

Stress and wellbeing after childbirth (STRAWB2)

Submission date 04/01/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 26/01/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/09/2023	Condition category Mental and Behavioural Disorders	☐ 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 midwives.

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 sent 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

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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

Primary study design

Interventional

Study design

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

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	version 5	29/11/2017	20/09/2023	No	No
Protocol file			17/08/2022	No	No