ISRCTN65217320 https://doi.org/10.1186/ISRCTN65217320

Using an arts-based program to reduce mental-health-related stigma in young people

Submission date
26/04/2024

Recruitment status
No longer recruiting

Registration date
02/05/2024

Overall study status
Completed

Last Edited
15/08/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The stigma surrounding mental health remains a significant barrier to help-seeking and well-being in youth populations. The invisibility of mental health issues highlights the critical need for improved knowledge and stigma reduction, underscoring the urgency of tackling this issue. Arts-based interventions have shown promise in addressing stigma, yet comprehensive longitudinal studies in community settings are limited. This research evaluates the "WeARTolerance'' arts-based program in reducing mental-health-related stigma among diverse youths.

Who can participate?
Teenagers and young adults aged between 11 and 24 years old who speak Portuguese, live in Portugal and are willing to participate in an arts-based program

What does the study involve?
Participants are randomly assigned to one of eight smaller groups according to age and developmental level (teenagers: 11-16 years old and young adults: 17-24 years old). The program consists of 12 sessions over four sequential full days. Each of the four days starts with a psychoeducational session led by the psychology team, followed by two sessions among visual arts, cinema, music, and theatre sessions, one in the morning and the other in the afternoon. Participants will be assessed using questionnaires at three time points (the week before the program, the week after the program and six months after the program).

What are the possible benefits and risks of participating?
Participants benefit from the group sessions and have the opportunity to reflect and increase knowledge about mental health and mental-health-related stigma using an arts-based approach. No risks are anticipated from participation in the program.

Where is the study run from?
Lusófona University, Lisbon, Portugal.

When is the study starting and how long is it expected to run for?
October 2022 to June 2024

Who is funding the study?
“la Caixa” Foundation (Portugal)

Who is the main contact?
Ana Beato, ana.beato@ulusofona.pt

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Ana Beato

ORCID ID
https://orcid.org/0000-0003-3177-3578

Contact details
Universidade Lusófona, Campo Grande 380
Lisbon
Portugal
1700-097
+351 967482475
ana.beato@ulusofona.pt

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
LCF/PR/SR22/52570002

Study information

Scientific Title
WeARTolerance: evaluating the impact of an arts-based program to reduce mental health-related stigma among teenagers and young adults in Portugal, employing a mixed-method study in two phases

Acronym
WeARTolerance

Study objectives

The arts-based program will increase the knowledge about mental health and decrease the social stigma related to mental health, intergroup anxiety towards individuals with mental health conditions and desire for social distance from individuals with mental health conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/03/2023, Ethics and Deontology Committee of the Psychology and Life Sciences of Lusófona University (Campo Grande, 376, Lisbon, 1749-024, Portugal; +351 217 515 500; ilind@ulusofona.pt), ref: CEDIC-2023-09-09

Study design
Mixed-method explanatory nested-design combining qualitative and quantitative methods study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Redution of mental-health-related stigma in young people

Interventions
After recruitment, participants will be randomly assigned to one of eight smaller groups based on age and developmental level: teenagers aged 11-16 and young adults aged 17-24. The allocation to groups will ensure a balanced representation of participants with mental health conditions. The program, designed to fit within official school vacations, will consist of 12 sessions spread over four consecutive full days.

Questionnaires, administered via Qualtrics, will be distributed at three intervals: one week before the program (T1: Baseline), one week post-program (T2: Post-intervention), and six months post-program (T3: Follow-up).

Participants will be randomly assigned to treatment groups using simple randomization (i.e., random number generators), ensuring no specific pattern or stratification. The intervention group will receive the active intervention, either one or two months after enrollment. The control group will consist of participants on the waiting list, who will not receive intervention during the assessment period but will eventually access the intervention.

This design will involve four intervention groups and four control groups, each undergoing the same questionnaire administration at the three time points. The intervention sessions, facilitated by psychology and arts teams, will cover psychoeducational and artistic activities (i.e., visual arts, cinema, music and theatre). Additionally, select participants from the intervention groups will engage in focus groups to provide qualitative insights into their perceptions and satisfaction with the program.

