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

Submission date	**Recruitment status**	[X] Prospectively registered
15/11/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2021	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/08/2022	Other	[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
See additional file

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 measure
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

Secondary outcome measures
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)

Overall study start date
21/04/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
86

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

Sponsor details
CIRF - Interdepartmental Center for Family Research
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Sponsor type
University/education

Website
https://www.unipd.it/en/

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

Publication and dissemination plan
First - research protocol; planned publication in a high-impact journal
Second - pilot study; planned publication in a high-impact journal
Third - complete study; planned publication in a high-impact journal

Intention to publish date
01/01/2026

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?
Participant information sheet		06/08/2021	19/11/2021	No	Yes
Protocol article		25/08/2022	26/08/2022	Yes	No