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Effects of online complex post-traumatic stress disorder treatment in women survivors of intimate partner violence with post-traumatic stress disorder

Submission date
19/03/2021

Recruitment status
No longer recruiting

Registration date
07/04/2021

Overall study status
Completed

Last Edited
21/07/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Intimate partner violence is where one person in a relationship attempts to control the other through threats, acts of physical, sexual, verbal or psychological violence. As a result of this type of violence, women survivors are at greater risk of suffering both psychological and physical health problems. One of the main problems for women who have suffered this violence is post-traumatic stress disorder (PTSD). However, the PTSD diagnosis does not adequately and totally explain the negative psychological impact experienced by victims of interpersonal trauma, and the World Health Organization (WHO) proposes a new diagnosis of complex post-traumatic stress disorder (complex PTSD), which relates to the appearance of symptoms of affective (emotion) regulation problems, negative self-concept and difficulties in maintaining relationships with others. The aim of this study is to test a specific treatment for complex PTSD in female victims and survivors of intimate partner violence.

Who can participate?
Women survivors of intimate partner violence aged 18-65 with a diagnosis of complex PTSD

What does the study involve?
Women survivors of intimate partner violence are assessed for PTSD (classic symptoms and complex symptoms). Of these, women with complex PTSD symptoms will be randomly assigned to a control group who will receive a classic PTSD intervention or an intervention group who will receive a complex PTSD intervention. Both interventions will be online and will be applied in small groups. Each session lasts around 60-90 minutes and the whole intervention has 12 sessions. Once the intervention is completed, each participant receives €50.

What are the possible benefits and risks of participating?
Complex PTSD treatment may improve the symptoms of both classic PTSD and complex PTSD.

Participants may experience some emotional discomfort when answering certain questions in the violence assessment questionnaires. They can choose to stop answering the questions and contact the researchers.

Where is the study run from?
University of Granada (Spain)

When is the study starting and how long is it expected to run for?
November 2019 to December 2024

Who is funding the study?
Ministry of Science, Innovation and Universities (Spain)

Who is the main contact?
1. BELIEVE Project (proyecto.believe21@gmail.com)
2. Prof. Natalia Hidalgo-Ruzzante (nhidalgo@ugr.es)
3. Prof. Miguel Pérez-García (mperezg@ugr.es)
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Study website
http://projectbelieve.info/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PID2019-110041GB-I00

Study information

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

Acronym
SUPERTEPTCOM

Study objectives
Women survivors of intimate partner violence with complex PTSD who receive a specific treatment for complex PTSD, will improve their symptomatology of classic PTSD as well as their symptomatology of Complex PTSD.
Women survivors of intimate partner violence with complex PTSD who receive a classic treatment for PTSD, will improve their symptomatology of classic PTSD but not their symptomatology of complex PTSD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/02/2020, Ethics Committee on Human Research (CEIH), University of Granada (Vicerrectorado de Investigación y Transferencia, Gran Vía nº 48, 2ª planta. 18071, Granada, Spain; +34 (0)958 243008; investigacion@ugr.es), ref: 975/CEIH/2019

Study design
Two-group parallel blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Complex PTSD in women survivors of intimate partner violence

Interventions
Current interventions as of 14/07/2022:

The intervention will be applied in a group format, online, consisting of 24 sessions.

The sample will be composed of 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 a specific assessment regarding violence, education level, mental health and hospitalizations, and PTSD/C-PTSD diagnosis (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 who assigns the intervention (C-PTSD treatment) or control (PTSD treatment) program to each participant.

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 cognitive-behavioural Treatment for Posttraumatic Stress Disorder (PTSD) (adapted from Resick, Monson, Chard, 2017). It is a treatment that is widely used to recover from traditional symptomatology associated with 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.

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Previous interventions:

The intervention will be applied in a group format, online, consisting of 12 sessions.

