Preventing Post Traumatic Stress Disorder: the Stress and Wellbeing after Childbirth Study (STRAWB2)
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1. Aims and objectives

Overarching Aim
To evaluate whether providing self help material can reduce the incidence of clinically significant symptoms of full (diagnostic) and partial (subdiagnostic) post traumatic stress disorder (PTSD) after childbirth.

Specific research question:
Is a programme of identification of women who have experienced their childbirth as traumatic, followed by provision of prevention for post traumatic stress after childbirth clinically effective when compared to usual care and if so what is the cost per case prevented?

Aims
(1) To train community midwives to administer a simple postnatal screening tool assessing whether women have experienced their childbirth as traumatic.
(2) In women who have experienced childbirth as traumatic, to compare the outcomes of those randomised to preventive self help or usual care, in terms of full and partial PTSD at 6-12 weeks postnatally.
(3) To investigate women's views on aspects of self help material that are most helpful.
(4) To provide a health economic analysis of cost per case (full or partial PTSD) prevented.
(5) To develop, if appropriate, a local implementation plan for integration of the training and self help material into the perinatal mental health care pathway.
(6) To disseminate the information to care providers nationally to facilitate implementation of preventive care.

When childbirth is experienced as traumatic, defined as when there is high fear of death or damage to self or baby during or shortly after childbirth, then women are at risk of developing PTSD. This is a debilitating and chronic condition with major adverse health consequences for a woman herself and her relationships with her partner and infant. Poor maternal mental health can also adversely impact upon the child's cognitive, emotional and social development.

The development of PTSD after a traumatic experience is strongly influenced by how a person reacts to what are normal but disturbing cognitive and emotional responses. This work will evaluate if midwives

providing easy to use written and web link self help material, which aims to help women understand normal responses and practise simple psychological exercises to facilitate normal resolution of traumatic memories, will prevent the development of PTSD.

The hypothesis is that if women who have experienced their childbirth as traumatic are provided with information about the normality of responses and can practise how best to manage these they will show a significantly lower incidence of PTSD at 6-12 weeks postnatally, both at diagnostic and subdiagnostic levels. The cost per prevented case will also be estimated to assess the economic viability of this preventive approach.

2. Scientific abstract of research

Background

Post traumatic stress disorder (PTSD) after childbirth is major cause of psychological distress postnatally, with 3% of women suffering at full diagnostic levels and 5-9% when sub-diagnostic levels (partial PTSD) are included. It adversely affects women's functioning at a critical time for family relationship development. Women with PTSD experience intrusions, repeatedly reliving the traumatic event with images, thoughts and feelings as if back in the original situation. They try to avoid situations or people that may trigger intrusions thereby restricting their life. Relationships, such as with the partner, are adversely affected as the woman feels irritable and constantly under threat. The developing mother-infant relationship can be compromised with negative effects on the infant's emotional and cognitive development.

Experiencing an event as traumatic does not inevitably lead to PTSD. Intrusive experiences can be normal early responses to traumatic events. Where women view these intrusive responses as signs of illness or failure to cope and they attempt to avoid these responses this contributes to traumatic memories not being processed in a normal way. It is the unprocessed memories that lead to the flashbacks and nightmares that are characteristic of PTSD. There is therefore potential to prevent the development of PTSD. We have developed and feasibility tested the following through a one year funded study (RCF 2012-13 07):
1) A simple screening tool for use by community midwives to identify women who have experienced birth as traumatic.
2) Self help material derived from the theoretical mechanisms about how PTSD develops.
3) A brief training programme to enable midwives to implement both screening and provision of self help material.

The self help material incorporates:
1) Simple explanations as to why women may experience early distressing responses to normalize these responses and reduce their negative evaluation.
2) Explanation why it is important not to block unpleasant images and thoughts and just allow them to be there without either distracting or dwelling on them with simple guided exercises to achieve this.
3) Explanation of how discussion in a supported context helps memory processing and provides an exercise
to identify a suitable person, time and place with whom to do this.
4) An exercise using implementation intentions (evidence-based ways of translating plans into actions). This aims to help women translate their new understandings into actions.

Aim
To assess whether the introduction of a routine programme of identification of women who have experienced their childbirth as traumatic, and the provision of self help material to prevent PTSD improves outcomes when compared to usual care. If this is confirmed what is the cost per case prevented?

Research Plan
2640 women will be screened early postnatally by community midwives to assess whether they experienced their birth as traumatic. Data from our external pilot work suggests 25% will screen positive. These women will be randomised, 330 per arm, to receive the self help material or usual care. Women will be followed up with the gold standard assessment for PTSD which will be completed by phone at 6-12 weeks postnatally. Data will be analysed using standard summary statistics and hypothesis tests. A cost per PTSD case prevented analysis will be completed.

3. Benefits to Patients and NHS

This project has the potential to provide a simple system to reduce the incidence of full and partial PTSD after childbirth that can be readily incorporated into the current care pathway. This will benefit the mental health of women and the quality of relationships with partner and infant. PTSD once established is chronic and treatment is expensive. The current work if successful can substantially reduce NHS care costs.

4. Background and rationale

The problem being addressed

Experiencing childbirth as traumatic can lead to post traumatic stress disorder (PTSD) (1). The most methodologically sound prevalence study of PTSD after childbirth (2) found at 4-6 weeks postnatally 5.6% of women showed full diagnostic or sub-diagnostic PTSD. A recent large postnatal survey found rates of 8.6% at 8 weeks of full or partial PTSD (3). A meta-analysis showed full PTSD rates alone, were 3.1% (4). In any one year, 20,640 women in England and Wales will develop full diagnostic PTSD following childbirth (5) with many more at sub-diagnostic levels. PTSD is defined as a *psychological response to exposure to an event incorporating threatened death or serious injury. The response causes clinically significant distress or impairment in the individual's social interactions, capacity to work or in other important areas of functioning* (6). PTSD adversely affects the relationship with the partner and the developing bond with the infant (7-9). By 6 months post trauma, PTSD does not usually remit spontaneously and requires specialist intervention (10, 11). It also adversely affects women's experience of subsequent pregnancies with increased anxiety and increased care costs for subsequent births through requests for caesareans (12).

The National Institute for Health and Care Excellence (NICE) antenatal and postnatal mental health guidelines suggest midwives should routinely enquire about birth experience to identify women with birth trauma and services should provide timely treatment from specialised staff for women with PTSD at both diagnostic and subdiagnostic levels (13). There is no guidance on how identification should be made. To screen and provide intervention for women who develop PTSD is expensive. Simple low cost preventive approaches are urgently required. PTSD is distinct from postnatal depression in its mechanisms, symptomology and treatment and requires specific consideration.

Background literature

The process of development of PTSD

PTSD requires the experience of a traumatic event. Childbirth fulfils this criterion for 25% of women (1). During childbirth women can be exposed to evidence of fetal distress and/or potential for physical damage to their own bodies. Women can experience intense pain, fear or helplessness. How a woman subjectively experiences her childbirth rather than the objective obstetric complications is the critical determinant of postnatal

psychological responses (14).PTSD is comprised of *intrusions* including reliving events as if back in the frightening situation (with accompanying emotional responses and in severe cases even the re-experiencing of pain), nightmares or intrusive thoughts about the event(6). A natural response is to try to distract from the distressing internal events and avoid potential triggers for reliving and this leads to *avoidance* (15). Postnatally this can include avoidance of other mothers for fear they may discuss childbirth and avoidance of health care professionals for example not attending the 'postnatal check' with the potential for physical morbidity related to childbearing remaining untreated. Intrusions and avoidance are coupled with irritability, poor concentration and a sense of ongoing threat (6). PTSD leads to adverse effects on the woman and her relationships. Positive maternal health and positive mother-infant relationships are needed for optimal child development (8, 16).

We understand some of the mechanisms that determine whether the experience of an event as traumatic leads to PTSD or is naturally resolved. After a traumatic experience intrusions can be a normal response as the brain attempts to process new and distressing material. If a woman believes these experiences are abnormal or an indication of not coping/ abnormality /illness she is likely to be highly distressed by her responses. A natural protective response is to try to ignore and block these. The greater the attempts to distract from the intrusions, the more memories remain unprocessed and therefore involuntarily intrude. As a result a woman is likely to become 'on edge' and hypervigilant for threat as she cannot predict when an intrusion will occur. This leads to further distress and irritability. As well as the cognitive avoidance there is also behavioural avoidance so she will avoid discussion of the childbirth events for fear of distress. Again this will block normal processing increasing the probability of PTSD developing (15,17,18). The social context of childbirth provides a specific set of circumstances where avoidance reactions are likely. If a woman has had a healthy baby then postnatally she is expected to be positive and contented and help seeking is not easy (19). Women feel guilty and try to hide their distress and may feel a failure (20). Partners and friends may try to protect the woman from distress through avoidance of discussion of the birth. However, blocking and distraction and avoidance of discussion are the key processes that incubate the development of PTSD after a traumatic event (15).

Prevention of PTSD

PTSD may be potentially preventable through targeting the cognitive and behavioural mechanisms identified (15,17,18,21-23). A Cochrane review on prevention of PTSD specifically recommended the development of new approaches focused on behaviours and coping (24). We have developed an acceptable, feasibility-tested prevention package tailored for the postnatal period. This facilitates women's understanding of the key processes and develops adaptive ways of managing responses to assist normal processing. There are a limited number of unsuccessful prevention studies in other contexts, namely after road traffic accidents which have incorporated complex information packs (21-23). There have been no prevention studies providing accessible information and practise, targeting cognitive and behavioural coping processes postnatally. The NIHR trials register shows only one related ongoing study: Health After Birth Trial (HABIT) testing if writing improves health postnatally. It does not focus on prevention of PTSD or include identification of women at risk.

Need for a trial

We have completed a successful feasibility and pilot study demonstrating acceptability of a screening procedure and self help material (RCF 2012-1307). To be useful this needs (i) to be targeted, and (ii) the relevance of the information needs to be linked to birth experiences by a midwife with an understanding of the psychological mechanisms. This is particularly the case postnatally when women receive an overload of information at a demanding life phase. We also need to ensure there are no associated adverse outcomes. Having established feasibility we need to systematically evaluate and cost this package against usual care.

Why is this research important in terms of improving the health of the public and/or patients and the NHS?

The importance of the research to women, families and public

Prevention of PTSD after childbirth will benefit women's mental health and their relationships with their partner and infant. Women will be able to experience the postnatal period without the experiences of birth continuing to intrude into their daily lives. Mothers will be able to form more positive relationships with their infants, providing life-long benefits to their child's cognitive and emotional development. They will be able to make decisions about further children on the basis of their preferences rather than fear. Their care in a future pregnancy will be less stressful

and complex and unaffected by high levels of anxiety which are a consequence of ongoing PTSD. The importance of this area to mothers is evidenced by the emergence of the Birth Trauma Association. This was established as a self help information site for women experiencing traumatic births. It receives 150,000 hits annually and has an active Facebook group of 250 members (http://www.birthtraumaassociation.org.uk/). A recent epidemiological study also shows public support for perinatal screening initiatives (25).

The NHS perspective

The study fits with the NHS 5 year Forward View which emphasises prevention rather than treatment (26).Mental Health Service reform is currently a priority for NHS England, which includes the Department of Health Maternal Mental Health Pathway (27). The increasing recognition of the importance of maternal mental health is also evident in 'The Healthy Child Programme' (28), government strategy (29), and recent midwifery and general practice good practice guides (30,31).

The importance of this research to the NHS is evidenced in a recently commissioned economic report: *The costs of perinatal mental health problem*s completed by the Personal Social Services Research Unit (PSSRU) and Centre for Mental Health (32). This indicated that the annual costs of perinatal mental health difficulties to health and social care are £8.1 billion. PTSD after childbirth is a key element of this and provides a significant opportunity for cost savings.

Where PTSD is untreated it becomes chronic. After 6 months spontaneous remission is rare and effectiveness of intervention reduces with time after the event. At 6 years post event even with specialist treatment effectiveness is poor (10-11). Psychological intervention for PTSD requires specialist input and current NICE guidance suggests 8-12 sessions of time (33). The cost per case of 12 sessions of specialist treatment is £1,656 (34).

The updated NICE antenatal and postnatal mental health guidelines (13) suggest that midwives should routinely enquire about birth experience although no systematic way of doing this is indicated. This work provides training for midwives, simple screening and self help material which can be readily integrated into routine care pathways at low cost. The study design has added value in providing a catalyst for closer collaboration between midwives and health visitors, which is a requirement of the new Maternal Mental Health Pathway (27).This work potentially provides a simple prevention system that can be readily implemented into routine

practice, providing benefits to women and families and NHS cost savings within a year of completion.

5. Research Plan

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Completed feasibility and pilot work

This project is developed from a one year feasibility and external pilot work funded by Liverpool Health Inequalities: the Stress and Wellbeing after Childbirth Study, STRAWB (RCF2012-1307). This involved a literature search concerning mechanisms of development and prevention of PTSD. It developed the self help materials based on the evidence and checked the feasibility and acceptability of processes for women and midwives. It provided information for sample size estimates and recruitment rates. It involved testing of staff training, screening and provision of self help material. 164 postnatal women were recruited by community midwives. 25% women reported a traumatic childbirth. Of at risk women who received the self help material, no women at 6-8 weeks postnatally met the full diagnostic threshold for PTSD on the gold standard Clinician Administered PTSD Scale (CAPS)(35) and 5 women were positive at sub-diagnostic threshold. Using the best prevalence estimates (2-4) between 8 and 13 women at full or partial (sub-diagnostic) PTSD levels without prevention were predicted so the results were encouraging. Interviews with women and a focus group with midwives concerning the training and integration of screening and self help into routine care indicated the package was highly acceptable and feasible. Key themes in the focus group were that this was an area that midwives *were expected to cover but did not know how* and that *it'd be easy to do* i.e integrate into routine practice.

Design

This constitutes a phase III randomised controlled trial (36) to assess prevention of PTSD after childbirth through self help against usual care, in a targeted sample, with outcome assessment at 6-12 weeks postnatally. The work includes both clinical and economic evaluation of cost per case prevented. Simple qualitative information on helpful intervention elements will be gathered. Further information on midwifery perspectives will not be gathered as this was covered in detail in the feasibility work.

Participants

2640 postnatal women under the care of 4 community midwifery teams located within Liverpool Women's Hospitals Trust (Liverpool) and Lancashire Teaching Hospitals Trust (Preston).

Inclusion and exclusion criteria

All women of 16 years and over who give birth to a live baby and who have sufficient English language to complete the measures will be eligible to participate. The aim is to be as inclusive as possible and we will include all women unless there are specialist services addressing their needs. Exclusion criteria will be simple and easily identified by recruiting midwives.

(1) Women after stillbirth,
(2) Women under the care of the enhanced midwifery teams for drug/alcohol or social care reasons.
(3) Women under the care of perinatal mental health teams.

Women with twins or a premature baby will be included. This information will be noted and accounted for statistically.

We will not, at this point, translate materials into different languages as there are issues about conceptual equivalence and meanings of terms. Also conducting follow-up telephone clinical interviews would require multiple interpreters and exact timings which would be logistically difficult to achieve within current funding. On trial completion, our community development worker collaborator (AQ) will review the screening and self help materials to identify modifications required for implementation within different ethnic communities to inform subsequent rollout.

Procedure

The procedure is specifically tailored to dovetail into existing midwifery practice and integrate into existing care pathways.

Phase 1

Training will be provided for the community midwives concerning

(i) PTSD, its presentation, mechanisms of development and implications.
(ii) the identification of experience of trauma and use of the screening questions
(iii) the randomisation process
(iv) how to provide the self help material.

Training has already been developed and tested and evaluated in the feasibility/external pilot study.

Recruitment, consent and screening of postnatal women
The following processes have all been tested and found to be acceptable and effective. Information about the study will be available to all antenatal women via trust research websites. All women cared for by recruiting community midwifery teams will be given an information sheet at the first postnatal visit.

Time 1
At a subsequent midwifery contact, before community midwives discharge women, they will ask for consent to participate. The study procedure will be initiated only after completion of standard clinical care which will involve any normal midwifery assessment of risk. All women consented will be asked the screening questions developed and tested within our feasibility study.

Development of the screening questions
DSM V has recently removed appraisal from their criteria in relation to PTSD (37). For PTSD after childbirth several studies clearly indicate that, for this context, appraisal of the event forms the best predictor of later responses (38). The questions developed were therefore based on the original DSM IV criterion A (39) but modified by the input from service users at the Birth Trauma Association to fit the childbirth context. These questions were tested against the Clinician Administered PTSD Scale (CAPS)(35) and found to demonstrate 83% sensitivity and 55% specificity in our feasibility/pilot study. They were quick for midwives to use and acceptable to women.

Screening questions
Thinking about your childbirth (and any time in hospital after) was there any time during this when you felt (i) horror or helplessness about what was happening Yes /No or (ii) really frightened about your own or your baby's wellbeing? Yes /No.

Women answering *'Yes' to either element* will be randomised to self-help prevention or care as usual by their midwife using an independent automated system *sealedenvelope.com* under the guidance of our statistician (SL). Usual care will involve routine postnatal care including any actions based on midwifery clinical judgement and will be complete prior to the screening questions.

Self help materials

Key mechanisms in the development of PTSD are negative appraisal of normal responses to traumatic events, which then lead to attempts at distraction and avoidance. Avoidance also occurs as women attempt to keep away from friends or other new mothers who might ask about childbirth. Family members inadvertently encourage this response by avoiding sensitive topics such as the birth for fear of causing distress. The intervention is specifically derived from the theoretical literature and developed by clinical psychologists with trauma-related expertise. The package incorporates the following elements:

1) Simple explanations why women may experience early distressing responses. This aims to normalize responses and reduce their negative evaluation.

