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Program to improve the quality of life due to unwanted loneliness in widowed women. Nature, an ally to accompany you

Submission date
10/07/2024

Recruitment status
No longer recruiting

Registration date
12/02/2025

Overall study status
Completed

Last Edited
12/02/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This project aims to combine tourism with the unique features of the Jerte Valley as a therapy to combat loneliness. It involves a series of nature-based activities that will position the Jerte Valley as a specialized tourist destination in therapeutic tourism, understood as tourism that aims to improve and maintain general health and specifically address loneliness, enhancing aspects that are impacted by this situation, such as quality of life, self-concept, resilience, etc. Particularly, this project addresses the issue of unwanted solitude among elderly widowed women, recognizing solitude in women as one of the social problems with the highest incidence and risk of social isolation, worsening the morbidity and mortality among women. Through a program of nursing interventions with other health agents and specialists in loneliness, we have developed a multi-component program based on therapeutic tourism. The main objectives of the presented project are to conduct a pilot experience of therapeutic tourism in the Jerte Valley and to analyse the efficacy of a multi-component program that combines nursing interventions, support from loneliness specialists, social anthropology, and psychology, along with nature activities, to foster socialization and improve the quality of life for these women. Lastly, the expected results of the program are the implementation of a pilot experience of therapeutic tourism in the Jerte Valley that could be generalizable to other vulnerable groups requiring special attention to the recovery of socialization. The study will involve the dissemination, in scientific, and cultural forums, and to the national loneliness observatory, of the program's efficacy.

Who can participate?
Women between the ages of 60 and 85 years old who live independently in the community and have feelings of loneliness

What does the study involve?
This study will:
SO1: Evaluate the variables of loneliness, despair, and quality of life before the intervention of the control group and the experimental group to establish the baseline.
SO2: Nursing interventions with emotional support in the experimental group over 6 weekends,

with the first four weekends being consecutive, taking a break on the fifth weekend, and then resuming for two more consecutive weekends, totaling 48 hours of interventions received by the end of the program.
SO3: Assess the variables of loneliness, despair, and quality of life after the completion of the intervention program.
SO4: Evaluate the intervention variable in both groups (control and experimental) one month after the intervention's completion to analyze the long-term maintenance of the results.
SO5: Disseminate the pilot experience of therapeutic tourism in the Jerte Valley through Conferences on therapeutic tourism in the Jerte Valley and the prevention of unwanted loneliness, reporting of scientific articles, and a documentary of the experience.

What are the possible benefits and risks of participating?
Benefits include being able to socialize as well as create support networks, and tools to combat loneliness and increase the quality of life. The study does not involve risks, the accompaniment of these women is fundamental, the group of professionals who will develop the interventions are trained to accompany and resolve any situation that may arise.

Where is the study run from?
University of Extremadura

When is the study starting and how long is it expected to run for?
January 2024 to September 2024

Who is funding the study?
The Diputación de Cáceres

Who is the main contact?
Belinda Basilio Fernández, bbasfer@unex.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocolo 1

Study information

Scientific Title
A multicomponent program to improve the quality of life of widowed women with unwanted loneliness: a study protocol for a pilot randomized controlled trial

Study objectives
Multicomponent intervention to improve the quality of life in widowed women with unwanted loneliness

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/03/2024, Bioethics and Biosecurity Commission of The University of Extremadura (Comisión de Bioética y Bioseguridad de la Universidad de Extremadura) (C/ Elvas s/n., Badajoz, 06006, Spain; +34 924289300; irocha@unex.es), ref: 46/2024

Study design
Prospective cohort randomized controlled trial (RCT) with a mixed approach

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Quality of life related to unwanted loneliness in widows

Interventions
This study will be carried out in the province of Cáceres, taking the population of widowed women. The sample size has been calculated using data from a previous study considering the mean and standard deviation of the UCLA Loneliness Scale-Revised standard deviation of the UCLA Loneliness Scale-Revised (UCLA LS-R) in women over 65 years of age. Because no studies defined the minimum clinical change it has been set at 4 points, it would require a minimum of 25 participants per group (50 in total) with a power of 80%, an α value of 0.05 and an estimated loss rate of 20%. To perform this calculation, an online sample calculator an online sampling calculator was used to perform this calculation. A member of the research team who will not be directly involved in the trial will create a simple computer-generated randomization sequence using Research Randomizer software (Version 4.0, Urbaniak GC and Plous S., Middletown, CT,

USA; http://www.randomizer.org). The assignment will be hidden with a password-protected file. Researchers involved in the data analysis processes will not know to which group each woman will be assigned (experimental or control).

Intervention
Both the experimental group (regular users + multicomponent program) and the control group (regular users) will undergo pre-intervention, post-intervention and follow-up phases for 1 month. The difference between the two groups lies in the fact that the participants in the experimental group will be the only ones who will undergo the intervention based on a multicomponent psychosocial program.

The intervention program will be composed of 6 sessions that will be carried out on 4 continuous weekends beginning in April. They will consist of outings to the Jerte Valley to participate in therapeutic tourism. The sessions will be divided into a therapeutic component (first part of the session) with at least two members of the team and up to 4 maximum, who are professionals in the field of nursing, with experience in the field of bereavement and work with women. The second component of the session (second part of the part of the session) will be focused on the realization of sports in nature led by experts in the field and supported by the team and its accompaniment.

Intervention Type
Behavioural

Primary outcome(s)
The following primary outcome measures will be assessed before and after the intervention (in the control group, at the beginning and the end of the program):
1. Sociodemographic variables (age, educational level, socioeconomic status, whether living alone, etc.) measured using a sociodemographic data sheet during the study
2. Experiences regarding loneliness and the experience of the intervention measured using semi-structured interviews
3. Feeling of loneliness measured using a focus group with the experimental group
4. Loneliness measured using the University of California Loneliness Scale
5. Health status and well-being measured using the EQ5-5D-5L HRQoL (health-related quality of life) measurement instrument
6. HRQoL measured using the SF-12
7. HRQoL measured using the 5-D
8. HRQoL measured using the AQOL-8D
9. Hopelessness measured using the Beck Hopelessness Scale
10. Depression measured using the Yesavage Depression Scale
11. Physical activity during the last 7 days measured using the International Physical Activity Questionnaires (IPAQ)

Key secondary outcome(s))
Interpretation of the participant's change in quality of life will be measured using the interview transcriptions during the study's qualitative research

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Be a woman between the ages of 60 and 85 years old
2. Living independently in the community
3. Feelings of loneliness

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
85 years

Sex
Female

Key exclusion criteria
1. Comorbidity with other mental health problems such as severe mental disorders (schizophrenia or bipolar disorders), personality disorders, dementias, and major depressions
2. Comorbidity of physical problems that prevent them from performing adventure activities in nature, such as severe musculoskeletal injuries
3. Women who do not know the Spanish language well enough to hold a conversation

Date of first enrolment
26/02/2024

Date of final enrolment
21/03/2024

Locations

Countries of recruitment
Spain

Study participating centre
University for Seniors - Democratic Union of Pensioners- Jerte Valley Commonwealth- Ambroz Valley Commonwealth - Vera Commonwealth
Avenida Virgen del Puerto,2
Plasencia
Spain
10600

Sponsor information

Organisation
University of Extremadura

ROR
https://ror.org/0174shg90

Funder(s)

Funder type
Government

Funder Name
Diputación Provincial de Cáceres

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			11/07/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes