# Cognitive behavioral treatment focused on positive memories for post-traumatic stress in intimate partner violence

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
01/03/2022		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
10/03/2022		[X] Results		
<b>Last Edited</b>	Condition category  Mental and Behavioural Disorders	Individual participant data		

#### Plain English summary of protocol

Background and study aims

This research is part of one of the lines of research that has aroused the most interest in the area of Clinical Psychology: the study of trauma. To address this problem, the starting point is a situation of great social relevance and high complexity in terms of psychological response: the trauma suffered by women victims of intimate partner violence.

Different cognitive-behavioral treatments focused on trauma have been shown to be effective, however, the potential effect of focusing on positive memories remains to be explored. Therefore, the general objective of the clinical trial is to evaluate the efficacy and effectiveness of cognitive-behavioral psychological intervention program for women victims of intimate partner violence with post-traumatic symptoms that incorporates a positive memories module.

#### Who can participate?

Women, aged 18 years and older, who are victims of gender-based intimate partner violence more than 1 month after the first aggression, who present significant post-traumatic symptomatology, and who agree to participate in the study.

What does the study involve?

Participants will be randomly allocated to one of three groups:

- 1. Waiting list control group (CG)
- 2. Cognitive-behavioral treatment (CBT)
- 3. Cognitive-behavioral treatment with a focus on positive memories (CBT-M+) Treatments are applied weekly for 8 weeks, in group format, with a duration of 90-120 minutes.

What are the possible benefits and risks of participating?

Benefits of participating in the program will be the improvement of posttraumatic and associated symptoms.

No risk or participation is foreseen.

Where is the study run from? Complutense University of Madrid (Spain) When is the study starting and how long is it expected to run for? September 2019 to April 2024

Who is funding the study? Ministry of Science and Innovation of the Government of Spain

Who is the main contact?
Prof. María Crespo López (mcrespol@ucm.es)

# Contact information

#### Type(s)

Principal investigator

#### Contact name

Prof Maria Crespo

#### **ORCID ID**

https://orcid.org/0000-0001-8762-7874

#### Contact details

Facultad de Psicologia - UCM Campus de Somosaguas s/n MADRID Spain 28223 +34 913942831 mcrespo@psi.ucm.es

# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

PID2019-105942RB-I00

# Study information

#### Scientific Title

Post-traumatic stress and intimate partner violence against women: development and evaluation of treatment focused on positive memories

#### Acronym

**MEMPOSITIV** 

#### Study objectives

- 1. The two intervention programs (i.e. cognitive-behavioral with and without addressing positive memories) will be shown to be effective. Specifically:
- 1.1 The two cognitive-behavioral programs will show, in post-treatment, a reduction of post-traumatic and associated symptomatology, improvement of affect and meanings associated with trauma, leading to clinically significant changes in these aspects.
- 1.2 The changes achieved by the two cognitive-behavioral programs (i.e. with and without incorporation of positive memories) will be maintained over time (follow-ups at 3, 6 and 12 months).
- 2. The two cognitive-behavioral programs will show, in post-treatment, a greater reduction of post-traumatic and associated symptomatology, greater improvement of affect and meanings associated with the trauma, than the wait-list control group.
- 3. The program that incorporates positive memories will show greater efficacy than the cognitive-behavioral program. Specifically:
- 3.1 The program that incorporates positive memories will show, in post-treatment, a greater reduction of post-traumatic and associated symptomatology, greater improvement of affect and meanings associated with the trauma, than the cognitive-behavioral program that does not address positive memories.
- 3.2 The differences between the two programs will be maintained over time (follow-ups at 3, 6 and 12 months).
- 4. The program that incorporates positive memories will show greater effectiveness than the cognitive-behavioral program. Specifically:
- 4.1 The program that incorporates positive memories will be more acceptable to the participants than the cognitive-behavioral program (i.e., it will result in less rejection and dropout and greater adherence and satisfaction in women).
- 4.2 The program that incorporates positive memories will be more acceptable to the therapists than the cognitive-behavioral program (i.e., greater therapist satisfaction).

