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Early online trauma-focused group intervention for perinatal trauma during the COVID-19 pandemic

Submission date
09/08/2021

Recruitment status
No longer recruiting

Registration date
19/08/2021

Overall study status
Completed

Last Edited
13/10/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Post-traumatic stress disorder (PTSD) following childbirth is experienced by up to 15.7% of women. There currently is no routine intervention for preventing postpartum PTSD. Eye Movement Desensitisation and reprocessing (EMDR) is one of two treatments recommended by NICE for PTSD. EMDR is based on the adaptive information processing theory that explains how a traumatic event can disrupt the way information is handled in the brain. The traumatic memory remains unprocessed in the brain, resulting in symptoms of post-traumatic stress. EMDR is thought to work by sensory stimulation including eye movements that process traumatic memories, just as our eyes move during REM sleep.
This study aims to compare an online trauma-informed early EMDR group intervention with usual care in preventing post-traumatic stress disorder in women who have experienced a caesarean section. The study will also investigate users' experience of the intervention and compare the intervention with usual care in reducing symptoms of depression.

Who can participate?
Women aged over 18 years who have had a recent caesarean section and are willing to take part in a 3-week online group intervention

What does the study involve?
Participants will be randomly allocated to either receive the online EMDR group intervention or usual standard care. The early EMDR group intervention will include three 90-minute face to face online sessions over 3 weeks. The early EMDR intervention will consist of resilience-building techniques and eye movement exercises that have been found to be beneficial in helping people deal with strong emotional experiences, manage strong emotions, and improve wellbeing. All participants will be asked to complete online questionnaires at 12 weeks after the birth.

What are the possible benefits and risks of participating?
Participants may benefit from receiving a new type of online intervention that is supported by evidence for reducing stress. The information we get from this study may help doctors to provide supportive therapy for women who have had a traumatic birth experience. Participants

will not receive financial payment for taking part in this study. However, with consent, their names will be entered into a draw to receive a Smart Trike.
The risk of taking part could be that participants become upset when thinking about their recent birth experience. As is the case with all psychological interventions, the researchers cannot guarantee that the online EMDR group intervention will benefit everyone who receives it.

Where is the study run from?
Ulster University (UK)

When is the study starting and how long is it expected to run for?
January 2019 to June 2022

Who is funding the study?
Department for the Economy, Northern Ireland (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
269534

Protocol serial number
IRAS 269534

Study information

Scientific Title
A multicentre, randomised, parallel-group study to compare the effectiveness of an early eye movement desensitisation and reprocessing group intervention with care as usual in preventing post-traumatic stress symptoms in women who have experienced a traumatic birth

Acronym
INTEGRATE

Study objectives
Is an early eye movement desensitisation and reprocessing (EMDR) online group intervention more effective than care as usual in preventing post-traumatic stress in women who have experienced a traumatic birth?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/07/2021, Health and Social Care Research Ethics Committee (HSC REC A) (Office for Research Ethics Committees Northern Ireland (ORECNI), Business Services Organisation, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 9536 1400; info.orecni@hscni.net), REC ref: 21/NI/0067

Study design
Multicentre interventional single-blind randomized parallel-group study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-traumatic stress disorder and depression in women who have experienced perinatal trauma

Interventions
Adaptive Information Processing (AIP) informed early Eye Movement Desensitisation Reprocessing (EMDR) psychological intervention compared to control treatment as usual (TAU). Randomisation to each arm by computer-generated randomisation list.
Dose: 3 x 90 minute sessions.

Women in the intervention group will be invited to receive three 90-minute intervention sessions in a group setting, delivered by midwives who have been trained in facilitating EMDR, comprising of psychoeducation, emotional regulation techniques and eye movement reprocessing exercises.

Women will be in the study for 16 weeks. Women in the intervention and care as usual groups will be asked to fill in online self-complete questionnaires before the intervention at up to 3 weeks postpartum and after the intervention at 12 weeks postpartum. A clinician-administered interview will be conducted at 12 weeks postpartum.

Intervention Type
Behavioural

Primary outcome(s)
Post-traumatic stress disorder measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), Impact of Events Scale - revised (IES-R) and Posttraumatic Stress Disorder Checklist (PCL-5) at baseline and at 12 weeks postpartum

Key secondary outcome(s))
Depression measured by the Edinburgh Postnatal Depression Scale (EPDS) at baseline and at 12 weeks postpartum

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Women who have had a caesarean birth
2. Women who have experienced their birth as traumatic
3. Women who meet subclinical symptom criteria for PTSD under 33 on the impact of event scale
4. Aged over 18 years with the legal capacity to consent
5. Willingness and ability to attend three online intervention sessions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

Key exclusion criteria
1. Score over >35 on the Dissociative Experience Scale
2. Presence of severe psychiatric disorder such as psychosis, bipolar or active suicide risk
3. Women currently diagnosed with PTSD
4. Presence of severe medical conditions including traumatic brain injuries
5. Currently receiving psychological treatment
6. Drug or alcohol abuse
7. Overt dementia
8. Ongoing injected or oral corticosteroid treatment
9. Women who have absolutely no social and familial support
10. Women who are critically ill

Date of first enrolment
18/10/2021

Date of final enrolment
20/02/2022

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Craigavon Area Hospital
Southern Health and Social Care Trust
Craigavon
United Kingdom
BT63 5QQ

Sponsor information

Organisation
University of Ulster

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
Department of Economy, Northern Ireland

Funder Name
Southern Health and Social Care Trust

Results and Publications

Individual participant data (IPD) sharing plan
The 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?
HRA research summary			26/07/2023	No	No
Protocol file	version 2.2	01/09/2021	10/09/2021	No	No