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Feasibility, effectiveness and experiences of creativity workshops for young adults with anxiety and depression

Submission date
26/05/2022

Recruitment status
No longer recruiting

Registration date
09/06/2022

Overall study status
Completed

Last Edited
11/11/2024

Condition category
Mental and Behavioural Disorders

[ ] 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
Anxiety and depression are frequent among young adults in deprived areas of large cities in Latin America. However, findings suggest that about 50% of affected adolescents recover after 1 year. This raises the question as to which personal and social resources they use and help them to overcome the episodes of mental distress. The OLA study includes a longitudinal cohort study addressing the above question and assessing potentially helpful activities such as participation in music groups. However, the design of the cohort study is observational and does not involve an experimental variation of activities. The researchers will conduct a trial within a cohort study where young adult participants in Buenos Aires (Argentina) and Lima (Peru), already participating in the OLA longitudinal cohort study, will randomly be assigned to a control group or a creativity workshop (intervention group). Thus, the trial will test the feasibility, effectiveness, and experiences of a creativity workshop in reducing symptoms of anxiety and/or depression in young adults in Buenos Aires and Lima. Whilst there is evidence for the effectiveness of art therapy groups, this trial tests the helpful potential of creativity workshops that have not been designed as therapy and could be more appealing to young adults.

Who can participate?
Young adults (20-24 years old when recruited for the cohort) who are already enrolled in the longitudinal cohort study, with symptoms of anxiety and/or depression at the start of the study and 6-month follow-up.

What does the study involve?
The creativity workshop will follow a program developed and led by Crear Vale la Pena (Buenos Aires) and Teatro La Plaza (Lima), offering an opportunity for youths to explore the concerns of young people at times of transition and the learnings from it. There will be a total of four workshops across the two sites: two in Buenos Aires and two in Lima, with 15 participants in each workshop. Each workshop will include a total of three in-person sessions, each lasting about 2-3 hours with a break.
Young adults who participated in the 6-month follow up, as part of the OLA longitudinal cohort study, and still reported symptoms of anxiety and/or depression will be randomly selected and

allocated to the creative workshop (intervention group); the remaining participants in the OLA study will be the control group.
Before the first workshop, participants will complete questionnaires. After the end of the intervention, participants will complete the questionnaires again and answer five open-ended exit questions about what they enjoyed and disliked, what they found helpful and unhelpful in the workshop and in what way – if any – they may benefit from them.

What are the possible benefits and risks of participating?
This study will aim to provide evidence on whether arts activities in the community reduce the mental distress of young adults. It will also build research capacity within Argentina and Peru and foster collaboration between established universities and arts organizations. A potential benefit for participants involved in the research is that they will be enabled to participate in creativity activities which otherwise might be difficult to access and that their suggestions and experiences might be incorporated into further adaptations, which will tailor the intervention to their needs.

Where is the study taking place?
The study will take place in Buenos Aires (Argentina) and Lima (Peru). Queen Mary University of London (UK) is the coordinating centre with local researchers from Universidad de Buenos Aires and Universidad Peruana Cayetano Heredia taking accountability for the research activities conducted in their countries.

When is the study starting and how long is it expected to run for?
December 2021 to October 2023

Who is funding the study?
1. Medical Research Council (UK)
2. Global Challenges Research Fund (UK)

Who is the main contact?
1. Prof. Stefan Priebe (UK), stefan.priebe2@nhs.net
2. Dr Luis Brusco (Argentina), lbrusco@fmed.uba.ar
3. Mr Francisco Diez-Canseco (Peru), fdiezcanseco@upch.pe
4. Ms Liliana Hidalgo (Peru), liliana.hidalgo.p@upch.pe

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
MR/S03580X/1

Study information

Scientific Title
Feasibility, effectiveness and experiences of creativity workshops for young adults with anxiety and depression: protocol for Trial Within a Cohort Study as part of the research programme: 'Building resilience and resources to reduce depression and anxiety in young people from urban neighborhoods in Latin America (OLA)'

Study objectives
The specific research questions are:
1. How effective are creativity workshops in reducing symptoms of anxiety and/or depression in young adults?
2. How feasible are creativity workshops as an intervention for young adults with anxiety and/or depression?
3. How are creativity workshops experienced by young adult participants?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/05/2022, Institutional Research and Ethics Committee of the Universidad Peruana Cayetano Heredia(Av. Honorio Delgado 430, San Martín de Porres, Apartado postal 4314, Lima, Peru; +51 (0)319 0000 Anexo 201302; duict.cieh@oficinas-upch.pe), ref: CONSTANCIA 187-18-22
2. Approved 24/08/2022, Ethics Committee of the School of Medicine of the Universidad de Buenos Aires, Buenos Aires, Argentina (Paraguay 2155 - 1° Piso M1- Decanato - Secretaría de Ciencia y Técnica, C1121A6B - Ciudad A. de Bs As; +54 (11) 528-52954 / 52955; comitedeetica@fmed.uba.ar)

Study design
Trial Within a Cohort study (TWIC)

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Young adults with symptoms of depression and anxiety

Interventions
A TWIC is nested within a large cohort study that recruited participants with the condition of interest and follows them up over a period of time. Participants from this cohort are then selected as participants for the RCT to evaluate an intervention. Outcomes for the whole cohort are measured repeatedly, providing longitudinal information about the progression of the condition both for participants in the control group and those having the trial intervention.

All participants in the young adult cohort in Buenos Aires and Lima who still have symptoms of anxiety and/or depression at the 6-month follow-up of the longitudinal cohort study and meet the eligibility criteria will be included in the trial. They will then be randomly assigned to the control group (no treatment) or creativity workshop (intervention group). A researcher from the QMUL team, but not involved in the TWIC or OLA project, will perform the randomization.

There will be a total of four workshops across the two sites: two in Buenos Aires and two in Lima, with 15 participants in each workshop. The creativity workshops will follow a programme developed, practiced and led by Crear Vale La Pena (Buenos Aires) and Teatro La Plaza (Lima). They will draw from different artistic disciplines and methodologies such as theatre, poetry, movement, visual arts and music to explore the concerns of young people at times of transition and the learnings from it. Each workshop will include a total of three in-person sessions, each lasting approximately 2-3 hours with a break.

Intervention Type
Other

Primary outcome(s)
Self-rated depression/anxiety symptoms measured using the Patient Health Questionnaire (PHQ-8) and the Generalised Anxiety Disorder Assessment (GAD-7) questionnaire at the 12-month follow-up rating in the cohort study, adjusted for the 6-months follow-up scores in the cohort study, of both the intervention and control group, supplemented with pre-post intervention changes (PHQ-8 and GAD-7 scores before and after the 3-week intervention)

Key secondary outcome(s))
1. Feasibility assessed by acceptance of workshop participation and attendance of workshop sessions at the end of the 3-session workshop
2. Experiences assessed by exit questionnaire responses expressed after the end of the intervention

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Young adults (20-24 years old when recruited for the cohort) who have symptoms of anxiety and/or depression at baseline and 6-month follow-up
2. Capacity to provide informed consent (intervention group only)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
24 years

Sex
All

Total final enrolment
82

Key exclusion criteria
1. Participants who at present already regularly attend organised creative (e.g. theatre, circus, dancing, drama) activities (based on baseline assessment)
2. Participants who expressed no interest in participating in any arts activities (based on baseline assessment)

Date of first enrolment
11/05/2022

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Argentina

Peru

Study participating centre
Facultad de Medicina, Universidad de Buenos Aires
Paraguay 2155, Ciudad Autónoma de Buenos Aires
Buenos Aires
Argentina
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Study participating centre
CRONICAS Center of Excellence in Chronic Diseases, Universidad Peruana Cayetano Heredia
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Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Global Challenges Research Fund

Alternative Name(s)
The Global Challenges Research Fund (GCRF), The Global Challenges Research Fund, GCRF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
After the publication of the main findings, the researchers will operate an open data policy, following the FAIR principles e.g. Findable, Accessible, Interoperable, and Reusable. The anonymized datasets generated during and/or analyzed during the current study will be available from the PI (Stefan Priebe: stefan.priebe2@nhs.net) and the local PIs (Luis Brusco: lbrusco@fmed.uba.ar, and Francisco Diez Canseco, fdiezcanseco@upch.pe) on reasonable request.

During the course of the study, data will be shared internally within the study using an online data collection platform called REDCap. The method for sharing the data externally (if required and only after the publication of the findings that reflect the given data) will be decided in due course. Informed consent will be obtained from all participants involved in the study.

All participants are assigned a participant ID at the point of enrolment and all subsequent data collected will be linked to this ID, without any link to identification data following Good Clinical Practice. The de-identified data generated during and/or analysed during the current study will be shared, for e.g. in online databases, for research purposes upon reasonable request from the PI (Stefan Priebe: stefan.priebe2@nhs.net) and the local PIs (Luis Brusco: lbrusco@fmed.uba.ar, and Francisco Diez Canseco: fdiezcanseco@upch.pe) and depending on a data sharing agreement. Informed consent regarding further sharing of de-identified data for future research purposes is obtained from all participants at the point of enrolment in the cohort. Informed consent for participation in creative workshops will be obtained from all participants assigned to the intervention group of the trial within the cohort. During the course of the study, data will be shared internally within the study using an online data collection platform called REDCap. The type of data will be qualitative and quantitative.

Research data will be retained and archived in accordance with the Research Governance Framework and IM&T Information and security policies. Records will be archived as per Queen Mary University of London procedures and kept for 20 years. The study PI (Priebe) will be the custodian of the data. The data collected in Peru will also be stored at the main study site in Universidad Peruana Cayetano Heredia, and Francisco Diez Canseco will be custodian of these data. The data collected in Argentina will also be stored at the main study site in Universidad de Buenos Aires, and Luis Brusco will be custodian of these data. This will be done according to the regulation for data storage and protection at Universidad Peruana Cayetano Heredia and Universidad de Buenos Aires, respectively.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	12/04/2022	06/06/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes