

Original title: Trastorno de Estrés Postraumático Complejo en mujeres supervivientes de violencia de género (SUPERTEPTCOM)

Scientific title: Effects of Online Complex Post-Traumatic Stress Disorder Treatment in Women Survivors of Intimate Partner Violence with Post-Traumatic Stress Disorder (PTSD) on their symptomatology of Classic PTSD and Complex PTSD

Public title: Effects of Online Complex Post-Traumatic Stress Disorder Treatment in Women Survivors of Intimate Partner Violence with Post-Traumatic Stress Disorder

Acronym: SUPERTEPTCOM

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STUDY PROTOCOL

Intimate partner violence is considered a type of interpersonal violence characterized by a coercive pattern of behavior within the relationship in which one person attempts to control another through threats, acts of physical, sexual, verbal or psychological violence (Heron et al., 2003).

As a result of this type of violence, women survivors are at greater risk of suffering both psychological and physical health problems. Nathanson et al. (2012) report that most women who have experienced this violence and who meet the criteria for a mental health diagnosis, they have post-traumatic stress disorder (PTSD). Positioning PTSD as one of the most serious consequences of intimate partner violence (McKee and Hilton, 2019; Perez, Johnson, Johnson and Walter, 2012).

However, the PTSD diagnosis does not adequately and it does not totally explain the negative psychological impact experienced by victims of interpersonal trauma and necessarily, the ICD-11 (World Health Organization's International Classification of Diseases, ICD-11, 2018) proposes the new diagnosis of complex post-traumatic stress disorder (PTSD Complex; PTSD; PTSD). It relates the appearance of symptoms of affective regulation problems, negative self-concept and difficulties in maintaining relationships with others with the negative impact of suffering severe, intense, chronic and difficult to escape interpersonal trauma, as in the case of women who have survived intimate partner violence (Pill et al., 2017; Hyland et al., 2018). Thus, it is proposed to distinguish between post-traumatic stress disorder (PTSD) and complex post-traumatic stress disorder (PTSD) based on the traumatic experience and symptoms manifested.

Therefore, the main reason for carrying out the present study lies within its contribution to research on complex post-traumatic stress disorder. The aim of this study is novel due to the lack of specific treatment for this type of trauma, specifically in female victims of intimate partner violence. As such, the objective of the present project is to test a specific treatment for its diagnosis in female victims and survivors of intimate partner violence.

Participants

The sample will be composed by 60 women who have suffered IPV and also have been diagnosed with a Complex Post-traumatic Stress Disorder (C-PTSD) according to the ICD-11 diagnosis. Participants will reside in Spain and attend Women's Centres of different Women's Institutes or Associations of female IPV victims. Participants will be randomly allocated to two interventions: (1) 30 women in the standard Post-traumatic Stress Disorder Intervention Group (PTSD Group), (2) 30 women in the Complex Post-traumatic Stress Disorder Intervention Group (C-PTSD group).

Inclusion criteria:

- Women who have experienced violence (exclusively psychological or psychological and physical) perpetrated by their partners/ex-partners.
- At least 18 years old.
- Diagnosed with Complex Post-traumatic Stress Disorder (C-PTSD) according to ICD-11 criteria.

Exclusion criteria:

- Illiteracy, difficulties in completing written tests, and altered mental state, requiring recent admission to hospital or intensive treatment for a psychological disorder.

Instruments

1. A socio-demographic questionnaire will incorporate elements such as age, gender, education background and exposure to violence among other variables.
2. Escala de Gravedad de Síntomas del Trastorno de Estrés Postraumático según el DSM-5: versión forense (EGS-F) (Echeburúa, Amor, Muñoz, Sarasua, & Zubizarreta, 2017): It is a structured evaluation instrument, of hetero-applied administration, in a Likert-type format (0 to 3) according to the frequency and intensity of the symptoms of PTSD. This scale has a nuclear part (EGS-R) and a complementary part. The core part consists of 21 core items in correspondence with the diagnostic criteria of the DSM-5 (APA, 2013). This core part (EGS-R) has shown adequate psychometric properties in the Spanish population. On the other hand, the diagnostic efficacy of this scale is very high (82.5%) (Echeburúa et al., 2016). The complementary part consists of a dysfunctional subscale and also a simulation subscale of 6 binary items.
3. International Trauma Questionnaire (ITQ) (Cloitre y cols., 2018; Fernández-Fillol, Hidalgo-Ruzzante, Pérez-García & Daugherty, 2020): It is a short, free access self-report measure developed at an international level in coherence with the ICD-11 (WHO) criteria. It focuses particularly on the definition of functional impairment for both PTSD and Complex PTSD, and in which the content of the items could be predictive of the results of differential treatments. It includes 18 items (9 for PTSD symptoms and 9 Self-Organization items). For the diagnosis of Complex PTSD, one of two symptoms of each of the three groups of PTSD symptoms (re-experiencing in the here and now, avoidance, and current feeling of threat) and one of two symptoms of each must be met. of the three

groups of Alterations in Self-Organization: (1) affective dysregulation, (2) negative self-concept and (3) alterations in relationships. In addition, it includes a measure of functional impairment. The internal reliability for both scales is satisfactory, with a Cronbach's alpha of ≥ 0.79 in a community sample.

4. Composite Abuse Scale (Revised)-Short Form (CASR-SF) (Ford-Gilboe, Wathen, Varcoe, MacMillan, Scott-Storey, Mantler, ... & Perrin, 2016): It is a self-report measure of 15 items to assess the severity and intensity of violence against a partner in the last 12 months. It includes measures for psychological, physical and sexual violence, evaluating the frequency of each type of violence on a scale of 0-5. The CAS-SF has an internal consistency of .94 (Ford-Gilboe et al., 2016).
5. Connor-Davidson resilience scale (CD-RISC) (Connor, & Davidson, 2003; Crespo, Fernández-Lansac, & Soberón, 2014): It is an instrument for measuring resilience of 25 items that has shown good psychometric properties of Spanish participants (alpha value of 0.86).
6. Emotion regulation questionnaire (ERQ) (Cabello, Salguero, Fernández-Berrocal & Gross, 2013; Gross y John, 2003): It is a 10-item scale designed to measure the tendency of respondents to regulation their emotions in two ways: (1) Cognitive reappraisal and (2) Expressive suppression. The response to each item will be given on a 7-point Likert-type scale that varies from 1 (totally disagree) to 7 (totally agree). ERQ shown adequate internal consistency, test-retest reliability, and convergent and discriminant validity (Cabello, Salguero, Fernández-Berrocal & Gross, 2013).
7. Rosenberg self-esteem scale (RSE) (Rosenberg, 1965): The RSE consists of 10 items assessing global self-esteem. The Rosenberg Self-Esteem Scale have been validated internationally and have been adapted for the Spanish population (Martín Albo, Núñez, Navarro, & Grijalvo, 2007). The scale showed satisfactory levels of internal consistency and temporal stability over a four-week period.
8. Revised UCLA Loneliness Scale (Russell y cols. 1980; Vázquez Morejón, & Jiménez García-Bóveda, 1994): It is a short, 20-item general measure of loneliness. All items are scored from one to four, one being never, two rarely, three sometimes, and four always. The measure has high internal consistency and test-retest correlation, and a moderate concurrent validity (Vázquez Morejón, & Jiménez García-Bóveda, 1994).
9. Perceived Change Index (Labrador & Rincón, 2002): It is a short, 7-item measure designed to measure emotional distress, typical PTSD symptoms, general well-being, and participants' assessment of the usefulness of each session. The response to each item is given on a Likert-type scale.
10. Self-reports to measure the homework tracking of both treatments.

Interventions

Randomized controlled trial. The intervention which will be applied in a format group, online, consists of 24 sessions.

The sample will be composed by 60 women who have suffered IPV and also have been diagnosed with a Complex Post-traumatic Stress Disorder (C-PTSD) according to the ICD-11 diagnosis. Participants will reside in Spain and attend Women's Centers of different Women's Institutes or Associations of female IPV victims.

Participants will be screened for the eligibility criteria in a presential or online interview. This includes specific assessment surrounding violence, education level, mental health and hospitalizations, and PTSD/C-PTSD diagnose (60/90 minutes).

Participants will be randomly allocated to two online-interventions. A member of the Research team not involved in the assessment or intervention will randomly allocate participants to the intervention (C-PTSD treatment) or control (PTSD treatment) group. The randomization list will be generated online using a web-based randomization tool. The number will be placed in an opaque envelope which is given to the Researcher whom assigns the intervention (C-PTSD treatment) or control (PTSD treatment) program to each participant: (1) 30 women in the standard Post-traumatic Stress Disorder Intervention Group (PTSD treatment), (2) 30 women in the Complex Post-traumatic Stress Disorder Intervention Group (C-PTSD treatment).

- The **Intervention Group (C-PTSD treatment)** receives the Skills Training in Affective and Interpersonal Regulation plus Modified Prolonged Exposure (STAIR/MPE) (adapted from Levitt y Cloitre, 2005; Cloitre, 2020), which consists of two phases. This Complex PTSD intervention will be implemented over 24 sessions delivered in 24 weeks.
- The **Control Group (PTSD treatment)** will receive an adaptation of the Trauma focused Cognitive Behavioral Treatment (adapted from Chard, 2005; Resick, Monson, Chard, 2017). It is a treatment that is widely used to recover from traditional symptomatology associated to PTSD. This PTSD Treatment will be implemented over 24 sessions delivered during 24 weeks.

In both treatments, the Guidelines for online intervention of Weiss, Azevedo, Webb, Gimeno, and Cloitre (2018) will be followed. Also, each treatment integrates skills in a way that is organized for and adapted to meet the needs of the women survivors of intimate partner violence.

Data Analysis

Regarding the data analysis for the indicated treatment conditions, the SPSS statistical program will be used. For the descriptive analysis of the sociodemographic variables of the participants and the measures evaluated with questionnaires, means, standard deviations and percentages will be calculated. In outcome measures of a continuous nature, treatment groups will be compared using linear mixed models. Baseline scores will be included as covariates, time as a categorical variable, and treatment condition as a fixed effect. In order to establish the clinical significance of the changes in those variables that are statistically significant, the value of the effect size will be calculated with the G Power program.

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