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Can expressive writing reduce the effects of stress from Hurricane Harvey on pregnant women and their unborn children?

Submission date
08/05/2020

Recruitment status
No longer recruiting

Registration date
20/07/2020

Overall study status
Completed

Last Edited
08/06/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Every year, hundreds of millions of people around the globe are affected by natural disasters. In pregnant women, not only mental health can be affected by this stress, but also the pregnancy itself, as well as the developing brain of their unborn children. To alleviate these consequences, the study aims to test an intervention called “expressive writing”, where affected women write in a journal their deepest thoughts and feelings related to current and past trauma.

Who can participate?
Women aged 18-45 years old who were living in the Greater Houston area and pregnant at the time of Hurricane Harvey’s landing (August 25, 2017) or who conceived in the six months that followed.

What does the study involve?
All recruitment, questionnaires and interventions are done online. Participants are randomly allocated to one of three groups. Participants in the expressive writing group are asked to write for daily sessions of 20 minutes, across four days, about intimate trauma-related topics. Participants in the neutral writing group are instructed to write about factual topics for an equal number of sessions. Another group of participants has no writing task (control group). None of the participants receive feedback about what they wrote, and all texts are de-identified and remain confidential. Participants are sent online questionnaires at recruitment and at 2 months after the intervention, as well as 6 months after childbirth.

What are the possible benefits and risks of participating?
Possible benefits of participating include a reduction of maternal stress levels, better pregnancy outcomes and better future development of the unborn children. Risks are minimal and relate mostly to the transient stress that can be experienced while disclosing intimate thoughts and feelings during the writing sessions.

Where is the study run from?
University of Houston, Houston, Texas (USA)

When is the study starting and how long is it expected to run for?
September 2017 to November 2019 (updated 11/12/2020, previously: December 2020)

Who is funding the study?
The study is self-funded by its investigators.

Who is the main contact:?
1. Dr. Johanna Bick (jrbick@uh.edu)
2. Dr. Suzanne King (suzanne.king@mcgill.ca)
3. Dr. David Olson (dmolson@ualberta.ca)

Study website
http://vantageppc.com/harvey-study/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
STUDY00000657 (University of Houston IRB)

Study information

Scientific Title
Randomized-controlled trial of expressive writing in pregnant women affected by Hurricane Harvey: effects on maternal distress and offspring development

Study objectives
1. Expressive writing will lead to a decrease in maternal symptoms of poor mental health compared to neutral writing or no writing as assessed two months after the intervention
2. Expressive writing will lead to better birth outcomes (less Caesarean delivery and less preterm birth), better growth and better cognitive, behavioural and motor performance in offspring

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/12/2017, Institutional Review Board of the University of Houston (4302 University Dr., Houston, TX 77204, USA; avargas2@uh.edu; +1 713 7439215), ref: STUDY00000657

Study design
Single-center randomized-controlled three-arm superiority trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Prenatal maternal stress

Interventions
Participants (mothers) are randomly assigned to one of the three groups: expressive writing (intervention), neutral writing (active control) and no writing (passive control). Participants are assigned to one of the groups using block randomization with full allocation concealment using an automatized, web-based platform (REDCap). Participants are not blinded to assignment but are blinded to the hypotheses. Masking is not conducted, since maternal and offspring outcomes are self-reported.

The intervention is expressive writing as per protocols described by James Pennebaker. Participants (mothers) in this arm are instructed to write their deepest thoughts and feelings about experiences of trauma and conflicts for daily sessions of 20 minutes, for four days. No feedback is provided.
The active control is neutral writing. Participants (mothers) in this arm are instructed to write about factual details of their lives for daily sessions of 20 minutes, for four days. No feedback is provided.
The passive control is no writing.

Intervention Type
Behavioural

Primary outcome measure
1. Maternal PTSD symptoms at baseline and at 2 months post-intervention, as measured with the Impact of Event Scale-Revised (IES-R)
2. Offspring birth outcomes (date and mode of delivery), as measured at 6 months post-partum using an online questionnaire
3. Offspring neurodevelopment at age 6 months as measured with the Ages and Stages-3 questionnaire. There is the potential to continue follow-up assessments of the children at a later date

Secondary outcome measures
1. Maternal depression and anxiety symptoms at baseline and at 2 months post-intervention, as measured with a modified 40-item version of the Inventory of Depression and Anxiety Scales (IDAS), including scales for depression, anxiety, panic, ill temper and well-being
2. Offspring temperament, as measured with the Infant Behavior Questionnaire-Revised at age 6 months

Overall study start date
15/09/2017

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Pregnant at the time of Hurricane Harvey's landing (August 25, 2017), or who conceived within 6 months after the flood, and their offspring
2. English-speaking
3. Aged 18 - 45 years
4. Living in Greater Houston area at the time of Hurricane Harvey

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1,000

Total final enrolment
1090

Key exclusion criteria
1. Twin or multiple pregnancy

Date of first enrolment
12/02/2018

Date of final enrolment
09/10/2018

Locations

Countries of recruitment
United States of America

Study participating centre

University of Houston
Department of Psychology
4849 Calhoun Road, Rm 482
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TX 77024

Sponsor information

Organisation
University of Houston

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Sponsor type
University/education

Website
https://www.uh.edu/research/

ROR
https://ror.org/048sx0r50

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The first manuscript is expected to be submitted for publication in a scientific journal by the end of 2020. Participants will be informed of the overall study findings as the study progresses.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		12/12/2017	07/08/2020	No	No
Basic results		08/06/2021	08/06/2021	No	No