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Fear of Childbirth: Improving accurate identification in maternity services

Submission date
18/04/2023

Recruitment status
No longer recruiting

Registration date
01/05/2023

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
How women feel about birth when they are pregnant is very varied. Some women may be quite fearful, and this can be distressing during pregnancy. Identifying fear of childbirth early in pregnancy is important, as it can help people to access the appropriate support.At the moment there are no acceptable and accurate questionnaires to measure fear of childbirth. A new measure, the Fear of Childbirth Questionnaire (FCQ), has been recently developed specifically for women in the UK. We want to check how we can use this to identify women with mild and more severe levels of fear by comparing scores with a brief interview. We also want to check if it gives results that are the same over several weeks during pregnancy. The findings from this study aim to improve our ability to identify fear of childbirth and help women to get support where needed. The study aims to provide an accurate way to identify women who experience fear of childbirth during pregnancy in routine maternity care. The study also aims to assess the feasibility and acceptability of routine use of the FCQ in maternity services.

Who can participate?
Pregnant women and community midwives at Liverpool Women's Hospital

What does the study involve?
Stage 1:
Taking part involves two steps.

Step 1: Completion of an online survey. This will ask questions about the person, their pregnancy and any previous experience of birth (if relevant). There will be some questions about how they feel about giving birth, the Fear of Childbirth Questionnaire, and general feelings of anxiety and depression. The survey will take around 15 minutes to complete.

Step 2: The participant will either be asked to complete the survey again two weeks later, or they will be contacted by a member of the research team to take part in a telephone interview at a time that is suitable for them. This telephone interview will include some questions about how they feel about childbirth, in particular, if there are any elements of birth that they are worried about. The interview will take around 20 minutes to complete.

Stage 2:
A member of the research team will contact potential participants to arrange a brief 15-minute telephone interview or online focus group at a date and time convenient for them. They will be asked about their experiences of being asked to complete the FCQ.

What are the possible benefits and risks of taking part?
Although there are no direct benefits in taking part, we hope that by exploring this new tool for fear of childbirth we can improve the ability to identify individuals who may benefit from further support throughout their pregnancy.

Participants who complete the telephone interview will receive £10 as reimbursement for their time.

Some of the questions in the survey touch on sensitive topics relating to mental health, pregnancy and childbirth. There may be potential for some of these questions to highlight existing stress. The participant does not have to answer questions that they feel uncomfortable with, and they do not need to explain why a question has not been answered.

If the participant feels distressed during a telephone interview, they will be asked whether they would like to pause the interview, move on to another question, or complete the interview at a different time. We can also contact a friend or family member of the participant on their behalf for support. The researcher can signpost them to relevant support services if they feel like they would benefit from additional support. They will be advised to contact their midwife for onward referral if we have concerns regarding their mental well-being.

Where is the study run from?
Stage 1 of the study is being run from the University of West England (UWE), Bristol, but is an online survey that can be completed by potential participants across the UK.
Stage 2 of the study is being run from Liverpool Women's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2022 to December 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit grant (NIHR203154)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315121

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55223, IRAS 315121

Study information

Scientific Title
Evaluating the properties of the Fear of Childbirth Questionnaire and feasibility of routine implementation for maternity services (FOCUS 2)

Acronym
FOCUS 2

Study objectives
To test a new measurement tool for fear of childbirth, including how reliable this is and if it measures what we think it does. To test a new way of asking women to complete this tool in early pregnancy during routine care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2023, South West- Frenchay Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)207 1048106, (0)207 104 8121; frenchay.rec@hra.nhs.uk), ref: 23 /SW/0015

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Reproductive health and childbirth

Interventions

Study Design

This project consists of two stages, involving quantitative and qualitative research methods. Stage One will evaluate the properties of the Fear of Childbirth Questionnaire (FCQ) and explore clinical cut-offs using an online survey and clinical diagnostic interviews. It will provide a full statistical and clinical validation of the FCQ and create a training package to support simple scoring and interpretation.

Stage Two will explore how feasible it is for the FCQ to be used during routine maternity care and include interviews/focus groups with women and interviews with midwives to explore acceptability.

Stage One (months 5-17, addressing objectives 1-3)

Setting

This Stage will take place remotely and will involve an online survey and clinical diagnostic interviews conducted over the telephone. Remote (online, telephone) data collection has been selected to enable participation from people throughout the United Kingdom.

Participants Pregnant women (N= 420) will be recruited online.

