
"Childbirth and Traumatic Shock. Subjective Elaboration." English version

Plan de gestion de données créé à l'aide de DMP OPIDoR, basé sur le modèle "Science Europe : modèle structuré" fourni par Science Europe.

Renseignements sur le plan

Titre du plan	"Childbirth and Traumatic Shock. Subjective Elaboration." English version
Version	Version intermédiaire
Objet/périmètre du plan	This is the detailed methodology of the Actes research project "Accouchement et Choc Traumatique. Subjective Elaboration". This observational study protocol for early intervention EMDR therapy following trauma is currently being published.
Domaines de recherche (selon classification de l'OCDE)	Psychology, Health sciences, Sociology
Langue	eng
Date de création	2024-01-15
Date de dernière modification	2024-02-16
Documents (publications, rapports, brevets, plan expérimental....), sites web associés	<ul style="list-style-type: none">article : https://zenodo.org/records/7447808

Renseignements sur le projet

Titre du projet	Childbirth and Traumatic Shock. Subjective Elaboration.
Acronyme	ACTES
Résumé	<p>To study the effectiveness and modes of action of EMDR therapy (Eye Movements Desensitization and Reprocessing) in the management of traumatic childbirth.</p> <p>When childbirth is traumatic for a patient, she is more likely to develop post-traumatic stress disorder (PTSD) and/or post-partum depression (PPD). The consequences of these psychological disorders are likely to be deleterious both to the mother's well-being and to the quality of her attachment to her child..</p> <p>EMDR is a therapy that has been shown to be effective in the treatment of Post Traumatic Stress Disorder (PTSD).</p> <p>The aim is to improve the psychotherapeutic management of patients who have experienced traumatic childbirth, and to prevent the development of any psychopathological states associated with traumatic childbirth (PTSD, post-partum depression, decompensation, etc.).</p>
Sources de financement	<ul style="list-style-type: none"> • PS Institut : Fonds privés
Date de début	2021-01-01
Date de fin	2022-12-31
Partenaires	<ul style="list-style-type: none"> • PS Institut () • SUBJECTIVITÉ, LIEN SOCIAL ET MODERNITÉ (EA 3071 - UR 3071 depuis 01.01.2020) (199914385V)

Produits de recherche :

1. Childbirth and Traumatic Shock. Subjective Elaboration (Jeu de données)

Contributeurs

Nom	Affiliation	Rôles
BACQUE Marie Frédérique	Institut de Psychologie UNISTRA	<ul style="list-style-type: none"> • Responsable des questions éthiques • Responsable juridique
Laboratoire SuLiSoM	UNISTRA UR 3071	
MERG ESSADI Dominique - 0000000259485079	UNISTRA UR 3071 SULISOM	<ul style="list-style-type: none"> • Responsable de la conservation à long terme des données • Responsable de la documentation des données • Responsable de la production ou de la collecte des données • Responsable de la protection des données • Responsable de la qualité des données • Responsable des questions éthiques • Responsable du dépôt et de la diffusion des données • Responsable du plan • Responsable du traitement et de l'analyse des données • Responsable juridique
RESCH Véronique	CAE COOPRODUCTION Clairementdit.fr	<ul style="list-style-type: none"> • Coordinateur de projet • Personne contact pour les données • Responsable du traitement et de l'analyse des données
SILHAN Daria	UNISTRA UR 3071 SULISOM	<ul style="list-style-type: none"> • Responsable de la documentation des données • Responsable de la qualité des données

Droits d'auteur :

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"Childbirth and Traumatic Shock. Subjective Elaboration." English version

1. Description des données et collecte ou réutilisation de données existantes

1.1 Description générale du produit de recherche

Nom	Childbirth and Traumatic Shock. Subjective Elaboration
Description	<p>Observational study: EMDR therapy and interviews with a cohort of women who had experienced traumatic childbirth and 18-month follow-up after therapy.</p> <p>Objective: to study the efficacy and modes of action of EMDR (Eye Movements Desensitization and Reprocessing) therapy in the management of traumatic childbirth. When a patient's experience of childbirth is traumatic, she is at greater risk of developing post-traumatic stress disorder (PTSD) and/or post-partum depression (PPD). The consequences of these psychological disorders are likely to be deleterious both to the mother's well-being and to the quality of her attachment to her child.</p> <p>Our main question is whether the intervention of a psychologist practicing EMDR would have an impact on a proven post-traumatic stress state in the aftermath of a shock delivery.</p> <p>We will also explore the question of early intervention, with a view to finding out whether intervention in the first few days after delivery may be more effective than late intervention, at a distance from delivery, or even at the time of the next pregnancy.</p> <p>According to our hypotheses :</p> <p>In the case of EMDR therapy following a traumatic birth (early or remote):</p> <ul style="list-style-type: none">- EMDR therapy can reduce the symptoms associated with traumatic childbirth.- Relief from PTSD (or prevention through early intervention) can be rapid and long-lasting.- Easing PTSD will help rebuild relationships with others and with oneself.- Alleviating PTSD can encourage the emergence of new projects, particularly in connection with a new pregnancy.- EMDR therapy can be offered even in the presence of comorbidities. <p>Additional benefits of early EMDR intervention:</p> <ul style="list-style-type: none">- EMDR therapy can have a preventive effect on the onset of post-partum depressive disorders.- EMDR therapy helps to limit psychic disturbances in the mother, and a fortiori on the construction of the mother-child relationship. <p>Our research plan has two main objectives:</p> <ol style="list-style-type: none">1. To determine whether the immediate use of the EMDR therapeutic method is effective in the treatment of psychological suffering related to traumatic childbirth, in particular by observing changes in scores on tests and evaluation scales submitted at the end of therapy.2. To verify whether the effect can be beneficial over the long term, in particular by means of evaluation stages proposed to patients over an 18-month period at the end of therapy, on the basis of interviews and changes in scores on evaluation tests and scales.
Type	Jeu de données
Mots clés	<ul style="list-style-type: none">• EMDR therapy, childbirth, trauma, method, observation, qualitative ()
Mots clés (texte libre)	EMDR therapy, childbirth, trauma, method, observation, qualitative study
Langue	eng
Identifiant pérenne	10.5281/zenodo.7447807
Type d'identifiant	Identifiant local
Contient des données personnelles ?	Oui
Contient des données sensibles ?	Oui
Prend en compte des aspects éthiques ?	Oui

1.2 Est-ce que des données existantes seront réutilisées ?

Justification	Literature review and related studies. Public data.
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1.3 Comment seront produites/collectées les nouvelles données ?

Nom de la méthode	Etude observationnelle
Description	<p>Observational study conducted as part of routine care.</p> <p>Course of the study :</p> <p>The study takes place in the Obstetrics and Gynecology Department of the University Hospitals of Strasbourg. A midwife, doctor or psychologist from the department will present the study and offer to take part, explaining the objectives and method, presenting the information sheet and signing the consent form. This presentation takes place before the first clinical interview, and has no impact on therapeutic management. The distance between the healthcare professional who informs the patient of the possibility of participating in the study and the professional who will carry out the psychotherapy is designed to reduce the latter's influence on consent.</p> <p>EMDR therapy for postpartum patients is provided by the research psychologist, a certified EMDR therapist. During the first meeting (T0 - evaluation of the psychic state after childbirth and EMDR):</p> <ul style="list-style-type: none"> - Identification of signifiers referring to childbirth and shock, through the usual clinical listening, during the interview. - SUD (Subjective Units of Disturbance): this scale is used to assess the amount of disturbance related to traumatic childbirth before and after EMDR therapy sessions, as an inherent part of EMDR treatment. - Post-traumatic stress disorder Checklist DSM-5 version, PCL-5 (Weather et al., 2013) <p>Four assessment interviews conducted by a clinical psychologist are offered at 1 month (T1), 6 months (T2), 12 months (T3) and 18 months (T4) after therapy. The purpose of these meetings is to assess the patient's psychological state after therapeutic follow-up.</p> <p>At each interview, the psychologists administer the SUD, PCL-5 and Edinburgh Postnatal Depression Scale. They use an interview grid to explore the patient's experience of childbirth. The interview is supplemented by two validated questionnaires: the PCL-5 and the Edinburgh Postpartum Depression Scale.</p> <p>Data collection is based on transcriptions of the interviews and scores on the various assessment scales.</p>
Nature des données	Observation
Références associées	<ul style="list-style-type: none"> • Observational study :

2. Documentation et qualité des données

2.1 Quelles métadonnées et quelle documentation (par exemple mode d'organisation des données) accompagneront les données ?

Description	Research presentation guide for caregivers. Data collection form for each patient.
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2.2 Quelles seront les méthodes utilisées pour assurer la qualité scientifique des données ?

Description	<p>Collection and analysis of qualitative and quantitative data</p> <p>The construction of the methodology was submitted to :</p> <ul style="list-style-type: none"> - Clinical psychologists working in maternity wards, who validated the choice of qualitative analysis. - Maternity doctors, who were interested in the prospect of a multicenter randomized controlled study. They validated the prospect of a follow-up of over a year, in view of the unresolved situations in their patient base. - Peers: the first interview before the first inclusions, then after 3 months and after one year; as well as a minimum of three supervisions with an accredited Supervisor: before submission of the protocol, one month and then six months after the start of the study. <p>All the data collected will be analyzed by a multidisciplinary team of researchers, using different methods to try to answer the question and justify the research hypothesis.</p> <p>Choice of tools:</p> <p>We identified which tools (scales, questionnaires, interviews...) were used to assess the patient's state before and after therapy, over what length of time, and which variables (duration of sessions, frequency, patient discourse) made it possible to scientifically establish the effectiveness of EMDR from non-randomized studies. The universal reference for assessing PTSD is the PCL5 scale, has been translated and validated in French (Ashbaugh et al., 2016).</p> <p>We drew mainly on two validated tools for assessing PTSD at baseline. The first is the Post-Delivery Perceived Stress Inventory (PDPSI), which assesses women's level of perception of post-delivery stressors. Validated in 2013 by a Geneva-based team, the PDPSI is composed of five post-delivery stress factors: 1) relationship with the newborn, 2) birth experience, 3) fatigue, 4) breastfeeding and 5) relationship with caregivers.</p> <p>This tool was used in a study in France (Bernard et al., 2017) and for our pre-interview grid (observation and collection of verbal and non-verbal information).</p> <p>On the other hand, a French childbirth experience evaluation questionnaire (QEVA) was carried out in 2016, (Carquillat et al.). This tool combines 25 items in 6 dimensions: representations and expectations, sensory perceptions, feeling of control, perceived social support (medical staff and partner), emotions (positive and negative) and first moments with the baby. It "would enable healthcare professionals not only to identify mothers experiencing difficult childbirth and in need of support, but also to adapt care according to the dimensions of the childbirth experience and associated difficulties".</p> <p>The tools selected for the study :</p> <ul style="list-style-type: none"> - SUD (Subjective Units of Disturbance) also called Subjective Scale Unit of Disturbance. This scale measures the amount of disturbance related to the traumatic birth before and after the EMDR therapy sessions, an assessment inherent in EMDR treatment. - The Cognitions expressed by the patients will be grouped according to Shapiro's baseline[1]. - Post-traumatic stress disorder Checklist version DSM-5, PCL-5: this scale is used in standard care to assess PTSD. - Edinburgh Postnatal Depression Scale, EPDS: a 10-item questionnaire specific to the postnatal period, which calculates a depression score ranging from 0 to 30. A score higher than 12 enables patients with major depressive episodes to be identified. This scale is not a diagnostic tool, but a screening tool to assess the existence of clinically significant depressive symptoms. (Cox & Sagovsky R, 1987)
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[1] <https://academy.iepra.com/wp-content/uploads/2014/09/croyances-negatives.pdf>

- Safety / Survival: I'm in danger, I'm going to die, I'm not going to make it...
- Responsibility / Guilt: I am guilty, I did something wrong, I should have done better...
- Self-esteem: I'm not good enough, I'm worthless, I don't deserve..., I'm incapable...
- Possibility of choice: I have no choice, I have no control, I can't have what I want...

