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

Submission date
19/01/2021

Recruitment status
No longer recruiting

Registration date
05/02/2021

Overall study status
Completed

Last Edited
12/09/2023

Condition category
Other

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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
Avda/De Portugal S/N. Pol Cepansa Nave, 1
Mérida
Spain
06800

Sponsor information

Organisation
University of Extremadura

ROR
https://ror.org/0174shg90

Funder(s)

Funder type
Government

Funder Name
Research Iniciation Proyect, 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?
Results article		02/05/2023	11/09/2023	Yes	No
Protocol article	protocol	06/05/2021	09/08/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes