CLINICAL TRIAL PROTOCOL

Clinical trials identifier: NCT03127982

Other Study ID Numbers: COLCIENCIAS 644-2014

Effects of a contextual adaptation of the Unified Protocol in multiple emotional disorders in victims of armed conflict in Colombia: A randomized clinical trial.

Lead Investigator: Leonidas Castro-Camacho, Ph.D., ABPP.

Universidad de los Andes

March 2016

Table of contents

1. PROTOCOL ABSTRACT

Armed conflict in Colombia among government forces and illegal armed groups, such as guerrillas and paramilitaries, has lasted nearly 60 years, leaving over 8 million victims and 7 million Internal Displace People (IDPs). Many have been exposed to extreme violence, including witnessing massacres, undergoing torture, surviving combat attacks, losing family and friends by homicide or forced disappearance, experiencing multiple sexual assaults and violence, and being under continuous threat for their lives, among other extreme situations.[1] Moreover, many have been forced to flee their homes, leaving behind property and possessions, social groups and family ties, and cultural and spiritual practices.[2] They frequently relocate to hostile urban environments, where they struggle to acquire employment and fulfill basic needs such as food and shelter[3 4] and access medical services. [5] Many faces continued threats as they share neighborhoods with former perpetrators of violent acts, some of whom have been victims themselves.[6]

These extreme contexts have effects at multiple levels- individual, family, community, and social- severely affecting mental health and quality of life. Studies in Colombia have shown a higher incidence of anxiety disorders, depression, and substance abuse in active conflict zones. [7 8 9] Studies found high rates of PTSD (88%), anxiety (59%), and depression (41%) among IDPs. [10] Without adequate treatment, these conditions become chronic and lead to other dysfunctions, like Major Depressive Disorder (MDD), substance abuse, and violence.[10 11 12] In summary, in reaction to contexts of violence and adversity, victims of armed conflict in Colombia, as in many other conflict zones, show high levels of distress and multiple emotional and behavioral disorders that interfere with their ability to face daily stressors, such as seeking and keeping jobs, maintaining a healthy family and social relationships, and taking effective actions to solve problems and improve their living conditions.[13] Therefore, interventions with this population should be geared not only towards reducing symptoms of specific disorders but, more important, to targeting the main factors of interference and improving the level of functioning and quality of life.

Unfortunately, in Colombia, evidence-based mental health programs to address this situation are lacking. Like many other LMIC countries, there is a shortage of mental health professionals with adequate training to provide effective psychological interventions.[14]

The World Health Organization has recommended using evidence-based interventions to treat the emotional sequelae of conflict violence. Within these, several short-term cognitive-behavioral intervention programs have been developed to treat different types of psychological disorders that have shown efficacy both in the clinical population and in victims of armed conflict worldwide. Within these, the Unified Protocol for Emotional Disorders (UP) has been developed, which targets common causal processes to different emotional disorders, is more applicable to the conditions of the armed conflict in Colombia, and has demonstrated effectiveness in different studies.

This study aims at adapting the original UP to the cultural and contextual characteristics of victims of armed conflict in Colombia and evaluates its efficacy in a sample of internally displaced persons living in Bogotá through a randomized clinical trial comparing the effects of the intervention with a waitlist condition on measures of anxiety, depression, PTSD, somatic complaints, quality of life and level of functioning. In the first phase, the cultural adaptation will be undertaken by rewriting the original treatment manuals in Spanish, maintaining the core characteristics of the original protocol in terms of module content and order while replacing textual with graphic content to address educational constraints, and modifying examples and assignments to match cultural and educational characteristics of the population. Pilot studies will be conducted to assess the intervention's comprehension, relevance, and acceptability and make the necessary changes. Once the adaptation has shown relevance and acceptability, and therapist manuals and participant workbooks have been tested for cultural relevance, therapists will be trained in delivering the intervention by the original developers of the protocol and in the culturally adapted version. In the second phase, a randomized clinical trial will be carried out where a sample of 100 victims of armed conflict accepting to participate will be randomly assigned to the culturally adapted version of the UP or a delayed-treatment 6-week waitlist condition. In the treatment condition, outcome measures will be taken at baseline, end of the intervention, and 3-months follow-up. In the waitlist conditions, outcome measures will be taken at baseline, end of the 6-week wait period, at the end of treatment, and 3 months follow-up.

Screening and outcome measures will be taken.

2. SPECIFIC AIMS

2.1. Translate and adapt the UP to the cultural, social, economic, and political context of individuals exposed to the violence of the armed conflict in Colombia.

2.2. Develop and culturally adapt assessment tools to identify victim's symptoms of anxiety, depression, and related disorders.

2.3. Conduct a randomized clinical trial comparing outcomes of 12 biweekly or weekly sessions of the culturally adapted UP in a sample of participants randomized to immediate treatment or to waiting list delayed treatment (6-week) intervention.

2.4. To identify potential variables that mediate or moderate the effects of treatment with the UP.

3. RESEARCH STRATEGY

3.1. Overview

3.1.2. **Phase 1. Cultural adaptation and initial pilot.** In the first phase, specific needs of the population will be identified through focus interviews and expert advice from victims' organizations. Based on the initial information, the original intervention manuals will be rewritten in Spanish preserving modules content and order and including an initial session to establish optimal relationship conditions and textual material will be replaced by graphic content. An exploratory pilot study with 5 victims will be conducted to assess for comprehension, relevance and acceptability and, based on the collected information the final versions of the adapted versions will be written. The following step in this initial phase is the training of therapists both in the original protocol and the culturally adapted version. Training will be carried out for graduate students in clinical psychology who will be the therapists of the study. Training in the original protocol will be carried out by a member of the Boston University research team that developed the original protocol for an intensive 2-day workshop. After the workshop, content and competencies will be evaluated for all participants. Another intensive workshop on the culturally

adapted version of the protocol will be required to be eligible to participate as therapist in the study. After certification, trained therapists will receive monthly supervision and session recordings will be randomly reviewed in order to rate fidelity to the protocol according to standards established by Boston University.

3.1.2. **Phase 2. Randomized clinical trial.** After initial cultural adaptation and therapist's training, sample recruitment and randomization will be undertakien as described in detail in a further section. Participants will be victims referred by various agencies. People will attend an evaluation session at the university clinical center. In this session, the nature of the program will be explained to them, the appointment of dates to receive care, and they will sign an informed consent. Subsequently, they will be randomly assigned to the experimental group or the control group by a research associate. People assigned to the experimental group will receive 12-14 treatment sessions. After completing the last treatment session participants will attend an evaluation session for the post-treatment measures. Participants assigned to waitlist condition after the 6-week wait period, will attend the assessment session where the same instruments will be administered by independent evaluators blind to assignment. After the post-wait period assessment, participants assigned to delayed treatment condition will initiate treatment. All participants are informed that they have to attend a final assessment session three months after finishing treatment.

3.2. Design. Single-blind two-arm parallel assignment randomized clinical trial.

3.3. Participants: 100 individuals registered at the Unit of Victims, accepting to participate in the study and meeting inclusion criteria. Participants will be recruited from several governmental, non-governmental agencies as well as community organizations of victims and randomly assigned to treatment condition (N=50) or to waiting-list control (N=50).

3.4. Recruitment: Potential participants will be recruited using word of mouth in victims' associations and victims' NGOs around Bogotá,

Colombia. Potential participants will have a telephone prescreening interview to evaluate eligibility criteria and interest in participating. During the pre-screening, participants would be invited to participate in the study. The Research Assistant will ask if they are receiving active treatment at that time, how much alcohol they currently take, and if they will live in Bogotá for the next 6 months. After that, a baseline assessment session will be set. The consent form will be read before entering the baseline assessment session. The participants will be informed about the risks, benefits, extension of sessions, randomization, and timeframes. If they agree to participate, the assessment session will start.

3.5. Eligibility

3.5.2. Inclusion criteria:

3.5.1.1. Older than18 years old

3.5.1.2. Being registered at the Colombian Victims Unit.

3.5.1.3. Sex: All

3.5.1.4. Gender based: Self-representation

3.5.1.5. Meeting diagnostic criteria according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as determined by the International Neuropsychiatric Interview (MINI) [15] on one or more anxiety disorders, depressive disorders, or posttraumatic stress disorder.

3.5.2. Exclusion criteria

3.5.2.1. Meeting diagnostic criteria for psychotic disorders, bipolar affective disorder, intellectual disability, dementia, substance abuse (as primary diagnosis with hospitalization requirement for treatment, or actively suicidal.

3.5.2. Individuals who present symptoms associated with anxiety disorders or mood disorders. The cases will be reviewed with the Clinical Director of the study to reach a diagnostic consensus and determine their eligibility.

3.6. Randomization and Blinding

Participants meeting the inclusion criteria will be invited to participate in the study. An eligibility form will be signed by the principal investigator, and the data manager will generate the randomization for the participant. The data manager will call the participant and inform about the date of the first session and the clinician's name. After that, the data manager will call the clinician to provide the appointment details of the new participant. The assessor and the clinician will not know the participant's condition.

3.7. Intervention. Treatment consists in 12 biweekly sessions covering the 8 modules of the original UP.

3.7.2. Initial session to establish rapport (1 session)

3.7.2. Areas of distress and motivation enhancement (1-2 sessions)

3.7.2. Psychoeducation and tracking emotional experiences (1 session)

3.7.2. Emotional awareness training (1 session)

3.7.2. Cognitive appraisal and reappraisal (1 session)

3.7.2. Avoidance and emotion-driven behaviors (1 session)

3.7.2. Awareness and tolerance of physical sensations (1 session)

3.7.2. Emotional exposure (4 sessions)

3.7.2. Maintenance and response prevention

3.8. Primary outcomes

3.8.2. Changes in diagnostic criteria for depression, anxiety and somatic symptoms as assessed by the Patient Health Questionnaire. PHQ – complete version.[16]

3.8.2. Change in symptoms of post-traumatic stress as measured by the Post-Traumatic Stress Disorder (PTSD). Checklist for the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) (PCL-5).[17]

3.8.2. Time Frame: Administered at baseline, post-treatment, and a 3-month follow-up.

3.9. Secondary outcomes

3.9.2. Overall Anxiety Severity and Impairment Scale (OASIS).[18] Administered at baseline, at weekly sessions, at the end of treatment and at 3-months follow-up.

3.9.2. Overall Depression Severity and Impairment Scale. (ODSIS). [19] Administered at baseline, at weekly sessions, at the end of treatment and at 3-months follow-up.

3.9.2. Quality of Life Enjoyment Questionnaire, Q-LES-Q.[20] Self-reported measure assessing the physical health, subjective feelings, leisure activities, social relationships, general activities, satisfaction with medications and life satisfaction.

3.9.2. World Health Organization Disability Assessment Schedule, WHODAS 2.0. [21] were evaluated at baseline, post-treatment, and 3-month follow-up. Adapted as Current level of functioning from ACOPLE.[22] (. [Time Frame: Baseline, and 3-month follow-up.

3.9.2. **Design Overview**

3.9.2. **Arm 1**. Experimental group: Unified protocol. Immediately following randomization, participants in this condition attend 12-13 biweekly face-to face individual sessions that last approximately 1.5 hrs each of the cultural adaptation of the Unified Protocol transdiagnostic treatment for emotional disorders.

3.9.2. **Arm 2.** Active comparator: Participants randomly assigned to this condition do not receive any active intervention during a six-week wait period after randomization, while completing assessment evaluation at the beginning and end of wait list period, after which they receive the same intervention (Unified Protocol) provided to the treatment condition (Group 1).

3.10. Site. University of los Andes, Bogotá.

3.11. Data Management and Procedures. All personal information data will be secure in a password-protected document only accessed by the principal investigator. The rest of the data will be de-identify in a separate document. They will be only accessed by the data manager in charge of maintenance and introducing new data from the different timelines assessments every week.

3.12. Statistical analysis and power

3.12.1 Primary and Secondary Efficacy Analyses. Treatment effect analysis will be conducted for both Intent to Treat (ITT), and Per Protocol (PP) approaches. For ITT data from all randomized participants will be used, and for PP only data for participants who completed all sessions and post-treatment measures will be used. To estimate the treatment effect multilevel regression models will be used; models

have specified with a random intercept for participants to model intra-individual variance across time, the treatment effect will be modeled as the interaction between treatment and time (pre-post), and direct effects for time and treatment will also include in the model. The effect for the treatment effects will be presented with the partial eta-squared index.

3.12.2. **Other Efficacy Analyses.** Analyses for follow-up measurements (12 weeks) for primary and secondary analysis will be conducted with data from participants that completed pre, post, and follow-up assessments, including those that received treatment after the waitlist period. Multilevel regression with random effects for individuals and time as a fixed effect will be performed for each primary and secondary outcomes.

3.13. Statistical Software: All analyses will be conducted with the statistical software R (Version 4.1.0). R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria, 2021. URL https://www.R-project.org/)

3.14. Determination of Sample Size: Sample size determination was conducted using G-Power (version 3.1.9.7) using a moderate effect size ($f^2 = 0.15$), two tails, an alpha of 0.05, and statistical power of 0.95 yielded an estimate of a total of 90 participants. Based on the difficulties that Internally Displaced People experience in their day-to-day activities, we expected up to 50% attrition. Therefore, we aimed to recruit at least 50 participants per group.

3.15. Compensation to Participants: Transportation fees will be covered for all the participants involved in the study.

4. HUMAN SUBJECTS PROTECTIONS

Because it is a project in which there is intervention, the risk classification of the project is risk greater than the minimum according to the guidelines of resolution No. 008430 of 1993 of the Ministry of Health on scientific, technical and administrative standards for research in Health, emphasizing: Title II (research on human beings), Chapter I (ethical aspects of research on human beings) and Chapter V (research in subordinate groups).

Of the potential participants referred for this study, a careful screening study will be carried out to select those who meet the inclusion criteria. People who, through screening, require specialized treatment different from the one offered in this study, will be referred to the institutions of the District's health system so that they receive the appropriate treatment. The risk of harm or harm to the participants is not different from a usual therapeutic process in which no measurements are being taken or which is not part of a research project. On the other hand, procedures are being applied that have been evaluated in various studies and in which no harmful negative effects have been shown for the participants. As it is a psycho-educational method based on scientifically derived knowledge, no risks or damages that may be caused by participating in the program are anticipated, apart from the possible temporary discomfort of speaking or facing painful aspects of life, which may in- include feeling unpleasant or uncomfortable sensations, such as anxiety, sadness, anger or frustration, among others. However, the tools that are going to be provided in this program indicate that, in the long run, they can contribute to a general decrease in discomfort and an improvement in the quality of life. In the event that during the intervention the need for the patient to require additional or alternative treatment is determined, the participant will be immediately referred to the District Health System Institution that can provide the specialized service. that requires.

The program will be applied by graduate psychologists who have had supervised experience in clinical intervention and who have also received training in the procedure. In addition, you will have the close and permanent supervision of clinical psychologists with experience in managing emotional problems.

To guarantee respect for the rights of the participants as well as their full knowledge, they will be informed about the nature, benefits and risks of the program, as well as the possibility of withdrawing at any time they wish. Since this is a randomized clinical trial comparing outcomes in participants randomly assigned to the treatment condition or to a waiting list, participants will be informed that the program will start at two points in time, with a difference of 120 days, and that the assignment to the dates will be carried out by lottery. They will also be informed that all participants will receive the same intervention procedure. By opting to participate in the study, all participants agree to answer the questionnaires and measures in different phases of the procedure. Those who

voluntarily wish to participate must sign the informed consent document before enrolling in the study. Upon registration, each participant will receive an identification code and the individual's privacy will be protected. They will be informed about the confidential nature of the data and information obtained during the intervention, as well as about the limits of confidentiality, in case the possibility of harm to themselves or to other people is detected. As in this project a series of instruments will be applied at the time of the evaluation sessions, it will be explained to the participants that their evaluations will be recorded anonymously and that the data will be part of a scientific study in which their identity will always be protected. The data from the assessments will be used for research purposes or to assess the usefulness of the measures.

To guarantee the integrity of the protocol instructions by the facilitators, the participants will be asked for written authorization to record the program sessions in order to guarantee the fidelity of the procedure used to the protocol. These recordings will be used to provide feedback on the management of the session and will later be deleted or destroyed.

4.2 POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO HUMAN SUBJECTS AND OTHERS

4.2.1 Potential Benefits to Participants

1. Participants will benefit from the study by learning strategies to manage emotional responses that are causing difficulties and altering their quality of life.

2. The participant will receive 12 to 14 free sessions from a clinical expert and will receive a treatment that has been proven that works in different settings around the world.

2. The scientific community will benefit from this study in that it will be possible to identify possible personal, emotional or behavioral factors associated with the emotional effects of exposure to violence in Colombia. Depending on the results, a greater number of people could benefit from it. this help.

4.2.2 Institutional Review Board (IRB)

The study will be reviewed by Los Andes Institutional Review Board, and the study will report the status of the study annually.

4.2.3 Procedures for Monitoring and Reporting Adverse Events

All adverse events will be reported annually to Los Andes University IRB. All documentation, incidents, and following actions will be discussed during weekly clinical supervision with the Principal Investigator. A report of the actions will be described in the annual reports.

5. STATISTICAL ANALYSIS PLAN

Overall Study Design and Plan

The present study aims at evaluating the effects of a CBT intervention, a cultural adaptation of the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP) in victims of the Colombian armed conflict.

A randomized clinical trial aimed at evaluating the effects of the UP in a group of 100 internally displaced victims of armed conflict living in Bogotá will be implemented. Participants will be recruited from several governmental, non-governmental agencies as well as community organizations of victims. Participants will be randomly assigned to treatment condition (N=50) or to waiting-list control (N=50). Treatment will consist of 12 biweekly sessions covering the 8 modules of the original UP. The effects of the UP is evaluated through Patient Health Questionnaire (PHQ) and several measures of co-morbid emotional disorders, Anxiety, Depression, PTSD as well as level of functioning and quality of life.

This study will consist of the following phases:

- Assessment phase: Includes the screening period and randomization.
- Treatment phase: Starting from the time of the first session until the end of the last session and post-screening period.
- Follow up phase: Starting after the post-screening period to 3-month follow up screening.

Determination of Sample Size

Sample size determination will be conducted using G-Power (version 3.1.9.7) using a moderate effect size ($f^2 = 0.15$), two tails, an alpha of 0.05, and statistical power of 0.95.

Outcomes

Primary outcomes

1. Changes in diagnostic criteria for depression, anxiety and somatic symptoms as assessed by the Patient Health Questionnaire. PHQ – complete version.[16]
2. Change in symptoms of post-traumatic stress as measured by the Post-Traumatic Stress Disorder (PTSD). Checklist for the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) (PCL-5).[17]
3. Time Frame: Administered at baseline, post-treatment, and a 3-month follow-up.

Secondary outcomes

1. Overall Anxiety Severity and Impairment Scale (OASIS).[18] Administered at baseline, at weekly sessions, at the end of treatment and at 3-months follow-up.
2. Overall Depression Severity and Impairment Scale. (ODSIS). [19] Administered at baseline, at weekly sessions, at the end of treatment and at 3-months follow-up.
3. Quality of Life Enjoyment Questionnaire, Q-LES-Q.[20] Self-reported measure assessing the physical health, subjective feelings, leisure activities, social relationships, general activities, satisfaction with medications and life satisfaction.
4. World Health Organization Disability Assessment Schedule, WHODAS 2.0. [21] were evaluated at baseline, post-treatment, and 3-month follow-up. Adapted as Current level of functioning from ACOPLE.[22] (. [Time Frame: Baseline, and 3-month follow-up.

Data Analysis General Considerations

Adjustments for Covariates: The analysis will not include adjustment for any covariates.

Multiple Comparisons/Multiplicity: No multiple comparison adjustments will be performed.

Examination of Subgroups: No examination of subgroups will be performed.

Handling of Missing Data, Dropouts, and Outliers

Of the 200 randomized participants, 109 (54%) completed the assessment at the end of treatment. Missing data in the primary and secondary outcomes were not predicted by MINI diagnosis, baseline measures, demographics, or current threat. The only significant

predictor was group assignment, with a higher attrition rate for the treatment condition (72 participants, 36%) compared to waitlist (16 participants, 8%). Within the treatment group, 24 participants (12%) dropped out before initiating treatment while 48 (24%) discontinued treatment. A telephone assessment was conducted to identify possible reasons for dropout. Forty-six percent of 26 participants who answered the interview stated that dropout was due to time limitations and transportation difficulties affecting session attendance. Based on these results, we assumed that data were missing at random (MAR) rather than due to symptom severity, treatment characteristics or therapeutic relationship. Missing data were addressed using the Maximum Likelihood estimation in the primary and secondary outcomes analysis (efficacy analysis is described in the next section).

Other Considerations

There are no additional considerations

Efficacy Analyses

Primary and Secondary Efficacy Analyses

Treatment effect analysis will be conducted for both Intent to Treat (ITT) and Per Protocol (PP) approaches. For ITT data from all randomized participants will be used, and for PP only data for participants who completed all sessions and post-treatment measures will be used. To estimate the treatment effect multilevel regression models will be used, models will be specified with a random intercept for participants to model intra-individual variance across time, treatment effect will be modeled as the interaction between treatment and time (pre-post), and direct effects for time and treatment will also be included in the model. The effect for the treatment effects will be presented with the partial eta squared index.

Other Efficacy Analyses

Analyses for follow-up measurements (12 weeks) for primary and secondary analysis will be conducted with data from participants that complete pre, post, and follow-up assessments including those that receive treatment after the waitlist period. Multilevel regression with random effects for individuals and time as a fixed effect will be performed for each primary and secondary outcomes.

Statistical Software

All analyses will be conducted with the statistical software R (Version 4.1.0).

R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria, 2021. URL https://www.R-project.org/)

6. REFERENCES

1 Unidad de víctimas (Unit of Victims) (2016). National Register of Victims. Retrieved from https://rni.unidadvictimas.gov.co/RUV 05/01/2016.

2 Shultz, J. M., Garfin, D. R., Espinel, Z., Araya, R., Oquendo, M. A., Wainberg, M. L., . . . Neria, Y. (2014). Internally displaced "victims of armed conflict" in Colombia: The trajectory and trauma signature of forced migration.Current Psychiatry Reports, 16(10), 475. https://doi.org/10.1007/s11920-014-0475-7 PMID:25135775

3 Bozzoli, C., Bruck, T., & Wald, N. (2013). Self-employment and conflict in Colombia. The Journal of Conflict Resolution, 57(1), 117–142. https://doi.org/10.1177/0022002712464849

4 Ibáñez, A. M., & Moya, A. (2010). Vulnerability of victims of civil conflicts: Empirical evidence for the displaced population in Colombia. World Development, 38(4), 647–663. https://doi.org/ 10.1016/j.worlddev.2009.11.015

5 Mogollón-Pérez, A. S., & Vázquez, M. L. (2008). Factors affecting access to health care institutions by the internally displaced population in Colombia. Cadernos de Saúde Pública, 24(4), 745–754. https://doi. org/10.1590/S0102-311X2008000400004 PMID:18392351

6 Arias, M. A., Ibáñez, A. M., & Querubin, P. (2014). The desire to return during civil war: Evidence for internally displaced populations in Colombia. Peace Economics, Peace Science & Public Policy, 20(1), 209–233. https://doi.org/10.1515/peps-2013-0054

7 Bell, V., Méndez, F., Martínez, C., Palma, P. P., & Bosch, M. (2012). Characteristics of the Colombian armed conflict and the mental health of civilians living in active conflict zones.Conflict and Health, 6(1), 10–19. https://doi.org/10.1186/1752-1505-6-10 PMID: 23171497

8 Campo-Arias, A., Oviedo, H. C., & Herazo, E. (2014). Prevalence of mental symptoms, possible cases and disorders in victims displaced by the internal armed conflict in Colombia: A systematic review.Revista Colombiana de Psiquiatría, 43(4), 177–185. https://doi.org/10.1016/j.rcp.2014.07.003 PMID: 26574074

9 Gómez-Restrepo, C., Tamayo-Martínez, N., Buitrago, G., Guarnizo- Herreño, C. C., Garzón-Orjuela, N., Eslava-Schmalbach, J., . . . Rincón, C. J. (2016). Violence due to armed conflict and prevalence of mood disorders, anxiety and mental disorders in the Colombian adult population. Revista Colombiana de Psiquiatría, 45(Suppl. 1), 147–153. https://doi.org/10.1016/j.rcp.2016. 11.001 PMID:27993250

10 Richards, A., Ospina-Duque, J., Barrera-Valencia, M., Escobar-Rincón, J., Ardila-Gutiérrez, M., Metzler, T., & Marmar, C. (2011). Posttraumatic stress disorder, anxiety and depression symptoms, and psychosocial treatment needs in Colombians internally displaced by armed conflict: A mixed-method evaluation. Psycho- logical Trauma: Theory, Research, Practice, and Policy, 3(4), 384–393. https://doi.org/10.1037/a0022257

11 Keller, A., Lhewa, D., Rosenfeld, B., Sachs, E., Aladjem, A., Cohen, I., . . . Porterfield, K. (2006). Traumatic experiences and psychological distress in an urban refugee population seeking treatment services. The Journal of Nervous and Mental Disease, 194(3), 188–194. https://doi. org/10.1097/01.nmd.0000202494.75723.83 PMID:16534436

12 World Health Organization. (2003). Mental health in emergencies: Psychological and social aspects of health of populations exposed to extreme stressors. Geneva: Author.

13 Miller, K. E., & Rasmussen, A. (2010). War exposure, daily stressors, and mental health in conflict and post-conflict settings: Bridging the divide between trauma-focused and psychosocial frameworks. Social Science & Medicine, 70(1), 7–16. https://doi.org/10.1016/j. socscimed.2009.09.029 PMID:19854552

14 Patel, V. (2009). The future of psychiatry in low- and middle-income countries. Psychological Medicine, 39(11), 1759–1762. https://doi. org/10.1017/S0033291709005224

15 Sheehan D, Janavs J, Baker R, Harnett-Sheehan KE, Knapp E, Sheehan M, Lecrubier Y, Weiller E, Hergueta T, Amorim P, Bonora LI, Lépine, JP. MINI international Neuropsychiatric Interview. Spanish version 5.0.0 Ferrando L, Bobes, Gibert J and Soto M, Soto O., 2000.

16 Kroenke K, Spitzer, RL. Williams J, Löwe B. "The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review". *Gen Hosp Psychiatry* 2010. **32**: 345-359. doi:10.1016/j.genhosppsych.2010.03.006. ISSN 0163-8343. PMID 20633738.

17 Blevins CA, Weathers FW, Davis MT, Witte TK & Domino JL. The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5): Development and initial psychometric evaluation. *J Trauma Stress* 2015, **28**, 489-498. https://doi.org/10.1002/jts.22059

18 Norman SB, Hami Cissel, S, Means-Christensen AJ, Stein MB. Development and validation of an Overall Anxiety Severity and Impairment Scale (OASIS). *Depress Anxiety* 2006; **23**: 245–249. https://doi.org/10.1002/da.20182.

19 Bentley KH, Gallagher MW, Carl JR, Barlow DH. Development and validation of the Overall Depression Severity and Impairment Scale. *Psychol Assess* 2014; **26**: 815–830. https://doi.org/10.1037/a0036216.

20 Endicott J, Nee J, Harrison W, Blumenthal R. Quality of Life Enjoyment and Satisfaction Questionnaire: a new measure. *Psychopharmacol Bull*. 1993; **29**:321-6. PMID: 8290681.

21 Üstün, N Kostanjsek, S Chatterji, J RehmTB. Measuring Health and Disability: Manual for WHO Disability Assessment Schedule (WHODAS 2.0). WHO 2010.

22 Santaella-Tenorio J, Bonilla- Escobar FJ, Fandiño- Losada A, Bass J, Gutiérrez-Martínez MI, Bolton P. Validating an Instrument for victims of violence in Colombia:

Evaluation of Two Community-based Mental Health Interventions for Violence-Displaced Afro-Descendants in Colombia. [Unpublished manuscript]. Colombia: University of Valle, Instituto CISALVA; 2013)