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

Submission date
01/03/2022

Recruitment status
No longer recruiting

Registration date
10/03/2022

Overall study status
Completed

Last Edited
20/06/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)

Study website
https://www.ucm.es/grupovictimologia/proyecto-mempositiv

Contact information

Type(s)
Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See study outputs table

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 (pre-treatment, 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 measure
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.

Secondary outcome measures

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.

Overall study start date
01/09/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
135

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
Spain
28823

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

Sponsor details

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Facultad de Medicina
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Sponsor type
University/education

Website
https://www.ucm.es/directorio-servicio-investigacion

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/04/2025

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

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