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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/05/2015

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

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 2640; UK Sample Size: 2640

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
England

United Kingdom

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

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Sponsor type
University/education

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

Publication and dissemination plan
1. The final project phase will involve implementation meetings one local and one national) for Heads of Midwifery, CCG and PPI representatives and perinatal mental health pathways coordinators to design local processes for implementation
2. Materials will be provided for CCG leads for maternity services for incorporation into care pathways. This will be facilitated by our Liverpool CCG coinvestigator. Information will also be disseminated via the Clinical Research Networks.
3. Professor Slade is Chair of the Faculty for Perinatal Psychology for the British Psychological Society which inputs to the Maternal Mental Health Alliance, an umbrella organisation of professional and service user groups. Information will be provided to all 50 member organisations
4. Information will be placed on the Birth Trauma Association website and included on the BTA Facebook site
5. Information will be provided to NETMUMS and articles provided for motherhood/parenting magazines with the aim that knowledge of the availability of prevention self help material becomes widespread so women themselves ask services about their provision
6. The work will be submitted to peer reviewed journals and presented to conferences for the relevant professional groups (both practitioners and educators), e.g. Royal College of Midwives (RCM) Conference and disseminated through the Lead Midwives for Education and Consultant Midwives e-lists (hosted by the RCM), Unite the Union (CPHVA). Planned publication in a high-impact peer reviewed journal, around October 2019.
7. The Royal College of Midwives and Royal College of Obstetricians and Gynaecologists support this work (letters from both Presidents: Appendix 6) and will disseminate findings via their organisations

Intention to publish date
31/01/2020

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

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