2) Explanation and demonstration of the importance of not blocking unpleasant images and thoughts and just allowing them to be there without either distracting or focussing on them. This is achieved by simple guided exercises.

3) Explanation of how discussion in a supported context helps memory processing and an exercise to identify a suitable person, time and place with whom to do this.

4) Finally there is an exercise using implementation intentions (evidence-based ways of translating plans into actions). This will help women translate their new understandings into actions to facilitate natural processing of the traumatic memories. Implementation intentions are widely used and highly effective in promoting behaviour change (40).

The self help material integrates explanation, normalization, experiential learning and implementation strategies. Although the material is based on sophisticated theoretical underpinnings it has been provided in easy to use formats of a short leaflet and web link. Whilst the content is set these require their presentation improving for the full trial. In addition service users have requested development of an option for a mobile app if feasible

The presentation of the information has been shaped by input from both the maternity service users' research group and midwifery and obstetric staff. We also conducted a real-time process with a sample of 5 women which confirmed that their understandings of the content mirrored the design aims.

Women randomised to self help will receive the leaflet and web link access to app if used from their midwives. After 2 weeks they will receive

an automated text message reminder that they had been given these materials to prompt usage as needed. A reminder card will also be sent to women in both groups prior to the follow up phone call. Both groups will receive routine ongoing care from their GP and health visitor which should encompass emotional care.

Phase 2

Time 2: 6-12 week postnatal follow up

At 6-12 weeks postnatally and at least 4 weeks after randomisation, women will complete a Clinician Administered PTSD Scale(CAPS)(35) as a telephone interview with a trained researcher, blind to group allocation. The CAPS is considered as the 'gold-standard' method for identification of PTSD at caseness or subdiagnostic threshold with either dimension of intrusion or avoidance fulfilling significant scores. The typical duration is 25-45 minutes however much of this normally focusses on identification of different relevant traumas.
As the focus is solely on whether PTSD occurs in response to childbirth in our pilot, time was reduced to 15-30 minutes. The interview is available from the National Center for PTSD (USA) and with free online training for suitably qualified individuals. The research psychologists and midwives will fulfil these criteria. Interviews will be recorded. Fidelity monitoring through dual coding of 30% of interviews (randomly selected) will be implemented and Cohen's Kappa will be calculated to assess reliability. The feasibility study demonstrated a Cohen's Kappa of 1.0 indicating that coding was highly reliable.

We will also administer the Hospital Anxiety and Depression Scale (41), brief questionnaire to measure the quality of partner relationship (42) and the Maternal Infant Attachment Scale (43) a measure of feelings for the infant. Full details of these measures which all have suitable validity and reliability and which take in total between 15 and 20 minutes to complete. We will also ask about any contacts specifically related to managing responses to birth experience, including joining of trauma-related internet groups and discussions with health professionals. Depending on the duration of the CAPS and with sensitivity for the needs of the woman and her baby this follow up could involve an additional phone call.

Follow up care

Where a woman fulfils diagnostic criteria for PTSD (full or sub-diagnostic levels) consent will be sought from the woman, to share this information with her GP and health visitor so that appropriate care can be offered. If

there are risk issues the normal trust policy concerning notification will be followed. In liaison with our health visiting collaborator (SG) all local health visitors at both sites will be alerted to the study.

Maternal views and experiences

In order to assess use a random subsample of 100 women in the self help arm will be emailed/texted and/or posted a brief feedback sheet covering (i) whether they had used the material provided, and to provide qualitative information on (ii) what had been helpful or unhelpful, and (iii) any actions taken as a result of the prevention information. This will be analysed by content analysis (44).

Outcome measures

The CAPS will form the primary outcome measure incorporating both diagnostic and subdiagnostic levels of PTSD. Secondary outcomes will be PTSD and depressive and anxiety symptoms as continuous variables, the quality of the couple relationship and feelings for the infant.

Sample size and power calculations

The feasibility study showed that 25% of women answered positively to one of the screening questions fulfilling criteria for having experienced childbirth as traumatic. On the basis of the pilot and literature we estimate one quarter (25%) of this at risk sample will be expected to develop clinically significant full or partial PTSD. We aim to determine if the self-help material can reduce this figure to 15% of the at risk sample. The most methodologically sound prevalence study of PTSD after childbirth (2) found at 4-6 weeks postnatally 5.6% of women showed full diagnostic or sub-diagnostic PTSD. A postnatal survey found rates of 8.6% at 8 weeks of full or partial PTSD (3). A meta-analysis showed full PTSD rates alone were 3.1% (4). We have conservatively estimated a full and partial PTSD rate at 6-8 weeks as 6.25%. We expect the self-help material to reduce the full and partial PTSD rate to 3.75% of the total population of women giving birth. Considering only high risk women, to detect a reduction in full or partial PTSD cases from 25% to 15% at 6-8 weeks follow-up will require a sample of 247 women in each group to give an 80% power at the 5% significance level. Allowing for 25% attrition at follow-up as indicated in our external pilot an initial sample size, of 330 per group, should achieve this. To identify sufficient high-risk women (660) it will initially require screening of 2640 women, although potentially we have access to more women if the high-risk prevalence rate is over-estimated.

Statistical Analysis

The initial data will be presented using summary statistics and standard hypothesis tests will be used to determine if any between group differences occur in the distribution of demographic factors. As the primary outcome is measured on a binary scale, the chi-squared statistic will be used to assess the primary hypothesis of change in the proportion of women experiencing PTSD between groups, the effect size will be presented using relative risks. If there are between group differences in demographic or other confounding factors, logistic regression will be used to estimate adjusted odds-ratios. Secondary outcomes, will be tested using either chisquared test for categorical variables and t-test for continuous variables. If data is not normally distributed then parametric equivalent methods will be used and if between group differences exist regression models will be used as appropriate.

Recruitment Issues

Our feasibility with external pilot study with one team of 18 midwives showed we could establish systems that successfully recruited over 50% of the potential sample. Ninety percent of women when asked agreed to take part. The single team for the final month of our pilot recruitment were recruiting on average 20 women *per week*. The current study will involve 4 teams of midwives and we will implement our successful package of recruitment processes for 12 months.

Our staffing and recruitment estimates are based upon our feasibility and pilot experience. The specified recruitment teams booked 3538 women in Liverpool and 4600 in Preston respectively over the last 12 months providing a potential pool of 8138 women prior to exclusion criteria. We believe our recruitment target is conservative and on the basis of our pilot easily achievable. Should rates fall below target at 4 months into recruitment, then as a contingency plan, we could recruit an additional Liverpool team. We are currently proposing recruitment from only 50% of Liverpool teams.

Health economics

From a service provider perspective we will cost the preventative intervention (screening and self help material) applying National unit costs where available (34,45) and conduct a primary cost effectiveness analysis (using the trial primary outcome CAPS and incidence of PTSD as our measure of effectiveness) to produce a cost per case prevented estimate.

Phase 3

With our co-investigator from Liverpool Clinical Commissioning Group (CCG)(AS) we will design a local implementation plan. We will work with our community development worker collaborator (AQ) to review implementation issues for communities with different ethnicities. We will hold two implementation meetings one local and one national for perinatal pathway leads, Heads of Midwifery, CCG representatives and service user organisations. Preparation of report, conference submissions and drafts of papers will be completed.

Time Frame of the full study
24 months commencing Nov 2016 with completion October 2018

6. Potential for longer term follow up study (STRAWB3)

We have been awarded Research Capability Funding to evaluate the literature on long term efficacy of prevention, rates of delayed onset, impacts of current interventions, and facilitators and barriers to uptake of services for post-traumatic stress following childbirth. The results of this review will provide a platform for STRAWB3, a Research for Patient Benefit (RfPB) application to be drafted, and the funding provided also supports the development of this bid. We therefore wish to ask all STRAWB2 participants for consent to contact them with information about a follow on study. STRAWB2 participants can agree or decline this entirely separate to STRAWB2 and any subsequent participation would require additional consent.

The proposed STRAWB3 study will potentially follow STRAWB2 participants depending on timing of funding at up to 2 points up to 4 years post childbirth. This will make use of a unique opportunity to provide long term follow up to an existing sample of postnatal women who have experienced a traumatic childbirth for whom we will have gold standard PTSD status data at two months after childbirth. Women will be asked about their mental health and wellbeing, additional input they have received or would have wanted, and facilitators and barriers to input.

The follow on study, if funded, will potentially provide definitive information on: (i) longer term impact of our preventive package in STRAWB2; (ii) the incidence of delayed onset PTSD following traumatic childbirth; (iii) the availability and impacts both for mother and mother-child relationship of psychological interventions provided in routine care

and; (iv) information on the facilitators and barriers to accessing such care.

7. References

1. Soet, J.E., Brack, G.A., & Dilorio, C. (2003). Prevalence and predictors of women's experience of psychological trauma during childbirth. *Birth, 30*(1), 36-46.
2. Alcorn, K.L., O'Donovan, A., Patrick, J.C., Creedy, D., & Devilly, G.J. (2010). A prospective longitudinal study of the prevalence of post-traumatic stress disorder resulting from childbirth events. *Psychological Medicine, 40*(11), 1849-1859.
3. Garthus-Niegel, S., Ayers, S., Van Soest, T., Torgersen, L., & Eberhard-Gran, M. (2015). Maintaining factors of posttraumatic stress symptoms following childbirth: A population-based, two-year follow-up study. *Journal of Affective Disorders, 172*, 146-152.
4. Grekin, R., & O'Hara, M.W. (2014). Prevalence and risk factors of postpartum posttraumatic stress disorder: A meta-analysis. *Clinical Psychology Review, 34*(5), 389-401.
5. Hogg, S. (2013). *Prevention in mind. All babies count: Spotlight on perinatal mental illness*. London: NSPCC.
6. American Psychiatric Association (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.)
Washington, DC: Author.
7. Iles, J., Slade, P., & Spiby, H. (2011). Posttraumatic stress and postnatal depression in couples after childbirth: The roles of partner support and attachment. *Journal of Anxiety Disorders, 25*, 520-530.
8. Davies, J., Slade, P., Wright, I., & Stewart, P. (2008). Post traumatic stress symptoms following childbirth and mothers' perceptions of their infants. *Infant Mental Health Journal, 29*, 537-554.
9. Parfitt, Y., & Ayers, S. (2014). Transition to parenthood and mental health in first-time parents. *Infant Mental Health Journal, 35*(3), 263-273.
10. Kessler, R.C., Sonnega, A., Bromet, E., Hughes, M., & Nelson, C.B. (1995). Posttraumatic stress disorder in the national comorbidity survey. *Archive General Psychiatry, 52*(12), 1048-1060.
11. Arnberg, F., Bergh Johannesson, K., & Michel, P. (2013). Prevalence and duration of PTSD in survivors 6 years after a natural disaster. *Journal of Anxiety Disorders, 27*(3), 347-352.
12. Tschudin, S., Alder, J., Hendriksen, S., Bitzer, J., Popp, K.A., Zanetti, R., et al. (2009). Previous birth experience and birth anxiety: Predictors of caesarean section on demand? *Journal of Psychosomatic Obstetrics and Gynaecology, 30*(3), 175-180.

13. National Institute for Health and Care Excellence (2014). *Antenatal and postnatal mental health: Clinical management and service guidance. NICE clinical guideline 192*. London: Author.
14. Andersen, L.B., Melvaer, L.B., Videbech, P., & Lamont, R.F. (2012). Risk factors for developing post traumatic stress disorder following childbirth: A systematic review. *Acta Obstetrica and Gynaecologica, 91*, 1261-1272.
15. Ehlers, A., & Clark, D.M. (2000). A cognitive model of posttraumatic stress disorder. *Behaviour Research and Therapy, 38*(4), 319-345.
16. Marryat, L. and Martin, C. (2010). *Growing up in Scotland: Maternal mental health and its impact on childbehaviour and development*. Edinburgh: The Scottish Government.
17. Holeva, V., Tarrier, N.T., & Wells, A. (2001). Prevalence and predictors of acute stress disorder and PTSD following road traffic accidents: Thought control strategies and social support. *Behaviour Therapy, 32*, 65- 83.
18. Briddon, E., Slade, P., Isaac, C., & Wrench, I. (2012). How do memory processes relate to the development of posttraumatic stress symptoms following childbirth? *Journal of Anxiety Disorders, 25*, 1001-1007.
19. Dennis, C.L., & Chung-Lee, L. (2006). Postpartum depression help seeking barriers and maternal treatment preferences: A qualitative systematic review. *Birth, 33*(4), 323-331.
20. Coates, R., Ayers, S., & de Visser, R. (2014). Women's experiences of postnatal distress: A qualitative study. *BMC Pregnancy and Childbirth, 14*: 359.
21. Turpin, G., Downs, M., & Mason, S. (2005). Effectiveness of providing self-help information following acute traumatic injury: Randomised controlled trial. *British Journal of Psychiatry, 187*, 76-82.
22. Scholes, C., Turpin, G., & Mason, S. (2007). A randomised controlled trial to assess the effectiveness of providing self-help information to people with symptoms of acute stress disorder following a traumatic injury. *Behaviour Research and Therapy, 45*, 2527-2536.
23. Bugg, A., Turpin, G., Mason, S., & Scholes, C. (2009). A randomised controlled trial of the effectiveness of writing as a self-help intervention for traumatic injury patients at risk of developing post-traumatic stress disorder. *Behaviour Research and Therapy, 47*, 6-12.
24. Roberts, N.P., Kitchiner, N.J., Kenardy, J., & Bisson, J.I. (2009). Multiple session early psychological interventions for prevention of post-traumatic stress disorder. Cochrane Database of Systematic Reviews 2009, Issue 3. Art No.: CD006869. DOI:10.1002/14651858.CD006869.pub2.

