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Feasibility, effectiveness, and experiences of music workshops for adolescents with anxiety and depression

Submission date
18/03/2022

Recruitment status
No longer recruiting

Registration date
21/04/2022

Overall study status
Completed

Last Edited
03/12/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Anxiety and depression are frequent among adolescents in deprived areas of large cities in Latin America. However, findings suggest that about 50% of affected adolescents recover after one 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 (ISRCTN99961401) 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.

We will conduct a trial within a cohort study, where adolescents in Bogota (Colombia) already participating in the OLA longitudinal cohort study will randomly be assigned to either attend a music workshop or no additional treatment. The trial will test the feasibility, effectiveness, and experiences of a music workshop in reducing symptoms of anxiety and/or depression in adolescents in Bogota (Colombia). Whilst there is evidence for the effectiveness of music therapy groups, this trial tests the helpful potential of music groups that have not been designed as therapy and could be more appealing to adolescents.

Who can participate?
Adolescents who are already enrolled in the OLA longitudinal cohort study (aged 15-16 years old at the time of initial recruitment), with symptoms of anxiety and/or depression at recruitment to the OLS study and the study's 6-month follow-up.

What does the study involve?
The music workshop will follow a program developed and practiced by Fundación Batuta, offering an opportunity for adolescents to learn, practice, and enjoy music using simple musical repertoires that will allow them to develop listening, rhythmic, and singing skills, and the creative ability to make their own musical piece. The workshop will consist of a total of five sessions, each session lasting approximately 90 min, once per week, for five weeks.

40 adolescents (15-16 years old) who participated in the 6-month follow up for the OLA longitudinal cohort study and still reported symptoms of anxiety and/or depression will be randomly selected and allocated to attend the music workshop (intervention group); the remaining participants in the OLA study will not receive any additional treatment (control group).

Before the first workshop, participants will complete questionnaires about their experiences of symptoms of anxiety and depression. At the end of the music workshop program, participants will again complete the questionnaires 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 benefited from the workshops.

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 adolescents. It will also build research capacity within Colombia and foster collaboration between an established university and a community music organization. A potential benefit for participants involved in the research is that they will be enabled to participate in musical 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.

We do not foresee any significant ethical, legal, or management issues arising from this study.

Where is the study run from?
The study will take place in Bogotá, the capital city of Colombia. Queen Mary University of London (UK) is the coordinating centre with local PI from Pontificia Universidad Javeriana (Colombia) assuming responsibility for research activities in their country.

When is the study starting and how long is it expected to run for?
From December 2021 to July 2022

Who is funding the study?
The Medical Research Council (UK) and Global Challenges Research Fund (UK)

Who is the main contact?
Natalia Godoy Casasbuenas: natalia.godoy@javeriana.edu.co
Dr Carlos Gómez-Restrepo: cgomez@javeriana.edu.co
Professor Stefan Priebe: stefan.priebe2@nhs.net

Contact information

Type(s)
Principal Investigator

Contact name
Dr Carlos Gómez-Restrepo

ORCID ID
http://orcid.org/0000-0002-9013-5384

Contact details

Cra. 7 # 40-62
Bogotá
Colombia
110231
+57 601 3208320 ext 2770
cgomez@javeriana.edu.co

Type(s)
Principal Investigator

Contact name
Prof Stefan Priebe

ORCID ID
https://orcid.org/0000-0001-9864-3394

Contact details
Newham Centre for Mental Health, London E13 8SP
London
United Kingdom
E13 8SP
+44-(0)20-75404210
stefan.priebe2@nhs.net

Type(s)
Scientific

Contact name
Dr Natalia Godoy -Casasbuenas

ORCID ID
http://orcid.org/0000-0002-1262-6436

Contact details
Cra. 7 # 40-62
Bogota
Colombia
110231
+57 3185581201
natalia.godoy@javeriana.edu.co

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MR/S03580X/1

Study information

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

Study objectives
1. How effective is the music workshop in reducing symptoms of anxiety and/or depression in adolescents?
2. How feasible are music workshops as an intervention for adolescents with anxiety and/or depression?
3. How is the music workshop experienced by adolescent participants?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2022, the Pontificia Universidad Javeriana Faculty of Medicine Institutional Research and Ethics Committee (Comité de Investigaciones y Ética Institucional (CIEI), Carrera 7a # 40-62, Piso 2, Bogotá, Colombia; +57-1 3208320 ext.2770; ciei@husi.org.co), ref: FM-CIE-0097-22

Study design
Randomized controlled Trial Within a Cohort study (TWIC)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

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

Interventions

This Trial Within a Cohort study (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 adolescent cohort in Bogota 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 music workshop (intervention group).

There will be a total of two music workshops taking place, following the same programmme that is developed and practiced by Fundación Batuta. The programme will offer an opportunity for adolescents to learn, practice and enjoy music using simple musical repertoires that will allow them to develop listening, rhythmic and singing skills, and the creative ability to make their own musical piece Each workshop will include a total of five sessions, each lasting approximately 90 min with a potential break. The workshops will take place once a week, for five weeks. Each workshop will be led by a music teacher and a logistics support staff, from Fundación Batuta.

Before the first workshop, participants will complete the patient health questionnaire (PHQ-8) and the generalised anxiety disorder assessment (GAD-7) questionnaire. After the end of the intervention, participants will again complete the PHQ-8 and GAD-7 questionnaires 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.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 14/02/2024:
Effectiveness measured using self-rated depression/anxiety symptoms by the patient health questionnaire (PHQ-8) and the generalised anxiety disorder assessment (GAD-7) questionnaire at the beginning (baseline) and five (5) weeks

Previous primary outcome measure as of 06/05/2022 to 14/02/2024:
Effectiveness measured using the patient health questionnaire (PHQ-8) and the generalised anxiety disorder assessment (GAD-7) questionnaire at 12-months follow-up, adjusted for the 6-months follow-up scores, of intervention and control group, supplemented with pre-post intervention changes (baseline and 5 weeks) of self-rated depression/anxiety symptoms as measured by PHQ-8 and GAD-7

Previous primary outcome measure:
Effectiveness measured using the patient health questionnaire (PHQ-8) and the generalised anxiety disorder assessment (GAD-7) questionnaire at baseline and 5 weeks

Secondary outcome measures
1. Feasibility measured using the acceptance of workshop participation and attendance of workshop sessions at 5 weeks
2. Experiences measured using open-ended exit questions at 5 weeks

Overall study start date
01/12/2021

Completion date
24/06/2022

Eligibility

Key inclusion criteria
All participants:
1. Enrolled in the OLA longitudinal cohort study
2. Aged 15-16 years when recruited to the OLA study
3. Symptoms of anxiety and/or depression at baseline and 6-month follow-up during the OLA study

Intervention group only:
1. Capacity to provide assent
2. Informed consent provided by a parent/guardian

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40

Total final enrolment
35

Key exclusion criteria
1. Already regularly participate in a music band/orchestra, or have advanced music skills as determined during baseline assessment
2. Expressed no interest in participating in any arts activities during baseline assessment

Date of first enrolment
07/05/2022

Date of final enrolment
14/05/2022

Locations

Countries of recruitment
Colombia

Study participating centre
Pontificia Universidad Javeriana
Carrera 7a # 40-62
Bogota
Colombia
110211

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Mile End Road
London
England
United Kingdom
E1 4NS
+44 (0)20 7882 5555
jrmo-helpdesk-smdpostaward@qmul.ac.uk

Sponsor type
University/education

Website
https://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

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

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Global Challenges Research Fund

Alternative Name(s)
GCRF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The aim of the dissemination activities will be to communicate findings in order to inform research, policy and practice. Target audiences include (but are not restricted to) adolescents and young people, policymakers, service managers, NGOs, education, health and youth organisations, charities and the public. Dissemination activities that we are already doing as part of the main OLA study, will also be used to disseminate the results from the TWIC (i.e. OLA study website, social media platforms, newsletter etc.).

Intention to publish date
01/09/2024

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 CI (Stefan Priebe: stefan.priebe2@nhs.net) and the local PI (Carlos Gomez-Restrepo: cgomez@javeriana.edu.co) 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 CI (Stefan Priebe: stefan.priebe2@nhs.net) and the local PI (Carlos Gomez-Restrepo: cgomez@javeriana.edu.co) 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 music 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 CI (Priebe) will be the custodian of the data. The data collected in Colombia will also be stored at the main study site in Pontificia Universidad Javeriana, and Dr Carlos

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	09/02/2022	04/04/2022	No	No
Results article		02/12/2024	03/12/2024	Yes	No