

# Self-concept intervention among intimate partner violence victims: a multicomponent pilot program

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<b>Registration date</b> 05/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/09/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and aims

Intimate Partner Violence (IPV) affects women's physical and mental health through direct pathways, such as injury, and indirect pathways, such as chronic health problems that arise from prolonged stress. One of the negative consequences is the negative self-concept IPV victims have. Self-concept refers to how someone thinks about, evaluates or perceives themselves. Research has shown that exercise is essential to improve self-concept among victims of IPV. Moreover, a natural setting might help women with the process of contemplation and introspection needed along with psychological therapy. This study aims to evaluate the effectiveness of a psychosocial multicomponent program which combines psychosocial group therapy along with adventure activities with the aim of reinforcing IPV victims' self-concept.

### Who can participate?

Women victims of IPV, aged over 18, from the region of Extremadura (Spain)

### What does the study involve?

Participants are randomly allocated into two groups. The control group receive the usual assistance (psychological, economical) and resources available to the public institutions they attend. The intervention group receive the usual assistance available at the public institution they attend, and they will also attend the multicomponent program. The multicomponent program is designed as a program combining psychosocial therapy sessions and wilderness therapy sessions. These sessions will take about 4-6 hours over 8 weeks.

### What are the possible benefits and risks of participating?

Potential benefits will be the improvement of participants' self-esteem, self-concept, and general body image. The potential risks are minimal, and they are related to the participants' concerns about data confidentiality and potential physical risk performing the activities. It is important to highlight that professionals will be with women during the complete course of the therapy to minimise possible risks.

Where is the study run from?  
Valle de Jerte (Cáceres, Extremadura, Spain)

When is the study starting and how long is it expected to run for?  
September 2020 to August 2021

Who is funding the study?  
University of Extremadura (Spain)

Who is the main contact?  
Dr Gemma Sáez  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
2020/00418/001

## Study information

**Scientific Title**  
Wellness tourism in Valle del Jerte: self-concept program in victims of interpersonal violence. A natural activities pilot program based on a randomized controlled trial

**Study objectives**

H1: The multicomponent program will be feasible and useful in intimate partner violence victims  
H2. Participant in the experimental condition will increase their self-esteem compared to the control condition  
H3. Participant in the experimental condition will enhance their self-concept compared to the control condition  
H4. Participant in the experimental condition will improve their body image compared to the control condition  
H5. Participant in the experimental condition will increase their self-efficacy compared to the control condition

Added 04/03/2022:

H6: Participant in the experimental condition will decrease their depression compared to the control condition.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 10/12/2020, bioethics and biosafety committee of the University of Extremadura (Campus Universitario, Avda de Elvas, s/n 06071 - Badajoz, Spain; +34 (0)924 28 93 05; vrinvestigacion@unex.es), ref: 187//2020

### **Study design**

Single-blind randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Quality of life

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

Intimate partner violence victims

### **Interventions**

Participants will be randomly assigned to the intervention group (usual care + multicomponent program) or the control group (usual care) arm in a 1:1 ratio.

Assessment points for both arms will be screening, baseline, 1 month and 3 months post-intervention.

Updated 06/04/2021: Assessment points for both arms will be screening, baseline, immediately after the intervention program, 1 month and 3 months post-intervention.

Usual care arm: Those randomized to the control group will receive any usual assistance (psychological, economical) and resources available to the public institutions they attend.

Intervention arm: Those randomized to the intervention group will receive any usual assistance available at the public institution they attend, and they will attend the multicomponent program. The multicomponent program consists of 1 weekly 4-6 hour sessions during 8 weeks. Each session of the multicomponent program is composed of a psychosocial group intervention

and wilderness adventure therapy (prescriptive use of adventure experiences in a natural setting).

### **Intervention Type**

Mixed

### **Primary outcome(s)**

Self-esteem measured using the Rosenberg scale at baseline, immediately after the intervention, 1 month later and 3 months later

### **Key secondary outcome(s)**

1. Self-concept measured using AF5 Self-Concept at baseline, immediately after the intervention, 1 month later and 3 months later
2. Self-efficacy measured using the general self-efficacy scale at baseline, immediately after the intervention, 1 month later and 3 months later
3. Body image concerns measured using the Body Shape Questionnaire (BSQ) at baseline, immediately after the intervention, 1 month later and 3 months later
4. Depression measured using the Beck Depression Inventory, Second Edition (BDI-II), at baseline, immediately after the intervention, 1 month later and 3 months later
5. Attendance rate assessed by an attendance sheet which will allow the researchers to know the number of female participants from the experimental group that attended at least 80% of the intervention sessions; measured immediately after each intervention session

Added 29/04/2021:

6. The main experiences of the activities developed in the experimental group, assessed using open-ended interviews at the end of the intervention

### **Completion date**

16/08/2021

## **Eligibility**

### **Key inclusion criteria**

1. Women
2. Aged older than 18
3. Intimate partner violence
4. From Extremadura (region where the project is carried out)
5. Read and signed the written informed consent

### **Participant type(s)**

Other

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

33

**Key exclusion criteria**

1. Women without psychopathology diagnosis (depression, mental illness (schizophrenia or bipolar disorder), personality disorders and eating disorders)
2. Physical problems that do not allow the participant to do the physical activities
3. Spanish skills not sufficient to be able to communicate effectively with the study staff

**Date of first enrolment**

08/03/2021

**Date of final enrolment**

20/03/2021

**Locations****Countries of recruitment**

Spain

**Study participating centre**

The study is distributed through public resources that have contact with IPV victims (dependent of the IMEX, Womens institute of Extremadura), as well as associations belonging to FADEMUR (Federación de Asociación de Mujeres Rurales), which helps with participant recruitment

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**Sponsor information****Organisation**

University of Extremadura

**ROR**

<https://ror.org/0174shg90>

**Funder(s)****Funder type**

Government

## Funder Name

Research Initiation Project, subprogram Diputación de Cáceres

## 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 Gemma Sáez (gemmasaez@unex.es).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		02/05/2023	11/09/2023	Yes	No
<a href="#">Protocol article</a>	protocol	06/05/2021	09/08/2021	Yes	No