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The acceptability of emergency cervical cerclage within a randomised controlled trial for cervical dilatation with exposed membranes at 16–27 + 6 weeks gestation: Findings from a qualitative process evaluation of the C-STICH2 pilot trial

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ABSTRACT

Objective: C-STICH2 is a randomised controlled trial of emergency cervical cerclage (ECC) vs routine care in women who present in pregnancy with premature cervical dilatation and exposed unruptured fetal membranes. Within the proposed trial an internal pilot was performed with an embedded qualitative process evaluation (QPE) to explore the feasibility of recruitment. The QPE aimed to collect and analyse data exploring the experiences of health care professionals (HCPs) involved in recruitment, and women approached about the trial.

Methods: Semi-structured interviews (telephone or face-to-face) were held with eligible participants who had consented to participate in the QPE. Interviews were audio-recorded, transcribed, and analysed to identify main themes. Interview transcripts were analysed using qualitative thematic analysis (QTA).

Results: 11 women and 23 HCPs were interviewed. Three super-ordinate themes of *Fluidity of Equipoise, A Complex Obstetric History*, and the *Influence of Gestation* were identified. Within these, the five main themes which influenced trial participation were: 1) Complex decision-making processes; 2) Predicting outcomes; 3) The importance of terminology and initial RCT approach; 4) Women's understanding of the need for research in this area; 5) Changes in practice which are trial influenced.

Conclusions: For both HCPs and women and their families, there was a conflation of the potential risks and outcomes of ECC with those of elective cerclage and the complexity around ECC placement was not always well understood by those with less experience and understanding of the intervention. Decision making was shown to be complex and multi-factorial for both HCPs and women. For complex trials in rare conditions with treatment uncertainty, clinical equipoise is likely to be fluid and influenced by multiple factors.

Introduction

Elective cerclage is an established treatment in the prevention of second trimester miscarriage and preterm birth. Most elective cerclage are placed based on previous history or ultrasound indicated based on a shortened, closed cervix. ECC involves placing a cerclage when there is cervical dilatation with exposed unruptured fetal membranes. Under these circumstances the evidence is unclear regarding the risks and benefits of ECC placement. NICE Guidelines for Preterm Birth [1] advise considering ECC but acknowledges this uncertainty and recommend further RCTs or a well-designed observational study. Usual care with or without ECC may include hospital admission, antibiotics, bed rest and treatments such as progesterone or tocolytics as indicated by individual circumstances. C-STICH2 is a national RCT funded by the NIHR comparing the use of ECC with expectant management in preventing pregnancy loss in women presenting with cervical dilatation and exposed unruptured fetal membranes between 16 + 0 and 27 + 6 weeks of pregnancy.

Abbreviations: ECC, Emergency cervical cerclage; RCT, Randomised Controlled Trial; QPE, Qualitative Process Evaluation; QTA, Qualitative Thematic Analysis; NIHR, National Institute for Health Research; HCPs, Healthcare Professionals; QRT, Qualitative Research Team; ROM, Rupture of Membranes.

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Historically RCTs are challenging to recruit to [2]. RCTs in maternity care are perceived to be more challenging due to the potential complexity of the population and whether the trial is focused on pregnancy management options or improving the health of baby or mother [3,11].

The C-STICH2 pilot embedded QPE was designed to explore the feasibility and acceptability of ECC within the context of randomisation, and experiences of women and HCPs in accepting and offering trial entry. The QPE aimed to collect and analyse data exploring the experiences of HCPs, and potential or recruited participants to identify themes and indicate how trial processes (design and recruitment) could be optimised. Identified barriers and facilitators to RCT recruitment for both women and HCPs were used to provide learning which could be implemented to improve recruitment [4].

Study aims

The qualitative process evaluation aimed to:

- qualitatively explore the feasibility, acceptability and appropriateness of the trial and intervention for women and healthcare professionals (HCPs).

Materials and methods

Qualitative process evaluation

The QPE used semi-structured qualitative interviews to collect data. Semi-structured interviews follow a guide and can be used to explore participants' thoughts, beliefs, and feelings around a pre-specified topic [5].

Participant eligibility and recruitment

Women

Women were eligible to participate in the QPE having been approached about C-STICH2, regardless of their agreement to participate in the trial. A discussion about consent to contact took place alongside or following the trial approach at site. All interviews took place using spoken English, therefore for inclusion women needed to be able to converse in English.

Healthcare professionals

HCPs were eligible for the QPE if they had been involved in caring for women with this condition and either involved in discussions about eligibility of potential participants who were being considered for C-STICH2 participation, or in the trial approach. Direct contact with HCPs was made by the QRT following either screening or recruitment of women into the trial and/or the QPE.

Data collection

Semi-structured interview guides were developed for women and HCPs and developed flexibly and iteratively as interviews progressed (Supplementary Information 1 and 2). Interviews took place either face-to-face or via telephone. Signed written consent was received for all interviews prior to participation. Confidentiality and right to withdraw was discussed further before audio-recording of each interview began and consent was verbally reconfirmed. Interview recordings were transcribed by a GDPR compliant transcription company. Transcripts were anonymised and checked against the recordings.

Data analysis

Qualitative thematic analysis

Interview transcripts were uploaded to NVivo-12 Plus and analysed using QTA. QTA is an inductive approach which searches for patterns within the data, whilst allowing for unexpected findings to also be considered. The interview guides were utilised to explore the data and identify themes.

Each transcript was read and coded line by line. Clusters of similar codes were grouped to form describable themes. These were grouped into themes across the data set. As the interviews progressed, transcripts were re-read and re-analyzed to identify other occurrences of these initial codes and themes. Further interviews were analyzed using the codes and themes generated in the initial coding and analysis, as well as exploration and identification of any further codes and themes.

PPI involvement

Study design, recruitment pathways, inclusion and exclusion criteria were all discussed with PPI representatives prior to starting the QPE.

Results/findings

Participant recruitment

Eleven women were interviewed: those who had declined randomisation (n = 8); and those who accepted randomisation (ECC = 2 and expectant management = 1). Twenty-three HCPs were interviewed: research midwives (n = 10), and senior clinicians (n = 13). Tables 1 and 2 describe demographic information for women and HCPs.

Table 1
Demographic information of women recruited to the CSTICH-2 QPE.

Characteristic	Women
	Total n = 11
Age (years)	
18–24	2
25–34	2
35–44	7
Ethnicity	
Black/British African	1
Black/British Caribbean	1
Mixed Ethnicity	1
Pakistani	2
White (British/Northern Irish/ Scottish/Welsh)	5
White Mixed Ethnicity	1
Parity at this pregnancy	
0	4
1	3
2	2
3+	2
*Living Children**	
Yes	9
Previous Pregnancy loss	
Yes	6
Gestational age at trial approach	
16–18	–
19–20	3
21–22	5
23–24	3
25+	–
Weeks pregnant at interview	
25–27	1
28–30	–
31–33	–
34–36	1
37+	–
N/A - postpartum	9
Weeks postpartum at interview	
1–5	1
6–10	2
11–15	–
16–20	2
20–24	2
25+	2
N/A – still pregnant	2

Table 2
Demographic information for HCPs recruited into the CSTICH-2 QPE.

Characteristic	Midwives = n	Senior Clinicians = n
	Total n = 10	Total n = 13
Age (years)		
25–34	3	–
35–44	5	8
45–54	1	3
55 – 59	1	2
60+	–	–
Ethnicity		
Arab	1	–
Any other white background	–	1
Mixed: White and Asian	1	–
White (English/Welsh/Scottish/Northern Irish/ British)	8	12
Gender		
Female	10	8
Male	–	5
Years since qualification		
0–9	5	–
10–19	–	8
20–24	3	1
25+	2	4
Years in role		
1–3	7	5
4–6	1	3
7–10	1	–
11–14	1	4
15+	–	1
Annual births at site		
<5000	2	1
5000–7500	4	7
7600 – 9900	–	1
10,000 +	4	4
Experience of caring for women with this condition		
Daily	–	–
Weekly	1	3
Monthly	–	3
1–2 × yr	1	1
3–4 × yr	4	5
Other	4	1

Qualitative thematic analysis

Following QTA of all transcripts, three super-ordinate themes of *Fluidity of Equipoise, A Complex Obstetric History*, and the *Influence of Gestation* were identified as influencing factors on lower-level (main) themes. Five main themes were identified as factors and beliefs which affected trial offering and acceptance:

1) Decision-making is complex for HCPs and women
2) Making predictions
3) The influence of terminology and pre-priming around ECC
4) Women's understanding of the need for research in this area
5) Changes in practice which are trial influenced

Tables which illustrate these main themes are attached in supplementary information, A4: Complex Decision Making, and A5 Main Themes 2–5 (Tables 3 and 4, respectively).

Interactions between super-ordinate and main themes are modelled in Figs. 1 and 2.

Super-ordinate themes

Fluidity of equipoise

Individual clinician's equipoise was shown to be fluid, meaning it was dynamic rather than static and related exclusively to the intervention within the context of multiple influencing factors for each individual decision. Influencing factors for decisions surrounding the offer

Table 3
Decision making is complex and influenced by multiple factors.

Sub-themes	Illustrative quotes
It is not an easy decision to make	"The real benefit of the trial, this is the real perk is you are faced with this awful decision, you will never know if it was the right one you made but you've still got the potential to feel guilty if you picked one over the other, whereas this takes it out of your hands, it makes the decision for you, and it might improve care generally so that other people don't have to make that awful decision." (C20 – Research Midwife)
	"But it still feels difficult to make a decision once potentially [you know] you could lose your baby. (W17 – declined randomisation – preference for ECC)"
	"But it was such a difficult choice to make that one, especially when your head is already all over the place, because you're just like oh my god they have already… they told us at [hospital] that was absolutely no hope, and we would deliver her that night and it would just be a late term miscarriage, we wouldn't even get a birth certificate, you wouldn't get a death certificate, because she was under the 24 weeks." (W23 – declined randomisation – preference for expectant management)
	"It's difficult because you have to counsel the women in equipoise, you have to say there are these options available of do nothing or give you progesterone which is probably just witchcraft, versus put a stitch in, my belief is put a stitch in but we don't really know […] do you want a stitch, or do you want to be part of this trial that will randomise you to nothing/ witchcraft, I don't say that, but to nothing/witchcraft versus an active step, but that then goes back to the we're just going to toss a coin and see whether we fulfil your wish to save your baby, I think that's quite hard to recruit them into the trial, because that's the choice they are faced with." (C29 – Senior Clinician)
Just knowing what [you have] to do – it feels like there is no decision to be made.	"Yeah pretty much we said give us five minutes but actually probably within about a minute of them leaving the room we'd already decided, so it wasn't too bad […] So yeah, we really had to… it was our only option really." (W13 – declined randomisation – preference for ECC)
	"In my head I knew that I wanted the stitch, at the end of the day because I was umm-ing and ah-ing and I was like well no I do want it, yeah. I had already made that decision before they even explained anything, I think you know yeah I want to try or… unless they had told us I'm going to give you the stitch and you're going to die, that's probably the only way I wouldn't have had the stitch sort of thing." (W06 – declined randomisation - preference for ECC)
	"I think we reached the decision ourselves as well, it was a no brainer to us, and it seemed common sense to take that small risk of the membranes rupturing, they could rupture anyhow, and it just seemed like the most logical decision to make at

(*continued on next page*)

Table 3 (*continued*)

Sub-themes	Illustrative quotes
	that time that perhaps as specialists…? I don't know." (W07 – declined randomisation – preference for ECC).
Cultural and religious influences impact on decision making	"She was very religious, and so was her partner, and they were not native to this country and she was saying, "I want my family nearby me, I want my friends nearby me," and a lot of her friends and family were people from the church. So she sought out their opinion in this as well, and she I guess interpreted that situation as leaving it down to God, being randomised that is" (C01- Research midwife) "I was just like if it picks me then I guess that's great and if it doesn't I have the saying of saying 'Alhamdulillah' which is it's worked out for the best, God knows everything. So I kind of just went along with it" (W19 – accepted randomisation – randomised to ECC [failed]) "I think religion is one of the things that informs our health, informing some of our… we were like okay we don't know really the situation, and we have got this very strong faith that if a life has to come in this world it will come at the time when it has to come, and at the place where it has to come, and the time for life and death is already determined by God, and no matter what you do you cannot probably influence it much. So we were like okay if this is something that is already not in our hands, and anyway we go for the procedure or not we cannot stop labour from happening, and if we go for the procedure we are going to probably introduce certain types of risks if we get procedure, and if you don't go for it then there's not much evidence that it will help, any implication really." (W24 – declined randomisation – preference for expectant management)
Previous experiences of offering ECC (for HCPs)	"Most consultants have experience that this is something that we have seen work in certain circumstances, even the most negative people will have had experience of it's worked in that particular person, and then women are more than happy to accept something that they think might work." (C03 – Senior Clinician) "The few cases I had seen had all had emergency cerclage and some had, well I think the majority had not been successful. But my understanding is that if we did nothing there is a very high chance they would go on to labour and deliver, but I just wasn't clear whether that chance came down significantly by actually doing the suture." (C17 – Senior Clinician)
Which clinician (is available) matters	"I think it's really important to collect up the factors that might influence it, particularly who does the stitch, how many stitches they have done before, what experience they have got" (C05 – Senior Clinician)
There is a wide diversity of information sources, and information seeking behaviour – and these have different levels of influence on individual decision making	"Another element which is the foreign population where they can consult with doctors outside the UK, and then the opinions become even wider. So I tend to investigate these things with patients to be honest because patients are well informed on what there is and there is no point to abscond from it. So I upfront ask them what your doctor in Spain told you or what you would have done, what your sister think of this, or did you Google, research, what you find out. I talk to healthcare professionals who are patients in a different way, okay you know about this and that" (C15 – Senior Clinician) "But the trouble is I've got a smartphone and I am sitting in a triage unit and my midwife says bulging membranes and I look it up on my smartphone, I've innocently contaminated my approach, and if you… that's what every-one does these days, they will look it up on Google and they will see what does it say about what the midwife or doctor was talking about." (C07 – Senior Clinician) "So what they did was they kept me there overnight, and of course I was frantically on the internet searching for anything that I could find to help me, because at that point I was only 20 plus two, and I read that bedrest on an inverted tilt helps, so I was like, "Right put my bed in an inverted tilt," and they were like what? And I was like, "Just put my bed in inverted tilt."" (W23 –declined randomisation – preference for expectant management) "After she gave me the leaflet I was reading through it, and obviously this was the night before, and I'm quite a big researcher myself so straight onto everything I could find on the internet, onto every [charity] website that I could find, every leaflet there was." (W15 – Randomised to ECC)
Is doing something always better than doing nothing? The perception of an active versus a passive treatment option.	"I think that is quite a difficult concept for people to sign up to when one option is something and one option is nothing, because sometimes if there are two treatments and you say I don't know which is better they will say well actually okay if you don't know which is better, then flip the coin essentially and I'll see which one I get, but if you're saying one is something and one is nothing I think that is harder for families to give themselves that lack of choice in." (C04 – Senior Clinician) "I think the challenge is in terms of if you offer someone an intervention that might work, so you mentioned suture, then even though it is maybe the high risk of rupturing the membranes, blah, blah, blah, I think people will latch on to that, and will want to try something rather than do nothing at all." (C09 - Senior Clinician) "I felt like in the trial we're not really withholding any care, because either way you are offering if they do get randomised to a stitch you are still going to be looking after them having that expectant management being in hospital, being cared for, if they are having expectant management" (C12 – Research Midwife)
Conflation with planned Cerclages muddies the waters	"It's not the same as a routine stitch that's trying to get you to the end of pregnancy,

(*continued on next page*)

Table 3 (*continued*)

Sub-themes	Illustrative quotes
	because I just sort of thought of course it is, that's what a stitch is, but then hearing that it's only to get you 50 days, actually you've got a woman who is 17 weeks pregnant and you think why do we even… why are we even bothering? And maybe I go back to the maybe we should just be preparing for what's going to happen point of view." (C20 – Research Midwife)
	"In my head I am just thinking they are going to just put a stitch in and that's it, I'm going to go term, do you know what I mean? That's what I thought in my head, because as soon as they told us that I was dilated I had said to my husband I am sure I have read about stitches and I've seen something, but I bet you they stitch my cervix shut, but I don't know where I've seen it. It will be some crazy… do you know when you've seen something, you're like some stupid programme and you've heard it, and then I'm like I don't even know if that's actually a real thing, and then it turned out that it was. But when they had mentioned the stitch then I was like 'oh yeah I've seen it on the telly', and they were like 'oh no, no you're thinking of the different stitch altogether' sort of thing." (W06 – declined randomisation – preference for ECC)
	"Probably about two thirds of the women want… "we want a stitch, we just want a stitch, I've read about it, I've been on Facebook", I've got one at the moment she's been on the Facebook group she says, "I know it's bad for me but everyone on Facebook says you've got to get your doctor to put a stitch in, they all say you've got… if your cervix gets short you've got to get your consultant to put a stitch in and you've got to stay in bed the whole pregnancy."" (C02 – Senior Clinician)
Please do anything – saving my baby	"I feel that in the moment the other physical risks to the women I feel that for me if I was in that position I think it would be more than okay to take that risk knowing that the benefit you may get from that. So I feel like in the moment it's such a crisis point, I feel that most women wouldn't be so concerned about risks to themselves" (C22 – Research Midwife)
	"Normally if it had been, I don't know, you was going down to have surgery for yourself you would be a little bit more mithered and a bit worried. But this was the life, the survival of my baby, and it didn't… I didn't even matter, do you know… well of course I mattered but you don't think about… I wasn't even worried about the operation, I just wanted it to be done and dusted and not the membranes, don't pop the membranes and let the baby survive the anaesthetic" (W07 – Declined randomisation – preference for ECC)
	"[Recruiting site] were much more proactive, what can we do, let's get a plan in place even if it is as simple as you're going to be upside down for the foreseeable future. With all the technological advances that we've got that's still the best option, apart from the stitch if it's suitable, but they were much more let's try it, if it doesn't work then at least you will know that you've tried everything that you can." (W23 – Declined randomisation – preference for expectant management)

of trial entry included HCPs previous experiences with ECC, complex obstetric histories, and gestational age at presentation.

> *"He [the senior consultant] was alluding to that she wouldn't necessarily be appropriate because she's quite an older lady herself, and this is a very desperate pregnancy." (C14 – Research Midwife)*

This definition encompasses the finding that the evidence from the QPE and fluidity of equipoise relates to individuals potentially moving in and out of equipoise on a case-by-case basis due to their interpretation of each specific case, and their clinical experience of such cases, and the use of ECC in similar or different scenarios, rather than being in equipoise or having a lack of equipoise in all circumstances for this intervention. This also linked to Decision-making is Complex and the Influence of Terminology (3.4.1 and 3.4.3). Some women were also influenced by their perceptions of the HCPs preferences.

> *"I could be wrong, but I always thought that yes they [surgeons] wanted us to go ahead with the stitch." (W07 – Declined randomisation – Opted for emergency cervical cerclage)*

A complex obstetric history

A complex obstetric history was identified as influencing HCPs and women (see 3.4.1 Decision Making is Complex). Differences in the perception of 'risk' for the current pregnancy were based on previous history of pregnancy loss or struggles with infertility.

> *"I think the women who being prima gravida, in their first pregnancy they are more of the, this is what life and popular culture tells you to expect, and actually it's massively shocking to say this is all going horribly wrong guys and we have… there may or may not be something we can do for you, and it may be a situation where we say we can't do anything at all, and you may end up with a horribly disabled child at the end of it. It is a massive shock, and I think that can make them less able to accept it than maybe a mum who has lost her baby before, because she's actually aware that bad things happen." (C29 – Senior Clinician)*

This meant that for families with a complex obstetric history, treatment options were identified as preference, but actually were more about what was considered to be necessity. In this context, randomisation was perceived as risking losing access to this 'preferred' treatment.

> *"It [expectant management] wasn't really an option for us, because of my age and it took us a while to get pregnant, and we'd already had a miscarriage, we just felt really, it's just we have to do everything we could to at least try" (W13 - declined randomisation – opted for emergency cervical cerclage)*

Influence of gestation

The *influence of gestation* described the way in which usual management of cervical dilatation within the target population (16–27 + 6 weeks) was also predicated on gestation at presentation. Gestational influence was identified to vary across 3 gestational windows: previability (<22 weeks), peri-viability and beyond 24 weeks. At earlier gestations the inherent perception of risk of immediate pregnancy loss

Table 4
Main other themes and supporting quotations.

Main theme and description	Sub-theme	Illustrative quotes
Making predictions Clinicians feel that it is impossible to predict outcomes and although they know some risk factors they don't apply to all women that are seen with this condition. This has raised the question: should we be asking, not, if the ECC works at all, but who and under what circumstances is the ECC considered succesful?	**'Who' is as important as 'if' and 'when'**	"I personally think if there's no signs of infection we should be doing it, because I think anything where we can prolong the pregnancy for a little bit longer is good for the baby and for the mother". (C12 – Senior Clinician) "I think you can be [in] equipoise as to know whether there's benefit or harm in doing it, but as a clinician what you don't know is that their outcome is, is different for each family I suppose." (C08 – Research Midwife) "You have a feeling whether things will work or not, is because if you know that they have literally just come in and the membranes are just visible, that's probably a far better situation than if they might have been out for a week or so, and it's hard to then randomise those people because they are totally different." (C08 – Senior Clinician) "Particularly if it was somebody who had part of their cervix taken away or got uterine anomaly or for some reason like a full dilatation for their infection, something like that, we would be more inclined to put in a stitch thinking that actually it was something physical, a problem with their actual cervix function rather than infection" (C05 – Senior Clinician) "Infection factors like MSU, group B strep, BV, where do they give antibiotics or not, what type of suture material they have, whether they have been in bed for a week or not, all those kind of things which I think will be useful in teasing out who then might be… Because you might end up with a negative outcome, in other words there's no benefit, but then you might be able to pull out some factors that suggest that in this population a stitch works better." (C05 – Senior Clinician) "I think it should be based on statistics and what's worked for people, why it's worked for those people. I can surmise and say I thought it was because of all the intervention with the IVF, D&Cs, endometrial biopsies and things like that. It's a tough one and I think it is almost still… I think it should always still be the woman's choice to have it done, but be properly equipped with the information to make that choice for them." (W07 – declined randomisation, preference for ECC) "You try to pick out of what you have done which are the ones that are going to work and which aren't. The more you do the more you realise there probably aren't any rules, but I am still looking for rules, I am hoping you're going to give me some more rules, and I go round in circles of trying to look for rules that will help and then think well actually there aren't any rules that help, you just have to accept that there are no rules and anybody might do really well or anybody might not do really well, and then I'm actually looking for my rules again, like the people that at presentation dramatically tend to do much better which I think they do but not always, but they are statistically likely to do better" (C02 – Senior Clinician)
	What is success, for whom, and how is it defined?	"A few years ago doing a rescue stitch at about 20 weeks, 21 weeks maybe and she only got a couple of weeks, she was clearly infected afterwards when I had put it in and she sromed at about 23 weeks, but she has taken her baby home and supposedly it's intact, but that for me was a big failure for me, but actually she was absolutely ecstatic and more than happy and she's got her baby, whereas I was thinking, oh my God at 23, take a 23 weeker home what the hell is that going to be like long term?" (C08 – Senior Clinician) "They are just thinking this is our baby and we want to save it, they are not necessarily thinking about those long term […] they just want you to try anything, I don't think they can rationalise very well what that may mean, it doesn't necessarily mean I

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Table 4 (*continued*)

