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

Protocol for Phase II (Work Packages 2, 3 and 4a)

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

Study summary

Study title	Building resilience and resources to reduce depression and anxiety in young people from urban neighbourhoods in Latin America – Phase II (WP2, 3 and 4a)
Subtitle	OLA Phase II (WP2, 3 and 4a)
Study design	Mixed methods
Summary of research activities	This protocol describes four research activities: Work Package 2 (WP2) Cross-sectional study to compare resources used to help prevent mental distress in adolescents (aged 15-16) and young adults (aged 20-24), with and without depression and/or anxiety. Participants will be invited to complete an assessment battery developed in WP1 of this research programme. Work Package 3 (WP3) Longitudinal cohort study to compare resources used to help recovery from mental distress in adolescents (aged 15-16) and young adults (aged 20-24), who have and have not recovered from depression and/or anxiety over a one-year period. Participants identified as experiencing mental distress from WP2 will be invited to complete a brief follow-up assessment at 6 months, and the assessment battery again at 12 months. Experience Sampling Method (ESM) study, which consists of a pilot, baseline and 12-month follow-up. The ESM study baseline compares resources used in adolescents and young adults, with and without depression and/or anxiety. Participants complete questionnaires using a mobile phone app (eMoodie) at random time points during their day. The ESM follow-up compares resources used in adolescents and young adults who have and have not recovered from depression and anxiety over a one-year period, using eMoodie. The pilot study will pilot the ESM study procedures and questionnaires. Work Package 4a (WP4a) In-depth interviews with participants of WP3 who have and have not recovered from depression and/or anxiety.
Study aims and objectives	Determine whether characteristics, resources and activities differ between young people with and without depression and/or anxiety. Identify which characteristics, resources and activities in young

	people are associated with recovery from depression and/or anxiety. Determine whether for short-term recovery (within hours or days), young people have similar characteristics, and use similar resources and activities as for long-term recovery (over one year). Explore what resources and activities did young people with depression and/or anxiety find helpful or not helpful for their recovery from mental distress. Explore young people's resource use in the last 12 months and their suggestions for how the community and/or services could help them with their recovery.
Study participants	For the cross-sectional study (WP2) and ESM baseline: Individuals aged 15-16 and 20-24 years, with and without anxiety and/or depression. For the longitudinal cohort study (WP3) and ESM follow-up: Individuals aged 15-16 and 20-24 years who took part in the cross-sectional study and baseline ESM, defined as experiencing depression and/or anxiety at the time of recruitment For the ESM pilot: Individuals aged 15-24 years, with and without current anxiety and/or depression. For the in-depth interviews (WP4a): Individuals aged 15-16 and 20-24 years who participated in the longitudinal cohort study, who have and have not recovered from depression and/or anxiety.
Planned sample size	WP2: Cross sectional study: Target sample of 2,040 adolescents (15-16 years old) and young adults (20-24 years old) will be recruited across the three countries: 1,020 participants with depression and/or anxiety (340 per country: 170 per age group in each country), and 1,020 without (340 per country: 170 per age group in each country). (As many individuals as needed to reach the target sample will be screened, up to 6,000 young people in total) WP3: Longitudinal cohort study: Follow-up the 1,020 individuals identified with depression and/or anxiety at the cross-sectional study (340 per country: 170 per age group in each country) ESM pilot: 18 adolescents and young people (15-24 years old) will be

	recruited across the three countries, including those with and without current depression and/or anxiety. ESM baseline and follow-up: 150 adolescents (15-16 years old) and young adults (20-24 years old) who participated in the cross-sectional study will be recruited across the three countries: 90 with depression and/or anxiety (30 per country: 15 per age group), and 60 participants without (20 per country: 10 per age group). 90 participants who participated in the ESM study baseline and with depression and/or anxiety at baseline (30 per country: 15 per age group) will complete follow-up ESM assessments. WP4a: In-depth interviews: 90 individuals from the longitudinal study (30 per country) will be purposively selected to include those classified as recovered or not recovered and have a mix of genders and age groups (15-16 and 20-24 year olds)
Planned study period	November 2020 - July 2024

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 each of the partner countries (Argentina, Colombia and Peru).

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

Protocol for Phase II (Work Packages 2, 3 and 4a)

1. Introduction

1.1 Background and rationale

Low- and Middle-Income Countries (LMICs) are increasingly urbanised. Urban regions, predominantly large cities, account for approximately 80% of the population in Latin America, making it the most urbanised region in the world. People within these environments are frequently exposed to risk factors for poor mental health, including those linked to depression and anxiety. These include social fragmentation, poverty, poor education, low employment rates, gang warfare, victimisation, violence, and wide spread substance misuse.[1-4]

The WHO has identified reducing adolescent depression and anxiety as a key priority required to promote sustained economic and social development.[5] Globally, depression and anxiety are leading causes of disability. Up to 4.4% of the global population suffer from depression and 3.6% suffer from anxiety disorders.[6,7] Higher and rising prevalence of both conditions are evident in adolescents, with 75% of all mental health conditions developing before the age of 18 years.[8] Both depression and anxiety are associated with high levels of distress and disability, future physical and psychiatric morbidity and educational and social impairment.[9] Furthermore, more than half of all adolescent suicides are attributable to depression[10], making it the leading cause of mortality for this age group.[11]

Depression and anxiety during adolescence and youth are a particular concern within LMICs, where the burden of common mental disorders (CMDs) is greatest.[5,7] This includes Latin America, where young people represent one quarter of the population. Estimated levels of depression and/or anxiety for adolescents within the region range from 17% in Colombia[12] to 26% in Argentina.[13] Those exposed to adversities such as conflict, internal displacement and poverty are at an even greater risk.[14] Despite all the risk factors, the majority of young people do not suffer from depression and/or anxiety.

Due to the scarcity of financial and human resources,[15] young people in Latin America rarely receive formal treatment when experiencing mental distress. Yet, evidence suggests that 50-60% experience symptomatic recovery within one year.[16,17] This raises the question as to which resilience factors individuals in these contexts can mobilise to overcome depression and anxiety, and prevent them once they occur. Previous research has focused on risk factors for developing mental disorders. However, as complete primary prevention of depression and/or anxiety among young people, particularly in adverse urban environments, is unrealistic, research on the factors that help young people recover is particularly relevant and may lead to future interventions to reduce the burden of poor mental health.

Resilience has been defined as overcoming adversity, trauma and stress and rebounding back from illness. Thus, it covers the two processes of mental distress in the face of risk factors and recovering from distress if and when it developed. A systematic review into the concept of resilience within mental health classified its characteristics into two components - personal and social resources.[19] Resources encompass a wide range of strengths, assets, materials, sources of information or help and means of support available to the individual. They may be individual in nature and relate to the

health behaviours or the skills and abilities of the person[20] (personal resources), or group-based and at the community or societal level, such as social capital or networks (social resources)[21]. Resources may also be applicable at a general level (e.g. medication), or they may be context and locality specific (e.g. local music group or street opera).

Consistent methods should be used for assessing resilience factors in young people with and without depression and/or anxiety and for studying which factors are linked with recovery. This will identify whether similar or different factors and resources help to avoid and to overcome depression and/or anxiety. Comparisons between those with and without mental disorders, and those who do and do no recover can build up a comprehensive understanding of resilience factors. This understanding can be used to develop new approaches to reduce the burden of mental distress in adolescents and young people in Latin America and other LMICs.

1.2 Study context

This research programme 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 will be coordinated by Queen Mary University of London. The research activities will take place in three large Latin American cities: Buenos Aires (Argentina), Bogotá (Colombia) and Lima (Peru).

This 5-year programme has been split into 3 phases and 4 work packages (WP). This protocol (phase II) details the cross-sectional study (WP2), longitudinal cohort study (WP3), ESM pilot and study, and in-depth interviews (WP4a).

Phase I included WP1, which was described in a separate protocol and consisted of developing methods to assess resilience factors in adolescents and young people. WP1 involved the development of the assessment battery that will be used in Phase II, for WP2 and WP3. This protocol was approved by IRBs of all partner institutions and the research activities are ongoing. A further protocol (phase III) will be developed at a later stage for case studies of good practice initiatives (WP4b).

1.3 Study objectives

The overall aim of the programme is to identify which characteristics, resources and activities help young people living in urban environments in Latin America to recover from depression and/or anxiety. Identification of these characteristics, resources and activities is a crucial step in the development of new approaches at an individual, community and societal level to reduce the burden of mental distress.

Objectives for phase II:
For the cross-sectional study (WP2) and ESM study
Determine whether characteristics, resources and activities differ between young people with and without depression and/or anxiety.

Additionally, for ESM study:
Determine whether young people have similar characteristics and use similar resources and activities for short-term recovery (within hours or days) as for long-term recovery (over one year).

For the longitudinal cohort study (WP3) and ESM follow-up:

Identify which characteristics, resources and activities in young people are associated with recovery from depression and/or anxiety.

In-depth interviews (WP4a):
Explore what resources and activities young people with depression and/or anxiety find helpful or not for their recovery from mental distress.

2. Methodology

2.1 Study design

To identify the characteristics, resources and activities that differ between adolescents and young adults with and without depression and/or anxiety, and those that help recovery from mental distress over a one-year period, phase II (WP2, 3, 4a) will include the following activities:

Activity	Aims	Description	Data collection
Cross-sectional study (WP2)	Determine whether characteristics, resources and activities differ between young people with and without depression and/or anxiety.	Compare 1020 (340 per country) adolescents (aged 15 and 16 years old) and young adults (aged 20-24 years old) with depression and/or anxiety, to 1020 (340 per country) adolescents and young adults without. We will approach and screen as many individuals as needed to reach the target sample numbers, up to 6,000 individuals in total	**Baseline Assessment:** Adolescent and young adult participants will complete the assessment battery developed in WP1 of the OLA programme. This will be self-administered in the presence of a researcher who will answer any questions they may have.
Longitudinal cohort study (WP3)	Identify the characteristics, resources and activities in young people are associated with recovery from depression and/or anxiety	1020 (340 per country) adolescents (aged 15 and 16 years old) and young adults (aged 20-24 years old) with depression and/or anxiety recruited to the cross-sectional study will be followed-up after six months and one year	**6-month follow-up:** Six months after their baseline assessment, adolescents and young adult participants will complete the 6-month follow-up assessment using an online form. **12-month follow-up:** Twelve months after their baseline assessment, adolescents and young adult participants will complete the 12-month follow-up assessment battery in the presence of a researcher.
Experience Sampling Method (ESM) pilot	Pilot the ESM questions, format, eMoodie app, debriefing	Before the ESM study below: 18 adolescents and young adults (aged 15-24 years old) with and without current	Adolescent and young adult participants will be asked to use the eMoodie App to complete a short

	questionnaire, study procedures including frequency of data collection (beeps) and duration of the study (7 days)	experiences of anxiety and/or depression. Members of the LEAPs will also be invited to take part	questionnaire at random time intervals, 5-8 times per day for 7 consecutive days. They will complete a debriefing questionnaire with a researcher after the 7 days, which will include questions to capture participants' experience of the study and thoughts on its improvement.
Experience Sampling Method (ESM)	Determine whether characteristics, resources and activities differ between young people with and without depression and/or anxiety. Identify which characteristics, resources and activities in young people are associated with recovery from depression and/or anxiety. Determine whether young people use similar characteristics, resources and activities for short-term recovery (within hours or days) as for long-term recovery (over one year).	Running concurrently with the cross-sectional study (WP2) and longitudinal cohort study (WP3): 150 (50 per country) participants already recruited to the cross-sectional study - 90 (30 per country) adolescents (aged 15 and 16 years old) and young adults (aged 20-24 years old) with depression and/or anxiety, and 60 (20 per country) adolescents and young adults without depression and/or anxiety. 12-month follow-up: 90 participants who participated in the ESM study baseline and with depression and/or anxiety at baseline (30 per country: 15 per age group) will complete follow-up ESM assessments.	Adolescent and young adult participants will be asked to use the eMoodie App to complete a short questionnaire at random time intervals, 5-8 times per day for 7 consecutive days. They will complete a debriefing questionnaire with a researcher after the 7 days. Some adolescent and young adult participants will complete follow-up data collection using the eMoodie App again at one year. They will complete the same questionnaire at random time intervals, 5-8 times per day for 7 consecutive days. They will complete a debriefing questionnaire with a researcher after the 7 days.
In-depth interviews (WP4a)	Explore what resources and activities young people with depression and/or anxiety find helpful or not for their recovery from mental distress Explore young	90 individuals aged 15-16 and 20-24 years (30 per country), who have and have not recovered from depression and/or anxiety – already recruited to the longitudinal cohort study	One-to-one audio-recorded interview facilitated by a researcher using a topic guide.

	people's resource use in the last 12 months and their suggestions for how the community and/or services could help them with their recovery		

2.2 Eligibility criteria

2.2.1 Inclusion criteria

For the ESM pilot:

- Aged 15-24 years old
- Capacity to provide informed consent (18-24 year olds)
- Informed consent provided by a parent / guardian (15-17 year olds only)
- Capacity to provide assent (15-17 year olds only)

For the cross-sectional study and ESM:

- Aged 15-16 or 20-24 years
- Capacity to provide informed consent (20-24 year olds)
- Informed consent provided by a parent / guardian (15-16 year olds only)
- Capacity to provide assent (15-16 year olds only)
- Live in the defined geographical area (within 50% poorest neighbourhoods in the city as defined in Section 2.3)

2.2.2 Exclusion criteria

For all activities: exclusion criteria for young adults and adolescents:

- Known diagnosis of severe mental illness (psychosis, bipolar disorder, schizophrenia)
- Known diagnosis of cognitive impairment
- Unable to provide informed consent
- Unable to read or write

2.3 Study setting

This study will take place in Buenos Aires (Argentina), Bogotá (Colombia) and Lima (Peru).

In all three cities, recruitment of adolescents will mainly be from schools and of young adults mainly from primary care centres. Other recruitment centres might include local arts centres, youth organisations, and other community and educational organisations within defined geographical areas. We are using measures of poverty that are available in each city: The Human Development Index (HDI) in Lima and Bogotá and unsatisfied basic needs in Buenos Aires; which will broadly lead to the identification of comparable 50% of the poorest neighbourhoods in each city for onward selection.

2.4 Study procedures

i) Cross-sectional study

Adolescents and young adults will be recruited from within the 50% poorest neighbourhoods in each city. The sampling procedure will focus on recruitment via schools and health centres for

adolescents, and health centres, universities, technical colleges and youth organisations/NGOs for young adults, where larger numbers of young people are expected to be located. If necessary, recruitment will be complemented by an online strategy through social media. Educational institutions, health facilities and youth organisations will be approached where research teams have existing working links and/or required permissions (from the local authority or government). Within each school, classrooms will be sampled, where all students in a defined classroom aged 15-16 will be approached by teaching staff or a member of the research team to see if they are interested in participating in the study. Interested individuals will be given a letter with information for their parents.

For health centres and clinics, all individuals identified as 15-16 or 20-24 years old on available patient lists will receive a letter inviting them to participate in the study. A similar strategy will be used to sample from youth organisations, where all 15-16 and 20-24 year old individuals will be approached or written to by staff or members of the research team to see if they are interested in participating in the study.

Interested individuals who meet the inclusion criteria will first go through the consent procedure (see section 2.5), after which they will be screened by a researcher using the PHQ-8 and GAD-7. Where an individual meets criterion for depression and/or anxiety, by scoring greater than 9 on either scale, they go on to complete the full assessment battery and will be approached to complete the follow-up assessment in 6- and 12-months' time. Individuals who do not meet criteria for depression and/or anxiety, will go on to complete the full assessment battery only (they will not be approached for the follow-up assessments). The sample will be stratified by gender to ensure variability within the sample.

Each participant will meet with an experienced researcher at a convenient, comfortable and private community location to complete the assessment battery. Alternatively, a small group of participants might complete the assessment battery at the same time in the presence of 1-2 researcher(s), e.g. in a school classroom. The researcher will answer any questions that the participant(s) might have about the questionnaires at any point. The meeting will last approximately 30 minutes. Data will be collected face-to-face but where this is not possible, we will ask participants to complete an online form or to complete the form over an audio call with a researcher.

ii) <u>Longitudinal cohort study</u>

The 1020 adolescents and young adults who during the cross-sectional study met criteria for depression and/or anxiety by scoring greater than 9 on the PHQ-8 or GAD-7, and who completed the baseline assessment, will be contacted to complete a short 6-month follow-up questionnaire. Each participant will be asked to complete the 6 month follow-up assessment (GAD-7, PHQ-8, life events and service use questionnaires) by completing an online form. The researcher will answer any questions that the participant might have about the questionnaires or the study at any point. The questionnaire will last approximately 15 minutes. If it is not possible for participants to complete an online form, we will ask them to complete the form over an audio call with a researcher.

The same participants will be contacted to complete a 12-month follow-up, consisting of the same assessment battery used at baseline, but excluding the sociodemographic questions. Each participant will meet with an experienced researcher at a convenient, comfortable and private community location to complete it. The researcher will answer any questions that the participant might have about the questionnaires or study at any point. The meeting will last approximately 30 minutes. Data will be collected face-to-face but where this is not possible, we will ask participants to complete an online form or to complete the form over an audio call with a researcher.

iii) Experience Sampling Method Pilot

Experience sampling methodology (ESM) is a self-report diary method that asks participants to report on their current feelings, thoughts, activities and environment at multiple daily time points over successive days. ESM allows for a detailed assessment of the interaction between real-world context and phenomena that is unaffected by issues of recall.[22]

Adolescent and young adult participants of ESM will be recruited as described above for the cross-sectional study. Members from the LEAP of the local research team will also be invited to take part. Interested individuals will complete the consent procedure (see section 2.5) before any data collection begins. Researchers will collect information regarding participants' age and gender during the consent procedure.

Selected individuals will provide data over an agreed 7-day ESM period. Each day, participants will be asked to complete an ESM assessment 5-8 times, which will be scheduled at random within set blocks of time. Young adult participants will complete the ESM assessment 8 times per day over 7 days, and adolescent participants will complete the ESM assessment 5 times per day for school days and 8 times per day for weekend days, again over 7 days.

At the beginning of the 7-day ESM period, participants will attend a briefing with a researcher, who will provide detailed instructions on how to use the ESM app (eMoodie), when and how to complete the ESM assessments, and to practice the questionnaires (i.e. complete practice questionnaires and explain each item in detail) and generate enthusiasm. Participants will be asked to use the eMoodie app to complete assessments on their mobile phones. Those with difficulty with connectivity will be given phones, and/or data cards to access the internet if this is needed. The researcher will also encourage participants to contact them with any questions about, or problems with, eMoodie or the content of the ESM items. The researcher will also agree a time with the participant for a midweek phone call to discuss any concerns or problems they are experiencing with completing the questionnaires, identify any barriers to completing questionnaires and motivate participants to complete as many ESM questionnaires as possible.

During the 7-day period, participants will be alerted by the eMoodie app to complete questionnaires via a "beep". On hearing this beep, participants should stop what they are doing to complete the questionnaires on the eMoodie app, which will take no longer than 2 minutes. If this first "beep" is missed, they will receive a reminder "beep" after 2 minutes. If this "beep" is also missed, then this assessment point is recorded as missed.

For participants who are low in compliance with the ESM protocol, researcher will contact them more often by phone to offer advice about any questions and assess their adherence to instructions.

At the end of the 7-day ESM period, the researcher will schedule a debriefing session where participants will complete a short debriefing questionnaire. This will briefly explore through open questions, participants' experience of the ESM study, any problems encountered and thoughts on any improvements to the study procedures. This debriefing session will take place face-to-face, via an online platform or over an audio call according to the participant's preference.

