

Evaluating The Women's EmotionS, Trauma, and EmpowErMent (W-ES.T.EEM) protocol: a psychological support for victims of domestic violence

Submission date 15/11/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/08/2022	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Intimate partner violence (IPV) is a widespread phenomenon that affects the physical and mental well-being of victims, and several barriers prevented sufferers from receiving face-to-face interventions. These obstacles increased with the advent of the Coronavirus (COVID-19) pandemic, and online psychological interventions can represent a valid solution to increase the well-being of IPV victims. This study aims to develop a psycho-education clinical protocol for a single-blind randomised controlled trial (RCT) that examines the effectiveness of a web-based psychoeducational intervention for IPV victims that integrates Dialectical Behavioural Therapy and Empowerment approach.

Who can participate?

Women aged over 18 years who were victims of IPV during the COVID-19 outbreak

What does the study involve?

Participants will be randomly allocated to the W-ES.T.EEM experimental group or the treatment as usual control group. Both interventions will be administered individually to each woman and will consist of eight weekly online treatment sessions over a period of 2 months.

What are the possible benefits and risks of participating?

The results of this study could contribute to an increase in the use of online interventions to overcome social and psychological barriers that prevent victims of IPV from asking for help and psychological support.

Where is the study run from?

University of Padua (Italy)

When is the study starting and how long is it expected to run for?

April 2021 to December 2025

Who is funding the study?
University of Padua (Italy)

Who is the main contact?
Prof. Stefania Mannarini
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A psycho-educational support intervention for victims of domestic violence: the Women's EmotionS, Trauma, and EmpowErMent (W-ES.T.EEM) study protocol

Acronym
W-ES.T.EEM

Study objectives
Compared to the treatment as usual only condition, the W-ES.T.EEM protocol may produce a better reduction of emotion dysregulation, negative affects and symptoms related to violence,

and alexithymia. Moreover, compared to the treatment as usual only condition, the W-ES.T.EEM protocol may produce a greater increase of both self-esteem and self-efficacy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/08/2021, Ethical Committee of the University of Padua (Comitato Etico Della Ricerca Psicologica, Dipartimenti/Sezione di Psicologia, Università degli Studi di Padova, Via Venezia 8, 35131 Padova, Italy; +39 (0)49 827 6600; comitato.etico.area17@unipd.it), ref: 4300

Study design

Single-blind randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intimate partner violence

Interventions

Participants will be randomized into two different groups:

1. A psycho-educational intervention plus treatment as usual
2. Treatment as usual

Both interventions will be administered individually to each woman and will consist of eight weekly online treatment sessions over a period of 2 months. The randomization scheme will be generated using the Web site Randomization.com. Due to the nature of the intervention the treatment group allocation cannot be concealed from the participants.

Intervention Type

Behavioural

Primary outcome(s)

Each of the following will be measured at baseline, at the end of treatment, at 3-months follow-up, at 6-month follow-up, and at 1-year follow-up:

1. Emotion regulation measured using the Difficulties Emotion Regulation Scale – SF (DERS-SF)
2. Well-being measured using the Clinical Outcomes in Routine Evaluation-Outcome Measures (CORE-OM)
3. The intensity of affects measured using the Intimate Violence and Traumatic Affect Scale (VITA)
4. Traumatic impact of the event measured using the Impact of Event Scale Revised (IES - R)
5. Self-esteem measured using the Rosenberg Self-Esteem Scale (RSES)
6. Self-efficacy measured using the Generalized Self-Efficacy Scale

Key secondary outcome(s)

Each of the following will be measured at baseline, at the end of treatment, at 3-months follow-up, at 6-month follow-up, and at 1-year follow-up:

1. The participants' experience of violence measured using the Conflict Tactic Scale – 2 (CTS-2)

2. Violence at the time of COVID-19 measured using a self-report questionnaire built ad hoc
3. Alexithymia measured using the Toronto Alexithymia Scale – 20 (TAS-20)

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Older than 18 years old
2. Victims of IPV since the outbreak of the COVID-19 pandemic
3. Able to speak and understand Italian
4. Female
5. Had their first contact with anti-violence centers within 2 weeks before recruitment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

Inability to understand/take part in the psychoeducation intervention due to hearing, visual, cognitive, or neurological difficulties

Date of first enrolment

01/01/2022

Date of final enrolment

31/12/2022

Locations

Countries of recruitment

Italy

Study participating centre

University of Padua

CIRF - Interdepartmental Center for Family Research

Via Venezia 12
Padua
Italy
35131

Sponsor information

Organisation

University of Padua

ROR

<https://ror.org/00240q980>

Funder(s)

Funder type

University/education

Funder Name

Università degli Studi di Padova

Alternative Name(s)

University of Padova, University of Padua, UNIPD

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

The data presented will be available on request from the corresponding author (stefania.mannarini@unipd.it). The data will be not publicly available due to privacy restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/08/2022	26/08/2022	Yes	No
Participant information sheet		06/08/2021	19/11/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes