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A research study in Colombia, to build capacity in school mental health and to adapt an intervention called DIALOG+ for use in adolescents in post-conflict Colombia during the COVID-19 pandemic

Submission date
09/04/2021

Recruitment status
No longer recruiting

Registration date
12/04/2021

Overall study status
Completed

Last Edited
05/10/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
It is estimated that there are around 8.5 million victims of armed conflict in Colombia. Tolima is one of the areas most affected. The national Mental Health Study (ENSM-2015) found high levels of mental distress and illness in Colombia's children and adolescents, including high levels of post-traumatic stress symptoms, in the context of poor levels of access to treatment. This means that the role of teachers and school counsellors is key. Mental health and well-being through adolescence are important for an optimal transition to adulthood. The impact of the armed conflict on children and adolescents is still poorly understood and there is a current need for a well-structured intervention to improve and deliver mental health interventions to this vulnerable group. Pontificia Universidad Javeriana has developed an online diploma to support mental health in the school community. Likewise, the Queen Mary University of London team has developed and tested a mental health intervention called DIALOG+, a low- cost/cost saving evidence-based therapeutically effective mental health intervention, which has been used and assessed in many clinical contexts internationally.
The overall aim of this study is to improve the mental health, resilience and quality of life of children and adolescents from Tolima, Colombia, taking into account the additional context of this post-conflict setting during the added stress of the current COVID-19 pandemic.

Who can participate?
Up to 150 teachers or school counsellors in Tolima will be enrolled in the diploma course. A sample of adolescents from schools in Tolima will be recruited for the prevalence survey. 70 adolescent students and 14 teachers will be enrolled in the DIALOG+ adaptation study.

What does the study involve?
To address the overall aim, there will be three interrelated work packages:
Work Package 1: The researchers will offer at least 150 places to teachers and school counsellors

from the four identified municipalities of Tolima on the School Mental Health diploma course. This academic programme lasts 120 hours, corresponding to 18 weeks of study. At least 80% of the activities need to be satisfactorily completed to receive a certificate from PUJ. Measurement of knowledge in school mental health topics will carried out before the start of the diploma programme (promotion, prevention and early detection) and repeated at the end of the diploma. The researchers will also assess the perception of the capacity and satisfaction of teachers and school counsellors to address the psychosocial problems of children and adolescents before and after the diploma.

Work Package 2: Concurrently with WP1, the researchers will undertake a survey of adolescents in eight public schools from Chaparral, Ataco, Rioblanco, and Planadas in Tolima. They anticipate the results of this survey will provide evidence regarding the prevalence of mental health problems and post-traumatic stress disorder (PTSD) symptoms in adolescents from Tolima. This information will not only allow for a better characterization of the population, but will also enable decision-makers to design and implement programmes that promote both individual and community wellbeing.

Work Package 3: The existing DIALOG+ intervention will initially be demonstrated to focus groups including teachers, school counsellors and adolescents in two schools (in Chaparral and /or Rioblanco). Based on this information, the researchers will iteratively develop the intervention and training materials to repurpose the existing intervention. A study will be conducted with teachers and school counsellors to assess the acceptability and feasibility of the intervention for adolescents in school settings. The researchers will administer questionnaires to the students at the start of the study and at 6 months on mental health outcomes, including symptoms of PTSD, depression and anxiety, quality of life, self-esteem, and resilience. Following this, two focus groups (one with teachers and counsellors, and the other with students) will be held in Chaparral municipality to learn more about the experience of implementing the intervention, what worked or did not work, and ways in which the intervention could be improved and implemented in existing public school settings. This information should make it possible to determine the feasibility of adapting the DIALOG+ tool within schools that serve vulnerable populations in post-conflict areas.

What are the possible benefits and risks of participating?
The immediate beneficiaries of this research will be the children and adolescents in the schools taking part in this study. They will be able to benefit from the added knowledge and skills of the teachers and counsellors who have been trained in the School Mental Health diploma, but they will also benefit from participation in the study through greater knowledge of, and support for, any mental distress that is identified through participation. The school teachers and counsellors will benefit from the formal education they receive in the diploma, and will be empowered to identify and manage mental health issues at school in this very vulnerable population. Through a sound characterisation of the mental health status, prevalence of disorders, and some description of risk factors in adolescents in this very vulnerable population, policymakers will be better informed as to the mental health needs of this group, as well as able to make better decisions about the necessary support and interventions in this under-researched area.
The researchers do not predict any significant risks from participating in this study; however, it is possible that whilst completing the research assessments or qualitative interviews, the questions asked might trigger feelings of distress or anxiety. To minimise this risk researchers with experience working with severe mental illness are employed and trained, research assessments can be stopped at any point, and further support can be provided to the participant if necessary.

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

When is the study starting and how long is it expected to run for?
February 2021 to October 2022

Who is funding the study?
1. Newton Fund (UK)
2. MInCiencias (Colombia)

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
ES/V013114/1

Study information

Scientific Title
Adapting DIALOG+ and building capacity in schools to support mental wellbeing and resilience in post-conflict Colombia during the COVID-19 pandemic

Acronym
SMART

Study objectives
The overall aim of this study is to improve the mental health, resilience and quality of life of children and adolescents from Tolima, Colombia, taking into account the additional context of this post-conflict setting during the added stress of the current COVID-19 pandemic. This will be done by training (online and face-to-face) teachers and school counsellors from this region in mental health in order to allow them to develop strategies for the promotion of mental wellbeing and the prevention and early detection of mental health problems. Strengthening of educators' capacities will be achieved whilst modifying and exploring DIALOG+ - a proven technology-assisted tablet/smartphone-based and resource-oriented intervention - as a generic approach for mental health problems identified in adolescents.

This aim will be addressed via specific objectives:
1. Building capacity in teachers and school counsellors in the promotion of mental wellbeing and the prevention and early detection of problems associated with mental health in the school context.
2. Determining the prevalence of mental health problems, post-traumatic stress disorder symptoms and resilience capacity in adolescents (12-18 years) in public schools.
3. Exploring the feasibility and acceptability of DIALOG+ as a tool for teachers and school counsellors to make routine meetings effective at addressing mental health problems within the context of an educational environment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/11/2020, 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: Adapting DIALOG+ and building capacities in schools to support mental wellbeing and resilience in post-conflict Colombia during the COVID-19 pandemic
2. Approved 09/04/2021, Queen Mary Ethics of Research Committee (Hazel Covill, Room W117, Finance Department, Queens' Building, Queen Mary University of London, Mile End Road, London, E1 4NS, UK; +44 (0)20 7882 7915; research-ethics@qmul.ac.uk), ref: QMERC20.226

Primary study design
Interventional

Study design
Exploratory cluster randomized controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental health problems in the school environment

Interventions
Current interventions as of 05/07/2022:

70 adolescents and 14 teachers and school counsellors will be recruited from at least four schools in Chaparral municipality. The unit of randomisation will be the teacher or school counsellor, who will be randomized in a 10:4 ratio to either the intervention (10 teachers/50 adolescents; to have twice-monthly DIALOG+ meetings for 6 months), or to the usual care control group (4 teachers/20 adolescents; meetings as requested, 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.

After the DIALOG+ adaptation intervention period, focus groups will be conducted with the teachers and also with the students. This will be done to learn more about the experience of implementing the intervention, what worked or did not work, and ways in which the intervention could be improved and implemented in existing public school settings. The group of teachers and counsellors will also discuss their experience with the tool, and their reflections on the diploma course and its impact on the implementation of the DIALOG+ tool.

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Previous interventions:

Sixty adolescents and twelve teachers and school counsellors will be recruited from at least four schools in the Chaparral and Rioblanco municipalities. The unit of randomisation will be the

teacher or school counsellor, who will be randomized in a 2:1 ratio to either the intervention (8 teachers/40 adolescents; to have twice-monthly DIALOG+ meetings for 6 months), or to the usual care control group (4 teachers/20 adolescents; meetings as requested, 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.

After the DIALOG+ adaptation intervention period, focus groups will be conducted with the teachers and also with the students. This will be done to learn more about the experience of implementing the intervention, what worked or did not work, and ways in which the intervention could be improved and implemented in existing public school settings. The group of teachers and counsellors will also discuss their experience with the tool, and their reflections on the diploma course and its impact on the implementation of the DIALOG+ tool.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 05/07/2022:

1. Symptoms of Post Traumatic Stress Disorder (PTSD) measured using the Post Traumatic Stress Disorder Checklist (PCL) at baseline and 6 months
2. Symptoms of depression measured using the Patient Health Questionnaire (PHQ- 8) at baseline and 6 months
3. Symptoms of anxiety measured using Generalised Anxiety Disorder assessment (GAD-7) at baseline and 6 months
4. Quality of life measured using the Manchester Short Assessment (MANSA) at baseline and 6 months
5. Family adaptability, partnership, growth, affection and resolve (APGAR)
6. Self-esteem measured using the Rosenberg self-esteem scale at baseline and 6 months
7. Resilience measured using the Connor-Davidson Resilience Scale (CD-RISC25) at baseline and 6 months
8. The Self-Reporting Questionnaire (SRQ) to assess mental health problems

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Previous primary outcome measure:

1. Symptoms of Post Traumatic Stress Disorder (PTSD) measured using the Post Traumatic Stress Disorder Checklist (PCL) at baseline and 6 months
2. Symptoms of depression measured using the Patient Health Questionnaire (PHQ- 8) at baseline and 6 months
3. Symptoms of anxiety measured using Generalised Anxiety Disorder assessment (GAD-7) at baseline and 6 months
4. Quality of life measured using the Manchester Short Assessment (MANSA) at baseline and 6 months
5. Objective social functioning measured using objective social outcomes index (SIX) at baseline and 6 months
6. Self-esteem measured using the Rosenberg self-esteem scale at baseline and 6 months
7. Resilience measured using the Connor-Davidson Resilience Scale (CD-RISC25) at baseline and 6 months

Key secondary outcome(s)
Current secondary outcome measures as of 05/07/2022:

The cross-section prevalence survey in Work Package 2 will provide prevalence estimates for key mental health indicators:
1. Symptoms of Post Traumatic Stress Disorder (PTSD) measured using the Post Traumatic Stress Disorder Checklist (PCL) at a single timepoint
2. Mental health symptoms measured using the Self Report Questionnaire (SRQ; WHO) for participants aged 16-18 years without the need for diagnosis at a single timepoint
3. Resilience measured using the Connor-Davidson Resilience Scale (CD-RISC25) at a single timepoint
4. Symptoms of depression measured using the Patient Health Questionnaire (PHQ- 8) at a single timepoint
5. Symptoms of anxiety measured using Generalised Anxiety Disorder assessment (GAD-7) at a single timepoint
6. Family functioning measured using the APGAR FAMILIAR, a validated scale in young students from Colombia for assessing family dysfunction, at a single timepoint

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Previous secondary outcome measures:

The cross-section prevalence survey in workplace 2 will provide prevalence estimates for key mental health indicators:
1. Symptoms of Post Traumatic Stress Disorder (PTSD) measured using the Post Traumatic Stress Disorder Checklist (PCL) at a single timepoint
2. Mental health symptoms measured using the Self Report Questionnaire (SRQ; WHO) for participants aged 16-18 years without the need for diagnosis at a single timepoint
3. Mental health symptoms measured using the Report Questionnaire for Children (RQC) for participants under 16 years at a single timepoint
4. Resilience measured using the Connor-Davidson Resilience Scale (CD-RISC25) at a single timepoint
5. Symptoms of depression measured using the Patient Health Questionnaire (PHQ- 8) at a single timepoint
6. Symptoms of anxiety measured using Generalised Anxiety Disorder assessment (GAD-7) at a single timepoint
7. Family functioning measured using the APGAR FAMILIAR, a validated scale in young students from Colombia for assessing family dysfunction, at a single timepoint

Completion date
31/10/2022

Eligibility

Key inclusion criteria
1. Mental Health Training: through the Secretary of Education, the researchers will offer places to teachers and school counsellors from the four identified municipalities of Tolima on the School Mental Health diploma course
2. Mental Health Survey: adolescents (aged 12-18 years) in eight public schools from Chaparral, Ataco, Rioblanco, and Planadas in Tolima. A convenience sampling method will be employed within the eight selected schools. Adolescents who are willing to participate and whose parents

provide informed consent will be enrolled into the study, over a 2 - 3 month recruitment period
3. DIALOG+ Adaptation: adolescents (aged 12-18 years) who request advice from a teacher or school counsellor

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 Years

Sex
All

Total final enrolment
921

Key exclusion criteria
1. Unwilling or unable to provide informed consent or assent

Date of first enrolment
15/04/2021

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
Colombia

Study participating centre
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Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Newton Fund

Alternative Name(s)
The Newton Fund, NF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Ministry of Science, Technology and Innovation (MInCiencias)

Results and Publications

Individual participant data (IPD) sharing plan
After the publication of the main findings, the researchers will operate an open data policy, following the FAIR principles e.g. Findable, Accessible, Interoperable and Reusable. 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).
During the course of the study, data will be shared internally within the study using an online data collection platform called REDCap. The method for sharing the data externally (if required) will be decided in due course.
Informed consent will be obtained from all participants involved in the study. All participants are assigned a patient ID at the point of enrolment and all subsequent data collected will be linked to this ID, without any link to identification data following Good Clinical Practice.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/10/2023	05/10/2023	Yes	No
Protocol article		09/11/2022	10/11/2022	Yes	No