**TITLE**

# A Multicentre, Single-blinded, Randomised, Controlled Parallel-group Study to Compare the Effectiveness of Early Online Eye Movement Desensitisation and Reprocessing (EMDR) Group Intervention With Care as usual (CAU) in preventing Post Traumatic Stress Disorder (PTSD) in Women who have experienced a Traumatic Birth (INTEGRATE): STUDY PROTOCOL


**Authors**

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|---|---|
| **Taylor-Miller, P.G.T.** | **Ulster University** |
| **Sinclair M.** | **Ulster university** |
| **Miller, P.W.** | **Ulster University** |
| **Gillen, P.** | **Ulster University** |
| **McCullough, J.E.M.** | **Ulster University** |
| **Farrell, D.** | **University of Worcester** |



**Trial sponsor:** **Nick Curry, Research Governance, Ulster University, Belfast Campus, Northern Ireland, BT15 1ED**
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## Abstract

### Background

It is reported that between 25 to 43% of women experience their birth as traumatic with 15.7% of women diagnosed with post-partum post-traumatic stress disorder (PP-PTSD) following birth. Negative effects of PTSD impact upon the mother infant bond, family dynamic, quality of life, physical health of the mother and the social and emotional development of the infant. EMDR is one of two recommended treatments for PTSD in adults. This study will investigate the safety and effectiveness of an early EMDR intervention, delivered within 12 weeks post-partum in the prevention of PTSD in women who have experienced birth trauma.

### Method

The INTEGRATE study is a single blinded, randomized, controlled parallel group study with a pragmatic design and approach to prescreening, screening, recruitment and safety measures. The study will be conducted in a large hospital. The intervention will take place in an online

digital environment. Study midwives will prescreen women for eligibility in antenatal clinics at 36-41 weeks gestation, postpartum on hospital wards and in the community. Women who have had a caesarean section and traumatic birth experience will be randomly allocated to receive either the early EMDR intervention or Care as usual (CAU) at up to 21 days postpartum. Women in the EMDR treatment condition will receive 3 x 90 minute face to face online EMDR group sessions, facilitated by registered and trained midwives. All women who are participating will be assessed at baseline (T0) and at 12 weeks postpartum (T5) in psychometric clinical measures of PTSD and depression.

**Discussion**

This study will provide information on the effectiveness and safety of an early online EMDR group intervention in prevention of PTSD administered by trained midwives following a traumatic birth experience, within a continuity of care model.

**Trial registration ISRCTN68624341**

**https://www.isrctn.com/ISRCTN68624341**

## STUDY PROTOCOL

### 1.0 Introduction

Perinatal mental health is a current public health concern (The Regulation and Quality Improvement Authority, 2017). The perinatal period is a celebrated stage in a women's development. It is also a time when she is most at risk of developing a mental health disorder. This is most poignant in the current climate, where the Globe is experiencing the negative psychological effects of a Pandemic (Moreno, 2020). Women in the perinatal period have reported receiving reduced social support, and experiencing heightened anxiety, stress, depression and isolation (Chmielewska et al., 2021).

The adaptive information processing theory describes that a traumatic event experienced as part of a person's lived experience can disrupt the way in which information is handled in the brain, leaving the traumatic memory unprocessed with resulting symptoms of post-traumatic stress. Unresolved and accumulated stress symptoms can trigger full PTSD diagnosis, late onset of the disorder and associated co morbidities of depression and anxiety. Traumatic birth is associated with traumatic memories related to the mothers antenatal and post-natal experience, as well as the experience of labour itself. This is defined as the traumatic birth episode. NICE (2018)

recognise that physically traumatic births can also be experienced as psychologically traumatic. Studies have reported a plethora of clinically significant adverse effects and women's accounts of the negative psychosocial impact following a traumatic birth experience.

There is currently no evidence-based screening process, clinical or non-clinical intervention or midwifery led intervention that can be recommended for introduction into routine practice to treat or prevent PTSD and associated psychopathology following a traumatic childbirth experience (Borg-Cunen., 2014; Bastos et al., 2015; De Graaff, et al., 2018; Roberts et al, 2019; Slade., 2021). A Recent systematic review and meta-analysis suggests that immediate response early psychological interventions are effective in reducing PTSD symptoms in women following a traumatic birth experience (Miller et al, in press). Further RCTS are required to substantiate the evidence of prolonged sustained effect as well as prevention of associated co morbidities. Testing a well-established transdiagnostic treatment method such as EMDR for prevention of PTSD in women following a traumatic birth experience is an important investigative enquiry as we are faced with the mental health emergency posed by COVID.

**1.1 Background and Rationale**

Prevalence rates for postpartum Post Traumatic Stress Disorder (PP-PTSD) range from 1 to 15.7% of postpartum women (Grekin O'Hara, 2014). It is reported that 1 in 10 women experience PTSD at 4-6 weeks postpartum (Hernandez-Martinez, 2019). Research suggests that individuals with a diagnosis of PTSD are six times more likely than someone without PTSD to develop depression and about five times more likely to develop another anxiety disorder (Kessler et al, 1995). There is a high co morbidity between PP-PTSD and post partum depression, as evident in up to 72% of cases of women with PP-PTSD (Yildiz et al 2017). Post partum depression is also a strong predictor of suicide ideation and is reported in 23% of cases (Dekel et al., in preparation). PP-PTSD following a traumatic birth is currently under diagnosed and is not included in the routine screening checks performed by midwives and health visitors. This may lead to mis-diagnosis related to high co-morbidity with postnatal depression, anxiety disorders including fear of birth, fear after birth and delayed diagnosis attributed to avoidance behaviour associated with PTSD symptomatology (Capik and Durmaz, 2018; Yildiz et al., 2017). There is risk that subthreshold PP-PTSD levels can develop into PTSD and chronic PTSD if left untreated (Zaers et al. 2008; Alcorn et al. 2010; Dikmen Yildiz et al. 2018). Researchers and clinicians have reported that a gap in service provision and care pathway for PP-PTSD following traumatic birth is currently evident (Bromley et al. 2017, McKenzie-McHarg et al, 2015, makebirthbetter.org.uk, 2020).

The physical, social, intergenerational psychopathological effects of post-traumatic stress disorder (PTSD) and co-morbid mental health problems following a traumatic birth on mother, infant and family unit are manifold. These include mothers' perceived quality of life, chronic pain syndromes, and negative effects on child's, cognitive, emotional and behavioural development. Significant adverse effects have also been reported on the mother child attachment relationship and psychosocial functioning. Delayed diagnosis additionally increases the risk of tertiary dissociative disorders and phobia of childbirth experienced by mothers resulting in elective caesarean; a current major public health concern as recognised by the World Health Organisation (2015). It is necessary that research investigates the efficacy of an early intervention in resolution of stress symptoms following a traumatic birth, given the increased risk to mother and child of a myriad of short- and long-term adverse outcomes as well as the accumulation of stress that the current environment of COVID may present to women, families and the wider community.

**1.2 Aim**

The aim of this study is to compare the effectiveness of i-GTEPm early online EMDR intervention with Care as usual (CAU) in preventing Post Traumatic Stress Disorder in Women who have experienced a traumatic birth.

Usual midwifery care was chosen as an appropriate comparator in this effectiveness study as there is currently no standard alternative comparator early intervention in place for preventing or treating PTSD following traumatic birth. Co-conducting of implementation between the researcher, experts by experience, midwifery manager and midwives will ensure that participant identification, screening and intervention is in alignment with current workflow processes on the ward and in the community.

**1.2 Objectives**

1.2.1 Investigate the effects of early online EMDR Group Intervention compared to care as usual on symptoms of PP-PTSD in a sample of post-partum mothers who have experienced a traumatic birth.

1.2.2 Investigate the effects of early online EMDR Group Intervention compared to care as usual on symptoms of postpartum depression in a sample of post-partum mothers who have experienced a traumatic birth.

1.2.3 Investigate user experiences of EMDR early group intervention in a sample of post-partum mothers who have experienced a traumatic birth.

### 1.3 Design

The study is a multi-centre, single blinded, randomised, parallel-group, controlled study. The researcher conducting clinical assessments will be blind to the participants' research condition. Women will not be blind to treatment as they will be aware of the treatment they will be receiving. The online EMDR intervention will be led by midwives who have received specialist training in EMDR-M and i-GTEP by EMDR consultants and trainers. All centers have maternity services that will facilitate recruitment of post-partum women following a traumatic birth. Clinical self-report psychometric tests will be scored by the researcher. Details of the study design can be seen in the participant flow diagram and timeline (figure 1.1). Women receiving the i-GTEP intervention will be asked to complete feedback questionnaires highlighting their experiences of taking part in the intervention.

## 2.0 Methods: Participants, intervention and Outcomes

### 2.1 Study Setting

Identification and recruitment of women will take place in antenatal clinics at women's final midwifery appointment at approximately 36-40 weeks gestation, on the maternity ward post-partum in a Health and Social Care Trust in Northern Ireland and in the community. Women will be provided with details of the study along with the researchers contact details with the expectation that women will then be able to give informed consent within 24hrs after the birth. The intervention will be delivered online by Midwives up to 12 weeks post-partum on an online platform.

### 2.2 Eligibility Criteria

Inclusion Criteria will be based on clinical need and includes; Definite experience of an unexpected caesarean section, traumatic birth, age over 18 years with legal capacity to consent, English reading and language literacy, meets subclinical criteria for PTSD, Willingness and ability to attend three interventional sessions over a three-week period.

Exclusion Criteria includes; current diagnosis of PTSD, presence of severe psychiatric disorder such as psychosis, bipolar or active suicide risk, currently receiving psychological treatment, presence of severe medical conditions including traumatic brain injuries, drug or alcohol abuse,

overt dementia, injected or oral corticosteroid treatment, women who have absolutely no social and familial support and women who are critically ill. These factors will be ascertained from women's medical records by midwives and the researcher during participant identification. Women who report scores indicative of dissociative disorder on the DES scale will be excluded from the study. Women who report subclinical scores of PTSD will be included in the study. These factors will be assessed by the researcher.

### 2.3 Interventions

EMDR therapy is a unique and effective therapy. This transdiagnostic mode of psychological therapy is supported by neurobiological theory and empirical research findings. A dual attention process involving the locating of a target memory, whilst following a mode of alternating bilateral stimulation is the overarching mechanism of action. The bilateral stimulation causes parasympathetic activation, resulting in physiologic calming (Sack et al, 2008). The online Early EMDR Intervention is 'blind to therapist' in that during processing, the patient is not required to verbally communicate, share the traumatic memory or create a trauma narrative and 'distancing from' rather than reliving the event is a feature of the therapeutic experience enabling the client to be in control of their therapeutic experience; given sufficient internal resources (Shapiro, 2014). This is therapeutically helpful for clients who may find it difficult to access the language required to communicate whilst processing and integrating traumatic memories into neural networks (Van der Kolk, 2018). The treatment has been described as "gentle" and may be particularly attuned to the therapeutic needs of women in the vulnerable post-natal period of developmental transition.

EMDR early interventions have been tested as effective in a short treatment duration with positive effects in trauma exposed populations in civilian and healthcare settings (Jarero et al., 2006; Jarero et al., 2016; Maslovaric et al 2017; Yurtsever et al., 2018, Jarero et al, 2020).

The early EMDR sessions will provide psycho-education and stabilisation exercises. Any woman who remains unstable following the stabilisation exercise and eye movement exercises will be triaged by the study midwife who will discontinue the individuals' treatment and will refer them to their mental health provider, GP and/or psychiatrist or private psychotherapeutic provider on a pro bono basis. Women in the experimental group will be asked not to receive any concomitant psychological therapy whilst taking part in the study.

The intervention will be carried out with fidelity to the intervention protocol with supervision and support provided to midwifery facilitators. Recorded intervention sessions will be assessed for fidelity by a qualified EMDR consultant as per current fidelity measures.

Standard care as usual will be provided by the Health and Social Care Trust. Care as usual following an unexpected caesarean includes a review of care with women by medical staff with a primary focus on the physical aspects of recovery and reasons for caesarean section prior to discharge from the hospital. Following discharge from the hospital, the Community Midwife will discuss the woman's experience of caesarean section, with referral to Head of Midwifery or Consultant Obstetrician if the women and Community Midwife feel it is necessary and would be helpful.

**2.4 Outcomes**

The primary outcome is post traumatic stress disorder (PTSD) and post-traumatic stress symptoms. Secondary outcome is depression. PTSD and depression will be measured at baseline pre intervention and post intervention 12 weeks following birth. Perceived future mode of birth will also be measured at 12 weeks following birth.

**2.5 Participant Timeline (please see Appendix)**

**2.5.1 Rationale for Timepoints:**

All psychometric measures (please see validated questionnaire assessments in Figure 1) will be administered at baseline up to 4 weeks post-partum pre-treatment. PTSD is diagnosable at 4 - 7 weeks following a trauma or after 4 - 7 weeks of clinically significant symptoms, according to DSM V criterion and ICD-11. Women who report subclinical scores for PTSD on the IES measure will be included in the study. This will be assessed by the researcher. The online EMDR early intervention is not designed to treat individuals who present with dissociative disorders. The measure of DES will exclude women who score > 35 on this scale at up to 4 weeks post-partum. This is the cut off score for dissociative disorder. The measures of emotional intelligence and resilience will test for protective safety factors before entering the study. The CAPS is a clinician administered interview for diagnosis of PTSD.

**2.6 Sample Size**

A formal power calculation has been conducted by a statistician based on the parameters of a previous study investigating the effectiveness of EMDR early group intervention (Yurtsever et al,

2018). The difference in means of the control and experimental group was extracted from the data (10.88 units), with the standard deviation of the response variable (control group) (sd 17.37). A difference of 10.88 units is of clinical scientific significance in the PTSD measure. The effect size of the scores were calculated as (d -0.63) indicating a moderate effect size of the intervention at post treatment based on the Impact of Events Scale-Revised (Weiss and Marmar, 1977) scores of traumatic response. Based on this effect size the statistician has calculated that at an alpha score of 0.05 (two tailed) and power of 80%, the study requires a total of 80 participants equating to 40 participants in the experimental and 40 participants in the control groups. Allowance of 20% was made for non-response, incomplete records and study attrition based on a previous study (Baas et al, 2017). A total of 48 participants in each of the control and experimental groups are required for the current study.

**2.7 Recruitment**

In order to maximize recruitment, women, midwives and gynaecologists will be informed of the study by posters and postings in Health and Social Care Sites, websites, and social media. Midwives and the researcher will work in collaboration remotely and online via fully encrypted online platform. Midwives will be trained in using the online platform and fully briefed on the purpose of the study, the importance of their role in the study, and identification of participants. Eligible women will be approached by midwives at antenatal clinic 36-40weeks gestation, 24 hours post-partum, and in the community, according to the inclusion and exclusion criteria for pre-screening 1. If women are interested in taking part they will be provided with a participant information sheet explaining the study in more detail and the woman's contact details will be taken with her permission. Women will be encouraged to take at least 24 hours to decide whether they would like to take part. Informed consent can be provided by women up to three weeks post-partum.

If women would like further verbal information on aspects of the study, in the absence of the researcher, midwives will take a note of the women's contact details for the researcher to contact to provide further information on the study. Women can alternatively contact the researcher for further details if preferred. Upon contact by WhatsApp or telephone, the researcher will screen women. If the woman meets the screening criteria, and the woman decides she would like to take part in the study, the researcher will post or email the consent form to her (see supporting documents) and follow up by verbally taking her through the consent form before completing the online set of psychometric tests if she requests.

An electronic method or signature for documenting consent may be provided by participants in accordance with the 'eIDAS' Regulation (EU) No 910/2014, transposed into UK law via the Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (SI 2016/696). Written consent can alternatively be provided and posted to the researcher at the Ulster University postal address.

## 3.0 Methods: Assignment of Interventions

### 3.1 Sequence Generation

Women who are interested in taking part in the study or have consented to be contacted, will receive an email, text or telephone call from the researcher who will answer any questions to women may have. The woman will be provided with a unique password and link to an online consent form and an online series of validated psychometric measures. The researcher will ask the woman how she experienced her birth in accordance with DSM-VR. Women who report their birth experiences as distressing will be included in the study after signing the consent form explained by the researcher. Women who score >35 on the DES scale will be excluded from the study and referred to their GP with their permission. Once baseline measures have been scored, eligible women who score on sub threshold levels of PTSD symptoms on the IES-R measure will be randomized to experimental and control groups. The study statistician will provide a unique set of computer-generated random numbers for simple randomisation to experimental and control groups.

### 3.2 Allocation Concealment mechanism

The researcher will be masked to randomisation, by telephoning the independent lab statistician who will hold the computer-generated random numbers list and assign women to intervention and care as usual groups as and when women have completed consent and screening at up to 21 days post-partum and are eligible to take part in the study. The researcher will then notify women of their group allocation by their preferred mode of contact. Women will be advised to confirm their intention to enroll in the study within 5 days. Once intention to participate has been confirmed, the researcher will forward women's contact details to intervention midwifery facilitators. Women's GPs will also be informed of their patients' inclusion in the study by email. An independent member of the research team will then provide each women with a sequential participant number in order to ensure anonymity before analysis. In the event that a women needs to contact the outcome assessor she will be reminded not to reveal her group allocation. In the event of crises, the distress protocol will be adhered to, unblinding will be permissible, the participant will be

removed from the study and referred to their GP, mental health provider or Mirabilis Health for further treatment on a pro bono basis by Consultant Psychiatrist (Professor Paul W. Miller).

## 4.0 Methods: Data Collection, management and Analysis

### Data Collection Methods

Population demographics, Baseline and outcome measurements will be completed by women on an online platform at up to 3 weeks (before the intervention) and 12 weeks (after the intervention). In the event of participant crises, facilitating midwives will complete a safety reporting unexpected adverse event form to include in case files. Midwives will provide a supportive online environment conducive to interventional work in order to maximize retention. The researcher will remind participants with an encouraging text message, when it is time to complete the follow up assessments on the online platform, further promoting follow-up.

### 4.2 Data Management

All details and information collected as part of this study will be anonymized with a unique identifier number (UIN) by the research team and all data will be kept confidential. All hard copy information will be securely stored for 10 years in a locked room in a locked filing cabinet, which can only be accessed by the research team in block 12 at the Ulster University according to the University Policy. Data from the online questionnaire platform will be uploaded to SPSS database with case codes. The researcher will code and calculate scores for symptoms and constructs with syntax for each variable. Data entry and values will be checked by a member of the research team. Data protection and storage will adhere to GDPR (2018) compliance. https://www.ulster.ac.uk/about/governance/compliance/gdpr9 Due to COVID-19, researchers will be working from home and therefore, data will be stored on a password protected Ulster University laptop computer. All data will be encrypted and uploaded onto a secure server and removed from the laptop at the earliest possible date. Any direct quotations will be annonymised prior to publication. Online data handling by Qualtrics conforms to current GDPR (2018) requirements for data protection. Participants will be made aware when providing consent that if they withdraw from the study their information cannot be removed as the data being reported is for the entire study (Parahoo, 2010) but they will remain anonymous. Any changes to the protocol will be communicated to all study researchers, participants the trial registry and journal if required.

### 4.3 Statistical Methods

Quantitative Analysis of data will be performed on SPSS including logistical regression, multivariate analysis of variance, MANOVA, and ANOVA will be used to test the effects of treatment on primary outcome PTSD and secondary outcome depression. MANOVA is a robust calculation when including multiple measures protecting against type 1 error. If a small percentage of data is missing, then those cases will be excluded. Missing value data at random will be coded accordingly in SPSS**.** The researcher will analyse midwive's reflective diaries; coding and categorising into concepts and themes that will add a rich set of data to guide and enhance an adaptive information processing model, processes, and procedure for treating the specific needs of this population. Participant feedback following the final interventional session will provide information on the acceptability of the intervention. Descriptive statistics and thematic analysis of open-ended questions will inform on the patient experience and any reported adverse effects.

## 5.0 Methods: Monitoring, Harms, Auditing

Self-reported wellbeing and consent forms will be completed by participants before every online intervention session. Intervention facilitators will review these forms and will complete a case report form checklist for each woman in the intervention group. Confirmation of consent to take part, adverse and significant events will be monitored by midwives during each of the four intervention sessions (please see submission form checklist). These will be recorded in midwifery reflective journals and safety reporting forms. Protective factors of participant's emotional intelligence and resilience will be assessed at baseline before the intervention. Facilitating study midwives will provide psychoeducation and stabilisation in session one. Participants who do not remain stable during this session will be referred to their GP, mental health or psychiatric provider for further treatment. Crises response will be recorded. Participant feedback on trial conduct and self-reported adverse effects will be assessed after the final intervention session 12 weeks post-partum, along with outcome measures on Qualtrics. Fidelity to protocol and auditing will be carried out by an EMDR consultant via recorded intervention sessions.

## 6.0 Ethics and Dissemination

This protocol has received approval by the Health and Social Care Research Ethics Committee. There will be no physical risk to participants. Formal consent will be requested when participants are invited to take part in the study. Participants will be informed of anonymity, confidentiality procedures and their right to withdraw from the study at any time.

The patient information leaflet and treatment will include psycho education on the agent of change and how EMDR therapy works to process traumatic memories. Participants will be reminded that they are not required to talk specifically about their trauma at any time during the intervention. This may reduce any feelings of anxiety upon starting the early online group intervention.

### 6.1 Distress Protocol

Participants who may be in immediate danger throughout the course of the study will be monitored for safety and referred for additional care as required. In the event that midwives, researcher or intervention facilitators may identify any participants who have an unexpected mental health crises at any time during the intervention they are required to complete the safety reporting adverse event form. The researcher will provide participants with a leaflet containing information and contact details for further support concerning perinatal mental health. A key component of person centred practice is that the patient has a voice (Epstein et al 2005; Marshall et al 2012). If a patient expresses discord or unease, it is vital that they have an opportunity to voice their feelings and experiences during their time under the care of the study midwives. The invitation to take part in the research may open such a conversation of disclosure. If a patient has a complaint, then the researcher will direct the patient to the necessary form of feedback to the ward manager if the complaint is related to care or the Chief investigator and University Sponsor if related to the research study.

If the participant discloses detail of previous or current traumatic life experiences that are not related to the current birth trauma and puts the woman in immediate risk of danger, in accordance with the National Early Warning Score; which includes the recognition of new onset confusion or delirium which can cause psychosis (Charlton, 2002; Griswold, 2015 et al), the researcher, and or midwife with the participant's permission will refer the participant on to their GP or a specialist mental health provider for therapeutic treatment. Permission has been granted for such referrals to be made to Mirabilis Health, a provider of psychiatric and psychotherapeutic services, on a pro bono basis (Ltn.), voluntarily without payment for the public good (transl.).

### 7.0 Dissemination Policy and Authorship

Results of the study and academic papers will be disseminated to Health and Social Care Trusts, external statutory organisations (The Department of Health), Midwifery service provider staff, patients and public, in peer review journals, social media and presented at international conferences. Authorship in accordance with the recommendation of Authorship by the ICMJE.

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## Appendix 1: Figure 1: Participant Timeline Spirit Table

| | Study Period | | | | |
|---|---|---|---|---|---|
| | Pre-Treatment | | | Treatment | Post Treatment |
| Time point | 1 | 2 | 3 | 4 | 5 |
| Enrolment | | | | | |
| Eligibility Screen 1 INCL/EXCL | X | | | | |
| Eligibility Screen 2 Primary Outcome | | X | | | |
| Informed Consent | X | X | | | |
| Allocation | | | X | | |
| Interventions | | | | | |
| Group EMDR | | | | | |
| Care as Usual | | | | | |
| Assessments | | | | | |
| PCL-5 | | X | | | X |
| IES-R | | X | | | X |
| DES | | X | | | X |
| TEIQue | | X | | | X |
| CD-RISC | | X | | | X |
| EPNDS | | X | | | X |
| CAPS-5 | | | | | X |
| Process measures | | X | | | X |
| Uptake/Reason for refusal/drop out | | X | | | X |

TIME POINT 1 Antenatal clinic 36 -41WEEKS, 24HRS-48HRS post-partum, and in community.

TIMEPOINT 2 – up to 4 WEEKS

TIMEPOINT 3 – 3-6wks ALLOCATION

TIMEPOINT 4 – 3-12 WEEKS, TIMEPOINT 5 – 12 WEEKS

Figure 1: Schedule of Enrolment, interventions and assessments. Abbreviations. PCL-5 Checklist for DSM-5; IES-R Impact of Event Scale; TEIQue trait Emotional Intelligence Questionnaire; CD-RISC Connor Davidson Resilience Scale; DES Dissociative experiences scale (31 median cut off score), CAPS-5 Clinician Administered Post Traumatic Stress Scale for DSM-5.