Feasibility, effectiveness and experiences of music workshops for adolescents 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 neighbourhoods in Latin America (OLA)'

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Study CI: Prof Stefan Priebe (Queen Mary University of London, UK)

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Committees	Programme Management Group (co-applicants), Overall Steering Group, Lived Experience Advisory Group

Study summary

Study title	Feasibility, effectiveness and experiences of music workshops for adolescents with anxiety and depression
Subtitle	Trial Within a Cohort study
Study design	Trial Within a Cohort (TWIC) study – an exploratory trial
Summary of research activities	The OLA Project is a study aiming to identify resilience resources that help youth to prevent or overcome depression or anxiety. The study includes participants from Lima, Buenos Aires and Bogota, and follows up on them for 12 months, including three measurements (baseline, 6-month follow-up and 12-month follow-up). This protocol describes a new activity taking place within the OLA Project: We will conduct a trial within a cohort study where adolescent participants in Bogota (Colombia), already participating in OLA longitudinal cohort study, will randomly be assigned to a control group or a music workshop (intervention group). The study will take place in Bogota, with a total of five sessions (approx. 90 minutes per session), once per week after school. The venue(s) will be identified by the local research team and arts organisation closer to time.
Study aims and objectives	Aim: To assess the feasibility, effectiveness, and experiences of a music workshop in reducing symptoms of anxiety and/or depression in adolescents in Bogota (Colombia). The specific research questions are: - How effective is the intervention in reducing symptoms of anxiety and/or depression in that group? - How feasible are music workshops as an intervention for adolescents with anxiety and/or depression? - How is the intervention experienced by adolescent participants?
Study participants	Adolescents (15-16 years old) who are already enrolled in the OLA longitudinal cohort study, with symptoms of anxiety and/or depression at baseline and the 6-month follow up.
Planned sample size	40 adolescents (15-16years old) who participated in the 6-month follow up (OLA longitudinal cohort study) and still had symptoms of anxiety and/or depression will be randomly selected and allocated to the music workshop (intervention group); the remaining participants in the OLA study fulfilling the same inclusion criteria will be the control group. The size of the control group is difficult to predict at

	this stage, but it is assumed to exceed the intervention group.
Planned study period	In line with 6- and 12-months follow-ups of the OLA longitudinal cohort study; music workshop interventions will happen from March 2022- May 2022

Role of coordinating centre and funder

Queen Mary University of London is the coordinating centre with local PIs assuming responsibility for research activities in their country. The Medical Research Council and Global Challenges Research Fund, from UK, have provided funding for the study.

Programme management committees/ groups

Study management committees

The study management committees for the whole OLA programme are outlined below:

- Programme Management Group

The Programme Management Group (PMG) includes the overall study PIs, 3 local PIs and 6 co-applicants, and main researchers.

- Overall Steering Group

The Overall Steering Group is comprised of individuals who are independent of the organisations involved in the OLA programme. The independent members include a Chair (UK based) and members from each partner country with knowledge and experience of mental health care in their country, expertise in research methodology and implementation of study designs in communities.

- Lived Experience Advisory Panel

The Lived Experience Advisory Panel (LEAP) will be comprised of 6-10 members aged 15-24 years old with knowledge and "lived experience" of mental distress, including depression and/or anxiety in Colombia.

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Building resilience and resources to reduce depression and anxiety in young people from urban neighbourhoods in Latin America (OLA)

Protocol for Trial Within a Cohort study

1. Introduction

1.1 Background and rationale

Anxiety and depression are frequent among adolescents in deprived areas of large cities in Latin America (1,2). However, findings suggest that about 50% of affected adolescents recover after one year (3,4). 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 (5) addressing the above question and assessing potentially helpful activities such as participation in music groups (6). However, the design of the cohort study is observational and does not involve experimental variation of activities. The planned TWIC will complement the design of the cohort study and conduct a randomized controlled trial within the cohort, testing the feasibility, effectiveness and experiences of music workshops for adolescents with anxiety and/or depression.

Whilst there is evidence for the effectiveness of music therapy groups (7,8), this study tests the helpful potential of music groups that have not been designed as therapy. As compared to formal therapies, they are supposed to be more appealing to adolescents, do not come with an implicit message that there is something wrong with the adolescents that requires professional help, are more flexible in their format, are lower cost and can be provided by a wider range of musical facilitators. They also have the advantage of teaching musical skills which can build self-esteem and be beneficial in future life (9). Although not formal therapies, such activities may be assumed to reduce mental distress. There is a large body of evidence suggesting that arts activities can have a range of health benefits and even increase life expectancy (10).

1.2 Study context

The overall research programme (OLA) is taking place in collaboration with researchers from Universidad Buenos Aires (Argentina), Pontificia Universidad Javeriana (Colombia), Universidad Peruana Cayetano Heredia (Peru), University College London, King's College London and is coordinated by Queen Mary University of London. The research activities take place in three large Latin American cities: Buenos Aires (Argentina), Bogotá (Colombia) and Lima (Peru).

The OLA Project is a study aiming to identify personal and social resources that help youth to prevent or overcome depression or anxiety in Lima, Buenos Aires and Bogota. OLA includes a cohort of adolescents with symptoms of anxiety and/or depression, 170 in each country, who are followed up for 12 months, including three measurements (baseline, 6-month follow-up

and 12-month follow-up). The OLA longitudinal cohort study has already been approved by Queen Marys Ethics of Research Committee on the 21st October 2020 *(QMERC2020/02 – Building resilience and resources to reduce depression and anxiety in young people from urban neighbourhoods in Latin America (OLA): Phase 2).*

The OLA activities started in May 2021, and the research team has recruited 73% of the sample in Bogota. With this new activity, we aim to use this innovative approach to assess the effectiveness of implementing music workshops to young people to decrease their depressive and/or anxiety symptoms.

Two protocols for TWIC have been developed as part of the overall research programme. In addition to the TWIC described here, there will be another one conducted Buenos Aires and Lima, testing artistic workshops for young adults with anxiety and/or depression.

