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A mixed-method study evaluating the effectiveness of a community-based psychosocial support (PSS) intervention for communities affected by conflict in Colombia

Submission date
17/09/2021

Recruitment status
No longer recruiting

Registration date
02/11/2021

Overall study status
Completed

Last Edited
02/11/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Heartland Alliance International (HAI) and La Universidad de Los Andes propose to study the effectiveness of HAI's community-based psychosocial support (PSS) services program Alianza Con Organizaciones Por lo Emocional (ACOPLE). This approach is designed to help communities to cope with mental health needs stemming from ongoing and past conflict as well as systemic crime and violence. ACOPLE is facilitated by community leaders, called community psychosocial agents (CPAs), who are trained and supervised by psychologists to provide services to strengthen resilience in their own communities. Since 2010 ACOPLE has provided these mental health and psychosocial support services to communities affected by the armed conflict on Colombia's Pacific Coast.
This study aims to test the community-based group intervention using a randomized controlled trial design to determine the effects of group participation on distress, wellbeing, functionality, coping, community resilience, and emotional regulation. If found to be effective, this intervention model can be disseminated for broader use in Colombia and globally.

Who can participate?
Women and men, current residents of Quibdo, Colombia who are age 18 years or over, and report being displaced by violence, are eligible to participate. Participants are healthy volunteers and are not assessed for distress to determine if they can participate. However, as Quibdo is highly affected by the civil conflict in Colombia, it is assumed that many participants will have distress related to conflict exposure. Participants can include both Colombian residents (majority from Afro-Colombian and indigenous communities) and Venezuelan migrants.

What does the study involve?
Participants will take part in psychosocial support group intervention over eight weeks. Participants will be randomly assigned to participate right away, or three months later. The intervention is led by trained community members who are supervised by mental health professionals. It includes problem-solving sessions and expressive activity sessions based in

cultural practices and can be completed in-person or remotely (by phone/internet) according to the preference of participants.
All participants will complete interviews at the beginning of the study and after three months, to measure wellbeing, distress, functionality, coping, and community resilience. Responses of those who participated in the intervention will be compared to those who did not yet participate to determine if the intervention caused improvement in these measures. In addition, after the intervention, a smaller number of participants will be invited to participate in qualitative interviews about their experience in the intervention and how it can be improved. Staff who were involved in facilitating the intervention will be asked to participate in a focus group discussion.

What are the benefits and risks of participating?
Participants are expected to benefit from participation in the intervention. Previous research on a related intervention showed that participation was associated with reduced distress. In addition, subjects may expect a sense of pride and recognition because of contributing to this research, which can help improve psychosocial support services in their own community and elsewhere in Colombia and globally. All participants will be provided with referral information for relevant services in the community, including mental health services. To ensure accountability to the affected population, results of the research will be disseminated in to target communities.
Participants in this research may experience psychological and social risks. Participants may feel uncomfortable talking about sensitive subjects such as mental health. They may also experience discomfort related to recalling distressing personal experiences. For interviews, there is a small risk that confidentiality may be compromised such that people other than the researcher(s) could find out what participants said during the interview. For the groups and FGDs, confidentiality may also be compromised if participants share information about other participants outside of the group. In addition, participants may face social risks if they disclose beliefs or experiences that are stigmatized or rejected by the group. The use of remote modalities (phone/internet) can increase risk due to possibility of that others in the household may overhear group sessions or interviews or may see call records or messages. However, HAI will take many steps to protect confidentiality and make sure participants understand their rights, and to protect the safety of virtual participants. Due to Covid-19, there is also potential for risk that participation in the study could increase potential exposure to the virus. These risks will be addressed through multiple safeguards.

Where is the study run from?
The study is run by Heartland Alliance International, in collaboration with La Universidad de las Andes, in Colombia.

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

Who is funding the study?
This study has been funded through the Health Evaluation and Applied Research Development (HEARD) mechanism, funded by the United States Agency for International Development (USAID). HAI has received a subaward from University Research Co., LLC (URC) (URC subagreement No FY20-A06-6024).

Who is the main contact?
Leah James, Co-Principal Investigator, ljames@heartlandalliance.org

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
URC subagreement No FY20-A06-6024

Study information

Scientific Title

A randomized controlled trial to test effectiveness of a community-based PSS intervention in reducing distress and improving wellbeing, functioning, coping, and collective resilience in communities affected by conflict in Colombia

Study objectives
This community-based group PSS intervention reduces distress and functional impairment and promotes wellbeing, adaptive coping, community resilience, and emotion regulation among conflict-affected community members in Quibdo, Colombia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 06/10/2020, Universidad de los Andes Ethics Committee (Cra. 1 #18a-12, Bogotá, Cundinamarca, Colombia; +5713324514; invdoctorado@uniandes.edu.co), ref: none
2. Amendment approved 02/09/2021, Heartland Alliance IRB (33 West Grand Avenue, Suite 500, Chicago, IL USA; +13128704949; irb@heartlandalliance.org), ref: IRB00004277, Federal Wide Assurance number: FWA00007224, IORG number: 0003598.

Study design
Multicenter interventional interviewer-blinded randomized controlled trial design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Reduction of distress (generalized distress and symptoms of anxiety, depression, and posttraumatic stress disorder) and functional impairment and promotion of subjective well-being and use of adaptive coping strategies among community members in Quibdo, Colombia.

Interventions
In this randomized controlled trial, members of communities affected by conflict in Quibdo, Colombia are randomly assigned to participate in a non-intervention waitlist control group or in a community-based group psychosocial support intervention. Randomization is conducted using a random number generation procedure through Excel.
The intervention group will participate in an eight-week, 2-hour-per-week community-based psychosocial support group (with 7-10 participants) conducted in-person or remotely (by phone /internet). This model was developed as part of Heartland Alliance International's Alianza Con Organizaciones Por lo Emocional (ACOPLE) project. Participants can choose whether to participate in person or remotely. In-person groups are held at community centers in various parts of the municipality. The groups are facilitated by trained non-professional community members, called community psychosocial agents, that receive supervision from mental health professionals. The groups include collective problem-solving sessions focused on teaching skills to collaboratively address personal and community-level problems, as well as expressive activity sessions which draw from cultural practices to practice coping and emotion regulation skills. Participants who provide consent will be randomized to intervention or waitlist control groups, including stratification by choice of modality (in-person or remote) and neighborhood. Both

groups participate in interviews at baseline and after three months. The waitlist control group will then participate in the intervention.

Intervention Type
Behavioural

Primary outcome(s)
Distress is measured using the Kessler-6 (generalized distress), Hopkins Symptom Checklist (Anxiety and Depression) and Harvard Trauma Questionnaire (HTQ) at baseline and 3 months.

Key secondary outcome(s))
1. Subjective Wellbeing is measured using the Personal Wellbeing Index (PWI) at baseline and 3 months.
2. Functioning is measured using the WHODAS at baseline and 3 months.
3. Coping is measured using the Brief COPE at baseline and 3 months.
4. Community resilience is measured using the Community Resilience Scale at baseline and 3 months.
5. Emotional Regulation is measured using the Gross Emotional Regulation Scale at baseline and 3 months.

Completion date
01/11/2021

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Resides in target location: municipality of Quibdó (Chocó, Colombia)
3. Experienced displacement as a result of conflict or gang violence

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
274

Key exclusion criteria

1. Significant risk of suicide/self-harm
2. Substance dependence
3. Severe mental illness (psychosis)

Date of first enrolment
20/12/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Colombia

Study participating centre
Heartland Alliance International
Carrera 6 # 29 -63 Piso 2 Barrio Cesar Conto
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Sponsor information

Organisation
Heartland Alliance International

Funder(s)

Funder type
Other

Funder Name
University Research Co., LLC (Under USAID Cooperative Agreement No. AID-OAA-A-17-00002 (USAID Health Evaluation and Applied Research Development (HEARD) Project)

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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