25. Kingston, D., McDonald, S., Tough, S., Austin, M.P., Hegadoren, K., & Lasiuk, G. (2015). Public views of acceptability of perinatal mental health screening and treatment preference: A population-based survey. *BMC Pregnancy and Childbirth, 14*: 67.
26. NHS England (2014). *Five year forward view*. Retrieved from: http://www.england.nhs.uk/wpcontent/uploads/2014/10/5yfv-web.pdf
27. Department of Health (2012). *Maternal mental health pathway*. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212906/Maternalmental-health-pathway-090812.pdf
28. Department of Health (2009). *Healthy child programme: Pregnancy and the first 5 years of life*. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167998/Health_Child_Programme.pdf
29. HM Government and the Department of Health (2011). *No health without mental health: A crossgovernment mental health outcomes strategy for people of all ages*. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213761/dh_124058.pdf
30. Royal College of Midwives (2012). *Maternal emotional wellbeing and infant development: A good practice guide for midwives*. London: Author.
31. Khan, L. (2015). *Falling through the gaps: Perinatal mental health and general practice*. London: Centre for Mental Health.
32. Bauer, A., Parsonage, M., Knapp, M., Lemmi, V., & Adelaja, B. (2014). *The costs of perinatal mental health problems*. London: Centre for Mental Health.
33. National Institute for Health and Care Excellence. (2005). *Post-traumatic Stress Disorder (PTSD): The management of PTSD in adults and children in primary and secondary care. NICE clinical guideline 26*. London: Author.
34. Curtis, L. (2014). *Unit Costs of Health and Social Care 2014.* Personal Social Services Research Unit. Retrieved from: http://www.pssru.ac.uk/project-pages/unit-costs/2014/
35. Blake, D.D., Weathers, F.W., Nagy, L.M., Kaloupek, D.G., Gusman, F.D., Charney, D.S. et al. (1995). The development of a clinician-administered PTSD scale. *Journal of Traumatic Stress, 8*, 75-90.
36. Craig, P., Dieppe, P., MacIntyre, S., Mitchie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ* 2008;337;a1655.

37. Friedman, M.J., Resick, P.A., Bryant, R.A., & Brewin, C.R. (2011). Considering PTSD for DSM-5. *Depression and Anxiety, 28*(9), 750-769.
38. Devilly, G.J., Gullo, M.J., Alcorn, K.L., & O'Donovan, A. (2014). Subjective appraisal of threat (criterion A2) as a predictor of distress in childbearing women. *Journal of Nervous and Mental Disease, 202*(12), 877-882.
39. American Psychiatric Association (2000). *Diagnostic and statistical manual of mental disorders* (4th ed.,text revision) Washington, DC:
40. Gollwitzer, P.M., & Sheeran, P. (2006). Implementation intentions and goal achievement: A meta-analysis
of effects and processes. *Advances in Experimental and Social Psychology, 38*, 69-119.
41. Zigmond, A.S., & Snaith, R.P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica, 67*(6), 361-370.
42. Sabourin, S., Valois, P., & Lussier, Y. (2005). Development and validation of a brief version of the dyadic adjustment scale with a nonparametric item analysis model. *Psychological Assessment, 17*(1), 15-27.
43. Condon, J.T., & Corkindale, C.J. (1998). The assessment of parent-to-infant attachment: Development of a self-report questionnaire instrument. *Journal of Reproductive and Infant Psychology, 16*(1), 57-76.
44. Morse, J.M., & Field, P.A. (1995). *Qualitative research methods for health professionals*. (2nd ed.).Thousand Oaks, CA: Sage.
45. Department of Health (2014). *Reference Costs 2013-2014.* Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/380322/01_Final_2013-2014_Reference_Costs_publication_v2.pdf