Main theme and description	Sub-theme	Illustrative quotes
		am going to give them an intact baby even if I get the stitch in." (C08 – Senior Clinician) "The default mode for mother is a sense of wishing to preserve the pregnancy and return things to normal when [inaudible – 26.34], and their calibration of risk is I think skewed by that wish to preserve their babies life and the desire even at, was going to say almost at all costs, but that desire to preserve life without necessarily thinking the quality of that life necessarily. Not saying life is not worth living with adverse neurodevelopmental outcomes, it's just not what I would be intending to do when I did a cerclage. I do a cerclage it's because I want that baby to be born healthy at term, not just to buy a week or two" (C07 – Senior Clinician) "As I said I had it in my head that I was going to be upside down for 18 weeks and then I should be full term and we're all good. Nobody had told me that, nobody, but I think my head was at that point just such a mess that my brain was just like yeah this is what's going to happen, I will be absolutely fine, which is… honestly it's amazing the ridiculous things that go through your head when you're in a situation like that. Even being upside down on the bed I was still not convinced that she was going to come at any point." (W23 – declined randomisation -preference for expectant management)
The importance of terminology How the intervention is presented to women, and how staff talk about it amongst themselves may influence the way it is perceived, both at site and when it is presented to families.	**Pre-priming**	"She had already essentially been told by another consultant that okay we're going to send you over to the other site for [myself] to see, she's on the other site and she was diagnosed by a consultant on the other site and "you need to go and Dr [name] and see if she can put a stitch in the cervix, because that would…" and she was incidental finding on her detailed scan." (C01 – Senior Clinician) "Trying to assure that people get continuity and the consistency of approach is really difficult because

Table 4 (*continued*)

Main theme and description	Sub-theme	Illustrative quotes
		they might present via the prematurity clinic, they might present via the assessment unit, they might present via delivery suite, via ultrasound, and to get a consistency of approach is quite tricky" (C02 – Senior Clinician). "I think with this bulging membranes population, I think, if they come in the middle of the night, someone quite junior or even a midwife they know that there is a possibility because they hear that we've rescued these situations, but actually maybe they don't quite realise how difficult that is, and actually it's 50/50 whether we can get a stitch in" (C08 – Senior Clinician). "I think probably before the trial if somebody had presented I think probably we wouldn't necessarily… I might not have seen it but I think the initial counselling probably would have been this is happening, we could give you a stitch do you want to try it?" (C28 – Research Midwife) "A consultant assessed me and she said indeed I was 23 mm dilated, well that's what they saw at the time, and that they could see the membranes coming down into my vagina. So they admitted me that day and they discussed briefly the issues and said that they would be doing a stitch the following day." (W17 – declined randomisation, preference for ECC) "He said that there could be a stitch and what would I prefer. At that time I didn't know what would be the best option, so we didn't have to make a decision, we weren't pressured to make a decision." (W07 – declined randomisation for ECC)
	Who wouldn't want to be rescued? Emergencies are time pressured – but there is no certainty of outcome.	"Rescue does give the connotation that we are the big hero that's going to come in and save the baby for them doesn't it? It does put that whole dramatic perspective on it, whatever dramatic perspective you get from things like wording around a crash section as well. It has got a bit embedded in the terminology hasn't it?

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Table 4 (*continued*)

Main theme and description	Sub-theme	Illustrative quotes
		Because you're right, it does give that connotation that's what it's going to do, it's going to rescue your baby, so that does have the implication that it's a good thing to do" (C02 – Senior Clinician). "A midwife came in and it was at first we had quite a bit of a… looking back on it now she basically said we wouldn't be in the pregnancy for much longer, which really scared us both because the doctor previously had said to me that there options and not to panic, yeah that I wouldn't be in it much longer and there is the option to terminate if I wanted to. So myself and my partner were really a little bit distressed at this point, a little bit all over the place, and then they told us that they would let us having overnight basically to see what happens." (W15 – randomised to ECC) "Emergency stitch would be better, because the word rescue would probably in people's heads give you a little bit more hope that the outcome will be positive. Emergency to me says you have no other option here, you make a choice whether you want to do or you don't. Psychologically if somebody spoke to me I will rescue you I would be thinking they are coming to help me and it will end up okay, where in emergency the outcome you can only hope is best." (W09 – randomised to expectant management) "It's a powerful connotation because you're saving something, so then if you don't do it you're not saving something. So it's just basically automatically assumed that if you do this better than not doing it. But that is what they call it, a rescue stitch isn't it? So actually never thought about that until you said it now. Emergency is different, it conveys the urgency of the stitch, but it's very different to rescue. Would you decline a rescue stitch? You're not rescuing your pregnancy then, yeah that's very different." (C18 – Research Midwife) "I try not to use rescue to the

Table 4 (*continued*)

Main theme and description	Sub-theme	Illustrative quotes
		patient because I don't think it's helpful and actually I think it's a bit scary for them hearing the word rescue, because then the way that it implies that it's all doomed and there's going to be all these problems, so I tend to try and use emergency. But I think that it is a bit scary being called… I wouldn't want to be in a situation or I am sure no one in my family or friends would want to be in a situation where they are having a stitch called a rescue stitch, I just think it sounds like something terrible" (C12 – Senior Clinician). "Whereas the word emergency I think is a bit more acceptable because it just shows that you're doing something that you need to do in if you need to do it you need to do it in a limited space of time, that there's maybe a critical window during which you have the chance to do this. But it's not got that same sense of desperation about it that the word rescue has" (C17 – Senior Clinician). "I think rescue sounds like you're Superman coming in to help everybody and it's going to work beautifully, whereas emergency sounds a bit more like well we've got to do it now if we're going to do it." (C05 –Senior Clinician)
Changes in practice Taking part in the trial itself has changed the way that ECC is viewed, and the influence that trial information and pre-trial training have changed practice at site	**This is how things have changed with CSTICH-2**	"Making it clear to the ladies that if they don't take part in the study which I find really confusing, because if they don't take part in CSTICH-2 can they choose to have a suture, and in her case the doctor had said to her we wouldn't usually put one in, so by taking part in the research you're getting a chance to have a suture." (C13 – Research midwife) "You are having a conversation going there's two options, we don't know which one is better, good luck deciding, and I feel actually better to able to go there is a trial because of how hard this decision is, because women struggle to make it and because doctors struggle to make it, and we're trying to find out for the better. The real purpose if you feel like you can't choose this will do it for you

(*continued on next page*)

Table 4 (*continued*)

Main theme and description	Sub-theme	Illustrative quotes
		because it will pick randomly, and I think actually it's a nice thing to offer at the time." (C20 – Research Midwife). "Would I put a suture in, in the past a woman who has minimal cervix, evidence on speculum examination no I wouldn't have done, so I don't know what the outcomes would be like for that woman and I would feel there's no harm in trying. So I feel more comfortable in putting it in women that ordinarily I would have thought no I probably shouldn't be doing that, it gives us the push to say this is something that's okay to do, and I think that's reasonable because like I said before if you don't do anything they are going to lose their pregnancy. So to be given the green light to say this is part of research, this is an important question, let's go ahead and give that a go" (CO3 – Senior Clinician)
Understanding the need for research in this area. Women understood the complexities around the question, and the lack of evidence. For those who have a strong preference for one treatment the risk of randomisation, and therefore potentially losing access to their preferred treatment option feels too high.	**Risk of randomisation**	"For me it was like okay so all of these inputs and whatever I could get at that point we just thought that probably if it has to happen it has to happen whether we go for this or not, and we have got all these extra things and we don't have any scientific evidence, nothing to rely upon, we don't have any specific statistics and not anything about… even the risks we don't know what's the exact percentage of people who actually go into labour or who actually have these cervical damage or whatever. So we were like okay we don't have anything to rely upon then probably best that we just leave it to nature, and it will just take care of it. So that's how we then decided that okay not going to go for it" (W24 – declined randomisation – preference for EM) "I am very pro research and I understand the importance of knowing… I understand that the more that you do these studies the more information that you have and therefore the more information you can give to mothers, because I would have liked that information for me, I would have liked to

Table 4 (*continued*)

Main theme and description	Sub-theme	Illustrative quotes
		know which of the two options was better, and you can only do that with having done studies, but I didn't feel like I could take the chance of having to stay in hospital." (W18 – declined randomisation, preference for ECC) "So yes again that night again I was reading […] unfortunately there's not much research at all, especially on the cases like mine - there are lots of people who go for cerclage from early, 13 weeks or 14 weeks, in the early stages of pregnancy. But at my stage then unfortunately there are only a few studies and the number of cases that get studied from this type it's a very small number of cases. So I was reading a lot, I was trying to do research but then again there wasn't much really to make a decision on." (W24 – declined randomisation – preference for expectant management)
	This [decision] is too precious to leave to chance	"I don't think there's any situation where I would have let somebody else decide that for us, unless they were telling us not to have it, we don't think you should have it, we don't think it's going to benefit, or that's why I had said what do you think, what shall I do? I kept asking them, they were like that doesn't matter what we think, it's what you feel like you need to do. But yeah I can't see you know your own mind don't you, you're never going to leave that decision up to somebody else." (W06 – declined randomisation for ECC) "And you're leaving it completely up to chance. It's odd. It's difficult because I understand the need for randomised clinical controlled trials, but it's when you're at the time it's a difficult decision to make." (W19 – randomised to ECC [failed]) "I was just like if it picks me then I guess that's great and if it doesn't I have the saying of saying 'Alhamdulillah' which is it's worked out for the best, God knows everything. So I kind of just went along with it." (W17 – agreed to randomisation)

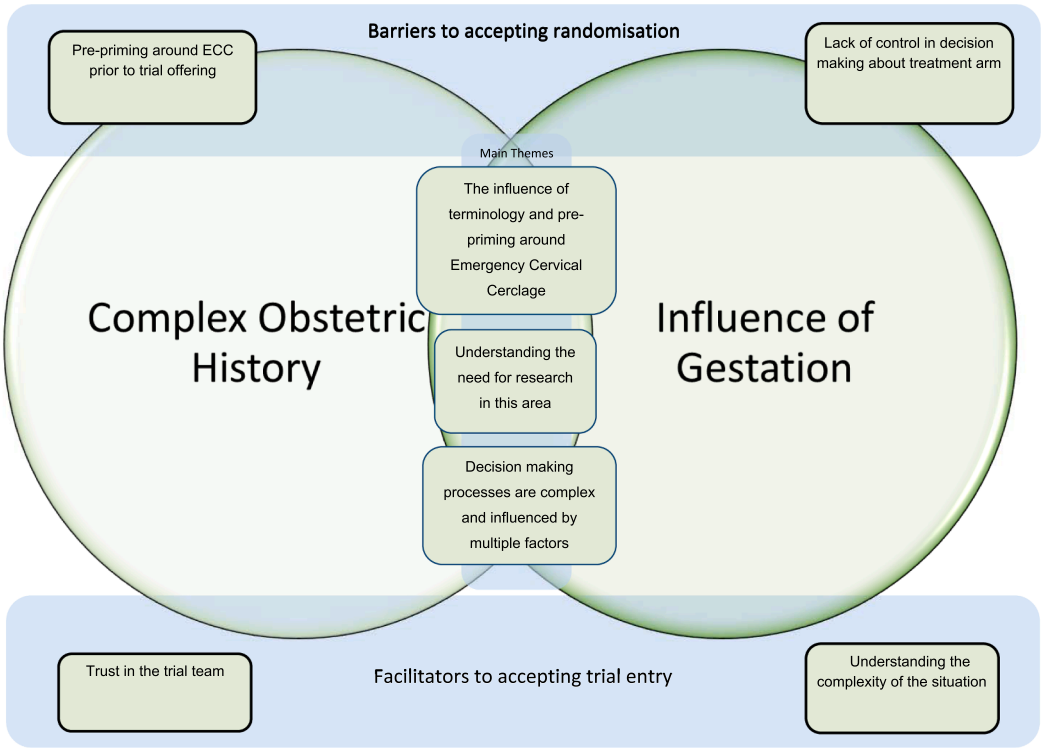

Fig. 1. Women Model of Factors which influenced RCT acceptability.

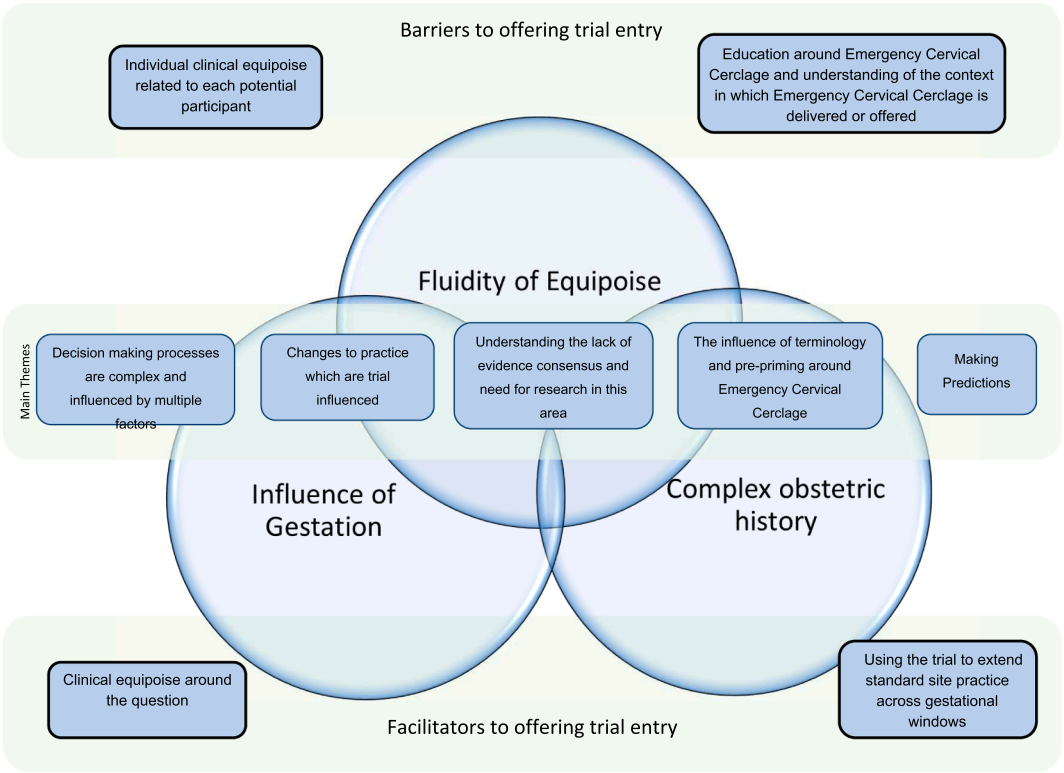

Fig. 2. HCP Model of Factors which influenced RCT offering.

was deemed to outweigh any risks of ECC placement.

"If you examined someone and you could see the membranes and they were less than 24 weeks you would call it an inevitable miscarriage. So, you would expect that if you see that scenario that they are likely to miscarry if you don't do anything" (C04 – Senior Clinician)

The closer a pregnancy was to viability the more risk was perceived around ECC (dependant on clinical equipoise) i.e., ROM.

"…the rescue cerclage itself could trigger labour, and the procedure is a high-risk procedure in terms of breaking the membranes." (C15 – Senior Clinician)

Many HCPs indicated they would not offer ECC after 24-weeks because of uncertainty about outcomes and lack of experience to inform the evidence-base, and because of improvements in neonatal care.

"We're not used to dealing with or we're absolutely not used to placing sutures at that gestation [over 24 weeks] so I think it would just be that we would be venturing into unknown territory with it, (C17 – Senior Clinician)

"I know NICE talk about you could put sutures up to 28 weeks, but we don't tend to do that just because I think neonatal care is so much more advanced, and I think as I say my concern is there's usually infection around in these extremely premature babies, and to leave a prem baby that's infected is far worse than getting a slightly more premature baby out that's not as infected in my opinion and therefore we generally just leave them to it as such." (C08 – Senior Clinician)

Women's decision-making about trial entry was also based on their own perceptions of gestation, viability, and risk.

"We said we can't justify doing it [trial entry] at 24 weeks because the survival rate the statistics at that time we were given were very low, but if my body can get to 25 weeks, because they jump so much higher, then we wanted to go ahead with the trial and try and get some more weeks after that" (W09 – accepted randomisation – randomised to expectant management)

Main themes

Decision-making is complex for HCPs and women

Both HCP and women experienced complex decision-making processes around trial offering and entry which were influenced by multiple factors. See Table 3 (Complex Decision-Making).

Many HCPs and some women viewed expectant management as offering no treatment. This perception of an active versus passive treatment influenced HCPs comfort with offering the trial, and assumptions about what women might want. Women's decision-making was also predicated on prioritising their baby's safety above their own.

"I've got to save myself I know, but I just said just leave her in as long as my life is not immediately at risk" (W06 – Declined randomisation – Opted for emergency cervical cerclage)

Information seeking was important for many women following diagnosis this sometimes resulted in conflating ECC outcomes with elective cerclage outcomes which influenced treatment preferences. For some HCPs, availability of clinicians to perform ECC influenced trial offering.

Making predictions

HCPs with previous experiences of ECC and/or of this condition tried to predict the likelihood of successful ECC placement and continuation of this pregnancy. Predictions were influenced by current presentation and perceptions of what worked last time.

"You try to pick out of what you have done which are the ones that are going to work and which aren't." (C02 Senior Clinician)

Predicting outcomes also implied judgement of definitions of success. HCPs and women's perceptions of success did not always coincide (Table 4).

The influence of terminology and pre-priming around Emergency Cervical Cerclage

Women and HCPs both described that 'rescue' carried different connotations of success, which may influence likelihood of offering or accepting randomisation. Terminology at sites between HCPs influenced ECC perception. This subsequently influenced site equipoise and led to pre-priming. Pre-priming was defined as the discussion of ECC as a management option prior to discussion around trial-entry and the lack of consensus of the evidence-base.

"We went for our 20-week scan, found that basically we needed a stitch" (W12 – Declined randomisation – Opted for emergency cervical cerclage)

Women's understanding of the need for research in this area

Women voiced frustration about the lack of clear information around ECC outcomes and wanted more research to support their own decision-making.

"I would have liked to know which of the two options was better, and you can only do that with having done studies, but I didn't feel like I could take the chance of having to stay in hospital [for EM]." (W17 – declined randomisation – opted for emergency cervical cerclage)

Changes in practice which are trial influenced

Usual practice around ECC varied between sites and was often based on HCP experience. Implementing C-STICH2 allowed some sites to expand their practice within the trial.

"So I feel more comfortable in putting it in women that ordinarily I would have thought no I probably shouldn't be doing that, it gives us the push to say this is something that's okay to do." (CO3 – Senior Clinician).

Discussion

Main findings

The main influences on HCPs trial offering trial entry were *complex obstetric history* interlinked with *influence of gestation* and *fluidity of equipoise*.

Clinical expertise and usual practice around ECC varied. Decision-making for women and HCP was complex and multi-factorial and HCP equipoise was fluid influenced by gestation and obstetric history. Women's decision-making was influenced by their own obstetric history, perceptions of risks of ECC and expectant management, lack of distinction between elective cerclage and ECC, and pre-priming.

Interpretation

Research has indicated that one overriding focus for women who agree to clinical trial entry in otherwise normal pregnancies is keeping baby free from harm [6].

Management preferences varied with gestational age, and gestational age at presentation influenced trial-offering and acceptability of randomisation/ECC. There is a potential ethical dilemma around using ECC on the cusp of viability [14], potentially translating pre-viable pregnancies to borderline survival, with consequential long-term outcomes related to extreme prematurity [13,15].

There are limited data on obstetric emergency research [9] although barriers and facilitators to trial entry in maternity care have been described [8,10–12].

Trials are at increased risk of low recruitment where clinical equipoise is in doubt or where a rare condition means experience across the clinical body is lower [14]. Miller and Joffe argue that RCTs and equipoise are necessary to continue to evaluate interventions without an adequate evidence base, to support implementation as standard care [15]. This assumes an infrequently used intervention where participants receive usual care outside of the trial. Within C-STICH2, ECC may be usual site practice thus randomisation to expectant managment, may not

be considered usual care as implemented outside of the trial.

Perceived risks of randomisation to non-active treatment arms influence HCPs decision making about offering trial entry [19]. Some HCPs considered expectant management as comparable to offering 'nothing' which implied negative consequences.

Research around randomisation descriptions indicates that where HCPs find gambling metaphors helpful, participants dislike the idea of random chance and do not find metaphors such as 'tossing a coin' or 'drawing straws' useful [2,8,16]. Women may not want to leave their babies survival 'to chance', and some participants do not want to lose decision making control [2] women also declined randomisation because they wanted personalised decisions made about their care [7].

Terminology used at sites had implications about the perception of ECC. Using 'rescue' implied higher chances of success. Careful and considered use of language is important in research around obstetric emergencies [17]. The lack of consistent terminology may exacerbate elective cerclage and ECC conflation given the more widespread knowledge around elective cerclage placement and outcomes [18]. Many online resources discuss elective cerclage and placement contraindications [19–21]. None provide information about iatrogenic risks of ECC [22].

Risk limitation is described as a reason for declining entry into trials in pregnancy [24,25]. We showed that women with an intervention preference were unwilling to accept randomisation as they perceived this risked losing access to their preferred option, and therefore increased the threat to their pregnancy continuation [7,10]. While women understood the necessity for the trial, their altruism was predicated on perceived risks to their baby [6,23,26,27].

Reasons for declining randomisation included practical considerations [8], for example, randomisation to extended bed-rest as a hospital in-patient, with a young family at home. Not all women who declined trial entry preferred ECC. Some participants reported decision-making being influenced by faith-based beliefs. Either that randomisation was contrary to a larger (natural) plan as to how/if the pregnancy should continue [8] or conversely that by accepting randomisation, the outcome would be the will of God/Allah.

Women who entered C-STICH2 talked about trusting the recruiting team at site. Open communication and having questions answered has been indicated to increase trial participation [12,23]. When recruiting HCPs were not those performing the procedure this increased families confidence that the trial information was not biased.

Strengths

A range of HCPs (n = 23) participated in the QPE across multiple sites. This captured the range of experience and a more accurate snapshot of current UK ECC practice. Over half the women interviewed declined trial entry (n = 8). This gave a depth of understanding of the myriad of influences on women's decision-making in complex situations.

Limitations

Only a small number of interviews with women were undertaken. The women interviewed who had accepted randomisation were recruited through one site where ECC is not offered as usual practice and is currently only offered within C-STICH2. These women may have accepted randomisation hoping to receive ECC as their preferred intervention.

Practical recommendations

1. Some sites may find having a robust on-call rota of experienced HCPs useful (whilst ensuring that this does not induce pre-priming).
2. Support and education around gestational cut-off guidelines may increase the likelihood of sites approaching participants who present outside of locally accepted limits for ECC (e.g., 24-wks plus).
3. Performing earlier qualitative studies exploring clinical equipoise may highlight areas which influence intervention understanding prior to trial initiation.

Research recommendations

1. Recruitment to RCTs may be improved by increasing awareness of the evidence-base around the question therefore reducing the risks of pre-priming.
2. Continuous support and education at sites may increase the likelihood of potential participants being approached appropriately.
3. Continuing complex RCTs helps support evidence-based discussions and informed decision-making for potential participants.
4. Embedding QPEs in a pilot trial can influence recruitment approaches in real time.

Conclusions

Decision-making about offering and accepting trial entry was shown to be complex and multi-factorial for HCPs and women, respectively. Where complex trials focus on rare conditions with treatment uncertainty, equipoise is likely to be fluid and influenced by multiple factors. Within C-STICH2 the factors with the widest influence on equipoise were gestational age at presentation, and complex obstetric histories. Women's' personal circumstances, pre-existing views including pre-priming for ECC, understanding of the options, and trust in the trial team all influence decisions to accept or decline randomisation. Any or all of these may be relevant at the same time. Not all HCPs involved in trials will discuss participation where they perceive this would have negative consequences for a potential participant. Embedding qualitative research into the pilot stage of complex RCTs allows the exposition and exploration of factors which may influence trial offering and entry, and thus optimises the chances of successful trial delivery.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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