Women will be eligible to participate if they are:

- Up to 16 weeks pregnant. This timeframe has been used to allow us to test the FCQ if completed in early pregnancy (a similar timeframe in Stage 2). This timeframe was also supported by our service user panel, who felt that asking about fears early in pregnancy would help women to access support
- Good understanding of the English language. This is because taking part involves completing a clinical diagnostic interview, which is completed in English

Women will not be eligible to participate if they:

- Are more than 16 weeks' pregnant
- Do not have a good understanding of the English language

Following advice from the Wirral Maternity Voices Partnership, the study will not exclude women who have previously experienced a miscarriage as this may exclude many women but will record this history in the survey.

Procedure

The team will share details of the project online through Liverpool Women's Hospital (LWH) general media/communication channels (their website, social media accounts), and through up to eight Maternity Voices Partnerships (specifically Cheshire and Mersey, Wirral), Cheshire and Merseyside's Women's and Children's Services Partnership (Improving Me), with Local Maternity Systems (LMS) contacts, and online websites for pregnancy. Self-selection to a study (online) was recommended by the Birth Trauma Association (BTA) in our previous work. To facilitate continued recruitment, details will be shared via these organisations sequentially. Our recruitment strategy will aim to recruit individuals from seldom heard groups.

The online survey will be hosted by Qualtrics. Adverts for the study will include a link to this Qualtrics survey. When participants click on the link, they will first see the full participant information sheet (with an option to download this). Contact details for the research team will be provided at the end of this PIS for any questions. Women who are willing to participate will be asked to complete a consent form before completing the survey. Completing the survey will take approximately 15 minutes. Those who do not consent to participate will be thanked for their time in reading the information sheet and support services will be shown. A full debrief will be provided at the end of the survey. Information on where and how to find further support will be included on both the information sheet and debrief.

Participants will be asked to provide their name and contact details (telephone number, email address) so that the researcher (RA, RM) can arrange either the clinical interview or repeated completion of the survey.

After the survey has been completed, some participants (N=60) will be asked to complete the survey again approximately two-weeks later. This is to test how reliable scores are. The timeframe has been chosen to reduce the likelihood that scores are different because of natural

changes in fear during pregnancy. Completing the FCQ at this point will take approximately 5-10 minutes. Total participation time (including the first online survey) is approximately 25 minutes over a two-week period.

The remaining participants (N= 360) will be contacted by the RA or RM to arrange a time to complete the clinical telephone interview. This interview will involve completing Module F (for specific phobia) of the Structured Clinical Interview for DSM-5 Research Version (SCID-5-RV). This is to see whether (and at what point) scores on the FCQ suggest clinical need. Participants who are found to be experiencing phobic levels of fear will be encouraged to speak with their midwife. A £10 voucher will be offered to participants completing the telephone interview as a reimbursement for their time. Taking part in a clinical interview (including the online survey) will take approximately 35 minutes.

Materials

The online survey will record:

Demographics: Age, ethnicity, city/town where they live, education, employment status, previous psychological difficulties, and whether English is a first language.

Previous birth experience: number of previous births, mode of any previous births, previous experience of birth trauma, previous experience of pregnancy loss.

Current birth information: current antenatal care (standard care vs enhanced care), birth preferences (epidural, mode of birth). The FCQ. This tool has 20 questions, measuring the ten key parts of FOC. An example of a question is “I am confident I will be able to cope with pain”. Answers to these questions are scored on a scale of 0 (strongly disagree) to 3 (strongly agree) with some items reverse scored.

The Fear of Birth Scale (FOBS). This scale measures fear and worry about birth using two responses to one question. The question asks: “how do you feel right now about the approaching birth?”. It is answered by marking a response on two, 100mm lines with options ranging from “calm/worried” and “no fear/strong fear”. A total score is calculated by averaging the two responses. A total score of 60 or above suggests high fear of birth. The scale has shown good internal consistency and construct validity. The State-Trait Anxiety Inventory (STAI) records anxiety using 40 questions. There are two subscales within this measure. One subscale (20 questions) measures current (state) feelings of anxiety. The second subscale measures more stable (trait) anxiety. The STAI has good levels of reliability and validity and has been used with pregnant populations. The General Anxiety Disorder 7 (GAD-7) measures generalised anxiety using 7 questions. The GAD-7 is used to measure anxiety symptoms, with high scores on the GAD indicating high anxiety. The internal consistency of the GAD-7 is excellent (Cronbach $\alpha = .92$). Test-retest reliability is also good (intraclass correlation = 0.83). The Patient Health Questionnaire 9 (PHQ-9) measures depression symptoms using 9 questions. The PHQ-9 is used to measure depression symptoms. PHQ-9 scores of over, or equal to 10 had a sensitivity of 88% and specificity of 88% for major depression. The PHQ-9 has been validated for use in primary care. Previous studies show that it has high internal reliability in primary care, with a Cronbach’s α of .89.

Analysis

The study will explore the validity and reliability of the FCQ in the following ways:

1) See whether scores for the questions on the FCQ are related to each other (internal consistency) using Cronbach’s Alpha. It is expected that scores for the questions on the FCQ will be like one another, and therefore have a higher Cronbach’s Alpha.

2) Check that scores on the FCQ correlate with those on the FOBS. This will inform as to whether both measure the same construct (convergent validity)

3) Examine the strength of correlation between scores on the FCQ and those from the STAI and PHQ-9 to explore the strength and direction of these associations (discriminant validity). As FOC is considered a related yet distinct construct, it is expected the FCQ to hold no more than a moderate and positive association with the STAI and GAD-7 and a low-moderate association with the PHQ-9.

4) Compare scores on the FCQ between people who have received standard care versus enhanced care. As it is expected that people receiving enhanced care will report higher levels of fear, these scores will be examined to see whether there is a difference (criterion-related validity).
5) Scores on the FCQ and birth mode preferences will be examined; it is expected that there will be a difference in fear based on a preference for caesarean section or vaginal birth (predictive validity)
6) Item-to-total correlations on the FCQ will be assessed to see whether the items represent measurement of one construct (uni-dimensionality)
7) Perform a factor analysis on scores from the FCQ to see whether there are any underlying dimensions
Reliability of the FCQ will be assessed by comparing scores provided at the first and repeated completion of the survey (test-retest reliability)
By using scores from the FCQ and SCID-5-RV, the team will assess whether (and at what point) the FCQ can identify clinical levels of fear using Receiver Operating Characteristic (ROC) curve analysis. Kappa value, sensitivity, specificity, negative predictive validity and positive predictive validity will be determined for a range of possible cut-off scores and an optimum cut-off score will be identified.
Further shaping of the FCQ will be undertaken if required.
Training for the scoring and interpretation of the FCQ will be developed in the form of an in-person training session (approximately 30 minutes), and a pre-recorded video (up to 45 minutes).
Stage two (months 17- 25, addressing objective 4 and 5)
Setting
This stage of the project will take place at LWH NHS Foundation Trust. LWH is a specialist Trust providing maternity services in Liverpool and the North Mersey region with approximately 7,600 babies born every year.
Participants
Pregnant women who register for antenatal care during the implementation period and are assigned to care under the midwives trained in the use of the FCQ will be invited to participate.
Community midwives at LWH (N=40) will be selected as advised from our LWH co-investigator (GH) to receive training in the use of the FCQ. A large community team and smaller continuity of care team will be involved.
Procedure
Midwives at LWH will receive training in how to use and interpret the FCQ from members of the study team. Training will be provided as part of community team meetings, and a link to the video provided for further guidance or reminders.
During the implementation period, all women fulfilling inclusion criteria will receive a copy of the FCQ at their booking appointment. Women will be asked to complete the FCQ at home and return this to their midwife at their next appointment (typically 16 weeks' gestation).
At the 16 weeks appointment, the midwife will discuss the FCQ with the woman and advise on onward referral if this is required. Midwives will note at the end of the FCQ whether onward referral was required, and to where. Completed FCQ's will be placed in a secure box on site at LWH for retrieval by the study team.
At the end of the FCQ there will be a QR code that will direct the person to a PIS, consent form and ask them for their contact details if they are willing to provide feedback on the process of receiving and completing the FCQ. Women who indicate willingness to participate in a telephone interview or focus group will be contacted by a member of the study team. Upon contact, a time and date will be arranged to complete the interview or focus group.
Of the forty midwives involved in Stage 2, twenty will be contacted to complete a brief telephone interview to provide feedback on the acceptability and feasibility of this process. The remaining midwives (n=20) will be invited to complete a brief, online survey about their experience of administering the FCQ.