Références associées

- Interview guide :

3. Exigences légales et éthiques, code de conduite

3.1 Quelles seront les mesures appliquées pour assurer la protection des données à caractère personnel ?

Description	<p>Data are anonymized on the basis of an inclusion code assigned to each participant. Correspondence is stored in a secure area.</p> <p>An anonymized file was created for each participant, containing :</p> <p>Written transcripts of EMDR sessions for statistical semantic analysis and qualitative analysis (ALCESTE software).</p> <p>Written transcripts of assessment interviews and test results (T0 to T4).</p> <p>An Excel database was set up to collect the characteristics of the study population, containing :</p> <p>General information characterizing the patients and the follow-up period</p> <p>Elements relating to the inclusion grid</p> <p>Medical history and birth history</p> <p>Previous episodes of psychopathological upheaval</p> <p>Type of relationship with family and friends (violence, depreciation, etc.)</p> <p>Cognitions at the beginning and end of sessions.</p> <p>Scores on scales (SUD, PCL-5, EPDS).</p> <p>This database can be used to draw up graphical representations of the results and provide a first level of analysis.</p> <p>At the same time, as part of her clinical practice, the EMDR psychotherapist records elements of anamnesis, characteristics linked to the history of each patient, and her own impressions during the sessions.</p> <p>Precautions for storing information:</p> <p>Recording of treatment sessions for research purposes, with the patient's consent. Sessions are audio recorded. Meetings with patients are face-to-face. It is therefore impossible to anonymize for the psychologists conducting the study, who are bound by professional secrecy.</p> <p>The voice files are deleted after the interviews have been transcribed. Transcription is carried out manually by temporary psychologists funded by SuLiSoM. The data transcribed from the recordings do not contain any information that could reveal the patient's identity.</p> <p>In order to guarantee patient anonymity, only the inclusion number will be recorded for the voice files.</p> <p>Collection of socio-demographic elements useful for the usual therapeutic approach, then kept anonymously for the study.</p>
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3.2 Comment les autres questions juridiques, comme la titularité ou les droits de propriété intellectuelle sur les données, seront-elles abordées ? Quelle est la législation applicable en la matière ?

Description	<p>Details of information prior to inclusion in the study :</p> <p>All pre-selected participants will be informed in advance of the study's objectives, methodology, duration, constraints and foreseeable risks.</p> <p>Details of the informed consent form to be signed and given to the participant:</p> <p>After ensuring that the information provided has been fully understood, the healthcare professional submits the consent to participate in the study. If she agrees, the participant will sign the consent form in duplicate.</p>
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3.3 Quels sont les aspects éthiques à prendre en compte lors de la collecte des données ?

Description	<p>Upon presentation of the project by the SuLiSoM UR 3071 Laboratory, the protocol for the "Accouchement Choc et Traumatisme, Élaboration Subjective" (ACTES) study underwent a review of the study's data management and processing methods by the Plateforme Universitaire des Données. The University of Strasbourg's Research Ethics Committee validated this study protocol on December 17, 2020 under accreditation number Unistra/CER/2020-31.</p>
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4. Traitement et analyse des données

4.1 Comment et avec quels moyens seront traitées les données ?

Description	How are the raw data collected processed? use of the content of the interviews conducted at the various stages of the study: symptoms and inclusion in the study, EMDR therapy, 4 evaluation phases at the end of therapy links with anamnesis and life events analysis of scores on the various scales, and graphical representations of changes in scores via Excel use of socio-demographic data
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5. Stockage et sauvegarde des données pendant le processus de recherche

5.1 Comment les données seront-elles stockées et sauvegardées tout au long du projet ?

Besoins de stockage	<ul style="list-style-type: none">Storage of recorded and transcribed interviews on Private SeafireData will be stored for ten years and then destroyed. If a research participant requests that her data be destroyed, it will be done immediately.
Mesures prises pour la sécurité des données	The data archiving protocol has been submitted to UNISTRA's RGPD delegate. In accordance with article L 1122-1 of the French Public Health Code (law of March 2002 on patients' rights).

6. Partage des données et conservation à long terme

6.1 Comment les données seront-elles partagées ?

Modalités de partage	<ul style="list-style-type: none">Data saved as PDF for storagedata sharing via https://dmp.opidor.fr/
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6.2 Comment les données seront-elles conservées à long terme ?

Justification	The data is stored in digital format on Private Seafire.
Date de début	2021-01-01
Date de fin	2031-01-01