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

Submission date
14/12/2020

Recruitment status
No longer recruiting

Registration date
16/12/2020

Overall study status
Completed

Last Edited
17/10/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The number of people with depression and anxiety greatly increases during adolescence. Adolescents who live in big cities more commonly experience stressful events such as conflict, poverty, substance misuse, and social isolation. This includes adolescents from Latin America, which is the most urban part of the world.

Although many individuals experience stressful events, the majority do not develop either depression or anxiety. Furthermore, up to half of the people who do develop these conditions recover within a year. This raises the question of what resources help in the prevention of depression and anxiety, and help people recover.

This study aims to understand the resources that are linked to either recovery or the prevention of depression and anxiety, so that new approaches can be developed to treat depression and anxiety. This study will focus on young people living in three large Latin American cities: Buenos Aires, Bogotá, and Lima.

Who can participate?
Adolescents (aged 15-16 years old) and young adults (aged 20-24 years old) living in specific areas of Bogotá, Buenos Aires, and Lima. Adolescents will need their parent's or guardian's consent to participate in this study.

What does the study involve?
This study will compare a group of adolescents (15-16 years old) and young adults (20-24 years old) with depression and anxiety with the same number of adolescents and young adults without depression and anxiety. Participants will all be asked to complete questionnaires about symptoms of mental distress, personal factors such as health behaviours and coping with problems, and social factors including relationships with friends and family. The study will test if there are differences between the two groups, and find out which resources are linked to prevention.

The individuals who have depression and anxiety will be asked to complete the same questionnaires after 12 and 24 months, and also a few questionnaires after the first six months. We will compare individuals who have recovered from depression and anxiety to those who did not. This will tell us about the resources that are linked to recovery.

In a separate but linked Experience Sampling Method (ESM) study, a subset of 150 participants will be invited to complete questionnaires using a mobile phone app. These young people will be asked to answer the same, very short ESM questionnaire between five and eight times-per-day over a period of seven days. This will include questions about mood, stress levels, what the person is doing, and who they are with. This will provide information about resources that are linked to recovery that happens over a short period of time, and allow the study team to compare these with resources that help recovery over a longer period of time (one year). Eighteen participants aged 15-24 years old, will be invited to test these study procedures using the mobile phone app before the ESM study takes place.

What are the possible benefits and risks of participating?
The information that participants provide will help with the aims of this study, to identify and understand the resources that help young people to prevent and recover from depression and /or anxiety. This might lead to new approaches to reduce the burden of mental distress in young people in Latin America and beyond.

There are no expected risks linked with taking part in this study, but participants may feel uncomfortable or saddened by some of the questions. The research team is trained to talk about these topics in a warm and respectful way, and participants may decide not to answer specific questions.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
From May 2020 to August 2024

Who is funding the study?
The Medical Research Council (UK)

Who is the main contact?
Catherine Fung
c.fung@qmul.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Catherine Fung

ORCID ID
https://orcid.org/0000-0002-3220-6930

Contact details

Unit for Social and Community Psychiatry
Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 (0)20 7540 4380 ext. 2312
c.fung@qmul.ac.uk

Type(s)
Scientific

Contact name
Prof Stefan Priebe

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

Contact details
Unit for Social and Community Psychiatry
Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 (0)20-75404210
s.priebe@qmul.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MR/S03580X/1

Study information

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

Acronym
OLA

Study objectives
1. To determine whether characteristics, resources, and activities differ between young people with and without depression and/or anxiety
2. To identify which characteristics, resources, and activities in young people are associated with

recovery from depression and/or anxiety
3. To 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)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/11/2020, Ethics Committee in Biomedical Research, Alberto C. Taquini Institute for Translational Medicine Research (Faculty of Medicine, University of Buenos Aires, Marcelo T. de Alvear 2270, C1122 AAJ, Cuidad Autonoma de Buenos Aires, Argentina; +54-11 5285-2751/2/3; infotaquini@fmed.uba.ar)
2. Approved 20/11/2020, Faculty of Medicine - Research and Ethics Committee of the Pontificia Universidad Javeriana, Bogota (Hospital Universitario San Ignacio, Carrera 7a No 40-62, Piso 2, Bogota, Colombia; +57-1 3208320 ext. 2770 - 2879227; ciei@husi.org.co), ref: FM-CIE-1138-20
3. Approved 16/11/2020 Institutional Ethics Committee of Research of the Universidad Peruana Cayetano Heredia (Av. Honorio Delgado 430, Apartado postal 4314, SMP Lima - Peru; +51 1 319-0000 ext. 201352; duict@oficinas-upch.pe), ref: 581-33-20
4. Approved 16/11/2020, Queen Mary Ethics of Research Committee (Room W104, Queen's Building, Mile End Road, London, UK, E1 4NS; +44 (0)20 7882 7915/6947; research-ethics@qmul.ac.uk), ref: QMERC2020/02

Study design
Multi-centre cross-sectional study, longitudinal cohort study, and experience sampling method study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Depression and anxiety in adolescents and young adults

Interventions
A cross-sectional study will be used to compare 340 young people per country with depression and/or anxiety with 340 young people per country without. Young people will be asked to complete an assessment battery developed in the first Work Package of this research programme.

A longitudinal cohort study will be used to follow-up, at 6 and 12 months, the young people identified with depression and/or anxiety. At 6 months, participants will complete a brief (much reduced) assessment battery remotely. At 12 months, participants will complete the full assessment battery, which they completed at baseline. Contingency plans are in place to allow remote data collection where needed.

Experience sampling method (ESM) pilot:
Six young people per country aged 15-24 years old will be invited to pilot the ESM study procedures. They will complete an ESM assessment (lasting no longer than 2 min), 5-8 times per

day over 7 days, using a mobile phone application. They will be asked to attend a briefing session and will be invited to a brief call during the week to troubleshoot any problems and answer some debriefing questions after the 7 day ESM period.

ESM study:
The procedures and ESM assessment will be refined using findings from the pilot. Young people participating in the cross-sectional and longitudinal cohort study will be invited to take part in the ESM study. 30 participants per country from either age group with depression and/or anxiety, and 20 participants from either age group per country without. 30 young people per country with depression and/or anxiety will be asked to complete the ESM assessments again after 12 months.

Intervention Type
Behavioural

Primary outcome(s)
1. Depression and anxiety symptom recovery measured using the Generalized Anxiety Disorder questionnaire (GAD-7) and the 8-item Patient Health Questionnaire (PHQ-8) scores at baseline and 12 months. Recovery is defined as no longer screening positive for depression and/or anxiety (scoring ≤9 at 12 months on the scale where the higher score was measured at baseline), or not recovered (scoring >9 at 12 months on the scale where the higher score was measured at baseline)

Key secondary outcome(s))
Current secondary outcome measures as of 17/10/2023:

1. Demographic information including current living situation, gender, age, education level, and history and family history of depression and anxiety measured using questionnaires at baseline, 12 and 24 months
2. Degree of distress measured using GAD-7 and PHQ-8 scores at baseline, 6, 12 and 24 months
3. Drug use measured using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) and the Adapted Teen Addiction Severity Index (T-ASI) at baseline, 12 and 24 months
4. Life events measured using the adolescent appropriate life events scale at baseline, 6, 12 and 24 months
5. Quality of life measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline, 12 and 24 months
6. Coping style measured using the child's coping strategy checklist at baseline, 12 and 24 months
7. Resilience measured using the Brief Resilience Scale (BRS) and the Connor-Davidson Resilience Scale (CD-RISC 25) at baseline, 12 and 24 months
8. Use of healthcare and other services measured using the Client Service Receipt Inventory (CSRI) at baseline, 6, 12 and 24 months
9. Social support measured using scale of perceived social support at baseline, 12 and 24 months
10. Social capital measured using Adapted Social Capital Assessment Tool (ASCAT) at baseline, 12 and 24 months
11. Sports activity measured using open/closed questions about sports activities including frequency of participation and the nature of these activities at baseline, 12 and 24 months
12. Arts activity measured using open/closed questions about arts activities including frequency of participation and the nature of these activities at baseline, 12 and 24 months
13. Internet use measured using question 59 from the adapted REACH study at baseline, 12 and 24 months

14. Current country situation measured using closed questions with responses on a Likert scale at 24 months
15. Online games and gambling behaviour using closed questions at 24 months

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Previous secondary outcome measures:

1. Demographic information including current living situation, gender, age, education level, and history and family history of depression and anxiety measured using questionnaires at baseline
2. Degree of distress measured using GAD-7 and PHQ-8 scores at baseline, 6, and 12 months
3. Drug use measured using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) and the Adapted Teen Addiction Severity Index (T-ASI) at baseline and 12 months
4. Life events measured using the adolescent appropriate life events scale at baseline, 6, and 12 months
5. Quality of life measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline and 12 months
6. Coping style measured using the child's coping strategy checklist at baseline and 12 months
7. Resilience measured using the Brief Resilience Scale (BRS) and the Connor-Davidson Resilience Scale (CD-RISC 25) at baseline and 12 months
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11. Sports activity measured using open/closed questions about sports activities including frequency of participation and the nature of these activities at baseline and 12 months
12. Arts activity measured using open/closed questions about arts activities including frequency of participation and the nature of these activities at baseline and 12 months
13. Internet use measured using question 59 from the adapted REACH study at baseline and 12 months

Completion date
30/08/2024

Eligibility

Key inclusion criteria
1. Aged either 15-16 years or 20-24 years
2. Capacity to provide informed consent (20-24 year olds) or capacity to provide assent and informed consent provided by parent/guardian (15-16 year olds only)
3. Live in the defined geographical area (within 50% poorest neighbourhoods in the city)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
2405

Key exclusion criteria
1. Known diagnosis of severe mental illness such as psychosis, bipolar disorder, or schizophrenia
2. Known diagnosis of cognitive impairment
3. Unable to provide informed consent
4. Unable to read or write

Date of first enrolment
01/04/2021

Date of final enrolment
29/09/2022

Locations

Countries of recruitment
Argentina

Colombia

Peru

Study participating centre
Universidad Peruana Cayetano Heredia
Avenida Honorio Delgado 430 Urb. Ingeniería
San Martín de Porres
Lima
Peru
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Study participating centre
Pontificia Universidad Javeriana
Carrera 7 No. 40 - 62
Piso 4
Edificio Emilio Arango S.J.
Bogota
Colombia
-

Study participating centre
Universidad Buenos Aires
Paraguay 2155
Buenos Aires
Argentina
-

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
In-line with the MRC's requirement for timely data sharing, the study team will have exclusive use of the data for 12 months following completion of the study. During this time, requests for data can be made to Stefan Priebe (s.priebe@qmul.ac.uk) or Catherine Fung (c.fung@qmul.ac.uk) and in accordance with the PCTU data sharing policy, which will be published on the study

website. Individuals wishing to access the data will need to sign a data sharing agreement, in accordance with QMUL and PCTU procedures. Data access will be considered by the PCTU Data Sharing Committee and individuals wishing to access the data will also be bound by the PCTU data sharing policy. Potentially identifiable data will be removed from the dataset and aggregated data used where possible. Consent from participants for data sharing will be obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1.0	07/09/2020	04/01/2021	No	Yes
Participant information sheet	version v1.0	07/09/2020	04/01/2021	No	Yes
Participant information sheet	version v1.0	07/09/2020	04/01/2021	No	Yes
Participant information sheet	version v1.0	07/09/2020	04/01/2021	No	Yes
Participant information sheet	version v1.0	07/09/2020	04/01/2021	No	Yes
Participant information sheet	version v1.0	07/09/2020	04/01/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v0.5	15/09/2020	04/01/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes