was used.¹³ Interviews were conducted by means of Microsoft Teams by a nonclinical member of the research team experienced in qualitative research (TD) and then transcribed. Two interviews were conducted by the Chief Investigator (SW). A maximum variation purposeful sampling strategy was used.¹⁴ Participants included 21 women across seven sites. Their experience included 12 VBBs (one diagnosed in labor), 1 forceps breech birth (FBB), 6 cesarean births in labor (ILCB), and 2 CBs before labor (PCB). Three cases involved difficulties with communication or births where the attendants did not meet the full proficiency criteria. Two women chose to give birth at home or in a midwifeled unit.

Anonymized transcripts were initially coded with reference to the TFA component constructs, using NVivo 12 qualitative data analysis software. Recurrent themes and patterns were compared across interviews. Nonclinician service user members of the team were provided with a sample of anonymized transcripts and supported to provide narrative feedback on the themes they identified. UES IN PERINATAL CARE -WILEY 3

They also commented on those identified by other members of the research team. Matrix and cross-tabulation features within NVivo were used to compare results across demographic categories and to observe how recurrent themes interacted with the TFA component constructs. Analytic memo writing, reflective meetings among the research team, and open meetings with stakeholders to discuss emerging results were used to refine the findings.

When the centrality of the breech-lead midwife's role in each setting became apparent, we also refined our topic guide to include an exploration of this role, as understood by our participants. The topic guide we used is available in the Supporting Information.

2.4 | Program theory

Clinical trials of complex interventions should articulate a program theory for how the complex intervention works, which can be summarized in a logic model. Refining the program theory is an important component of feasibility work.⁷ Rather than dictate how sites should achieve the proficient team attendance criteria, given the significant uncertainties in the current clinical and research context, we elected instead to observe our participant sites' own strategies, how these varied across sites, and how they related to our key outcomes. We then used these observations to refine our program theory.

Our original logic model included "funding for team training" as one of the key OptiBreech inputs. As our feasibility testing progressed, it was evident that this was not working as intended. The OptiBreech 1 protocol recommended that an initial multidisciplinary team (MDT) of 10, including 5 obstetricians and 5 midwives, complete the in-person physiological breech birth training program, and funding was set aside to back-fill staff time to attend. However, the need for social distancing precautions during the COVID-19 pandemic and the effects on staffing levels created a context in which this was impossible for all but two sites to achieve. To adapt to the new contextual constraints, the training package was put online (https://breechbirth.org.uk/the-training/courses/). The local hands-on training was organized at each site through mandatory training and ad hoc activities, primarily led by the breech-lead midwives.

2.5 | Stakeholder engagement

The OptiBreech Trial research team has facilitated the involvement of multiple stakeholders from the start of the project (https://optibreech.uk/category/ppi/). The project grew out of a body of evidence indicating that women who WILEY-B

wish to plan a VBB do not always feel that services meet their needs.^{15–17} We recognized a need to identify a more effective model of service delivery, in collaboration with service users. Because of concerns about low recruitment in previous breech trials,^{18,19} it was a priority that our method of testing is acceptable to women currently using maternity services. Service users valued accurate effectiveness and safety data. They also favored the development of a model of care that reliably supports informed decision-making and the autonomy of the birthing person, rather than a model that promoted CB, VBB, or external cephalic version (ECV) as the "best" option. This priority informed our decision to study the experiences of women and birthing people who actively sought out a VBB, rather than randomizing women to one mode of birth or the other. Stakeholder engagement in analysis and interpretation was facilitated through regular online meetings with the OptiBreech Patient and Public Involvement (PPI) group. These were advertised by email to participants by means of the OptiBreech website and blog and relevant social media channels.

RESULTS 3

Recruitment rates 3.1

Between February 2021 and June 2022, 82 women requested a vaginal breech birth and were recruited to the study across 13 sites (Table 2). Recruitment rates varied significantly, ranging from 1 to 14 women, and study setup times were heavily affected by COVID-19 pressures. The four highest-recruiting sites each had a breech-lead midwife who was formally enabled to lead the service as part of her role and enabled to work flexibly to attend most breech births that occurred. In these settings, recruitment averaged 1 woman/month. A total of 16/82 (19.5%) women self-referred to the study from another hospital to access this model of care.

3.2 Intervention feasibility

We achieved 87.5% (35/40) of births attended by a professional who had completed OptiBreech training. Three of the remaining births were precipitous, and OptiBreechtrained providers did not have time to attend; in two cases, no one who had completed the OptiBreech training was called. A provider who met the full proficiency criteria was present at 27/40 (67.5%) births. Three of the four neonatal admissions occurred following a birth where a provider who met the proficiency criteria was present, so were not attributable to failure to ensure experienced attendance.

To achieve this rate, primarily midwives and a small number of obstetricians spent an average of 3.38 days (range 0-16) and 6.49 nights (range 0-29) on call per birth. Only one of the midwives reported receiving on-call payments for planned breech births, but all were paid bank hours for time spent at breech births, which also provided clinical negligence insurance coverage.

3.3 Mode of birth

Mode-of-birth outcomes are presented in Table 3. Eleven women changed their minds and requested a planned CB. These are removed in the central column, which represents the final intention to treat by planned VBB sample. In the final column, we removed all PCB to identify the rate of in-labor CB among women who began labor planning a VBB.

Fidelity 3.4

As indicated in Table 4, fidelity criteria were more often met when OptiBreech-trained and/or fully proficient attendants were present.

3.5 Safety

Among planned VBBs, there were four neonatal admissions (4/73, 5.5%) and no neonatal deaths. The neonatal admission rate among actual VBBs was 3/40, 7.5%. In two cases, the decision made together with the Study Steering Committee was to pause the site until further in-person training can be provided to the team. In one case, a breechlead midwife had not been identified before the birth; this was required before progressing further in the study.

To assess whether the initiation of OptiBreech team care would introduce a risk of poorer outcomes, we also identified the neonatal admission rate in five of our participating sites before the start of the study. During the 2 years preceding the start of OptiBreech 1, these five sites admitted 8/61 (13%) neonates after VBBs, and one of these babies died. The rate of neonatal admissions after VBBs in OptiBreech 1 of 3/40 (7.5%) is encouraging for a future, more substantive study.

Acceptability 3.6

Analysis of our interviews with women revealed three pivotal needs for breech care in late pregnancy. Meeting these needs made care acceptable to women and led to higher

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	Other notes			++ self-referral transfers									Obstetric PI	Site closed—unable to release staff for training/team	Site closed after adverse outcome, pending FTF training	Obstetric PI, Site closed after adverse outcome, pending FTF training	Obstetric PI				^a BSM: Hands-on training was facilitated by an internal breech specialist midwife. Study team: A separate study day was provided by the research team. Previous: Some sites had hosted physiological breech birth training days before the start of the study and had staff members who had historically completed the enhanced training.
	Breech specialist midwife?	Formal	Formal	Formal	Formal				Informal	Informal	No	No	Informal	No	No	No	Informal				n. Previous: Some sites had l
	Face-to-face training? ^a	BSM	BSM	BSM	Study team				Study team	BSM	Previous	No	No	Previous	No	No	No				rovided by the research tean
acteristics	Dedicated clinic?	Yes	Yes	No	Yes				No	No	No	No	No	No	No	No	No				parate study day was pi ced training.
	Average per n month	1.5	1	1.2	0.8	1.1		1	0.8	0.7	0.3	0.3	0.5	0.8	0.3	0.3	0.75	0.75		0.67	wife. Study team: A se y completed the enhan
	Months open	×	8	12	8	36		36	11	12	10	15	11	S	4	6	4	109		109	l breech specialist mid rs who had historically
Recruitment figures and site characteristics	Total recruitment	12	8	14	9	40	4	36	6	8	3	5	9	4	1	ω	3	82	6	73	s facilitated by an interna udy and had staff membe
TABLE 2 Recruitmen	Code	100-A	100-B	101	102	Total	Changed mind (PCB)	Pilot trial sites net	103	105	106	107	108	115	119	120	128	Total	Changed mind (PCB)	Net total	^a BSM: Hands-on training was facilitated by an internal breech specialist midwife. Study team: A separate study days before the start of the study and had staff members who had historically completed the enhanced training.

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	Total sample (%)	Total w/o maternal request CB	Total w/o planned CB
Vaginal breech birth	38 (46.3)	38 (52.1)	38 (57.6)
Forceps breech	2 (2.4)	2 (2.7)	2 (3.0)
Cephalic birth	3 (3.7)	3 (4.1)	3 (4.5)
Total vaginal births	43 (52.4)	43 (58.9)	43 (65.2)
In-labor cesarean	23 (28.0)	23 (31.5)	23 (34.8)
Planned cesarean	16 (19.5)	7 (9.6)	-
Total cesarean birth	39 (47.5)	30 (41.0)	23 (34.8%)
Total	82	73	66

TABLE 3 OptiBreech 1 mode of birth outcomes

	Attendant with OptiBreech training	None present with OptiBreech training	Attendant who met proficiency criteria	None present with enhanced training	Total sample (%)						
Maternal birth position											
Upright	28 (80)	2 (50)	22 (81.5)	8 (66.7)	30 (76.9)						
Supine	7 (20)	2 (50)	5 (18.5)	4 (33.3)	9 (23.0)						
Encouraged movement and effort											
None required	6 (17.1)	1 (25.0)	5 (18.5)	2 (16.7)	7 (17.9)						
Yes	25 (71.4)	2 (50.0)	21 (77.8)	6 (50.0)	27 (67.5)						
No	4 (11.4)	1 (25.0)	1 (3.7)	4 (33.3)	5 (12.5)						
<5 Minutes pelvis to birth											
Yes	31 (88.6)	3 (75.0)	24 (88.9)	10 (83.3)							
No	4 (11.4)	1 (25.0)	3 (11.1)	2 (16.7)							
Total	35/39 (89.7)	4/39 (10.2)	27/39 (69.2)	12/39 (30.7)	39 ^a						

^aBBA/unassisted birth eliminated.

recruitment rates. These were as follows: balanced information, access to skilled breech birth care, and shared responsibility. We have included exemplary quotes in a Supporting Information table, available online (Table S1: Exemplary Quotes).

We identified that some breech-lead midwives fulfilled several roles reflecting their operation as specialists within the service, working in collaboration with breech-lead obstetricians. These included counseling and clinic coordination, communicating plans, attending breech births, supporting less experienced team members, providing training, and leading service development. Interviews with women indicated that these roles were understood by the recipients of the service, who referred to them as "specialists" or "consultants" and often by name.

At the beginning of their breech care, women described needing "balanced information." Clear, unbiased counseling about their options enabled them to make informed decisions, which in turn gave them a sense of self-efficacy, choice, and control over the situation. They valued being fully informed about both the potential risks and potential benefits of VBB. Women consistently described the information they received from specialists as balanced, detailed, and delivered in ways that met their needs. This also applied to information about the research study.

This contrasted with the way they described counseling from other professionals, which they often experienced as brief and biased. Women reported that cesarean birth was often presented as a completely safe option with no risks, and many described doubts or knowing this not to be true. This conflicted with their values, undermined their trust in their care team, and sometimes created conflict between women and their partners. They also described attempting to access online information about their options; this was described as being difficult, time-consuming, and laborious, with little information available about VBB, even on NHS and hospital websites. This led participants to express ethical concerns that counseling and publicly available information did not always reflect the fact that they had a choice about how to give birth.

In sites with routine referrals to a breech specialist clinic and/or midwives, women experienced less conflicting information. Women particularly valued the breech midwives' ability to describe complications and their resolution. They interpreted this as a reflection of the midwives' skill and experience, which they perceived could contribute to their safety and their baby's safety. Detailed counseling instilled confidence not only in the midwife but also in themselves, with some stating that they would likely have had an unwanted cesarean birth without OptiBreech guidance. Although women all reported receiving information about potential risks, some reported feeling doubt that the risks could apply to them. Others reported that they particularly valued the detailed antenatal information, especially when they or their babies experienced complications.

"Access to skilled breech birth care" also affected women's ability to plan a VBB when they desired one. They understood the importance of skill and experience in making VBB as safe as possible and therefore perceived that this was only a reasonable option if skilled professionals were available. Participants found it convenient to access care when referred during their routine care. Others found it difficult, even within OptiBreech sites, if they were not referred to an OptiBreech midwife for detailed counseling and planning. Women expressed reassurance when they perceived there was a good chance a breech specialist would be at their birth, and that a plan would be in place if not. Women who were referred to dedicated clinics valued the input of consultant obstetricians who also appeared knowledgeable and confident about VBB.

On the other hand, for some women, trust and confidence in specialist breech care were centered solely around the breech specialist midwife. In some cases, when the woman was not reassured that the specialist could attend her birth, she chose to plan a CB instead. The focus on the breech specialist midwife rather than a team was especially apparent when women felt that not all staff appeared to be aware of the service or supportive of its purpose. Even within units with a specialist clinic and a formal role in place, services were not always fully embedded. In multiple sites where there was no specialist clinic or breech specialist midwife, women were told the service was not available; some found out later it had been available, whereas others transferred to another OptiBreech site.

Some women (19.5%) who had no access to skilled breech care locally transferred their care to an OptiBreech hospital; a few even moved their place of residence temporarily. Accessing specialist care for these participants was sometimes associated with opportunity costs such as time off work, financial costs, traveling long distances to the hospital, additional trips, and a lack of antenatal continuity they would have received in local care. However, many were happy to make the increased effort because they had chosen to plan a VBB, and they could not access skilled care in hospitals close to their home. Women expressed concern that the situation raised equity of access issues, and perhaps others who lacked similar resources would not be able to give birth the way they wanted to.

Finally, participants who planned a VBB benefitted from "shared responsibility" with their care team. Before accessing supportive care, women often felt a significant emotional burden. They felt alone to bear the responsibility of any potential adverse events. They reported that other people in their lives, including professionals, family, and friends, expressed judgment of their birth choices and suggested that they were perhaps being irresponsible. This led to feelings of guilt, selfishness, and shame.

For many, transferring care to the OptiBreech site meant developing a relationship with an experienced breech midwife who supported the women's choices, which lightened this emotional burden. Women perceived the specialist midwives as taking responsibility for cultivating a safe-as-possible service, including accurate counseling about complications, spending time on-call to attend births, and training other members of the team. Some women focused on the breech specialist midwife in contrast to other members of the team in whom they did not have confidence. But others perceived that the provision of a specialist service reflected a shared commitment to skill development within the wider team, which they were prepared to trust, even while they understood that not all members of the team had the same level of experience (Figure 1).

4 | DISCUSSION

In contexts where women have the option of choosing to plan a VBB with an OptiBreech-trained provider, breech specialist midwives have been a central mechanism of service delivery and maternity team skill development. This model of service also appears to be comparatively much more acceptable to women than standard care, especially when obstetric colleagues are involved and supportive. In sites with a dedicated clinic, the model may have additional benefits, as this has also been shown to correlate with higher ECV success rates.²⁰

In this study, specialist midwives and clinics improved women's ability to plan a VBB and participate in research. This does not appear to be a result of "normality-centered care" or encouraging vaginal birth "at all costs."²¹ Our findings suggest that when women are given clear and balanced information about risks and benefits, and there is a high likelihood of having skilled and experienced support at their birth, more women feel able to express their preference to plan a VBB. This is

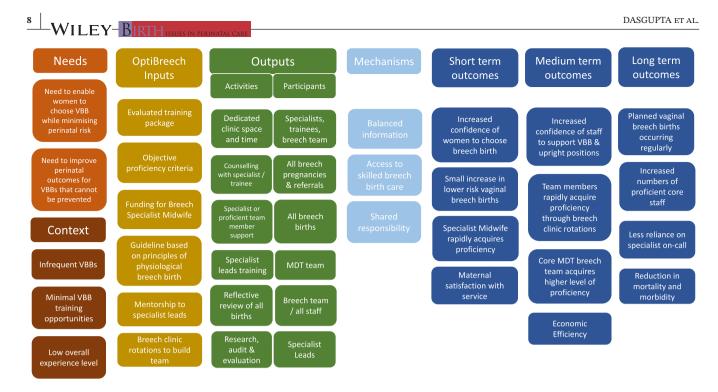


FIGURE 1 The logic model for OptiBreech Care as of July 4, 2022, including refinements from our ongoing implementation process evaluation

consistent with previous research^{22–24} and the ethical principles of informed choice²⁵ about medical interventions. The women we interviewed who ultimately chose to plan a CB also indicated they felt supported in their choice and provided with information appropriate to their needs. We have therefore incorporated specialist midwives and clinics into the description of our OptiBreech Care intervention.

We have identified a relationship between qualitative aspects of service delivery and women's preference or ability to plan a VBB. We have been able to describe these features with enough detail to be replicated and tested in a clinical trial. Women's descriptions in this study are consistent across multiple services, despite varying outcomes. They are also resonant with previous research on women's experiences.²⁶ The level of involvement of the OptiBreech PPI group and service user members of our research team have been significant and meaningful.

Our study also has some limitations. Our finding that a model in which a dedicated clinic and OptiBreechtrained team are coordinated by a breech specialist midwife is the most successful implementation model does not mean other models are ineffective. Our findings are heavily influenced by context, including the continuing impacts of the COVID-19 pandemic on staffing levels within the NHS and low overall breech experience levels in these settings after decades of erosion. Successful breech services involving midwives have been reported internationally,^{27,28} but other models have been reported in other contexts.^{29,30} We have focused on interviews with women in this analysis. Further work is needed to describe the roles of breech specialist midwives and to evaluate the acceptability of the role among the wider MDT team. Also, the OptiBreech Chief Investigator fulfills multiple roles, including service leadership and delivery. This may introduce bias. To balance this, a nonclinical member of the team conducted and independently analyzed all interviews. The findings were subject to member checking with participants and service user research team member feedback (SH, SR).

While the care model delivered by breech specialist midwives is effective at enabling access to research, is acceptable to women, and is able to achieve reasonable fidelity, more time will be required for the service to embed. Meanwhile, the burdens of time and responsibility on these midwives are significant, and the service may be vulnerable when they are not available. This model depends on the ability of the specialists to protect their time and work flexibly to cover the service,^{31,32} which will require funding to be sustainable. Ongoing implementation and evaluation work should focus on the best way to develop additional proficient team members and on economic implications. Safety outcomes should be evaluated in a large-scale observational study, in addition to any trial of comparative effectiveness.

AUTHOR CONTRIBUTION

SW, JS, and AS designed the study and supervised the data analysis. TD collected and analyzed the data and drafted

the first summary of results. SH and SD contributed to the analysis and interpretation. SD reviewed qualitative and quantitative analyses. SW finalized the manuscript and all authors approved it.

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CONFLICT OF INTERESTS

SW is a co-Director of Breech Birth Network, a Community Interest Company, that provides breech training and donated the online training package used in the study. SW receives speaking fees and expenses for her activities.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in Figshare at https://figshare.com/articles/dataset/OptiBreech_1_IRAS268668_outcomes_FINAL_for_deposit_xlsx/20410971, reference number 20410971.

ORCID

Tisha Dasgupta Delttps://orcid.org/0000-0002-7874-9519 Jane Sandall Delttps://orcid.org/0000-0003-2000-743X Andrew Shennan Delttps://orcid.

org/0000-0001-5273-3132

Siân M. Davies D https://orcid.org/0000-0001-5662-7038 Shawn Walker D https://orcid.org/0000-0003-3658-8988

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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