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# BRiCs: Improving the quality of life for adolescents with mental health problems in Colombia

**Submission date**
01/03/2022

**Recruitment status**
No longer recruiting

**Registration date**
18/03/2022

**Overall study status**
Completed

**Last Edited**
14/05/2024

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Depression and anxiety are common mental health problems affecting one in four people at some point in their lives. The number of people who experience depression and anxiety greatly increases during adolescence, particularly for those who experience stressful events. This includes adolescents who live in Low and Middle-Income Countries (LMICs). In fact, depression and anxiety are the top causes of disability for adolescents in LMICs. Despite the negative impact of depression and anxiety, a treatment gap exists. Less than half of people with depression and anxiety in LMICs access treatment. Even when people do get treatment, only a small proportion (20%) receive a minimum standard of care. This is often due to a lack of resources including enough specially trained staff and services to help people. Therefore, to improve health outcomes for adolescents with depression and anxiety, new approaches are needed. These new approaches need to be low-cost, effective, and have the potential to be used by a range of staff. We aim to achieve this goal.

DIALOG+ is an existing low-cost/cost-saving evidence-based therapeutically effective mental health intervention, which has been used and assessed in many clinical contexts internationally. During the initial phases of the project, we conducted focus groups and interviews to "repurpose" the intervention to ensure that it was suitable for adolescents. The new intervention is called DIALOG-A.

We will evaluate DIALOG-A in a cluster randomised controlled trial (RCT) conducted in two regions of Colombia - one deprived inner-city area and one rural location.

The overall aim is to improve health outcomes for adolescents with depression and anxiety in Colombia by adapting an existing effective intervention.

Who can participate?
Clinicians (aged 18 and over) who have regular contact with adolescents and adolescent patients (13-16 years old) with anxiety and/or depression from Bogotá and Duitama.

What does the study involve?
We will include 18 clinicians and 108 adolescents. 12 clinicians a72 adolescents will use DIALOG-A, and the remaining 6 staff and 36 adolescents will be in the control condition. To test whether DIALOG-A helps adolescents with depression and anxiety, we will ask participants to complete questionnaires at the start of the study and at 6 and 9 months. We will collect data on mental health outcomes, including symptoms of depression and anxiety, quality of life, social situation, and self-esteem.

What are the possible benefits and risks of participating?
Overall, the study will build both mental health and research capacity within Colombia. A potential benefit for all participants involved in the research, is that their suggestions and experiences might be incorporated into the adaption of DIALOG+ for use in an adolescent population. Additionally, for adolescents who will be involved in the testing of the modified intervention (DIALOG-A), this might lead to improved quality of life, social functioning, and symptoms. The project will also benefit the clinicians involved as they will be provided with training and supervision to enable them to implement the intervention.

The researchers do not predict any significant risks from participating in this study. All researchers will be trained in safe-guarding procedures and will be provided with on-going supervision in policies and procedures for, and in working with, individuals who disclose risks of harm. All research activities will be completed by researchers with experience of working with people with mental health difficulties.

Participants may also experience anxiety in trying new interventions. Throughout the intervention-testing period, individuals will continue to receive their routine care, including any medication, in addition to the test intervention, furthermore, the intervention can be stopped at any point.

Where is the study run from?
Pontificia Universidad Javeriana (Colombia)

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

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

Who is the main contact?
Professor Victoria Bird
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# Contact information

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Building Resilience in adolescence – Improving quality of life for adolescents with mental health problems in Colombia

### Acronym
BRiCs

### Study objectives
DIALOG-A can significantly improve outcomes for adolescents with anxiety and/or depression compared to usual care.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Approved 05/06/2020, Queen Mary Ethics of Research Committee (Queen Mary University of London, Queens' Building, Mile End Campus, Mile End Road, London, E1 4NS, UK; +44 (0)20 7882 7915; research-ethics@qmul.ac.uk), ref: QMER2020/13.
2. Approved 27/02/2020, Comité de Investigaciones y Ética Institucional, Facultad de Medicina, Pontificia Universidad Javeriana (Institutional Research and Ethics Committee, Faculty of Medicine, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio, Carrera 7 # 40-62, piso 2, Bogotá, Colombia; +57 (0)1 3208320 Ext 277; ciei@husi.org.co), ref: Building resilience in adolescence – improving quality of life for adolescents with mental health problems in Colombia (BRiCs) 2019/183.

### Study design
Multi-site cluster exploratory randomized controlled trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Adolescents with anxiety and/or depression

### Interventions
Adolescents and clinicians will be recruited from at least three primary care/community health centres in the Bogota and Duitama municipalities. The unit of randomisation will be the clinicians, who will be randomised in a 2:1 ratio to either the intervention (DIALOG-A once per month over 6 months) or to the usual care control group (routine care, without DIALOG).

The researchers will also collect data on effect estimates, variability, and recruitment and retention rates that would be required for a fully powered, definitive, efficacy trial.

In the intervention group, clinicians and adolescents will use the repurposed DIALOG-A once per month over a 6-month period. Thereafter, they can use DIALOG-A flexibly depending on need. This will be documented and considered in the analysis. The intervention will be compared to a usual care control group. Clinicians in the active control will ask individuals to rate their quality of life on a tablet. This however will occur at the end of their meeting and will not involve a discussion of the ratings or the four-step solution-focused approach.

### Intervention Type
Behavioural

### Primary outcome(s)
Primary outcomes will be collected at baseline and 6 months:
1. Symptoms of depression measured using the Patient Health Questionnaire (PHQ- 8) at 6 months
2. Symptoms of anxiety measured using Generalised Anxiety Disorder assessment (GAD-7) at 6 months

### Key secondary outcome(s))
All secondary outcomes are collected at baseline, 6 and 9 months (unless otherwise stated), for the 108 patient participants:
1. Depression on the PHQ-8 (at 9 months)
2. Anxiety on the GAD-7 (at 9 months)
3. Quality of life will be measured using Manchester Short Assessment Quality of Life (MANSA)
4. Mental health symptom levels (YP-CORE)
5. Social Support measured using the Multidimensional Scale of perceived Social Support
6. Empowerment measured using the Youth Efficacy/Empowerment scale
7. Self-esteem measured using the Rosenberg self-esteem scale
8. Economic outcomes measured using a modified Client Service Receipt Inventory (CSRI)

### Completion date
17/11/2023

## Eligibility

### Key inclusion criteria
Clinicians:
1. Aged 18 years or over
2. Regularly sees adolescents with anxiety and/or depression
3. Experience of working with adolescents for at least 3 months
4. No plans to leave the current post within the next 6 months

Patients:
5. Aged 13-16 years old
6. Currently experiencing depression or anxiety (defined as a score ≥7 on the Self-Reporting Questionnaire)
7. Capacity to provide informed assent and consent is provided by a parent/guardian

### Participant type(s)

Mixed

**Healthy volunteers allowed**
No

**Age group**
Mixed

**Lower age limit**
18 years

**Sex**
All

**Total final enrolment**
149

**Key exclusion criteria**
Clinicians:
1. Does not have regular contact with adolescents

Patients:
2. Severe mental illness (psychosis, bipolar or schizophrenia)
3. Cognitive impairment and/or severe learning disability
4. Unable to provide informed assent and/or a parent/guardian does not provide consent

**Date of first enrolment**
14/02/2022

**Date of final enrolment**
14/10/2022

# Locations

**Countries of recruitment**
Colombia

**Study participating centre**
**Pontificia Universidad Javeriana**
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# Sponsor information

**Organisation**
Pontificia Universidad Javeriana

**ROR**
https://ror.org/03etyjw28

# Funder(s)

**Funder type**
Research council

**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**
The project will operate an open research data policy, following the FAIR principles e.g. making the research data generated by the project Findable, Accessible, Interoperable and Reusable. At the same time, the research team will ensure that any sensitive data is not inappropriately accessed. The anonymised datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request Carlos Gomez-Restrepo (cgomez@javeriana.edu.co).
All data will be anonymised to protect confidentiality. Potentially identifiable data will be removed from the database, and aggregated data used where possible. Consent procedures will outline what data will be stored and how it may be shared. This will include outlining any current or potential future risks associated with data confidentiality.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 08/02/2023 | 09/02/2023 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |