Intervention Through EMDR and CBT With Women Victim of Childhood Sexual Abuse. A Randomized Controlled Trial. Date March 20th, 2021

Confidentiality commitment and declaration of informed consent

COMMITMENT OF CONFIDENTIALITY: "In accordance with the provisions of article 5 of Organic Law 15/1999, of December 13, and current European regulations for the Protection of Personal Data, we inform you that personal data that voluntarily provided to us through interviews, questionnaires and observations will be incorporated into a confidential database. The purpose of this database is the archive, management, and analysis of the same. If you agree to participate in the study, you agree that the battery of psychological tests can be administered to you and that behavioral observations can be made during the application of the intervention program. The project researchers agree not to share the required information with other institutions. You can exercise the rights of rectification, cancellation and opposition through the indicated email address (mariateresa.mitjans@campusviu.es)".

This project follows the regulations of the Declaration of Helsinki of 1964 and its subsequent updates (the most recent one made in Brazil, October 2013). The evaluation tests that will be administered to you are the following:

1. Satisfaction with Life Scale (SWLS, Diener et. al. 1985)
2. Rosenberg Self-Esteem Scale (RSE, Rosenberg, 1965; Atienza, Balaguer y Moreno, 2000)
3. Symptom Checklist-90-Revised (SCL-R) (Derogatis, 1975)
4. Posttraumatic Stress Disorder Symptom Severity Scale according to DSM-5 (EGS-R) (Echeburúa et al., 2016).
5. DSM-5 Personality Inventory - Short Version (PID-5-BF) Adultos
6. Dissociative Symptoms Scale (DERS, Gratz y Roemer, 2004)
7. Escala de síntomas disociativos DES (Bernstein and Putnam, 1986)
8. Scale of satisfaction with the treatment received Scale of satisfaction with the treatment received. (CRES-4). Spanish version. (Feixas et al., 2012)

The objectives of the project and your personal data will be protected and included in a file subject to the guarantees of law 15/1999 of December 13.

This project has an approximate duration of 6 months including 4 evaluations. The evaluation passes will be: before treatment, after 8 weeks, after 16 weeks and after 24 weeks. The structure of the intervention consisting of 8 treatment sessions is described below. Two types of data will be collected:

1) Socio-demographic data, such as age, marital status, or educational level, among others. These data will only be collected before treatment.

2) Psychological data. These data will be obtained from the completion of a series of a clinical interview and the questionnaires described above, which rapidly measure ways of being and being in life and symptoms related to the traumatic experience.

After each assessment session, a short emotional regulation session will be held to address possible unpleasant sensations that may be triggered by accessing information about the traumatic event and its impact on your life. Therapeutic sessions will be weekly 90 minutes

long, in online group format, through the zoom platform. The groups will have a maximum of 4 participants to ensure adequate attention to them during the therapeutic process. In these sessions, emotional regulation strategies, coping resources and specific treatment of traumatic memory will be addressed with the therapeutic strategies recommended by the World Health Organization for the treatment of post-traumatic stress. This intervention will be always completely free, through a program based on scientific evidence. The correction of the tests will be carried out by the technical team, led by Maria Teresa Mitjans, who will oversee assigning a user number to protect the identity of the participants throughout the process and safeguard the data. Likewise, the two psychologists in charge of applying the treatment protocols will not know the results of this evaluation, so as not to interfere with the expectations of change in the therapeutic process (double-blind procedure) until the end of the project.

To protect the confidentiality of the identity of the participants in the data collected, it complies with the provisions of article 5 of Organic Law 15/1999, of December 13, and current European regulations for the Protection of Personal Data, we inform you that the personal data that you voluntarily provide us through interviews, questionnaires and observations will be incorporated into a confidential database. The purpose of this database is the archive, management, and analysis of the same. If you agree to participate in the study, you agree that the battery of psychological tests can be administered to you and that behavioral observations can be made during the application of the intervention program. The project researchers agree not to share the required information with other institutions. You can exercise the rights of rectification, cancellation and opposition through the indicated email address (mariateresa.mitjans@campusviu.es)".

For any further questions, you can contact Dr. María Teresa Mitjans Lafont, principal investigator and coordinator of this project, and / or with Dr. Maria Jesús Hernández Jiménez, clinical psychologist who will apply the intervention:

mariateresa.mitjans@campusviu.es, phone: 961924997

mariajesus.hernandez@campusviu.es phone: 961924997

Informed consent statement

I, _____, with Identification Number_____

I have read the “patient information sheet” that they have given me, and all the content has been explained to me.

I have had the opportunity to ask questions about the study and have received a satisfactory answer to all of them.

I have received enough information about the study.

I have had enough time to weigh my participation.

I have spoken to:
Dr_____

I will be given a signed and dated copy of this document.

I understand that participation is voluntary and that I can leave the study:

1. Whenever I want
2. Without giving any explanation.
3. Without this affecting my medical care.

I hereby certify that I voluntarily agree to participate.

_____

Date Name and signature of the Participant

_____

Date Name and signature of the Researcher