The sample will be composed of 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 a specific assessment regarding violence, education level, mental health and hospitalizations, and PTSD/C-PTSD diagnosis (60/90 minutes).

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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.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 14/07/2022:

1. Symptoms of PTSD measured using the Escala de Gravedad de Síntomas del Trastorno de Estrés Postraumático según el DSM-5: versión forense (EGS-F) at baseline, session 4, session 8, session 12, session 18, session 24, and 6 months follow-up
2. Symptoms of PTSD and complex PTSD measured using the International Trauma Questionnaire (ITQ) at baseline, 3 months and 6 months follow-up

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Previous primary outcome measure:

1. Symptoms of PTSD measured using the Escala de Gravedad de Síntomas del Trastorno de Estrés Postraumático según el DSM-5: versión forense (EGS-F) at baseline, session 4, session 8, session 12, and 6 months follow-up
2. Symptoms of PTSD and complex PTSD measured using the International Trauma Questionnaire (ITQ) at baseline, 3 months and 6 months follow-up

Secondary outcome measures
1. Sociodemographic characteristics measured using a survey with questions developed by the study team at baseline
2. Exposure to violence measured using a survey with questions developed by the study team at baseline, 3 months and 6 months follow-up
3. Intimate partner violence experiences measured using the Composite Abuse Scale (Revised)-Short Form (CASR-SF) at baseline, 3 months and 6 months follow-up
4. Resilience measured using the ConnorDavidson resilience scale (CDRISC) at baseline, 3 months and 6 months follow-up.
5. Emotion regulation measured using the Emotion regulation questionnaire (ERQ) at baseline, session 4, session 8, session 12, and 6 months follow-up.
6. Negative self-perception measured using the Rosenberg self-esteem scale (RSE) at baseline, session 4, session 8, session 12, and 6-months follow-up
7. Difficulty with relationships and social isolation measured using the Revised UCLA Loneliness Scale at baseline, session 4, session 8, session 12, and 6-months follow-up
8. Perceived change measured using the Perceived Change Index at the end of each session
9. Retention rates assessed as the number of participants who consent to participate that remain in the trial by 3- and 6-month follow-up

Overall study start date
01/11/2019

Completion date
31/12/2024

Eligibility

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

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Illiteracy
2. Difficulties in completing written tests
3. Altered mental state
4. Requiring recent admission to hospital or intensive treatment for a psychological disorder

Date of first enrolment
01/03/2020

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Spain

Study participating centre
The Mind, Brain and Behavior Research Center
Campus Universitario de Cartuja
Granada
Spain
18011

Sponsor information

Organisation
Ministry of Science, Innovation and Universities (Spain)

Sponsor details
Calle Torrelaguna 58
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Sponsor type
Government

Website
https://www.ciencia.gob.es/portal/site/MICINN/?lang_choosen=en

Funder(s)

Funder type
Government

Funder Name
Ministerio de Ciencia, Innovación y Universidades

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-review journals about trauma, psychology and intimate partner violence.
Other outputs will be the final study report; conference presentations; publication of a manual; a synopsis of findings to participants and experts-by-experience groups.
In addition, the status of the project and the results will be disseminated on the following websites: the BELIEVE project (http://projectbelieve.info/), International Trauma Consortium (ITC, https://www.traumameasuresglobal.com/) and G-Stress Project (https://www.global-psychotrauma.net/g-stress).

Intention to publish date
30/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Dr Natalia Hidalgo Ruzzante (nhidalgo@ugr.es) following the publication of the main trial findings. The dataset will be in Excel format and will be shared with other research teams for the purpose of contributing to systematic reviews, meta-analyses and other analyses focused on replicability of results. All participants gave their consent to participate in this study, signing a written consent form. All data will be anonymized, and data that may risk identification will be deleted before sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/05/2021	No	No
Participant information sheet			14/07/2022	No	Yes
Protocol file	version 2022		14/07/2022	No	No