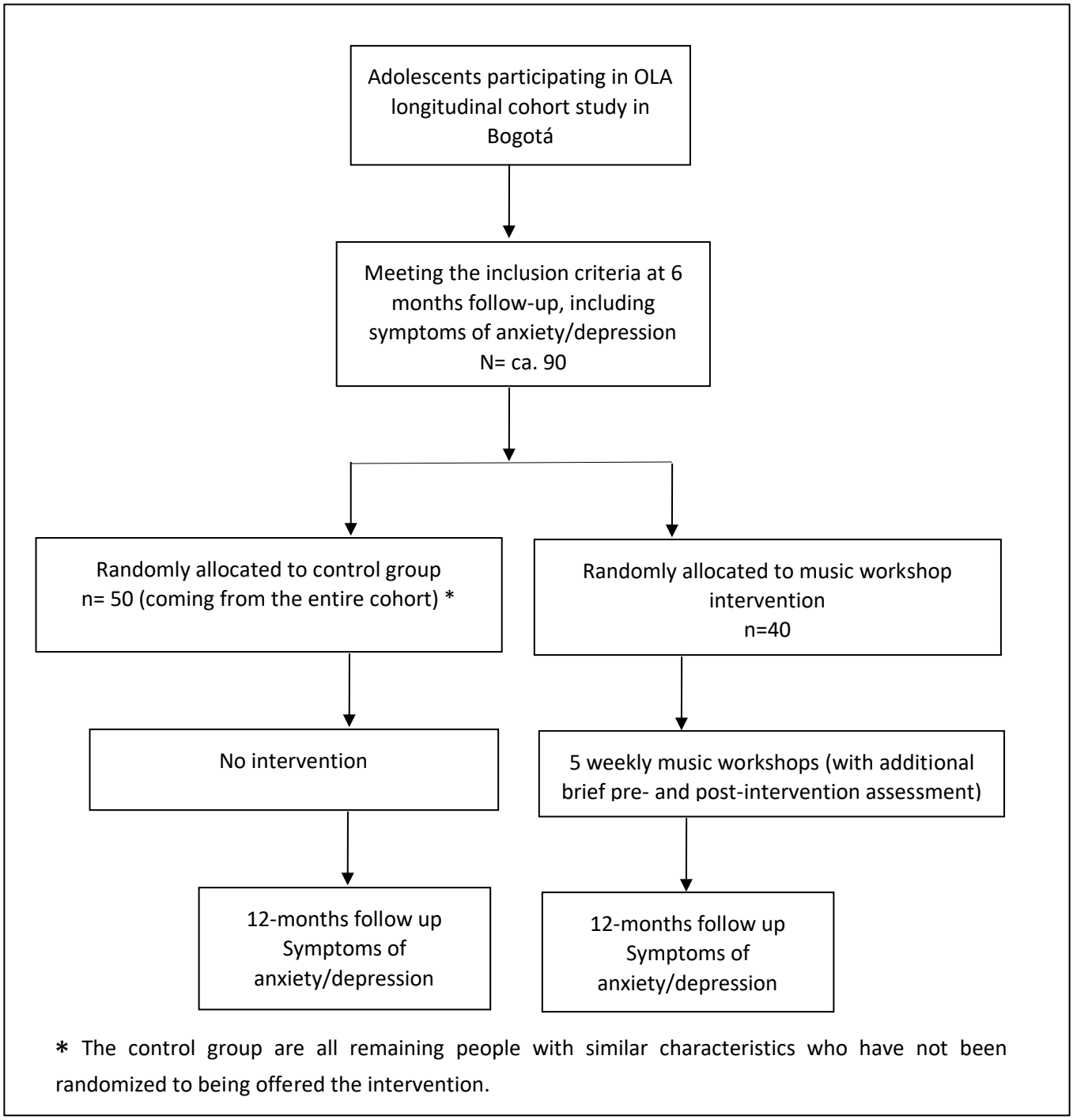
1.3 Study objectives

Objectives

To assess the feasibility, effectiveness and experiences of a music workshop intervention for adolescents with symptoms of anxiety and/or depression.

- Feasibility will be assessed by acceptance of workshop participation and level of session attendance.
- Effectiveness will be assessed by comparing the outcomes of intervention and control group (pre and post intervention) and changes overtime (12-months follow up).
- The experience of the intervention will be assessed by exit questionnaire responses.

1.4 Study flow charts



* The control group are all remaining people with similar characteristics who have not been randomized to being offered the intervention.

2. Methods

2.1 Study design

The study design used in this research will be a Trial Within a Cohort study (TWIC) (11) as an exploratory trial.

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 an 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.

Consent for the use of data is gained from all cohort members at the offset, whereas consent for participation in a trial is sought only from participants offered the intervention (post-randomisation), which means that blinding is not possible.

In OLA, the TWIC study will be embedded within the longitudinal cohort study.

2.2 Eligibility criteria

2.2.1 Inclusion criteria

- Adolescents (15-16 years old when recruited for the cohort) who have symptoms of anxiety and/or depression at baseline and 6-month follow-up.
- Capacity to provide assent (intervention group only)
- Informed consent provided by a parent/guardian (intervention group only)

2.2.2 Exclusion criteria

- Participants who already regularly participate in a music band/orchestra, or have advanced music skills (based on baseline assessment).
- Participants who expressed no interest in participating in any arts activities (in baseline assessment)

2.3 Study setting

Both the local research team and arts organisation will be in charge of identifying venue(s) close enough, preferably within a 30 minutes travel radius, for participants to be able to travel via public transport/taxi/their own vehicle.

2.4 Study procedures and data collection

- All participants in the adolescent cohort in Bogota who still have symptoms of anxiety and/or depression at the 6-month follow-up and meet the eligibility criteria will be included in the study.
- They will then be randomly assigned to the control group or music workshop (intervention group).
- A total of 40 participants will be assigned to the music workshop, the rest of the adolescents meeting the inclusion criteria will be allocated to the control group; the exact size of this group cannot be anticipated with certainty at this stage. We expect it to exceed the intervention group and estimate that we will have 50 or more participants in the control group.

- Participants assigned to the intervention group, will then be provided with an information sheet and if interested asked to sign a consent form.
- A parent/guardian may be present for the consent meeting. If they cannot be present, the research team can solve their doubts by phone. A meeting using an online platform or in-person will be arranged.
- All adolescent participants who provided informed consent will complete the patient health questionnaire (PHQ-8) and the generalised anxiety disorder assessment (GAD-7) questionnaire before the first workshop. This will be either online as other assessments in OLA have been conducted or self-administered in the presence of a researcher who will answer any questions they may have.
- There will be a total of two workshops (20 participants in each workshop) taking place.
- The venues will be identified by the local research team and arts organisation closer to time.
- Each workshop will include a total of five sessions, each lasting approximately 90 minutes with a potential break.
- Each workshop will be led by a music teacher and a logistics support staff, from Fundación Batuta.
- The workshops will take place once a week, after school on a weekday.
- After the end of the intervention, adolescents 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. This may happen online or in person with a researcher present at the end of the last workshop, or within the week following the last workshop.

2.4.1 Music Workshop

The music workshop will follow a programme 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 *(see Table 1 for brief summary of each session)*.

Table 1. Brief summary of activities in each session of the workshops

Workshop	Objective	Repertoire
Session 1: Finding my singing voice	To provide an experience of making instrumental and vocal music together using a ludic and participatory process.	"La ola loca" Olga Lucía Jiménez Cumbia "The power of a new day" OLA workshop group

		Pedagogical repertoire
Session 2: Body rhythm	To develop a bodily process through motor activities associated with developing rhythmic abilities at various sound levels.	Rhythmic canon “La ola loca” Olga Lucía Jiménez Cumbia
Session 3: Making music with others	Conscious listening: identifying the different roles within a sound texture for the development of parallel social skills.	“A song to peace” Víctor Hugo Guzmán Vallenato
Session 4: Imagine and create music	To generate awareness of one's own creative capacity and musical thinking.	Activities with glasses Drawing and rhythmic reading Improvisation with pentatonic plate scale and C major scale
Session 5: Teamwork	Assembly of a musical piece through active participation and collective construction, putting into practice the learning from the sessions and stimulating the recognition of a collaborative achievement.	"The big hammock” Vallenato

2.5 Consent procedure

Adolescents who respond to the study information with interest will be invited to attend an in-person or virtual meeting or a phone call with a researcher. Researchers will go through information sheets and answer any questions or concerns raised. A parent/guardian may be present for this meeting. If they cannot be present, the research team can solve their doubts by phone. A meeting using an online platform, or a phone call will be arranged if a face-to-face meeting is not possible.

Parents/guardians of adolescent participants will be asked to provide informed consent, by signing and dating an informed consent form prior to the collection of any data. Adolescents (15-17 years old) will be asked to sign the assent form to participate in the study. Two copies of the written assent/consent form will be signed by the participant, the parent/guardian, and a member of the research team in order to proceed with study participation. The participant and parent/guardian will keep one copy of the informed consent form and the research team will keep the other, storing it in a locked filing cabinet. If face-to-face meetings are not possible, researchers will make alternative arrangements with participants to receive copies of the signed consent form or to record informed consent over a recorded audio call, in-line with procedures approved by the local IRB.

All researchers taking consent are already Good Clinical Practice (GCP) trained. The researchers will re-assess each individual's level of understanding during the recruitment and consent process. If there are any doubts regarding the individual's capacity to consent, this will need to be resolved before proceeding with study participation. If any doubts about capacity emerge during the recruitment process, or capacity to consent appears to change during their participation in the study, their capacity to consent will be re-evaluated before continuing.

2.6 Withdrawal criteria

During the consent process, researchers will ensure that participants and parents/guardians are aware of their right to decline participation at any stage of the research and that withdrawing participation will not affect their rights. Participants who withdraw will be able to ask that their data from the TWIC is eliminated providing this occurs before the end of month 15 from their inclusion in the project (the one-year follow-up assessment of the cohort study will also be the follow-up assessment of the TWIC).

If a participant wishes to withdraw from the intervention, researchers will record date of withdrawal and reason(s) for withdrawal (if provided). Participation in the OLA cohort will not be affected if participants decide to withdraw from the intervention in the TWIC.

2.7. Data collection and data management

The process of data collection will be closely monitored by the local research team, who will have ongoing and close communication with the UK-based research team (at least one teleconference per week during the data collection periods).

Every week, recruitment and follow-up figures will be compiled in a CONSORT diagram and sent to the UK-based research team. This will include the number of individuals approached, screened, included, excluded and for what reasons, withdrawn (and for what reasons if available) and assessments completed in Bogota. Numbers will be reported weekly and any challenges to recruitment will be discussed and solutions agreed. Any issues or problems that arise can also be discussed on an ad-hoc basis with the UK-based and wider team by email or video-conferencing if and as needed.

Quantitative data collected will be entered onto the study database that will be developed on the online REDCap platform by a participating research team and shared with the wider research team. All researchers who will be collecting data will be trained on the PHQ-8 and GAD-7 questionnaires and how to use REDCap. Data should be entered within one month of the date of data collection.

Datasets can be directly downloaded in various formats from REDCap by researchers with the required permissions, and the final datasets will be analysed using SPSS or STATA data analysis software packages as appropriate.

Quality assurance checks will be taking place as part of the main OLA study, and include any extra data collection from the TWIC. This will be conducted by the UK-based research team.

Any queries about mismatching or incomplete data will be discussed and resolved with the local research team.

2.8 Participant reimbursement

Participants in the intervention group will be reimbursed (about $5 USD/voucher equivalent) for their time for each of the additional research assessments, i.e. one before and one after the intervention (completing the PHQ-8 and GAD-7 scales at each time point and also answering open questions after the intervention). Refreshments will also be provided during the workshops. Travel costs to and from the workshops will be reimbursed, if and as required.

2.9 End of study definition

The intervention ends after the last workshop session. The TWIC ends with the end of the OLA longitudinal cohort study.

2.9.1 Early termination

If the local IRB determines it is within the best interests of the participants to terminate the TWIC, written notification will be given to the local PI, who will inform the study Chief Investigator (Priebe).

3. Data analysis

Data analysis will be conducted as outlined below, with scope for further exploratory post-hoc analyses.

3.1 Sample sizes

3.1.1 Quantitative sample size

This is an exploratory trial. For a formal sample size calculation, we assumed that a difference of 3 scale points on the GAD-7 and/or PHQ-8 (the scale with the higher baseline symptom level will be used as the primary outcome) is clinically relevant. Considering the different standard deviations for GAD-7 and PHQ-8 that have been reported in the literature for different samples (12-14), this will be overall equivalent to an effect size of 0.7. To detect that effect size with 80% probability on a 5% significance level, a sample of 2x34 participants are required. Assuming a drop-out rate of 15%, we will require 40 participants at baseline in the intervention group. The control group will be at least of a similar size, so that the sample size calculation appears realistic. Since the control group are all remaining people with similar characteristics who have not been randomized to being offered the intervention, the exact size is impossible to define at this stage. 50 is an initial conservative estimate.

Once the final sample is obtained, the power found will be recalculated and included in the discussion of the results.

3.1.2 Qualitative sample size (Brief exit-questionnaire)

To capture the full range of experiences, all participants in the intervention group will be asked to complete the brief exit questionnaire, with 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.

3.2 Statistical Analysis

Descriptive statistics will be reported for socio-demographic baseline data that have already been assessed for all participants, as part of the longitudinal cohort study. To assess for effectiveness of the intervention, mean and standard deviations over the two time points (6-months and 12-months follow-ups) will be calculated, and analysis will test the significance of the differences between the means of outcomes measured. The primary outcomes will be the PHQ-8 and GAD-7 score (primary outcome will be the scale with the higher symptom level at 6 months, both scales z-transformed for equivalence) at 12 months adjusted for the 6 months scores. The process evaluation will assess the number of attended workshops and pre-post differences in the intervention group. A full analysis plan will be developed prior to data analysis, which will consider which covariates should be adjusted for in the model and methods for dealing with missing data. The data analysis plan will be agreed and signed off by researchers in both Bogota and London.

3.3 Qualitative data analysis

The data from the brief exit-questionnaire will be analysed for each question using inductive content analysis.

Overall, the three aims of the research will be addressed as follows:

Feasibility – acceptance of workshop participation and attendance of workshop sessions
Effectiveness – comparison of outcomes in intervention and control group supplemented be pre-post changes of self-rated depression/anxiety symptoms
Experiences - experiences expressed after the end of the intervention

4. Ethical and regulatory considerations

The local Principal Investigator, Gomez-Restrepo (Colombia) will ensure that the study is carried out in accordance with local and national ethical principles. We will be applying to the IRB of Universidad Javeriana, and any further required approvals before implementing the research activity described in this protocol. As the research studies are being funded by the Medical Research Council (MRC) in the UK, ethical approval will also be sought from Queen Mary Research Ethics Committee, hosted at Queen Mary University of London.

The local research team and UK-based research team will keep a record of all correspondence with the IRB and copies will be sent to the MRC if required. The local PI will ensure that any progress reports to the IRB or other relevant organisations are submitted as required. The

local PI will notify the IRB of the end of the study, and will immediately notify them should the study end prematurely, including the reasons for premature termination.

4.1 Benefits of the project

Depression and anxiety are leading causes of youth disability worldwide. This study will aim to provide evidence on whether arts activities in the community reduce mental distress of adolescents. The study will also build research capacity within Colombia and foster collaboration between an established university and a community music organisation. 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.

4.2 Risks of the project and measures to prevent them

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

4.2.1 Strategies to minimise risk

To minimize any risks or negative effects of taking part in the research, the following measures will be taken:

1. The workshop sessions will be led by facilitators from Batuta who have extensive previous experience of working with individuals with mental health difficulties.
2. Researchers will be trained in conducting the measures in the PHQ-8 and GAD-7, and general Good Clinical Practice principles.
3. The purpose of the study will be clearly explained to participants and their parents/guardians, and it will be stressed that participants do not have to share any information they are uncomfortable with.
4. Participants will be reminded about their right to withdraw (without giving reason) at any point in the study.
5. All participants, including parents/guardians, will be provided with an information sheet about the study with the contact details of local resources within each area.
6. Participants and their parents/guardians, will be informed that the research team are able to contact a mental health service if they would like further support.
7. A clinician from the research team will be available for support and supervision to the facilitators if and when useful.
8. In the unlikely event that any individual becomes highly distressed during the study procedures, or where the participant discloses risk of harm to self or others, data collection and their participation in the workshop will be terminated immediately and, where appropriate, parents/guardian will be contacted.
9. In the very unlikely event that a participant discloses information regarding immediate risk to the self or others, their participation will be immediately terminated and one of the researchers will inform the relevant safeguarding authorities (e.g. clinic).

4.2.2 Informed consent

Before any data collection begins, participants who were randomly assigned to the intervention groups will provide their informed assent, and their parents/guardians will provide their informed consent (as described in section 2.5). Individuals who do not have capacity to provide informed consent will not be included in the study. To ensure that individuals can make informed decisions about their participation, they will be provided with written information and they will be given time to consider whether they wish to participate. The researcher and the IRB's contact details will be provided on the information sheet to allow potential participants to obtain further information about the study.

All individuals will be given the opportunity to raise any questions or concerns to the researcher during the meeting to sign or record the informed consent.

4.2.3 Confidentiality

To ensure confidentiality, all participants will be pseudonymised using their participant ID from the OLA longitudinal cohort study. Information connecting the participant identity to their participant ID will be stored on a secure drive within password protected folders and documents that are only accessible by members of the local research team. Electronic data collected using online forms will be collected and stored directly onto the secure online platform, REDCap. Only members of the research team will have access to REDCap and only those involved in data analysis will have access rights to download data for the analysis. Paper copies of documents (i.e. consent forms) will be stored in a securely locked cupboard on the premises of Pontificia Universidad Javeriana. The outcome data of the PHQ-8 and GAD-7 questionnaire will be stored in separate, secure cupboards to paper documents containing personal information. If local researchers are required to work remotely, they will adopt data storage and sharing procedures approved by local IRB as part of the amendment to the Phase II protocol to conduct research activities remotely.

To further protect confidentiality, we will:

1. Remind all participants that they do not have to answer any questions or make any personal disclosures if they do not wish to.
2. Personal information will not be stored alongside non-identifiable outcome data on the study database (using the REDCap platform). For data analysis, non-identifiable data will be transferred either .dta or .csv files using a secure Citrix connection, or directly downloaded from REDCap. Only members of the research team will have access to the database and permission to download data. The resulting database will be held securely on encrypted university computers.
3. Personal information will be destroyed in-line with national regulations when the project concludes

Where the researcher has concerns regarding the participant's safety or the safety of others, through participant disclosures of thoughts/plans of harming themselves or others; then the researcher is obliged to break confidentiality and inform the relevant authorities. This will be made clear to the participants during the consent process to ensure their understanding.

4.3 Amendments

Any substantial amendments requiring review by the IRB will be presented to the overall steering group for approval. Guidance from the MRC will be sought where required. The amendment history will be tracked via version and date control of protocols, with changes to the protocol highlighted in Appendix 1.

5. Monitoring, audit and inspection

Members of the UK-based research team will carry out annual monitoring visits (in person or remotely) to ensure that research activities are being implemented as outlined in the protocol and standard operating procedures, and in accordance with ethical guidelines. This will include checking the secure storage of electronic and paper records/data; the correct completion of agreed recruitment and enrolment logs and case report forms; and accurate data entry.

Further monitoring, audit and inspection will be carried out as required by local research procedures.

6. Public and youth involvement

This research aims to engage adolescents living in urban environments who are exposed to multiple risk factors for poor mental health, in the research and mental health discourse.

A lived experience advisory panel (LEAP) of 6-10 young people has been set up in Colombia for the whole OLA programme. All participants have some experience of anxiety and/or depression.

7. Data protection and confidentiality

All investigators and study staff will comply with the requirements of the data protection laws in Colombia regarding the collection, storage, processing and disclosure of personal information and will uphold the law's core principles throughout the study. Only pseudonymised data will be shared with the coordinating centre (QMUL, UK) where the research team will comply with the Data Protection Act, 2018 and General Data Protection Regulations.

7.1 Personal information

All personal information will be managed and stored as described in section 4.2.3.

8. Record retention and archiving

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 Colombia will also be stored at the main study site in Pontificia Universidad Javeriana, and Dr Carlos Gómez will be custodian of the data. This will be done

according to the regulation for data storage and protection at Pontificia Universidad Javeriana, Bogotá.

9. Dissemination

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.).

Appendix

Appendix 1 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**

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