STOPPIT II Qualitative Study Plan - Summary

15.04.15

Research Aims

I. To understand the experience of staff and women participating in the STOPPIT II trial.
II. To understand the physical and emotional experience of receiving the pessary treatment.

Research Questions

Staff

1. How does the occurrence of the trial impact on the emotional and logistical aspects of delivering antenatal care for twin pregnancies?

2. How to do staff integrate their roles as clinician and researcher/recruiter where they hold a dual role?

3. What challenges do staff perceive in recruiting women, retaining them in the trial, administering the intervention and collecting trial data?

4. What is the staff experience of relaying the results of the cervical scan and subsequent randomisation and allocation to women?

5. What activities do staff carry out as part of the trial? How do these coincide with what is intended in the trial protocol?

6. How do staff experience and manage women's responses to the trial processes and intervention?

7. How do staff experience and manage women's informational needs during the trial?

Women

8. What influences women's decision to take part in and remain in the trial?

9. What are their expectations of taking part and how do these differ according to the type of participation (e.g. intervention arm or not)?

10. How do women respond to and make sense of the cervical scan process and results?

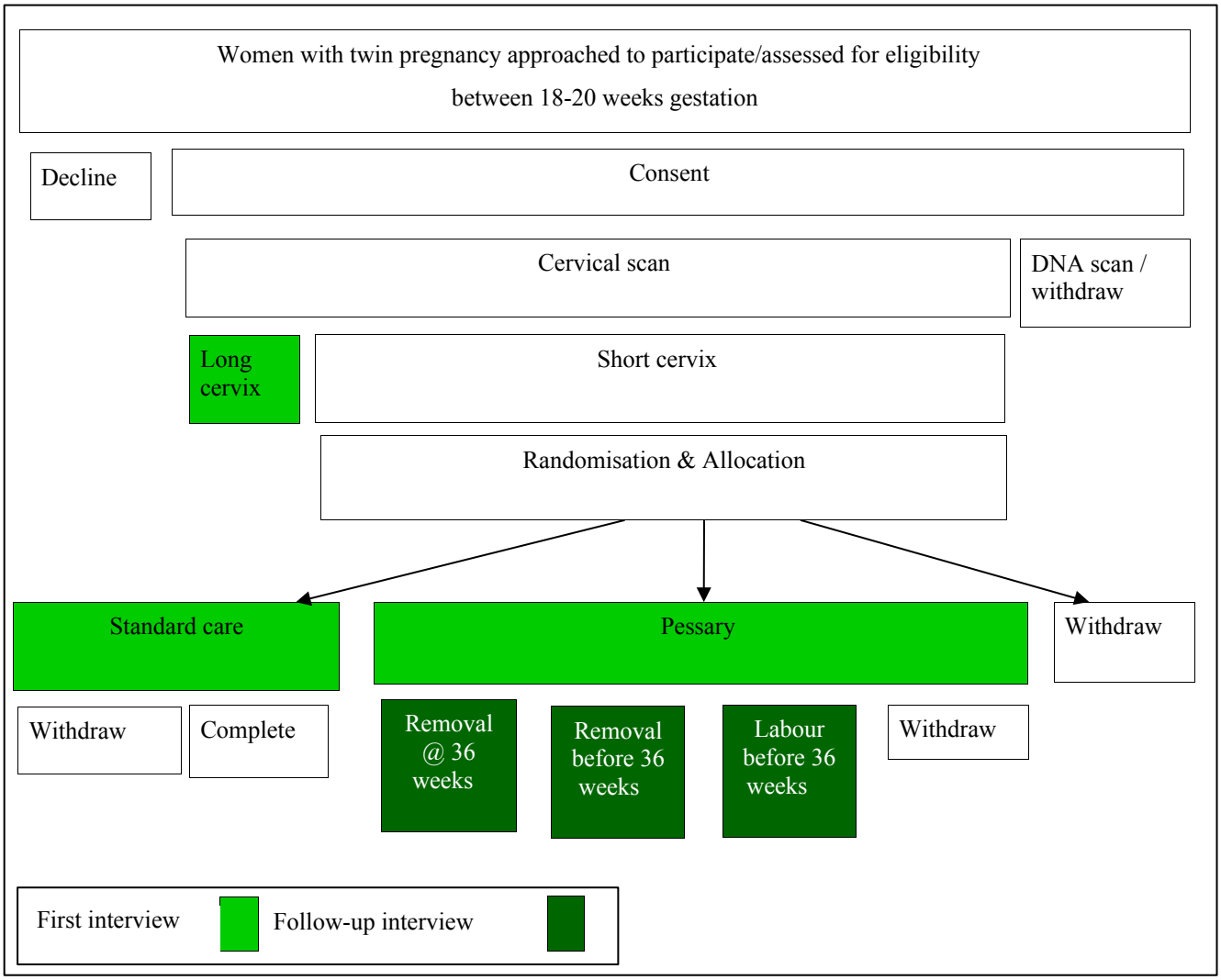
11. What are women's perceptions of risk and how do they feel about the different types of risk applied to their twin pregnancy by healthcare professionals?

12. To what extent do women understand key trial processes and concepts (eligibility, randomisation, allocation, control, right to withdraw)?

13. What is the impact of being identified as high-risk of pre-term birth on women enrolled into the trial? What differences are there in experience between the intervention and control women?

14. What is women's lived experience of the pessary? How do they feel after insertion and removal? What is the impact of the pessary slipping out prematurely?

Figure 1: Women's pathways through the trial and planned recruitment



Methods

Recruitment & consent

All women who are recruited to undergo the cervical screen for eligibility assessment complete a consent form in which they are asked whether they would consent to the qualitative researcher contacting them to provide further information about taking part in an interview study about their experiences. This is an optional clause in the main study consent form for the research midwife to share their contact details with the qualitative researcher.

There is a separate participant information leaflet specifically relating to the qualitative study and proposed interviews, if a woman expresses interest in taking part.

Women who agree to take part in an interview will be interviewed in person within Scotland, if in reasonable travel distance from Edinburgh. Women recruited in English sites will be interviewed by telephone. Women will be asked to provide informed consent specifically for the qualitative interviews on each occasion of being interviewed.

Healthcare staff will be recruited through PIs or coordinating clinical research staff in each site. Informed consent will be obtained and a separate PIL provided.

Sites

Edinburgh will be the main recruitment site for both the pilot and the main study but, depending on the recruitment rate, selected sites in England will be used, with telephone communication used for coordination with recruiting staff and for interviews. Some site visits may be required to build rapport with study staff, so sites in the north of England will be considered in the first instance.

Pilot study

Ten interviews will be conducted with pregnant women in the pilot study to explore:

- the acceptability of trial processes (recruitment, consent, scanning and results, randomisation/allocation, monitoring)
- the delivery of the intervention
- their expectations of trial participation and the degree to which these were met
- their information requirements through the whole process
- their views on how any information should be communicated
- the impacts of their risk categorisation and trial participation on their feelings about pregnancy.

These data will be used to:

- feedback to the trial team on aspects of trial processes and information provision
- Improve the topic guides for the main interview study.

In order to find out about all aspects of participation in the trial from consent to the end of intervention we will interview women who:

- Consented, were screened but found to have a long cervix
- Consented, were screened, have a short cervix and were randomised and allocated to the control group

- Consented, were screened, have a short cervix and were randomised and allocated to the intervention group.

Taking women from all three groups will ensure that the information provided to women at every step of the trial process is adequate. This approach will also enable exploration of women's experience of their pathway of participation through the trial. At the pilot stage we will particularly focus on any adverse emotional effects to which staff should be alerted before beginning the main trial. We will base these interviews on the topic guide for the main study (see below).

The interviews will be conducted between weeks 24 and 28 of pregnancy where possible, within the time constraints of the pilot study. Where a woman is recruited in the pilot study but her 24th week of pregnancy falls after the end of the pilot study we will interview her earlier, but still after the pessary has been fitted. Where possible up to 4 follow-up interviews will be conducted with women form the intervention and control arms to examine longer term emotional and physical impacts of trial participation, beyond the initial recruitment/screening/randomisation/intervention delivery. These follow-up interviews will be conducted at pessary removal (intervention) or at 36 weeks (control).

Five members of healthcare staff involved in recruitment, enrolment, randomisation/allocation and administering the pessary and follow-up will be interviewed to understand their perspective on the trial processes and highlight any areas for improvement ahead of the main trial. These interviews will focus on staff views on and experience of:

- the trial processes (recruitment, consent, scanning and results, randomisation/allocation, monitoring)
- the delivery of the pessary
- integrating routine care for twin pregnancies with the trial processes and intervention (emotional and logistical aspects, dual professional role as researcher and clinician)
- supporting women through the trial and attending to their informational needs.

A maximum of ten women will also be interviewed about the process of completing the acceptability questionnaire in order to assess the face validity of the questions. They will be recruited via the research midwife in the pilot sites, including those taking part in pilot

interviews for the qualitative study if they wish to complete an additional interview/addition to their interview. During these interviews the participants will be asked to complete each section of the questionnaire, annotating with any thoughts and comments. At the end of each section the researcher will ask women about how they found filling in the questions, what was problematic or unclear, and what women interpreted to be the meaning of each question.

Main study

Dependent on the outcome of the pilot interviews the main study will focus on the experience of women who were:

- Consented, screened, have a short cervix and were randomised and allocated to the control group (n=10)
- Consented, were screened, have a short cervix and were randomised and allocated to the intervention group (n=20)

And may optionally include women who were consented and screened but found to have a long cervix (n=10).

The initial interviews will be conducted between 24 and 28 weeks gestation. Follow up interviews (up to 20) will be conducted with women in the intervention arm, after the pessary has been removed (at 36 weeks or earlier for indicated reasons), to explore on-going experience of the pessary, pessary removal and experience of the end of pregnancy. Where women give birth before there is an opportunity to conduct the follow-up interview they will be offered the opportunity to participate postnatally, usually by telephone. This will include women who go into spontaneous labour before the pessary has been removed. The interviews will be designed to address research questions 8 to 15, using the topic guide below.

A maximum of 15 healthcare staff involved in recruitment, enrolment, randomisation/allocation and administering the pessary and follow-up will be interviewed to address research questions 1 to 7, using the topic guide below.

Time plan

	2015									2016					
	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June
Study month	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
	|----------PILOT----------|							|----------MAIN STUDY----------|					
Planning, ethics, R&D	X														
Pilot study:															
Interviews		X	X	X	X										
Analysis			X	X	X	X									
Report to study team							X								
Update topic guides						X									
Main study:															
Interviews								X	X	X	X	X	X		
Analysis								X	X	X	X	X	X		
Write-up														X	X

Topic Guides

Healthcare Professionals

Role

Please could you tell me a little about your work as a midwife/obstetrician

Prompts:

- experience of caring for twin pregnancies

What things do you have to consider when managing women with twin pregnancies?

Prompts:

- Are they considered high risk?
- What things make them high risk?
- Emotional aspects of the pregnancy and pregnant woman
- Medical/physiological aspects of the pregnancy and pregnant woman

Taking part in research

Please could you tell me about previous(clinical) research you have been involved in?

Prompts:

- What did you enjoy about the research?
- What things did you find challenging/less enjoyable?

How has STOPPIT-2 compared to those previous experiences?

Prompts

- What led you to be involved in STOPPIT-2?
- How are you feeling about it now that it's been running a little while?
- What are you hoping will come out of the trial?
- Are there any positive aspects to being part of the trial? I wonder if this might be phrased differently even as a prompt e.g. What were the most positive aspects of being part of the trial
- What things have you found less enjoyable? What were the most challenging aspects of being part of the trial?
-

STOPPIT-2

What has been your role within STOPPIT-2?

How have you found fitting this with your other work? (any tensions between clinical and research role)

How do you decide which women to invite to take part?

How have you found approaching women about taking part?

Prompts:

- What kind of response have you received from women? (any worry about women feeling pressured to take part)
- What questions do they ask?

What happens during the consenting process?

What happens during the scan?

How do you relay the results of the scan?

Prompts:

- How do women respond?
- How do you feel?

How have you found the process of randomisation and allocation?

Prompts:

- How do women respond?
- How do you feel? (preferring intervention over control, worries for individual women)
- Have women withdrawn at that point? What happened? How did you feel?

What happens at the pessary insertion appointment?

Prompts:

- What do you talk about with women before/afterwards?
- Have you encountered any difficulties at these appointments?
- How do women react to the procedure?

What monitoring do women receive?

Prompts:

- What is your focus in those appointments?
- What do you talk about with women?
- Are there any special instructions for women during this time? How do women respond to these?

What happens at the pessary removal appointment?

Prompts

- What do you talk about with women before/afterwards?
- Have you encountered any difficulties at these appointments?
- How do women react to the procedure?
- Have you removed the pessary early at all for any women? How did the woman respond?

Do women find the pessary slips out on its own?

Prompts:

- What do you do in these instances?

Have women removed the pessary themselves?

Prompts:

- What do you do in these instances?

Have there been any preterm births in the intervention or control group since the trial started?

Prompts:

- How did your colleagues respond?
- How did you feel?

Routine antenatal care

What care do women receive routinely for a twin pregnancy?
How have you found delivering this care alongside the trial?

Prompts:

- Have any particular issues cropped up with the control group?
- Have any particular issues cropped up with the intervention group?
- Have any particular issues cropped up with women who were ineligible based on cervix length?

Ending the interview

Is there anything else you would like to tell me about your experience of being part of the STOPPIT-2 trial? Anything important that I haven't asked about?

Is there anything else you would like to ask me before we finish?

Thank you very much for your time and sharing your thoughts with me.

Trial Participants – First Interview

Experience of pregnancy

Could you tell me about your pregnancy so far?

Prompts:

- How did you feel when you found out you were pregnant?
- How are you feeling now that you're further along in the pregnancy?
- How has your health been during the pregnancy?
- Have there been any issues in the pregnancy?
- How does this compare to previous pregnancies?

Has there been anything that has particularly concerned or worried you during your pregnancy?

Have you done anything in particular to keep healthy during your pregnancy?

How have you found your antenatal care?

Prompts:

- with your midwife and obstetrician?
- With the trial staff? (if different)

Taking part in the trial

How did you come to take part in the trial?

What made you decide to take part?

What things did you think about before making a decision?

What were you hoping to get out of taking part?

Could you tell me about what happened after you agreed to take part?

Prompts:

- What things were you told about before signing the consent form?
- Were there things did you want more information about?
- How did you feel?

How did you find the scan?

Prompts:

- How did you feel about being told the results of your scan?
- Did you want more information about anything?

INELIGIBLE: How did you feel about not being able to take part? Was there anything you wanted more information about? What has happened since then?

RANDOMISED: What treatment have you received since then?

Prompts:

- How was this decided on?
- What do you think about that process? What is it for?
- How did you feel when you found out your treatment? (expectations of the trial, worries/disappointment about being in intervention/control arm)
- Was there anything you wanted more information about?

INTERVENTION: Could you tell me how you've found having the pessary?

Prompts:

- What was the insertion appointment like?
- How have you been feeling since then?
- Have you had any issues with the pessary? What happened? How did you feel?
- On a day to day basis, what is it like (do you forget it/are you aware of it; impact on day to day activities, including sex life)
- Have you needed support from the trial staff? Have you received this?
- On the whole has having the pessary been a good or bad thing for you?

RANDOMISED: What has happened since then? How have you been feeling about being in the trial? Have you wanted to stop being part of the trial for any reason?

If time went backwards would you take part again?

Have there been any benefits to taking part?

Have there been any things you've found difficult or not enjoyed about taking part?

Ending the interview

Is there anything else you would like to tell me about your experience of being part of the STOPPIT-2 trial? Anything important that I haven't asked about?

Is there anything else you would like to ask me before we finish?

Thank you very much for your time and sharing your thoughts with me.

Intervention arm – follow-up interview

Experience of pregnancy

How have things been since we last spoke?

Prompts:

- How have you been feeling?
- How has your health been?

Has there been anything that you have been particularly concerned or worried about?

STOPPIT-2

How have you found having the pessary since we last spoke?

Prompts:

- What has it been like day to day (effect on activities, including sex life) Are you aware of it at all?
- Has it slipped out at all?
- What did you do?
- What happened?
- How did you feel?
- What has happened since then?

How have you been feeling about being in the trial?

Have you wanted to stop being part of the trial for any reason?

Could you tell me how you found having the pessary removed?

Prompts:

- What was the appointment like?
- How were you feeling?
- How do you feel now?

EARLY REMOVAL: What led you to have the pessary removed early?

What has happened since then?

Prompts:

- How have you been feeling?
- Have you had any issues since the pessary was removed? What happened? How

did you feel?

- Have you needed support from the trial staff? Have you received this?

On the whole has having the pessary been a good or bad thing for you?

If time went backwards would you take part again?

Do you feel there been any benefits to taking part?

Have there been any things you've found difficult or not enjoyed about taking part?

Ending the interview

Is there anything else you would like to tell me about your experience of being part of the STOPPIT-2 trial? Anything important that I haven't asked about?

Is there anything else you would like to ask me before we finish?

Thank you very much for your time and sharing your thoughts with me.