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approved 10/03/2021, Ethics Committee of the Faculty of Psychology of the Complutense University of Madrid (Campus de Somosagua, Ctra. de Húmera, s/n, 28223 Pozuelo de Alarcón, Madrid, Spain; +34 913 9431 78, correo@ucm.es), ref: 2020/21\_025

# Study design

Multicenter interventional blinded randomized controlled trial

# Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Treatment of posttraumatic stress symptoms in female intimate partner violence survivors

#### **Interventions**

A multigroup design (three groups) with repeated measures will be used, with five levels (pretreatment, post-treatment and follow-ups at 3, 6 and 12 months) for the experimental groups and two levels (pre- and post-treatment) for the control group. Participants will be randomized through a block randomization procedure.

The three treatment groups would be:

- 1. Waiting list control group (CG)
- 2. Cognitive-behavioral treatment (CBT)
- 3. Cognitive-behavioral treatment with focus on positive memories (CBT-M+)

CBT is based on the cognitive-behavioral treatment for battered women developed by Labrador et al. (2009), which is a multicomponent program focused on trauma and based on the analysis of women's needs and the indications of experts in the field. The treatment is applied in 8 weekly sessions, in group format, for groups of 6-8 women with sessions of about 90-120 minutes.

The core components of the program are: psychoeducation about the abuse, activation control (breathing training), self-esteem improvement, mood improvement (by planning rewarding tasks), exposure to the history of abuse, exposure to hot spots in the history of abuse, and relapse prevention. CBT-M+ is an update of the CBT program that also incorporates exposure to other types of situations, specifically, memories of experiences with positive affective valence. In order to make both proposals equivalent in the CBT, exposure to neutral valence images has been incorporated.

#### Intervention Type

Behavioural

#### Primary outcome(s)

Posttraumatic stress symptoms and PTSD diagnosis are measured using the Global Posttraumatic Stress Evaluation 5 (Evaluación Global de Estrés Postraumático 5 -EGEP-5) (Crespo et al., 2017) at Pre-treatment; Post-treatment assessment: to be performed in the first 14 days, after the last treatment session; Follow-up 3 months; Follow-up 6 months; and Follow-up 12 months.

#### Key secondary outcome(s))

Measured at Pre-treatment; Post-treatment assessment: to be performed in the first 14 days, after the last treatment session; Follow-up 3 months; Follow-up 6 months; and Follow-up 12 months (unless noted otherwise):

- 1. Level of physical, psychological and sexual violence of intimate partner abuse measured using Conflict Tactics Scales version 2 (CTS2, Loinaz, 2012)
- 2. Acceptability of intimate partner violence measured using Acceptability of Intimate Partner Violence Against Women short form scale (A-IPVAW-8, Martín-Fernández et al., 2021)
- 3. Victim-Blaming attitudes measured using Victim-blaming Attitudes in Cases of Intimate Partner Violence against Women Scale Short Form (VB-IPVAW, Martín-Fernández et al., 2018)
- 4. Meanings associated with trauma measured using Brief Version of The Posttraumatic Cognitions Inventory (PTCI-9; Wells et al., 2019)
- 5. Self-Concept and Identity measured using Self-Concept and Identity Measure (SCIM; Kaufman et al., 2015)
- 6. Trauma centrality measured using Centrality of Event Scale (CES; Bernsten & Rubin, 2006)
- 7. Positive and negative affect measured using Positive and Negative Affect Schedule (PANAS; Watson, et al., 1988)

- 8. Anxious symptomatology measured using Beck Anxiety Inventory (BAI; Beck et al., 1988)
- 9. Depressive symptomatology measured using Beck Depression Inventory-II (BDI-II; Beck et al., 1996)
- 10. Level of self-esteem measured using Rosenberg Self-Esteem Scale (RSE; Rosenberg, 1965)
- 11. Difficulties in Emotion Regulation measured using Difficulties in Emotion Regulation Scale Short Form (DERS SF; Kaufman et al, 2016)
- 12 Difficulties in Positive Emotion Regulation measured using Difficulties in Emotion Regulation Scale–Positive (DERS-P; Weiss, et al., 2015)
- 13. General health status measured using 12 Item Short Form Health Survey Version 2 (SF-12 v2; Ware et al., 2002)
- 14. Motivation for change for victims measured using an ad hoc generated questionnaire
- 15. Satisfaction with treatment measured using Client Satisfaction Questionnaire (CSQ-8; Larsen et al., 1979) at (1) Post-treatment assessment: to be performed in the first 14 days, after the last treatment session.
- 16. Participants' satisfaction with each program component measured using an ad hoc generated questionnaire at the end of the last session.
- 17. Satisfaction with any sessions measured using an ad hoc generated questionnaire at the end of each of the 8 sessions.
- 18. Weekly evolution of anxious symptomatology during the programme measured using Overall Anxiety Severity And Impairment Scale (OASIS; Norman et al., 2006) at the end of each of the 8 sessions.
- 19. Weekly evolution of depressive symptomatology during the programme measured using Overall Depression Severity And Impairment Scale (ODSIS; Bentley et al., 2014) at the end of each of the 8 sessions.
- 20. Satisfaction with the treatment by the therapist measured using an ad hoc generated questionnaire at the end of the last session.
- 21. Adequacy of each session to the treatment manual measured using an ad hoc generated questionnaire at the end of each of the 8 sessions.

