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Therapeutic tourism program for women victims of gender violence

Submission date
07/09/2022

Recruitment status
No longer recruiting

Registration date
18/10/2022

Overall study status
Completed

Last Edited
24/07/2023

Condition category
Other

[_] 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
This project is a cost-effectiveness analysis of a program to improve the physical and psychological health of women victims of gender violence from a previous project where the Valle del Jerte was positioned as a therapeutic tourism destination.
Women who are victims of gender-based violence can suffer from disorders that affect their mental well-being and alter their physiological responses at the endocrine (hormone) and immune levels, which could give rise to situations of prolonged stress, anxiety disorders, or depression.
Therefore, the aims of this project are to give continuity to the program, again combining psychological therapy and adventure sports in the Valle del Jerte and adding new variables to measure the effects of stress, such as the production of hormones and substances related to stress (cortisol, dehydroepiandrosterone). In addition, the researchers intend to establish a cost-effectiveness analysis so that the program can be used with other vulnerable groups or mental health areas. The program will be disseminated in scientific, cultural, and social forums to promote the effectiveness of the program based on cognitive-behavioural therapy, adventure activities, nature, and clinical experimentation, always with the Valle del Jerte as a therapeutic-tourism destination.

Who can participate?
Women victims of intimate partner violence (IPV), aged over 18 years, from the region of Extremadura (Spain)

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

What are the possible benefits and risks of participating?
The potential benefits will be the improvement of participants' self-esteem, self-concept,

general body image, depression and regulation of hormonal levels. The potential risks are minimal, and they are related to the participants' concerns about data confidentiality and the potential physical risk of performing the activities. It is important to highlight that professionals will be with women during the complete course of the therapy to minimize 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 2021 to June 2022

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

Who is the main contact?
Dr Violeta Calle Guisado
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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
2022/00005/001

Study information

Scientific Title
Cost-effectiveness analysis of a program to improve the physical-psychological health of women victims of gender violence

Acronym
CostViolence

Study objectives
H1. The program will be a cost-effective intervention
H2. Participants in the experimental condition will improve their health-related quality of life compared to the control condition
H3. Participants in the experimental condition will enhance their self-concept body image and their self-efficacy compared to the control condition
H4. Participants in the experimental condition will get lower scores on questions related to depression compared to the control condition
H5. Participants in the experimental condition will improve their hormonal regulation (DHEA and cortisol) related to chronic stress compared to the control condition

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2022, 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
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

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
Intimate partner violence victims

Interventions
Participants will be randomized 1:1 to the intervention group (usual care + multi-component plan) or the control group (usual care). A research team member who will not be directly involved in the trial will create a simple computer-generated randomization sequence using the software Research Randomizer (Version 4.0, Urbaniak G.C. and Plous S., Middletown, CT, USA; http://www.randomizer.org [accessed on 20/04/2022]). The assignment will be hidden with a password-protected file. The researchers involved in the data analysis processes will not be aware of the group to which each woman will be assigned (experimental or control).

Scores for both groups were screening, baseline, and post-intervention.

The point of assessment for both groups was the screening baseline immediately after the intervention program.

General care group: Those randomly assigned to the control group received all conventional support (psychological, financial) and resources available to the public institution they attended.

Intervention group: Individuals randomly assigned to the intervention group will receive the usual support in the community facility they attend and participate in a multi-component program.

Each session of the multi-part course includes a group psychosocial intervention and wilderness adventure therapy (using a prescription for adventure experiences in a natural environment).

The multi-component program consists of 1 weekly 4-6 hour session for 4 weeks.

The Shapiro-Wilk test will be conducted to check the normality of data and choose between parametric or non-parametric statistical analyses. Socio-demographic continuous variables will be presented as mean (SD) or median (interquartile range) when appropriate, while categorical variables will be reported as proportions. Between-group differences at baseline will be analysed using independent samples tests. To evaluate the effects of the program, two types of analysis will be conducted. The effects of the intervention will be evaluated using a repeated-measures ANCOVA test, adjusted by age and baseline values. Cohen’s d effect size is 95% confidence interval and statistical significance for time and group interaction effects is group × time.
Data imputation will only be used if the reasons for missing data are not related to the exposure /outcome. All analyses will be conducted using the SPSS statistical package (version 26.0; SPSS, Inc., Chicago, IL, USA). The significance level will be set at 0.05.

Intervention Type
Mixed

Primary outcome measure
Incremental cost-effectiveness ratio measured using EQ-5D-5L questionnaire for cost-effectiveness analysis at baseline and the first week after the last session of the intervention

Secondary outcome measures

1. Sociodemographic variables: sociodemographic data sheet and history of gender violence at baseline, in the first interview with participants.
2. Self-efficacy measured using the general Baessler and Schwarzer General Self-Efficacy Scale at baseline and immediately after the last session of the intervention
3. Self-esteem measured using the Rosenberg Self Esteem Scale (1965) at baseline and immediately week after the last session of the intervention
4. Body image concerns measured using the Body Shape Questionnaire (BSQ) at baseline and immediately after the last session of the intervention
5. Depression measured using the Beck Depression Inventory, Second Edition (BDI-II) at baseline and immediately after the last session of the intervention
6. Stress condition measured using the Perceived Stress Test (PSS) at baseline and immediately after the last session of the intervention
7. Stress hormonal levels measured by analysis of glucocorticoids, inflammatory and biochemical factors and using a saliva test to evaluate cortisol and the hormone DHEA, at baseline and during the first week after the last session of the intervention
8. 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

Overall study start date
01/09/2021

Completion date
28/06/2022

Eligibility

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

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
24

Total final enrolment
22

Key exclusion criteria
1. Participants with comorbidity with other psychological problems such as depressive disorder, severe mental disorder (schizophrenia or bipolar disorders), personality disorders, and eating disorders such as anorexia or bulimia will be excluded. These psychological problems require interventions that are more specific to their nature.
2. Participants with comorbid physical problems that prevent them from carrying out adventure activities in nature
3. Women who do not know the Spanish language enough to hold a conversation
4. Patients with diabetes or cardiovascular pathology with medication or metformin will be excluded, since the results of the analyzes of the physiological variables may vary

Date of first enrolment
26/03/2022

Date of final enrolment
19/04/2022

Locations

Countries of recruitment
Spain

Study participating centre
IMEX
C. San Salvador, 9
Mérida
Spain
06800

Study participating centre
Malvaluna Association
C, Anas
Mérida
Spain
06800

Study participating centre
Casa de la mujer de Badajoz
C. Federico Mayor Zaragoza, 181
Badajoz
Spain
06006

Study participating centre
Equipo de Promoción de la mujer
Estación de Autobúses
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/0174shg90

Funder(s)

Funder type
Government

Funder Name
Research Iniciation Proyect, subprogram Diputación de Cáceres

Results and Publications

Publication and dissemination plan
1. Additional documents not available, planned publication of protocol
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
20/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Violeta Calle Guisado (violetacg@unex.es). For the randomization process please contact Daniel.collado@urjc.es. The data will be available for 2 years. All data have been registered since July 2022 (when laboratory experiments were performed). Data have not been analysed yet. The data from the measures mentioned are continuous or categorical variables. The data were coded to be fully anonymised, so all research groups could work with the data for analysis. Only Violeta Calle Guisado knows the code and keeps the originals safe. Participants voluntary contacted the principal researcher and, when the process was explained, they signed a consent sheet with all details of the project. Also, the consent signed sheets have been saved.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/02/2023	13/03/2023	Yes	No