Intervention Type
Mixed

Primary outcome(s)
Social stigma measured using the Attribution Questionnaire-9 (AQ-9) for adults and AQ-8-C for children and adolescents in the week before the program (T1: Baseline), the week after (T2: Post-intervention) and six months after the program (T3: Follow-up)

Key secondary outcome(s))
The following secondary outcome measures will be assessed in the week before the program (T1: Baseline), the week after (T2: Post-intervention) and six months after the program (T3: Follow-up):
1. Knowledge of mental health measured using the Mental Health Knowledge Schedule (MAKS)
2. Social distance measured using the Social Distance Scale
3. Intergroup anxiety measured using the Intergroup Anxiety Scale

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. 11 to 24 years old; for participants aged under 18 years, it was also a criterion to have their legal guardian’s formal authorisation to participate
2. Speak Portuguese
3. Live in Portugal
4. Willing to participate in an arts-based program

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
11 years

Upper age limit
24 years

Sex
All

Total final enrolment
151

Key exclusion criteria
Significant cognitive, motor, and speech impairments that might hinder the completion of the activities

Date of first enrolment
01/03/2023

Date of final enrolment
11/06/2023

Locations

Countries of recruitment
Portugal

Study participating centre
HEI-Lab - Universidade Lusófona
Campo Grande 380
Lisbon
Portugal
1700-097

Sponsor information

Organisation
Universidade Lusófona

ROR
https://ror.org/05xxfer42

Funder(s)

Funder type
Charity

Funder Name
'la Caixa' Foundation

Alternative Name(s)
Caixa Foundation, Fundación Caixa, 'la Caixa', Fundación Bancaria Caixa d'Estalvis i Pensions de Barcelona, Fundación 'la Caixa', Fundação 'la Caixa', Fundación Bancaria Caixa d'Estalvis i Pensions de Barcelona, 'la Caixa'

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during the study will be stored in a publicly available repository: https://osf.io/hwrka/?view_only=b52e2475c9b145eda84d140188ee8102. The full dataset with all coded variables is available.

In this randomized controlled trial (RCT) we incorporate surveys and focus groups, corresponding to various types of data, collected to evaluate the effectiveness, acceptability, and impact of interventions: (a) Survey Data, used to collect quantitative data on various aspects related to the intervention, outcomes, and participant characteristics (ex. demographic information; baseline measures: pre-existing conditions; outcome measures, such as changes in behavior, attitudes, knowledge, etc., before and after the intervention; adherence and satisfaction with the program and sessions provided. (b) Focus Group Transcripts: Focus groups are used to gather qualitative data through facilitated discussions among participants. Data stored from focus groups were: Transcripts: Verbatim records of the discussions, capturing participants' perspectives, experiences, and opinions related to the intervention; themes and patterns: Analysis of the transcripts to identify recurring themes, patterns, or insights relevant to the research questions; Quotes and excerpts; Audio or Video Recordings stored to ensure accuracy in capturing participants' responses and non-verbal cues. (c) Quantitative Analysis Results, including descriptive statistics, inferential tests (e.g., t-tests, ANOVA), and regression analyses stored along with relevant summary tables and figures. (d) Qualitative Analysis Results, such as thematic coding matrices, summaries of themes and subthemes, and illustrative quotes, are stored to support qualitative interpretations and conclusions. (d) Documentation and Administrative Data, including documentation related to the conduct of the trial, such as informed consent forms, study protocols, ethics approvals, and participant recruitment and retention records. (e) Data Management Documentation (i.e., information on data handling procedures, data cleaning, coding schemes, and data storage protocols to ensure data integrity and compliance with regulatory requirements).

It is expected that most datasets, scripts and excerpts might be publicly available. Further material will be provided by the team after justified requests (e.g., survey data; transcripts). The program Toolkit will be soon protected by copyright. Any file containing personal or identifiable data will be shared (e.g., contacts, audio files, video files). Outputs stored in repositiitiums with open access will be available for reuse without time restrictions (e.g., databases attached in publications). Written informed consent forms were signed by parents and minors before the intervention. Oral consents were obtained from all parties to participate in the focus groups. Each participant had a code and all the questionnaires were filled using that code in all phases. In the excerpts of focus groups, we used no names or identifiable descriptors.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			15/08/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes