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# Stress and wellbeing after childbirth (STRAWB2)

**Submission date**
04/01/2017

**Recruitment status**
No longer recruiting

**Registration date**
26/01/2017

**Overall study status**
Completed

**Last Edited**
20/09/2023

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Experiencing an event where a person feels their life or another's life has been threatened can lead to symptoms of post-traumatic stress. These can be extremely distressing, and may involve reliving the event, having nightmares, unpleasant thoughts and seeing distressing images. It often leads to the sufferer avoiding activities that can trigger reminders and feeling on edge and irritable. Feeling like this early just after having a baby (postnatal) at a time when a woman is forming a relationship with her new baby is particularly harmful. Not everyone who has a traumatic event develops post-traumatic stress symptoms. These come about because the person has been so distressed by their early responses to the traumatic event they have avoided thinking and talking about them so the brain has been unable to process the unpleasant memories. Understanding what can be distressing but normal responses and reacting to them in a way that can help the brain to make sense of these can help prevent post-traumatic stress developing. The aim of this study is to look at the effectiveness of self-help material given by midwives to women whose childbirth has been traumatic in preventing post-traumatic stress symptoms.

Who can participate?
Women aged 16 years and over who have had a baby and are receiving postnatal care from community midwifes.

What does the study involve?
Community midwives identify women who found childbirth to be traumatic. Women who agree to take part are then randomly allocated to one of two groups. Those in the first group are given the self-help material, which consists of a leaflet and a web link to a film. The material aims to explain about ways of reacting to stressful situations and what can be done to help. A text message reminder to look at the material is send after two weeks. Those in the second group receive care as usual. Women in both groups are followed up by telephone 6-8 weeks after they have had their baby (at least 4 weeks after those in the first group have been given the material). They are then asked a number of questions in order to see how many have developed post-traumatic stress.

What are the possible benefits and risks of participating?
Women who receive the leaflet and film will have some simple ways to help themselves that may prevent longer term difficulties. All women, whether they receive the leaflet and film or

usual care, will have improved access to help via their health visitor if they continue to have difficulties at 6-8 weeks after birth. There are no notable risks involved with participating.

Where is the study run from?
1. Liverpool Women's Hospital (UK)
2. Royal Preston Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2015 to January 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Pauline Slade
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Pauline Slade

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# Additional identifiers

### Protocol serial number
31794

# Study information

### Scientific Title
Preventing Post Traumatic Stress Disorder: the Stress and Wellbeing after Childbirth Study (STRAWB2)

### Acronym
STRAWB2

### Study objectives

The aim of this study is to evaluate whether providing self-help material to women identified as having experienced childbirth as traumatic can reduce the incidence of clinically significant symptoms of full (diagnostic) and partial (subdiagnostic) post-traumatic stress disorder (PTSD) after childbirth.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
North West – Liverpool Central Research Ethics Committee, 13/12/2016, ref: 16/NW/0680

## Study design
Randomized; Interventional; Design type: Screening, Diagnosis, Prevention, Education or Self-Management, Psychological & Behavioural

## Primary study design
Interventional

## Study type(s)
Diagnostic

## Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Maternal/ Fetal medicine; UKCRC code/ Disease: Mental Health/ Neurotic, stress-related and somatoform disorders

## Interventions
Community midwives will give women an information sheet at the first postnatal visit. Women will be asked for consent to participate at the discharge visit (7-28 days postnatally). All women consented will be asked the screening questions developed and tested within our feasibility study: “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 receive self-help prevention (Group 1) or care as usual by their midwife (Group 2). Randomisation will be done by the midwife sending a text message to an independent automated randomisation system (sealedenvelope.com).

Group 1: Women will be given a brief information leaflet and a web link to a film. This explains how we can react to stressful situations and what we can do about these responses to help ourselves. They will get a text reminder about the leaflet/link about 2 weeks later.

Group 2: Women will receive care as usual, involving routine postnatal care including any actions based on midwifery clinical judgement which will be complete prior to the screening questions.

Women in both Groups 1 and 2 will be followed up by telephone at 6-8 weeks postnatally and at least 4 weeks after provision of the self help material. During this telephone interview, the woman will complete a Clinician Administered PTSD Scale (CAPS) and other questionnaires. 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 GP and health visitor so that appropriate care can be offered. Women's views of the leaflet and film will also be collected from a subsample of women.

### Intervention Type
Other

### Primary outcome(s)
Diagnostic and subdiagnostic levels of PTSD are measured using the Clinician Administered PTSD Scale (CAPS) at 6-8 weeks postnatally.

### Key secondary outcome(s))
1. PTSD symptoms are measured as continuous variables using the CAPS at 6-8 weeks postnatally
2. Depressive and anxiety symptoms are measured as continuous variables using the Hospital Anxiety and Depression Scale (HADS) at 6-8 weeks postnatally
3. Quality of the couple relationship is measured using a brief questionnaire at 6-8 weeks postnatally
4. Feelings for the infant are measured using the Maternal Infant Attachment Scale at 6-8 weeks postnatally

### Completion date
31/01/2019

## Eligibility

### Key inclusion criteria
1. Women being provided postnatal care by community midwives employed by the study sites*
2. Aged 16 years and over
3. Gave birth to a live baby
4. Sufficient English language to complete the measures will be eligible to participate.

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

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
16 years

### Sex
Female

### Total final enrolment

2419

### Key exclusion criteria
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

### Date of first enrolment
01/04/2017

### Date of final enrolment
30/09/2018

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Liverpool Women's Hospital**
Crown Street
Liverpool
United Kingdom
L8 7SS

### Study participating centre
**Royal Preston Hospital**
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

## Sponsor information

### Organisation
University of Liverpool

### ROR
https://ror.org/04xs57h96

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health 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 current data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2020 | 10/02/2020 | Yes | No |
| HRA research summary | | | 20/09/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | version 5 | 29/11/2017 | 17/08/2022 | No | No |