Materials
Women will receive the FCQ at their booking appointment.
Training feedback will be collected via a short (approximately 10-minute) Qualtrics survey. This survey will include questions about the clarity, understandability, and utility of the training provided with open-ended questions for further feedback on improvements.
Interview guides will be used to structure the qualitative feedback from women and midwives. For women, the interviews/focus group questions will ask about how helpful it was to receive the FCQ at their booking appointment, and how they viewed the process of completing this at home and returning it to their next appointment. There are also questions about how women approached completing the FCQ, and views on any barriers to completing this.
For midwives, the interview and online survey will ask about the perceived helpfulness of using the FCQ in this way and whether there were any negative aspects. There are also questions about confidence in discussing the FCQ with women, and in scoring and interpreting the FCQ. Perspectives on further improvements will also be sought.
Analysis
Audit data for the completion and onward referral arising from the FCQ will be collected.
Basic descriptive analysis will be conducted on the training feedback survey.
Interviews/focus groups will be audio recorded and transcribed. Content analysis will be used to explore the practicality and acceptability of using the FCQ and to shape future usage. The RA will lead the analysis of interviews, supported by the RM. NVIVO will be used to organise the data analysis.
Integration and dissemination (months 25-27)
Findings from Stages 1 and 2 will be integrated, and recommendations for the use of the FCQ in maternity care determined. Brief reports for dissemination with service user and maternity groups will be developed.
Two dissemination events will be held to present findings to participants, service users and maternity professionals. To facilitate inclusion, an in-person event will be held at LWH in addition to an online event. Local, regional, and national liaison with service user and maternity service groups will be undertaken. The study team will liaise with local Maternal Mental Health Services, sharing the tool, training and recommendations for completion. The team will share findings and outputs with North West Maternal Mental Health Services, the Cheshire and Mersey perinatal clinical network, and local maternity voices partnerships. Findings will also be shared nationally with the Consultant Midwives Network, shared through National Perinatal Clinical Network meetings, national Maternity Voices Partnerships and the Future NHS Platform. Findings will also be shared at national and international scientific meetings and conferences to enable sharing amongst clinicians directly engaged in the provision of perinatal psychology and maternity care.

Intervention Type
Behavioural

Primary outcome(s)
Fear of childbirth measured using the Fear of Childbirth Questionnaire (FCQ) when the woman is up to 16 weeks pregnant. The Structured Clinical Interview for DSM-5-RV will be used 2 weeks later to further assess fear of childbirth. Scores on the FCQ and responses to the SCID-5-RV clinical interviews will be compared. Sensitivity and specificity will be calculated for a range of possible cut-off values.

Key secondary outcome(s))
1. Fear of childbirth measured by the Fear of Birth Scale up to 16 weeks gestation.
2. State and trait anxiety measured by the State-Trait Anxiety Inventory up to 16 weeks

gestation.
3. Generalised anxiety measured by the General Anxiety Disorder 7 up to 16 weeks gestation.
4. Depressive symptoms measured by the Patient Health Questionnaire 9 up to 16 weeks gestation.

Completion date
20/12/2024

Eligibility

Key inclusion criteria
Stage 1:
1. Participant is willing and able to give informed consent for participation in the study
2. Female, aged 18 years or above
3. Currently up to 16 weeks pregnant. This timeframe has been selected to examine the properties of the FCQ if completed early in pregnancy and is aligned with the proposed use of the FCQ between booking and 16-week midwife appointments (Stage 2). This timeframe was also supported by our service user panel, who felt that early identification of fears would provide the best opportunity for women to access further support
4. Good understanding of the English language. Due to the inclusion of clinical diagnostic interviews, it is required that participants are able to understand the English language

Stage 2:
1. Participant is willing and able to give informed consent for participation in the study
2. Female, aged 18 years or above
3. Pregnant
4. Booked by a midwife trained in administering the FCQ at Liverpool Women's Hospital
5. Good understanding of the English language

Community midwives at LWH (n = 40), selected as advised by our LWH co-investigator (GH)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
449

Key exclusion criteria

Stage 1:
1. More than 16 weeks pregnant
2. Women who do not have a good understanding of the English language

Stage 2:
Women who do not have a good understanding of the English language

Date of first enrolment
02/05/2023

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Womens Hospital
Crown Street
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Sponsor information

Organisation
University of the West of England

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The databases generated and analysed during the current study will be stored in a non-publicly available repository, managed by the University of West England, Bristol for a minimum of 5 years. Any personal data collected that is not fundamental to the project will be destroyed earlier; however, information from consent forms may need to be kept for the whole archiving period.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	version 4	22/02/2023	01/05/2023	No	Yes
Participant information sheet	version 4	22/02/2023	01/05/2023	No	Yes
Participant information sheet	version 4	22/02/2023	01/05/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes