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Improving adolescent mental health by reducing the impact of poverty

Submission date
26/04/2024

Recruitment status
No longer recruiting

Registration date
29/04/2024

Overall study status
Ongoing

Last Edited
11/06/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Depression and anxiety are the leading contributors to the global burden of disease among young people, and contribute significantly to suicide. Investing in the health and human capital of young people, 90% of whom live in low- and middle-income countries (LMICs), is critical for future generations, and a key driver of the future health and economic prosperity of LMICs. Yet, the evidence base for interventions that effectively prevent adolescent depression and anxiety is weak, particularly in LMICs. One major shortcoming is that interventions often fail to address socioeconomic adversities due to multidimensional poverty, which are powerful determinants of adolescent depression and anxiety. Some antipoverty interventions, such as cash transfers and economic empowerment, have shown modest benefits for reducing youth depression in LMICs. However, anti-poverty interventions on their own are likely to be insufficient to reduce depression and anxiety, as are psychosocial interventions alone in the context of extreme poverty. Evidence is lacking on the potential of combining the science of anti-poverty interventions and psychosocial interventions, including those specifically targeted at strengthening self-regulation, in order to prevent adolescent depression and anxiety. The aim of ALIVE is to conduct a pilot evaluation of an intervention that both addresses poverty and strengthens self-regulation among adolescents living in urban poverty.

Who can participate?
Non-depressed and non-anxious 13-15-year-old adolescents and their primary caregivers who live in multidimensional poverty in Bogotá (Colombia), Kathmandu (Nepal), and Cape Town (South Africa).

What does the study involve?
In each site, eight schools will be randomly selected, and a total of 30 adolescents and caregivers will be recruited in each school. The schools will be randomly allocated to receive one of four interventions: (i) self-regulation intervention (focused on learning to regulate emotions and thoughts, to set goals and to maintain goal-directed behaviour), (ii) economic intervention (focusing on gaining financial skills, learning more about education, and how to manage money, including receiving a monthly cash transfer), (iii) combined intervention (which includes elements of both self-regulation and economic interventions); (iv) control intervention (care as usual).

Each intervention will consist of 20 weekly 1.5- to 2-hour group sessions with adolescents, and 6 monthly group sessions with their caregivers, over a period of 4-6 months. Sessions will be delivered by lay facilitators, all with experience working with adolescents and recruited from similar communities to the participants.

Adolescents and caregivers will be assessed on key measures before the start of the intervention, and they will be followed up once the intervention is over, and again 6 and 12 months after that. The adolescents will be assessed on topics relating to mental wellbeing, emotion regulation, behavioural difficulties, hope, sleep and economic questions around education, aspirations and financial education. These will be assessed via questionnaires and neuropsychological tasks or games. Participants' heart rate variability will also be measured. Caregivers' questionnaires will cover topics such as mental wellbeing, parenting, service use and economic-related questions.

Interviews with adolescents, caregivers and intervention facilitators will also be conducted after the intervention is over to understand their experience of the interventions better, and to see how the interventions could be delivered in a better way.

What are the possible benefits and risks of participating?
There are some benefits to participating in the pilot cluster RCT, should participants be enrolled in the study after screening. Participants who are allocated to one of the three intervention arms will gain some level of self-regulation or financial skills, which will be beneficial for their mental health and in budgeting in future. Participation in the study will also contribute towards developing an intervention that is culturally adapted, appropriate and accepted by adolescents living in poverty.

There is a possibility of increased burden on participants who have to complete the questionnaires at the different timepoints during the study. The risk that adolescent or caregiver participants will experience psychological stress or discomfort during the intervention is low. Indeed, the interventions provided are preventive, and thus will be targeting adolescents who are not currently experiencing depressive or anxiety symptoms. However, adolescents and their caregivers are recruited because they live in areas with high levels of poverty, and thus it is possible that the contents covered in the interventions may trigger psychological stress or discomfort.

Where is the study run from?
Kings College London (KCL) (UK) is the lead institution, to which the two principal investigators are affiliated. Local researchers and data managers in charge of data collection, data curation and analysis will be based in Colombia (Innovation for Poverty Action (IPA) Colombia), Nepal (Transcultural Psychosocial Organization (TPO) Nepal) and South Africa (University of Cape Town).

Who is funding the study?
Wellcome Trust (221940/Z/20/Z)

When is the study starting and how long is it expected to run for?
March 2024 to November 2025

Who is the main contact?
Emily Garman (emily.garman@uct.ac.za) – ALIVE Scientific Coordinator

Study website

https://www.alive4mentalhealth.org/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
WT 221940/Z/20/Z

Study information

Scientific Title
Improving adolescent mental health by reducing the impact of poverty: pilot cluster randomised controlled trial

Acronym
ALIVE

Study objectives
The aim of this pilot cluster randomised controlled trial is to evaluate the feasibility, acceptability and cost of the ALIVE intervention(s), and to test the trial procedures and measures to inform a future fully powered multi-site trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/03/2024, King's College London Health Faculties Research Ethics Committee (5-11 Lavington Street, London, SE1 0NZ, United Kingdom; +44 (0)20 7836 5454; rec@kcl.ac.uk), ref: HR/DP-23/24-40543

2. Submitted 24/04/2024, Nepal Health Research Council, Ethical Review Board (Ramshah Path, PO Box 7626, Kathmandu, 44600, Nepal; +977-1-5354220; approval@nhrc.gov.np), ref: 167 / 2024

3. Submitted 24/04/2024, University of Cape Town's Health Sciences Human Research Ethics Committee (Old Main Building, Groote Schuur Hospital, Main Road, Observatory, Cape Town, 7935, South Africa; +27214066338; hrec-enquiries@uct.ac.za), ref: 315/2022

4. Approved 19/04/2024, IPA Institutional Review Board (1701 Rhode Island Ave NW, 3rd Floor, Washington, DC, 20036, United States of America; n/a; humansubjects@poverty-action.org), ref: 4062

Study design
Pilot four-arm single-blind cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community, School

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Prevention of depression and anxiety among at-risk adolescents living in poverty

Interventions
This is a pilot four-arm cluster randomised controlled trial, taking place in three sites: Bogotá (Colombia), Kathmandu (Nepal) and Cape Town (South Africa). Schools will be considered clusters, and in each site, two clusters will be randomly allocated to one of the four arms: (i) self-regulation intervention, (ii) economic intervention, (iii) combined (self-regulation + economic) intervention, and (iv) control group. Randomisation will be stratified by site and computerized using a computer-based pseudo-random number generator. Each cluster will comprise of approximately 30 adolescents and 30 caregivers.

Each intervention consists of 20 weekly group sessions with adolescents, and 6 monthly group sessions with their caregivers, over a period of 4-6 months. Each group will comprise of 15 adolescents and 15 caregivers, respectively. Sessions in the self-regulation and economic interventions will last 1.5 hours, while sessions in the combined intervention will last 2 hours. Sessions will be delivered by lay facilitators, all with experience working with adolescents and recruited from similar communities to the participants. Participants will be assessed on key measures before the start of the intervention (T0), post-intervention (T1), 12-months post baseline (T2) and 18-month post baseline (T3).

The self-regulation intervention will combine group physical activity with core active components that strengthen self-regulation, selected based on an extensive review of the literature assessing the effect of key intervention ingredients in preventing depression or anxiety among youth globally. The purpose of the self-regulation intervention for adolescents will be to strengthen self-regulation among adolescents living in circumstances of poverty, through the creation of safe spaces for youth to build strong social connections, learn and

master new skills, and experience respite from adversity and stressors. This will be done by: (i) providing access to caring adults and a supportive peer group; (ii) building a positive self-concept by independently mastering challenging new tasks such as martial arts-based physical activity (Nepal), skateboarding (Colombia) and surfing (South Africa), and; (iii) offering relief from the stress caused by the adversity they experience daily. The caregiver part of the intervention will also cover elements of psychoeducation, parenting and communication techniques, and stress reduction, based on the Caregiver Support Intervention.

The economic intervention will consist of three phases: (i) The first phase will focus on education specific to financial needs and wants and developing skills to improve short- and long-term handling of finances, for both caregivers and adolescents; (ii) the second phase will focus on exploring opportunities through bargaining/negotiation and finding solutions when possible; this builds on recent research that emphasises the interdependence of decision making within the household, and the importance of adolescent negotiation skills to elicit investments from their caregivers on their education and well-being; (iii) the third phase will focus on creating awareness around benefits, challenges and solutions for accessing education. Alongside the delivery of the intervention sessions, both adolescents and caregivers will receive 6 cash transfers delivered at regular intervals over the intervention period, which equate in each site to the country's one-month's average household income. In Nepal the cash transfers will consist of the equivalent of 27 GBP per month for the caregivers; 12 GBP per month for the adolescent, using a cash in hand approach. In Colombia the cash transfer will consist of the equivalent of 57 GBP in total per month, of which 38 GBP will go to the caregiver and 19 GBP to the adolescent, using bank transfer or instant digital mobile transfers. In South Africa, the equivalent of 44 GBP will go to the adolescent, and 88 GBP to the caregiver, using instant digital mobile transfers.

The combined intervention combines the content of the self-regulation and economic interventions, but presented in a condensed format. The intervention also includes the cash transfers to the adolescent and caregivers, as well as a section to explore the connections between the economic and self-regulation contents of the intervention.

The control arm will follow a 'care as usual' approach, which means that there will be no active comparator condition. The reasons for this choice are: (1) this is a preventive intervention, not a clinical treatment (no adolescents scoring above a validated threshold of depression and anxiety will be included); (2) it is in line with a recently published decision framework for the selection of control condition in randomized controlled trials, considering the ALIVE interventions can be categorized as an early phase trial and as low-risk; (3) we want to compare our intervention arms with the reality of what adolescents currently receive in these communities; and (4) there is genuine equipoise about the effects of self-regulation intervention and economic interventions (including cash transfers) on the prevention of depression and anxiety.

Intervention Type
Behavioural

Primary outcome measure
The feasibility outcomes to determine progression to a full trial will be:
1. Feasibility of randomization using demographic information from the baseline assessment
2. Feasibility of data collection using proportion of missing items on the GAD-7 and PHQ-A items of the MMAPP instrument (described under future primary outcome measures)
3. Feasibility of masking of field workers using self-report questions added at the end of each assessment
4. Feasibility of retention using the proportion of recruited adolescents lost to follow-up at the

18-month post baseline follow-up
5. Fidelity of ALIVE interventions (all arms) across all sessions (average across intervention arms) based on observations of 10% sessions, assessed using self-developed instruments designed to assess the implementation of the intervention according to intervention protocols.
6. Adherence to intervention using session-by-session attendance, monitored using TeamPACT, a mobile app that can be used offline, which helps facilitators collect information on attendance, length of sessions, and allows facilitators to provide feedback on the sessions.
7. Reported (severe) adverse events reported during the ALIVE interventions (average across arms) compared to control
8. Safety of the cash transfer using post-session reports/feedback of any negative event due to cash transfer (e.g. theft, fights, arguments, drug use)

Future primary outcome measure will be thMeasurement of Mental Health among Adolescents and Young People at the Population level Tool (MMAPP). The ALIVE version of the MMAPP tool includes 28 items, which allow to generate equivalency scores for the Patient Health Questionnaire (PHQ-9) Adolescent version (PHQ-A) and Generalised Anxiety Disorder Scale (GAD-7). The primary outcome will be defined as cumulative incidence of depression or anxiety over the 18-month follow-up period, as identified using validated cut-off scores on these instruments. That is, incidence will be defined as scoring above depression or anxiety cut-offs at any of the follow-up assessment (i.e., at least one assessment above cut-off at T1—immediately after the intervention, T2 – 12 months post baseline, or T3 – 18 months post baseline).

Secondary outcome measures

Additional feasibility measures will be assessed to help adapt procedures where needed. These include:
1. Feasibility of recruitment using
1.1. The proportion agreement to participate in the study using numbers screened, number of eligible participants, number invited to participate, consent rate (adolescents/caregivers), refusal rates.
1.2. The proportion of contamination using the responses to a question at the end of assessments asking participants if they had any contact with another participant from another arm/intervention (without disclosing information about the nature of the other intervention arms).
2. Competence of facilitators using the proportion of potentially harmful and proportion of adequate competency scores amongst intervention facilitators following observations using standardized tools. This will be assessed using an adapted version of the 13-item Working with Children Assessment of Competencies Tool (WeACT), and the 15-item Enhancing Assessment of Common Therapeutic factors (ENACT) instruments.
3. Acceptability of the intervention and study methods assessing whether the intervention and trial procedures are deemed acceptable to participants (via semi-structured interviews with adolescents and caregivers).

Future secondary outcome or hypothesized mediator measures for adolescents will include (unless otherwise stated, all collected at all timepoints in all sites):
1. The Disruptive Behavior International Scale (DBIS)
2. The Identifying Depression Early in Adolescence Risk Score
3. The Difficulties in Emotion Regulation Scale – Short form
4. The Children's Hope Scale
5. The Child and Youth Resilience Measure (in Nepal only)
6. Rugged Resilience Measure (in Nepal only)
7. Academic grades, school enrolment/education, aspirations and beliefs
8. Child labour

9. Questions relating to financial education and negotiation
10. The Client Service Receipt Inventory, adapted version (at T1, T2 and T3 assessments only)
11. Heart rate variability (HRV, variation between beat-to-beat intervals), height and weight
12. Three neuropsychological tasks:
12.1. The Balloon Analogue Risk Task – Youth version (BART-Y)
12.2. The Emotional Go No-Go Task (Colombia and South Africa only)
12.3. The Delay Discounting Task

Future secondary outcome or hypothesised mediator measures for caregivers will include (unless otherwise stated, all collected at all timepoints in all sites):
1. The positive parenting, positive involvement and corporal punishment subscales of the Alabama Parenting Questionnaire
2. The Patient Health Questionnaire
3. The Client Service Receipt Inventory, adapted version (at T1, T2 and T3 assessments only)
4. Economic-related questions covering:
4.1. Multi-Dimensional Poverty Index for each country
4.2. Contextual stressors and adverse life events
4.3. Welfare benefits
4.4. Income, debt and household expenditure
4.5. Aspirations and beliefs for index child/self
4.6. Social security

Overall study start date
18/03/2024

Completion date
30/11/2025

Eligibility

Key inclusion criteria
The inclusion criteria for the participants recruited in the pilot cluster RCT are as follows:

1. Adolescents
1.1. Aged 13-15 years at the time of the first assessment;
1.2. Fluent in the local language (Spanish in Colombia, Nepali in Nepal, and English in South Africa);
1.3. Living in high level of multidimensional poverty, defined:
1.3.1. In Colombia, as living in one of two districts categorised as multidimensionally poor by the National Statistics Office using the Multidimensional Poverty Index;
1.3.2. In South Africa, as attending schools from quintiles 1, 2 or 3, which are public schools that have been declared exempt from charging school fees based on the economic level of the surrounding community;
1.3.3. In Nepal, as screening positive on a self-developed poverty screener, developed using items from the Global Multidimensional Poverty Index and based on poverty assessment-related literature and expert consultations (since children attending public schools come from diverse backgrounds);
1.4. With symptom scores below thresholds for depression and anxiety using the validated Patient Health Questionnaire – Adolescent version PHQ-A (for depression) and Generalized Anxiety Disorder (GAD) (for anxiety)
1.5. Whose primary caregiver is enrolled in the study (in Colombia and South Africa).

2. Caregivers
2.1. Aged 18 years or more; with their consent to participate in the pilot cRCT;
2.2. Fluent in the local language (Spanish in Colombia, Nepali in Nepal, and English, isiXhosa or Afrikaans in South Africa);
2.3. Living in high level of multidimensional poverty, defined as (i) living in an area with reported high levels of multidimensional poverty (Colombia), (ii) their child attending a school from quintile 1, 2 or 3 (South Africa), (iii) their child screening positive on a self-developed screener (Nepal);
2.4. Their child (biological or foster) is enrolled in the study.

Participant type(s)
Carer, Learner/student

Age group
Mixed

Lower age limit
13 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
1440

Total final enrolment
1170

Key exclusion criteria
The exclusion criteria are:

1. Adolescents self-reporting suicidality (also referred to high suicide risk), defined as current suicidal ideation with intent or plans over the past month, or suicidal attempt during the past 3 months (Nepal) or lifetime suicidal attempt (Colombia and South Africa)
2. Adolescents or caregivers with a significant disability that impacts participation in intervention or assessments (that cannot be overcome with reasonable adjustments)
3. Unaccompanied minors, and adolescents who are married, due to challenges with legal consent of caregivers

Date of first enrolment
19/04/2024

Date of final enrolment
11/05/2024

Locations

Countries of recruitment
Colombia

Nepal

South Africa

Study participating centre
TPO Nepal
Baluwatar, G.P.O Box 8974
Kathmandu
Nepal
44600

Study participating centre
Innovations for Poverty Action Colombia
Cl. 93 #11A 28, Localidad de Chapinero
Bogotá
Colombia
Cl. 93 #11A 28

Study participating centre
War Child Colombia
Cl. 73 #22-49, Barrios Unidos
Bogotá
Colombia
Cl. 73 #22-49

Study participating centre
University of Cape Town
46 Sawkins Road, Rondebosch
Cape Town
South Africa
7700

Study participating centre
Waves for Change
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7945

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol and the results of the study will be published in peer-reviewed journals. We also intend on disseminating our results via conferences, and through the publication of PhD theses.

Intention to publish date
30/08/2026

Individual participant data (IPD) sharing plan
All data obtained via ODK, HRV Logger and the neuropsychological task applications will be anonymised by use of participant ID numbers. Audio-recordings of interviews, which contain identifiable data, will be destroyed as soon as the transcripts are finalised. Only the consent forms will be stored in an identifiable format. The link file, containing information on participants' names and ID will be kept in a separate location beyond the completion of the research, to allow participants to potentially be part of future research activities linked to the ALIVE study.

During data collection, anonymised data arising from the project may be shared and used among the partner institutions listed within the collaboration agreement. All data arising will be considered confidential, and will not be shared with external researchers without prior consent from all institutions. In that case, a data sharing agreement will need to be completed with the external researcher or institution before de-identified data are shared.

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Following project completion, the datasets generated during the current study will be stored in a publicly available repository called King's Open Research Data System (KORDS), a data repository which provides long-term storage and access for datasets (https://kcl.figshare.com/). The data will include an embargo of two years, after which the quantitative data will be openly available. Qualitative data will also be stored using KORDS, but will not be publicly available, and instead shared upon request. This is due to the sensitive and context-specific nature of qualitative data. Both data and the consent forms will be kept for at least 10 years. After 10 years, the principal investigators will, however, reconsider whether the data should be kept for longer, depending on the usefulness of the data to national or international researchers external to the ALIVE team at that time, keeping in mind the FAIR principles.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		11/06/2025	11/06/2025	No	No