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International Survey of Childbirth-Related Trauma (INTERSECT): the Australian INTERSECT study V.1

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Perinatal well-being

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Abstract

Giving birth is a significant and transformative event. Many women emerge from their birth feeling empowered, viewing the events as positive and coming out of birth feeling emotionally and physically well. Unfortunately, other women emerge from childbirth feeling traumatised. Global literature indicates between 20 to 50% of women report birth to be psychologically traumatic. Of this, around 4% will develop posttraumatic stress disorder (PTSD) as a result of birth. In Australia, prevalence research indicates between 14% to 45% report a traumatic birth, and between 3 to 6% of these women will go on to develop clinically significant PTSD.

Birth trauma and PTSD have deleterious impact on the women, her baby, her family, and society as a whole. Childbirth PTSD is highly comorbid with adverse postpartum outcomes, such as postnatal depression, fear of subsequent births (tokophobia), reduced breastfeeding, poorer child development, and strain on the couple's relationship. Negative experiences with birthing staff (perceived discrimination) is associated with greater PTSD in global literature. Childbirth PTSD is comparatively understudied in Australia, particularly for women from a rural and remote background. The relationships between childbirth PTSD and adverse postpartum outcomes – tokophobia, intimate partner violence, and discrimination – is not known in Australian women. Deepening understanding of childbirth PTSD and postpartum outcomes will help to inform clinical pathways to potentially prevent or reduce negative effects of birth trauma for women and their families.

The objective of the Australian INTERSECT study is study to fill knowledge gaps in childbirth PTSD in the Australian context, while contributing to global knowledge of childbirth PTSD. The INTERSECT (International Survey of Childbirth-Related Trauma) study was developed by Professor Susan Ayers at City University London to study childbirth PTSD in an international context. This protocol describes the Australian INTERSECT study which will explore childbirth PTSD – and key adverse postpartum outcomes - in Australian women. The Australian INTERSECT study will collect cross-sectional survey data on women 6-12 weeks postpartum at various Australian antenatal clinic recruitment sites.

The PIs of the Australian INTERSECT study will oversee the Australian research outputs, as part of the 'INTERSECT Consortium' of international PIs. The Australian PIs will be responsible for recruiting women, distributing the survey, and uploading data to the project database. The data will contribute to INTERSECT – the international head of the project at City University London.

Attachments

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Aims:

1 The primary aims of the Australian INTERSECT project are to:

1.1 To explore the prevalence of birth trauma and childbirth PTSD in Australian women;

1.2 To explore the symptom presentation of childbirth PTSD in Australian women across varying demographic and obstetric variables.

1.3 To explore the association between childbirth PTSD and adverse postpartum outcomes in the Australian context:

1.4 a. Childbirth PTSD and intimate partner violence;

1.5 b. Childbirth PTSD and secondary tokophobia; and

1.6 c. Childbirth PTSD and discrimination;

The secondary aims are to:

2 Investigate the applicability of the City Birth Trauma Scale (City BiTS) in the Australian context; and

2.1 Investigate the utility of the Tokophobia Severity Scale (TSS) in the Australian context.

Design

3 A cross-sectional survey of postpartum PTSD, depression, trauma exposure as well as demographic and obstetric details. Women will be recruited through hospital sites antenatally between 30 – 36 weeks gestation to participate in the postnatal survey at 6 to 12 weeks postpartum. Women will complete a consent form at the antenatal time point. The survey will be texted or emailed to the participating women at the postnatal time point (6 to 12 weeks postpartum) with a link to the online survey. Women will be given

the option to select 'STOP' in the text/email message if they do not wish to receive further message.

Inclusion criteria are that (i) participants are within 30 to 36 weeks gestation, (ii) aged 18 or over and (iii) give informed consent to participate. In the adverse event of a stillborn or neonatal death, women will still have the option to participate in the survey. The survey includes measures of obstetric details, birth satisfaction, birth trauma, PTSD, depression, trauma history, tokophobia, domestic violence and the everyday discrimination scale.

The survey will be administered online via Redcap. One central survey will be created at the University of Technology (Sydney) that will be accessed by all participants.

All participants will be approached in person via antenatal clinics at each participating site. There will be a designed person – research midwife (NSW/South Australia) and research assistant (Queensland) - who will recruit women on site. The study will be explained, and participants will give informed consent to be contacted between 6 to 12 weeks postpartum via text message or email. Survey completion can take place at any time in the postpartum period, between 6-12 weeks postpartum. Participants will be sent a text once a week during the 6 to 12 week postpartum period. The women will receive a weekly text/email reminder to complete the survey. Participants will also have the option to send a text message 'STOP' to withdraw from the study at any point.

Sample

4 Systematic samples of women will be recruited from participating hospitals. Women will be eligible if they are aged 18 or over and are within 30 to 36 weeks' gestation. Incidental recruitment of women from Indigenous backgrounds may occur in this study.

Measures

5 The measures that will be used are detailed below.

5.1 Birth trauma

5.2 Perceived birth trauma will be assessed using a single item question on 10 point scale for women to rate whether they perceived their birth to be traumatic from not at all (0) to extremely (10).

Child birth-related PTSD

The City Birth Trauma Scale (City BiTS) consists of 29 questions which map onto DSM-5 diagnostic criteria. Symptoms are rated for frequency over the last week and scored on a scale ranging from 0 ('not at all') to 3 ('5 or more times'). A higher score indicates greater symptoms of PTSD. Diagnostic criterion A items are scored on a yes/no scale. Distress, disability and potential physical causes are rated as yes/no/maybe. The scale can be used as as a continuous measure of symptoms or as a diagnostic tool.

Birth Satisfaction

The Birth Satisfaction Scale-Revised (BSS-R) is a 10-item, self-report scale that was reduced from the original 30-item BSS. The BSS-R assesses women's perceptions of birth in order to determine women's satisfaction with their birth experience. The BSS-R consists of one, higher-order factor (experience of childbearing) containing three lower-order factors (quality of care provision, women's personal attributes, and stress experienced during labour). Four items measure quality of care provision; four items measure stress during labour; and two items measure women's attributes. The BSS-R is a Likert-type scale that requests participants to rate their level of agreement with each item (0=Strongly Disagree to 4=Strongly Agree), with four of its items being reverse-coded (e.g. "I found giving birth a distressing experience").

Previous trauma

Lifetime history of trauma will be measured using the trauma checklist taken from the Post-Traumatic Stress Diagnostic Scale. This scale has good reliability and validity, has been translated into multiple languages and has been well used in the perinatal population. Previous traumatic birth and pregnancy loss/stillbirth will also be measured in 2 additional items. See Appendix C.

Postpartum depression

The Edinburgh Postnatal Depression Scale (EPDS) was developed as a screening tool for postpartum. The scale consists of 10 items rated on a 4-point scale, ranging from 0 to 3, with a maximum score of 30 with higher score meaning high depression. The EPDS demonstrated good internal consistency previously (α = .87).

Demographic and Obstetric Information

Demographic and obstetric Information comprises basic demographic (age, ethnicity, relationship status) and obstetric details (number of children, gestation, time since birth, type of birth (i.e. vaginal, assisted vaginal, emergency or elective caesarean),

maternal/infant complications). The purpose of this information is to gauge representativeness of the participating sample as well as study the aetiology of childbirth-related PTSD.

History of psychological problems and treatment

Previous and current psychological disorders and treatment will be included to identify women who do or do not obtain treatment. For example, women will be asked whether they had had professional help or treatment ('have you received professional help or treatment for your psychological or mental health problems?') and what type of treatment they received ('if you are currently receiving any help or treatment, what type of treatment is it?).

Composite Abuse Scale Revised – Short Form (CASR-SF)

The CASR-SF is a comprehensive and validated brief instrument; it captures physical, sexual and psychological abuse and overall Intimate Partner Violence (IPV), with a focus on severity and intensity of experiences. The CASR-SF is a revised 15 item version of the Composite Abuse Scale. It includes 12 items developed from the original CAS and 3 items suggested through expert consultation and the evolving literature. Items cover 3 abuse domains: physical, sexual and psychological, with questions asked to assess lifetime, recent and current exposure, and abuse frequency.

Fear of Birth Scale (FOBS)

The Fear of Birth Scale (FOBS) is a two-item visual analogue scale, asking to rate feelings about the approaching birth with the question: "How do you feel right now about the approaching birth?". The degree of worry and of fear are associated in two separated items. Both elements of worry and fear are scored on a 0 to 100 mm scale. For the worry scale, the scale has 'calm' at one end and 'worried' at the other end. For the fear scale, there is 'no fear' to 'strong fear'. A cut-off of 50mm is used to identify a fear of childbirth. The FOBS has been validated in primigravid and multigravida samples of Swedish and Australian populations.

Tokophobia Severity Scale (TSS)

The Tokophobia Severity Scale (TSS) is 13-item measure of a severe fear of childbirth. Participants are asked to rate the degree to which the statements applied to them over the past 2 weeks. Each statement is rated on a 4-point Likert scale from 0 (not at all) to 3 (always). Higher scores indicate higher levels of anxiety about pregnancy and childbirth. The scale is a brief, reliable, and valid measure of tokophobia in women.

5.3 Everyday Discrimination Scale

The Everyday Discrimination Scale (EDS) is a 10-item scale of everyday discrimination. The scales addresses chronic, routine, and relatively minor experiences of unfair treatment. Participants are asked to rate the degree to which the events happen to them every day. Each statement is rated on a 4-point Likert scale from 0 (never) to 3 (four or more times). The scale is a robust and well-validated measure of everyday discrimination worldwide.

Adverse events

6 This study is a survey of birth trauma and birth-related PTSD. For many women who take part there is no risk of adverse events. However, for some women there is a risk that thinking about events during the birth of their child could be temporarily upsetting. These include women who have had complicated births where babies died, or babies with special needs. This will be avoided through careful wording of the participant information so that women are aware of the questions that will be asked before they consent to take part.

Safeguarding – The study is thought to be low risk, however, if a participant experiences distress the participant information sheet ("Frequently Asked questions") will provide details of organisations that offer appropriate support. Participants will also be reminded of these again at the beginning and the end of the survey. Women will also be advised to contact their health care provider for additional support if they are experiencing distress from their birth experience.

Valid consent and right to withdraw - to ensure as best we can that participants have read and understood the participant information sheet, in particular, that they understand their participation is confidential and anonymous and they have a right to withdraw from the study. The first page of the survey provides brief information about the study and has a link to the participant information sheet. Participants must tick a box to confirm that they consent to participate in the study and are over 18 years of age. The participant information sheet provides information on how their answers will be used and their right to withdraw.

Confidentiality – will be maintained by using software that is secure and data will be transferred to password protected files and encrypted on the researchers' computers. Data will be kept by the Australian INTERSECT team for at least ten years after the research is published, in accordance with current guidelines.

Data provided to INTERSECT UK will not include participants names so answers will be anonymous. Where personal information such as email addresses have been volunteered by the participant, they will be held by the Australian researchers in files that are password protected until data are anonymised. This personal information will not be

provided to the international INTERSECT team. This allows for a period where participants can opt to withdraw their data. The data collected via the survey will not be identifiable. Therefore, if participants choose to withdraw their consent after they have already completed part of the survey, their responses may not be able to be removed. Participants will be made aware of this during the consent process.

Security and privacy threats Data will be collected by local researchers in Australia under the Australian Chief Investigator. Data will be transferred to the UK INTERSECT Oversight team without any identifying information. The supplemental measures, specific to the Australian data, will remain in Australia. This will allow the Australian researchers to conduct their own analyses relevant to their specific research questions.

Data will be held using a secure software programme that we have used in similar studies. The survey host has a privacy policy that treats data as private and confidential. Online data is only accessible through password protection by the principal researcher until the time the survey ends and data is deleted from the host site. Data is encrypted and secure connections are used when transferring data from the survey host to the principal researcher's electronic storage. The survey host has rigorous procedures to ensure network, organisational and administrative security and procedures to deal with security breaches.
Email is not necessarily secure and care will be taken when emailing participants with details of the study. The researcher will email using a secure university email account, and all emailed documents will be password protected.

Debriefing
Participants who opt to be informed about the findings of the study will be emailed the details on publication. However, individual feedback on questionnaire scores cannot be provided.

Reliability of measurement: Participants will be recruited to the study in person from 30 to 36 weeks' gestation. Participants will be contacted via phone text message or email 6 to 12 weeks postpartum. At 6 to 12 weeks postpartum, the participant will be contacted and will be provided with an online link to the survey via email or phone. Participants will be reminded about their right to withdraw consent. Participants will be contacted weekly from 6 – 12 weeks by text to remind them to complete the survey. Participants will be able to opt – out of the text messages if they have completed the survey or no longer wish to participate.

Although this not an open survey, researchers have no way to verify the information participants provide. If data are collected using online survey software, there is the potential for participants to enter multiple times and give false answers which has implications for the validity of the study. Survey results can be checked by demographic

information such as date of birth of the child to guard against women entering more than once.

Complaints: If a complaint is made by a participant of the study, it will be dealt with through the relevant state specific ethics committee. All such complaints will be followed up until there is resolution or the event is considered stable. Serious Adverse Events will be governed by the definitions and procedures set out in Good Clinical Practice guidelines. All SAEs will be reported to the Chief Investigator in Australia and, if needed, to the international INTERSECT Oversight Team.

Statistics

7 Sample size

A minimum of 250- 300 women from each site in Australia will be recruited. There will be 4 sites in total covering antenatal clinics in New South Wales, Queensland, and South Australia. It is anticipated that a total sample of over 10,000 women worldwide will be recruited into INTERSECT.

Analysis plan

Prevalence of birth trauma and PTSD will be examined using descriptive statistics (frequencies, percentages, 95% confidence intervals). Multivariate models, such as multiple regression or logistic regression will examine the relative contribution and predictive power of aetiological factors in different samples. The association between relationships will be assessed using multivariate statistics as appropriate. Validity, reliability and the psychometric properties of the City Birth Trauma Scale (City BiTS) and the Tokophobia Severity Scale (TSS) will be examined using confirmatory factor analysis (CFA). For the City BiTS, CFA will check whether the four symptom subscales specified by the DSM-5 or two symptoms found in other studies of the City BiTS are observed in these samples. For the TSS, CFA will check whether the unidimensional structure for tokophobia is found.

For both, the fit will be evaluated using the following model fit indices: chi-square test, the comparative fit index (CFI), and the root mean-square-error of approximation (RMSEA). Reliability will be explored by looking at: a) McDonald's ω (omega) coefficient as indicator of internal consistency . A minimum value of ωh (omega hierarchical which estimates variance due to general factor only) for multidimensional measures of 0.65 is considered as acceptable and a value of ωt (omega total which estimates overall variance due to general and specific factors) for unidimensional measure to be >0.80 (; b)(47). Corrected item total correlations as indicator of item discrimination – this is a correlation of individual questions with the scale total, omitting that question. A coefficient of above 0.3 is considered acceptable.

Data handling

8 All data will be managed in accordance with the Australian Code for the Responsible Conduct of Research (NHMRC 2018). All project data will be entered on a project specific database with participants identified only by a unique ID number. The INTERSECT database will be developed and maintained by the INTERSECT Oversight Team. All databases will be stored on a secure server. Access to this information will be restricted to members of the research team, as authorised by the INTERSECT Oversight Team. After 10 years data will be destroyed, in accordance with the Australian Code for the Responsible Conduct of Research (NHMRC 2018).

Funding and indemnity

9 The set up and launch of the project is funded by the City, University of London, Global Challenges Research Fund (PI: Webb). University of London and the Tel-Aviv Academic College will act as the main sponsors for this project. Standard indemnity applies.

Publication and dissemination

10 Reporting, dissemination and notification of the results
Results will be disseminated to participants, the wider community, clinical and academic community as follows:

Research participants
If requested, results will be available to participants through an e-newsletter if they have provided their email address. Results will also be publicised though social media, service user organisations, the local press, university and media.

Health services and clinical community
The INTERSECT Consortium consists of people with strong clinical backgrounds and significant roles in primary and secondary care health services. Results will be presented at relevant conferences, e.g. International Confederation of Midwives Conference, International Marce Society Conference. This will ensure results are widely disseminated to those working with postpartum women.

Academic community
Project results will be presented at conferences and published in a peer reviewed journal. Reporting will be in compliance with methodological guidelines provided by the EQUATOR network (see **http://www.equator-network.org/**).

Intellectual Property (IP)
IP for data collected in each country remains with the Principal Investigator for that country. The Principal Investigator in each country agrees to share data for the

INTERSECT measures with the INTERSECT Oversight Team and agrees for this data to be publicly available to other researchers for secondary analysis at the end of the project. Requests from INTERSECT Consortium members to conduct secondary analyses will be invited before the end of the project, so that they are prioritised.

Additional measures collected in Australia (Tokophobia, Intimate Partner Violence, and Everyday Discrimination Scale)) are not shared with the INTERSECT Oversight Team. As Principal Investigators hold the Intellectual Property for their data, they are free to analyse and disseminate results from the INTERSECT data in their country (i.e. within-country analysis) as they wish.

Policy for publication and authorship

INTERSECT project results will be published with the INTERSECT Oversight Team and all international Principal Investigators who have contributed data as named authors. Other collaborators will be included as authors under the authorship of 'The INTERSECT Consortium'. Secondary publications may be published by named individuals, subject to approval by the INTERSECT Oversight Team and with appropriate acknowledgement of members of the INTERSECT Consortium. We will adhere to the recommendations for authors set out by the International Committee of Medical Journal Editors (ICMJE). These state that authorship should be based on the following 4 criteria:

1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2) Drafting the work or revising it critically for important intellectual content; AND
3) Final approval of the version to be published; AND
4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

All named authors will meet all four of these recommendations for authorship