Data from the debriefing questions will be analysed and used to inform any changes to the study procedures for the main study described below.

iv) Experience Sampling Method

Adolescent and young adult participants of ESM will be recruited from the sample of participants of the cross-sectional study and longitudinal cohort study. 150 interested individuals: 90 with

depression and/or anxiety (30 per country: 15 per age group), and 60 participants without (20 per country: 10 per age group) will be recruited as described above for the cross-sectional study and will go through an additional consent procedure (see section 2.5). The sample will be stratified by gender to ensure variability within the sample.

The study procedure will be as described above subject to change as informed by the pilot findings, including the length of the study period, frequency of data collection each day, methods of communicating with participants over the 7-day period, the questions asked and the format of these.

90 adolescents and young adults (30 per country, 15 per age group) who met criteria for depression and/or anxiety by scoring greater than 9 on the PHQ-8 or GAD-7 at baseline, and who participated in both the ESM study baseline and in the longitudinal cohort study, will be contacted to complete the ESM assessments again after one year.

v) In-depth interviews

Adolescent and young adult participants of the in-depth interviews will be recruited from participants of the longitudinal cohort study. Interested individuals who have indicated consent to be approached for the in-depth interviews, will be contacted after the 12-month follow-up assessment to attend an interview. Participants will be purposively selected to include those who are recovered or not recovered, a balance of genders and age groups.

The interviews will take place face to face in convenient, comfortable and private community-based locations and will last up to 90 minutes. If face-to-face meetings are not possible, we will ask to meet participants using an online platform or to interview them over an audio call. The researcher will use a topic guide to facilitate the discussion, which will explore with individuals which resources they used and found helpful or not helpful, which resources they are aware of, and any suggestions for ways in which the community or/and services could help them with their recovery.

2.5 Consent procedure

Individuals who respond to the study information with interest will be contacted and invited to attend a face-to-face meeting with a researcher. Researchers will go through information sheets and answer any questions or concerns raised. Where individuals are under 18 years of age, 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 will be arranged if a face-to-face meeting is not possible.

Adult participants and parents/guardians of participants under 18 years old will be asked to provide informed consent, by signing and dating an informed consent form prior to any data collection commencing. Participants under 18 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 (where applicable), and a member of the research team in order to proceed with study participation. The participant and parent/guardian (where applicable) 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 IRBs.

There will be three assent/consent forms: one form for participants of the cross-sectional, longitudinal cohort study and in-depth interviews, one for participants who also wish to participate in the ESM study, and another for participants who wish to participate in the ESM pilot. The consent procedure will be as described above and include consent for researchers to contact participants to complete follow-up assessments 6 and 12 months after baseline. For in-depth interviews, there will be an additional tick box for participants to indicate whether they consent to researchers approaching them for participation, and for the interviews to be audio-recorded.

All researchers will receive training based on Good Clinical Practice (GCP) by attending existing GCP courses online. The researchers will 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 (where applicable) 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 is eliminated providing this occurs before the end of month 15 from their inclusion in the project.

If a participant wishes to withdraw from the study, researchers will record date of withdrawal and reason(s) for withdrawal (if provided).

2.7 Data collection

2.7.1: Cross-sectional and longitudinal cohort study

Socio-demographic information and quantitative data will be collected using the paper or online case report form (CRF). The CRF was developed and all questionnaires piloted as part of Phase I of the OLA programme.

Researchers will be trained in the measures within the CRF. The CRF was designed and piloted for self-administration, but researchers will be present to answer questions that participants might have. The questionnaires included in the CRF are summarised in Table 2.7.2 below.

2.7.2 Schedule of assessments

The table below summarises the questionnaires included in the CRF.

Item measured	Scale/ assessment method	Description of scale	Baseline	6-month follow-up	12-month follow-up
DEMOGRAPHICS					
Demographics	Current living situation	Includes variables like gender, age, education level etc	X		
	History of depression and anxiety	Asks about participants' and their parents' experiences of mental distress and	X		

		treatment received			
MEASURES OF MENTAL DISTRESS					
Degree of distress	Patient Health Questionnaire – 8 (PHQ-8)	Measures degree of experiencing a list of symptoms associated with depression	X	X	X
	Generalised Anxiety Disorder Assessment (GAD-7)	Measures degree of experiencing a list of symptoms associated with anxiety	X	X	X
Drug use	The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)	Measures drug use in the lifetime and last 3 months	X		X
	Adapted Teen Addiction Severity Index (T-ASI)	Measures drug use including alcohol use and severity	X		X
Life events	Adolescent appropriate life events scale	Captures experience of life events in their lifetime and in the last year or six month respectively	X	X	X
MEASURES OF PERSONAL RESOURCES					
Quality of life	Manchester Short Assessment of Quality of Life (MANSA)	Measures perception of how satisfied they are with different aspects of their lives	X		X
Coping style	Child's Coping Strategy Checklist	Measures how individuals deal with problems and stress	X		X
Resilience	Brief Resilience Scale (BRS)	Measures capacity to "bounce back" when faced with stressful events	X		X
	Connor-Davidson Resilience Scale (CD-RISC 25)	Measures resilience in response to stressful events, tragedy or trauma	X		X
MEASURES OF SOCIAL RESOURCES					
Use of healthcare and other services	Client Service Receipt Inventory (CSRI)	Measures frequency of use of healthcare and social services	X	X	X
Social support	Scale of Perceived Social Support	Measures perception of social support network	X		X
Social capital	Adapted Social Capital Assessment Tool (ASCAT)	Asks about perceptions of and engagement with community groups	X		X
MEASURES OF ACTIVITIES					
Sports activity	Open/closed questions	Asks about sports activities including frequency of participation and the nature of these activities	X		X
Arts activity	Open/closed questions	Asks about arts activities including frequency of participation and the nature of these activities	X		X
Internet use	Question 59 from REACH study - adapted	Measures internet use via agreement with a list of statements	X		X

2.7.4: Experience sampling method (ESM)

Researchers will be trained in the ESM measures, study procedures and eMoodie app. The questions to be asked in the ESM study are summarised in Table 2.7.5 below. They will be piloted in the ESM pilot, and so subject to change depending on the pilot findings.

For the ESM pilot, we will ask participants to complete a brief sociodemographic questionnaire, to capture their age, gender and whether they are currently experiencing mental distress, including depression and anxiety.

2.7.5 Schedule of ESM assessments

The table below summarises the questionnaires that form the ESM assessment.

Item measured	Question	Description
Affect	How are you feeling now?	1item asks participants to rate how they are feeling on a 7-point Likert scale ranging from 1 ("extremely unhappy") to 7 ("extremely happy")
Arousal	How nervous or relaxed are you now?	1 item asking participants to rate how nervous/relaxed they are feeling on a 7-point Likert scale ranging from 1 "very nervous" to 7 "very relaxed"
Location	Where are you?	1 item asking participants to state their location. Participants choose from predefined categories or select "other" and provide more detail
Company	Who are you with? Time spent with since last "beep" (notification)?	1 item asking participants to state who they are with. Participants choose from predefined categories or select "other" and provide more detail. 1 item asking participants to indicate time spent with the identified person since the last notification
Activity	What are you doing?	One open question asking participants what they are doing
Thoughts	What are you thinking about?	One open question asking participants what they are thinking about

2.7.3: In-depth interviews

Qualitative data will be collected by researchers who will be trained or have experience in conducting individual interviews. Interviews will explore resources that participants found helpful or not helpful for their recovery and will capture their experiences of community resources used in the last 12 months, knowledge of available resources and suggestions of how the community and/or

services could help them with their recovery. The interviews will be audio-recorded and transcribed verbatim.

2.7.4 Documentation of data collection

The process of data collection will be closely monitored by each partner 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 for each participating site and totals. Numbers from each partner research team will be reported at the weekly researcher teleconference and any challenges to recruitment will be discussed and solutions agreed. Arising issues and problems can also be discussed on an ad-hoc basis with the UK-based and wider team by email or video-conferencing as needed.

2.7.4 Data entry and data quality assurance

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 questionnaires within the CRF 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.

Throughout the data collection period, there will be quality assurance checks. Researchers are responsible for ensuring that CRFs are correctly completed and data are accurately entered onto the database. There will be annual (at a minimum) quality assurance checks by the UK-based research where at least 10% of CRFs will be checked against the REDCap database. Any queries about mismatching or incomplete data will be discussed and resolved with the local research team.

2.8 Participant reimbursement

Participants will be reimbursed for their time and travel expenses as outlined below and will be subject to variation across the partner countries:

Argentina:
Cross-sectional study first research/baseline assessment:
Longitudinal cohort study 6 month follow-up:
Longitudinal cohort study 12 month follow-up:
ESM pilot:
ESM baseline:
ESM follow-up
Transportation costs?

Colombia:
Cross-sectional study first research/baseline assessment:
Longitudinal cohort study 6 month follow-up:
Longitudinal cohort study 12 month follow-up:
ESM pilot:

ESM baseline:
ESM follow-up:
Transportation costs?

Peru:
For all activities where a face-to-face encounter occur, we will reimburse their transportation costs to attend the meeting for up to S/ 10.00
Cross-sectional study first research/baseline assessment: Small present with an estimated value of S/ 30.00
Longitudinal cohort study 6 month follow-up: Small present with an estimated value of S/ 15.00
Longitudinal cohort study 12 month follow-up: Small present with an estimated value of S/ 30.00
ESM pilot: Small present with an estimated value of S/ 50.00
ESM study: Small present with an estimated value of S/ 50.00
ESM follow-up: Small present with an estimated value of S/ 50.00
In-depth interviews: Small present with an estimated value of S/ 30.00

2.9 End of study definition

This study ends when the last participant has completed the 12-month follow-up for the longitudinal cohort study or in-depth interview, whichever comes last. Completion of the analysis will signify the end of phase II of the OLA programme.

2.9.1 Early termination

If the local IRB determines if it is within the best interests of the participants to terminate the study, 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 for the cross-sectional and longitudinal cohort study

The sample size has been calculated for identifying variables that predict recovery over a one-year period. Assuming a predictor variable (participant characteristic, personal or social resource, or activity performed) exists in 10% of the population, we can detect a difference in recovery rate between 40% and 60% with 90% power and at a 5% significance level with a total sample size of 762 people. Assuming a dropout rate of 25%, 1000 people in total are required. Recruiting 340 people with mental distress at each of the three countries provides a total sample of 1020.

3.1.2 Quantitative sample size for ESM study

The sample sizes for the ESM are based on the assumption that a minimum of 30 participants is required for a separate sub-group analysis, i.e. for each age group and at each partner site in the first assessment, and overall, for people who recovered and who have not at the follow-up.

3.1.3 Qualitative sample size for in-depth interviews

The sample size for the in-depth interviews (30 per country) is assumed to be sufficient to reach saturation of the emerging material[23]. This reflects the experience of similar procedures in other international studies. However, if no saturation has been reached with a sample of 30, more

interviews of purposively selected participants (selection criteria based on aspects where more material is needed to reach saturation) might be required.

3.2 Statistical data analysis

The number of screened participants, eligible participants and of those who refused participation will be recorded. Descriptive statistics will be reported for socio-demographic data.

3.2.1 Cross-sectional and longitudinal cohort study

Differences between the groups on each of the measures will be assessed using t-tests and chi-squared tests, with logistic regression used to model the data – including the impact of covariates such as gender. The distribution and level of resilience factors will be summarised using the median, whilst frequency and counts will summarise exposure to different community resources.

Long term recovery is recovery over a one-year period. At one-year follow up, based on the PHQ-8 and GAD-7 scores, individuals will be classified as recovered – defined as no longer screening positive for depression and/or anxiety (scoring 9 or less on the higher scoring scale at baseline), or not recovered (scoring greater than 9 on the higher scoring scale at baseline). The primary outcome is the proportion of people classified as recovered after one year. Analyses will initially be conducted separately for each age group. Multivariate logistic regression analyses using a random effects model will assess the relationship between predictor variables and recovery. Where a variable has an association with recovery significant at $p \leq .1$ level, it will be included in the multivariable model. The model will then be adjusted for socio-demographic characteristics such as gender. Multiple imputation by chained equations will explore the impact of missing data. To address the sub-objectives regarding whether the same resilience factors are associated with recovery for both age groups and genders, the analysis will be re-done across the whole sample and an interaction term between any variable showing a significant association with recovery and i) age group and ii) gender will be fitted. Finally, sensitivity analyses will assess the impact of including individuals classed as recovered.

3.2.2 ESM study

The data will be multilevel as multiple observations are nested within participants. Short term recovery means any recovery within the 7 days assessment period, whether it is within hours or over the full seven days. Recovery will be assessed as a continuous variable, as improvement of any reported distress. The analysis of this will be exploratory and consider different levels of distress and improvement. Long term recovery will use the same definition as the longitudinal cohort study (see Section 3.2.1).

Initially the multilevel models will focus on the stress-related variables and the link to negative affect and positive affect. Within the models, we will control for potential confounding factors such as gender and sociodemographic variables. Differences between groups will be assessed by fitting a two-way interaction (stress variable x group). Resource data from the ESM baseline will be analysed separately. Different types of resources will be categorised and the frequency of resources within each category calculated. Group differences will be tested using linear regression models where the number of resources is the focus, and with logistic regression for dichotomous outcomes e.g. did or did not use a resource.

3.3 Qualitative data analysis

The data from the ESM pilot: responses to the debriefing questionnaire will be analysed to identify suggestions for improving the ESM study procedures and questions, and problems faced by participants to be resolved for the main ESM study.

The interviews will be audio-recorded and transcribed verbatim. Transcripts will be coded line-by-line and analysed using Framework Analysis following the stages of familiarization; identifying a thematic framework; indexing; charting; and interpretation[24]. This will focus on common features of the identified practices and resources, which could be scaled up and more widely disseminated.

4. Ethical and regulatory considerations

The local Principal Investigators, Brusco (Argentina), Gomez-Restrepo (Colombia) and Diez Canseco (Peru) will ensure that the study is carried out in accordance with local and national ethical principles. We will be applying to the Institutional Ethics Committee on Research of the Universidad Buenos Aires, IRB of Universidad Javeriana, and Institutional Ethics Committee of the Universidad Peruana Cayetano Heredia, and any further required approvals before implementing the research activities 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 teams 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 PIs will ensure that any progress reports to the IRB or other relevant organisations are submitted as required. The local PIs 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. A benefit for all participants involved in this phase of research, is that their participation contributes to the wider aim of the research programme to identify which resilience factors help adolescents and young people to prevent and recover from mental distress. Participating in this study might allow individuals to recognise and become aware of the resources that help them manage mental distress generally and in specific day-to-day situations.

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. A potential risk of participating in the study is that within the CRF and ESM assessment, questions will be raised with participants that might trigger feelings of distress or anxiety.

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 research activities will be conducted by researchers who have previous experience of working with individuals with mental health difficulties.
2. Researchers will be trained in conducting the measures in the CRF, ESM methodology, conducting interviews and general Good Clinical Practice principles.
3. The purpose of the study will be clearly explained to participants and their parents/guardians (where appropriate), and it will be stressed that participants do not have to share any information they are uncomfortable with.
4. The CRF for the cross-sectional and longitudinal cohort study will be piloted in Phase I of the OLA programme. The ESM study will be piloted in its entirety.

5. Participants will be reminded about their right to withdraw (without giving reason) at any point in the study.
6. All participants, including parents/guardians (where appropriate), will be provided with an information sheet about the study, depression and anxiety and with the contact details of local resources within each area.
7. Participants and their parents/guardians (where appropriate), will be informed that the research team are able to contact their clinicians or a mental health service if they would like further support.
8. In the unlikely event that any individual becomes highly distressed during the research, or where the participant discloses risk of harm to self or others, data collection will be terminated immediately and, where appropriate, their clinician or a mental health service or their school 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. school, clinic). All researchers will be trained in country-specific safe-guarding procedures, approved by local ethics committees, for working with individuals who disclose risks of harm and will be provided with on-going supervision.

4.2.2 Informed consent

Before any data collection begins, eligible individuals (adolescents, young adults, parents/guardians of adolescents) will provide informed consent (as described in section 2.5). Where individuals are under 18 years of age, a parent/ guardian will provide informed consent for participation. 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 local 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 this meeting.

4.2.3 Confidentiality

To ensure anonymity, all participants will be pseudonymised by being assigned a participant ID. 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, including socio-demographic forms, consent forms and participant reimbursement receipts, will be stored in a securely locked cupboard on the premises of Universidad de Buenos Aires, Pontificia Universidad Javeriana and CRONICAS at Universidad Peruana Cayetano Heredia. Paper CRFs with outcome data 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 IRBs as part of the amendment to the Phase I 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 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 young adults and adolescents living in urban environments who are exposed to multiple risk factors for poor mental health, in the research and mental health discourse. We will work with local arts organisations based in urban communities to identify a broad range of young people to participate in the programme.

A lived experience advisory panel (LEAP) of 6-10 young people per country has been set up for the whole OLA programme. All participants have some experience of anxiety and/or depression and are providing input and advice into the design and conduct of the study.

7. Data protection and confidentiality

All investigators and study staff will comply with the requirements of the data protection laws within their countries 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.

7.2 Audio recordings

Interview data will be audio-recorded using an encrypted device with explicit permission (as indicated on the consent form) from participants. Audio recordings will be stored in password-protected folders on computers using a secure drive, which will only be accessible to the research team. The audio recordings will be destroyed immediately after data analysis. All transcriptions will be completed by a professional transcription service or researchers from the local research teams. All identifiable information will be removed and/ or replaced with pseudonymised labels and audio recordings will be transferred to the transcription service in a secure way.

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 PIs (Bird and Priebe) will be the custodians 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.

The data collected in Argentina will also be stored at the main study site in Universidad de Buenos Aires, and Dr Brusco will be the custodian of the data. This will be done according to the regulation for data storage and protection at Universidad de Buenos Aires, Buenos Aires.

The data collected in Peru will also be stored at the main study site in CRONICAS, at Universidad Peruana Cayetano Heredia, and Mr Diez Canseco will be the custodian of the data. This will be done according to the regulation for data storage and protection at Universidad Peruana Cayetano Heredia, Lima.

9. Dissemination

The aims and impact of the programme will be achieved through a comprehensive communication plan, which will inform the different stakeholders of the research findings and provide information relating to the programme outputs. This will ensure that the new knowledge obtained translates into improved health outcomes. The communication plan will be developed in the initial stages and will aim to disseminate the findings to different target audiences. 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.

Communication activities will include both printed format and online materials. The following activities will be included in the communication plans of the wider research programme:

Project-specific website: The website will provide an interactive environment and will aim to engage different stakeholders including adolescents and young people. It will be linked with other popular social media platforms such as Facebook and twitter.

Twitter and social media accounts: To allow for fast and regular communication responsive to the developments throughout the programme and more widely with reference to mental healthcare for adolescents and young people with depression and anxiety, the project will make use of existing twitter accounts, with a project specific hashtag (e.g. #OLAstudy). Information, findings and related news about the study in an accessible form will be tweeted and we will link in with other twitter accounts, including the WHO, MRC, and GCRF to promote the study to a wider audience.

Peer-review publications and conference presentations: We will disseminate the knowledge generated to academic audiences worldwide via the publication of high-impact scientific publications. A focus will be placed on building research capacity; therefore, junior researchers will be supported to write publications. The publications and presentations will be circulated via the extensive networks of the applications. Publications will be produced in both Spanish and English to ensure that academics in Latin America can easily access the evidence. We will aim to publish all findings open-access and will ensure that all data is handled in accordance with the FAIR principles.

Appendix

Appendix 1 – Amendment History

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

References

1. Patel V, Flisher AJ, Hetrick S, McGorry P. Mental health of young people: a global public-health challenge. Lancet. 2007; 370: 901-1005.
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