#### Completion date

30/04/2024

# Eligibility

#### Key inclusion criteria

- 1. Participants must all be women
- 2. Participants must be over 18 years old.
- 3. Participants must be proficient in the use of the Spanish language
- 4. Participants must be victims of gender-based intimate partner violence.
- 5. Participants must have endure said violence at least one month before the start of the trial.
- 6. Participants show absence of suicide risk. Suicide risk is assessed using a Likert-type question in the screening in the last two weeks (item 9 of the Spanish version of the Beck Depression Inventory II BDI-II; Beck et al., 1996 –). The person will match the criteria for inclusion whenever the answers given are option 0 ("I do not consider committing suicide") or 1 ("I have thought about committing suicide but I'm not willing to go through with it").
- 7. Participants must present PTSD according to DSM-5 criteria. PTSD symptoms and trauma history were assessed using the Global Assessment of Posttraumatic Stress Scale 5 (EGEP-5; in Spanish: Evaluación Global de Estrés Postraumático 5; Crespo et al., 2017).
- 8. Participants must have agreed to take part in the study voluntarily.

#### Participant type(s)

#### **Patient**

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

**Female** 

#### Total final enrolment

103

#### Key exclusion criteria

- 1. The participant suffers from physical or mental conditions or has any other limitation (illiteracy, disability, etc) that further complicates her participation in evaluation or treatment sessions.
- 2. The participant has been diagnosed or suffers from psychotic disorders
- 3. The participant is currently receiving or has received psychological treatment over the last 6 months.

#### Date of first enrolment

01/10/2021

#### Date of final enrolment

30/04/2023

# Locations

#### Countries of recruitment

Spain

#### Study participating centre

Center for Information, Documentation and Counseling for Women

Dolores Ibárruri Square, 1. Coslada - Madrid Spain

28823

# Study participating centre

Coslada Municipal Point of the Madrid Observatory of Gender Violence

Dolores Ibárruri Square, 1.

Coslada - Madrid

# Study participating centre Aranjuez Municipal Point of the Madrid Observatory of Gender Violence

Zorzales, 17 Aranjuez - Madrid Spain 28300

#### Study participating centre Leganés Municipal Point of the Madrid Observatory of Gender Violence

El Charco, 23 Leganés - Madrid Spain 28911

# Sponsor information

#### Organisation

Complutense University of Madrid

#### ROR

https://ror.org/02p0gd045

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Ministerio de Ciencia e Innovación

#### Alternative Name(s)

CienciaGob, Ministerio de Ciencia e Innovación de España, Ministry of Science and Innovation, Spanish Ministry of Science and Innovation, Ministry of Science and Innovation of Spain, Spain, Ministry for Science and Innovation, Ministeri de Ciència i Innovació, MCIN, MICINN

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

#### Location

Spain

# **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from María Crespo (mcrespo@psi.ucm.es) as SPSS database. Data will become available from publication of the results and for a year. Access will be granted to researchers. No personal information about the participants will be provided. Agreement about the use of the data should be firmed between both parts.

#### IPD sharing plan summary

Available on request

#### Study outputs

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Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/11/2024	20/06/2025	Yes	No
Results article		09/10/2025	10/10/2025	Yes	No
<u>Protocol article</u>		23/07/2022	25/07/2022	Yes	No
Other publications		27/05/2025	28/05/2025	Yes	No
Participant information sheet			02/03/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes