



Screening for psychological difficulties in young children in crisis: complementary cross-cultural validation

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Background: Detection of children's psychological difficulties in crises and low resource settings is challenged by the lack of a validated, rapid and simple tool. We present the results of two confirmatory validations of the Psychological Screening for Young Children aged 3 to 6 years (PSYCa 3–6) scale.

Methods: We performed cross-cultural validations, assessing the performance of the scale in different contexts. These were conducted in Mathare, Nairobi, Kenya and Buenaventura, Colombia between December 2009 and February 2012. External validity was assessed comparing the PSYCa 3–6 against a clinical interview and the Clinical Global Impression Severity scale (CGI).

Results: A total of 160 mothers or caregivers of children 3 to 6 years old in Mathare and 148 in Buenaventura were included in the study. Both demonstrated good concurrent validity (Buenaventura $\rho=0.49$, $p<0.0001$; Mathare $\rho=0.41$, $p<0.0001$). Inter-rater reliability was found to be acceptable in Buenaventura (intraclass correlation [ICC]=0.69 [0.4–0.84]) and high in Mathare (0.87 [0.75–0.94]).

Conclusions: As shown by its validation in diverse contexts, use in other populations may help improve the delivery of mental health care to children in crises and low-resource settings. Additional research on the design and delivery of intervention models for crises remains essential.

Keywords: Children, Cross cultural validation, Humanitarian emergency, Intervention, Mental health, Screening tool

Introduction

Despite constituting more than half the population in low and middle income countries,¹ the mental health needs of children are often ignored. This is especially true in crises, where children may be exposed to violence, abject poverty and displacement.^{2,3} Crises may be either a singular or series of events that threaten the health, well-being and safety of a community and often necessitate humanitarian intervention. In addition to the direct effects of trauma on child mental health, other potential consequences such as anxiety, depression, and somatoform disorders are often not included even when screening and treatment programs exist.^{4–6} Although recent progress has led to the development

of international guidelines and multiple initiatives to support effective and feasible service delivery models in crises, screening tools remain limited.^{7,8} Detection of child mental health difficulties is important not only for providing care to children in need, but also because such difficulties, if left undetected, can lead to life-long social and potentially psychiatric problems^{9,10} adding additional burden for children already growing up with many challenges. In most published studies, prevalence of psychological disorders in children is described in the range of 10 to 15%.^{11,12} Few studies have been implemented in crises, using different methodologies, thereby leading to a paucity of prevalence estimates.

The combination of few mental health professionals able to accurately diagnose and provide appropriate treatment¹³ and

the absence of simple, rapid and validated screening tools leads, more often than not, to children in crises going without care.^{14–18} Further complicating matters, psychological distress in young children is particularly difficult to evaluate as many behaviours are normal at certain ages but not at others. Unmet needs in these young children may have an impact on their emotional, cognitive, and physical development, notwithstanding their immediate suffering.^{19–21}

Cross-cultural validation of a simple, rapid screening scale would fill one of the many gaps in responding to the mental health needs of young children. Of the available screening scales suitable for crises, most are Western instruments which were simply translated into the local language^{22,23} without rigorous cross-cultural validation and are often disorder specific.^{11,24–26} Recognition of the diversity of psychological responses in children is an essential step towards providing appropriate care.

Cross-cultural validation necessitates the evaluation of the scale in different contexts, ensuring that it can be generalized to the diversity of potential responses. The extent to which findings from one cultural unit can be generalized to other populations is still open to debate. Although primary validation of screening scales may be conducted rigorously and appropriately, it is essential to evaluate their validity in other populations to establish their public health utility. Conventionally, a primary validation is conducted followed by two confirmatory validations, where the validity of the scale is assessed without adaption to determine its generalizability and public health utility in order for a scale to be cross-culturally validated.

Here, we report the results of two confirmatory cross-cultural validations of the Psychological Screening for Young Children aged 3 to 6 years old (PSYCa 3–6) scale. It is a short and context sensitive instrument administered by non-specialists to facilitate screening in contexts with scarce mental health resources. Children aged 3 to 6 remain a highly vulnerable group with few tools available to facilitate identification of psychological distress and thereby the need for additional evaluation. The two complementary cross-cultural validations aimed to explore and determine the capacity of the tool, to identify children in need of additional evaluation and referral to care. In crises, often involving constraints of time and security, a tool that could be implemented quickly, requiring only a rigorous translation, would thereby aid in identifying children most in need to be referred to scarce professionals.

Methods

Study sites

These two complementary cross-cultural validations were done in Buenaventura, Bogota, Colombia, and Mathare, Nairobi, Kenya. The primary validation in Maradi, Niger was conducted in a population where we expected a lower prevalence of post-traumatic disorder than in populations of children evaluated in other post-conflict contexts. This validation included item reduction which led to the version we hypothesized could be generalized. To evaluate the scale's eventual public health utility and test the trauma component, the two confirmatory validations were conducted in settings where children 3 to 6 years may be exposed to violence during their development (Buenaventura and Mathare).

Buenaventura is a port city and municipality located in the department of Valle del Cauca, Colombia. It is the main port of

Colombia on the Pacific Ocean. The vast majority of the 124 neighbourhoods of the city are situated along the city's main road. The city is affected by very high levels of poverty and violence, and is considered a centre for the cocaine trade in Colombia. Mathare is a collection of slums in Nairobi, Kenya. The population is affected by high levels of poverty, violence and insecurity. Households are mainly headed by single working mothers.

Sites were chosen for the following reasons: first, the choice of language is crucial as semantic equivalence must be guaranteed. By choosing to translate the tool into Spanish and Swahili, we were able to use both locally known and internationally recognized specialists in the language and culture. Moreover, the instrument would be available in a language spoken by over 400 million individuals globally (Spanish) and in two of the languages used most widely in Africa as both Hausa (from the primary validation) and Swahili are spoken by more than 40 million people each. Although we recognize the panorama local languages, both Spanish and Swahili are lingua francas among many populations thereby these two languages would be understood by a wide range of individuals. Second, selection of study sites and populations also took into account the political and security situation, the possibility of referral for children screened positive, therefore increasing the possibility of providing mental health treatment to children detected to be in difficulties in the future. In both sites, Médecins Sans Frontières implements specific psychological consultation programs and we were able to ensure that children could be referred for evaluation and care.

Psychological screening for young children aged 3 to 6 years old

The PSYCa 3–6 is a screening tool that aims to assess non-specific disorders as opposed to a disorder specific focus, in children 3 to 6 years old. The tool is specifically designed for screening of distress. By screening for psychological distress, a sub-set of children, perhaps most in need, can be referred for further evaluation. Screening positive indicates the child's need for further evaluation by a clinical psychologist or psychiatrist.²⁷ It is a questionnaire completed by the parent or caregiver through a lay interviewer (Box 1). It includes 22 items concerning child behaviour addressing the following: depression, phobia, anxiety, regression, psychosomatic complaints and post-traumatic disorder. The questionnaire is in the form of simple questions that caregivers answer by never/not at all, or sometimes/a few times or often/frequently/always.

At this early age, the mother is often the closest caregiver and the person responsible for the child's daily activities, protection and growth. Each interviewer reads the questions and then scores depending on the response. At the end of administration, responses are summed to compute a total score ranging from 0 to 44 with higher scores indicating greater distress. Additional details on the item reduction process and development of the scale have been published elsewhere based on the primary validation in Niger.¹⁹

Translation

Two translators performed a linguistic translation of the tool from French to Spanish and Swahili independently.^{28,29} The two resulting versions were compared and a few differences were resolved. Experienced child mental health professionals in each country of validation reviewed the translated version. Local psychologists

Box 1. The 22 items of the Psychological Screening for Young Children aged 3 to 6 years old (PSYCa 3–6) scale

The modality of response is 0, 1 or 2 (never, sometimes, often) for each item

- 0 1 2 The child stammers
- 0 1 2 The child refuses to eat repeatedly
- 0 1 2 The child wakes up frequently, insomnia
- 0 1 2 The child is absent, seems somewhere else, in “his world”, has difficulties to interact with you
- 0 1 2 The child had a bad dream or nightmare that comes often
- 0 1 2 The child is frightened, worried, anxious
- 0 1 2 The child has difficulty to be clean (pee, poop)
- 0 1 2 The child refuses to separate with one of his parents, siblings etc
- 0 1 2 The child eats too much
- 0 1 2 The child does not speak or very little, his language is very different from children of his age
- 0 1 2 The child refuses to eat certain foods and chooses what to eat at every meal
- 0 1 2 The child has difficulty falling asleep
- 0 1 2 The child has outbursts, have uncontrolled movements for no apparent reason
- 0 1 2 The child complains of pain or complains about his body without obvious medical reason
- 0 1 2 The child is unable to sit still, he moves constantly
- 0 1 2 The child refuses to leave the household
- 0 1 2 The child is tired, discouraged
- 0 1 2 The child’s behavior is really too aggressive, he is violent (at home and/or outside)
- 0 1 2 The child isolates himself or often moves away from others
- 0 1 2 The child is easily overwhelmed by his emotions anger, sadness fraternal jealousy etc
- 0 1 2 The child plays repetitive games or activities
- 0 1 2 The child runs away or avoids sounds, images or specifics situations

were asked to review the translations to ensure that questions were worded appropriately to guarantee that the underlying concept of the question was addressed. Prior to implementation, the tool was administered to a small group of mothers and caregivers in a pilot phase for acceptance, adequacy and applicability. Mothers and caregivers in the pilot phase were not a part of the validations.²⁹ The final versions were fixed by consensus taking into account differences between spoken and written languages and the opinions of the experienced local psychologists. Finally, focus group discussions with community key informants (senior women in villages, health care workers and community liaisons) were conducted to elucidate understandings of the beliefs and perceptions about child development, expectations of the outcome of treatment and to ensure that misclassification was minimized.^{30–35}

Training

All interviewers were experienced in questionnaire administration, fluent in Swahili and Spanish as well as other local languages and

with no mental health background. After a general presentation of the PSYCa 3–6 as well as of informed consent including inclusion and exclusion criteria, items were presented and discussed one by one. Role-play was used to simulate administration of the questionnaire. A pilot phase followed the theoretical training to ensure standardized administration and reinforce the theoretical training. Interviewers were supervised during data collection to respond to any difficulties or questions.

Sampling

As this was not a study of prevalence, our aim was to obtain a sample of the population in each of the two study areas. Although we could have selected a different sampling scheme (for example, convenience sampling at a health centre), interviews conducted within households ensure confidentiality and privacy. Comprehensive information and awareness campaigns were organized to inform the population about the aims and objectives of the study before implementation. Households within the study areas with at least one child aged 3 to 6 years and speaking Spanish or Swahili were eligible for inclusion. Systematic random sampling was used in accessible neighbourhoods to select the sample of mothers and caregivers. Accessible areas were those which did not pose disproportionate security constraints for the study team. Delineated neighbourhoods in each of the two study areas were drawn on a map using local landmarks. In each of the neighbourhoods, households were pre-identified, by the study team, and then following a hand-drawn map, were visited. Interviewers visited households door-to-door in the selected areas.

As mothers were the most knowledgeable concerning children’s daily activities and behaviour, they were asked preferentially to participate. All mothers and caregivers were read an information letter describing the study and asked for written informed consent before enrolment. Interviewers excluded children who met visible, recognizable criteria of mental retardation or grave development disorders based on the 10th version of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by WHO (ICD-10).³⁹ These children were referred immediately for adapted care.

Procedures

For these complementary validations, implementation occurred over three weeks and included two separate analyses. First, we examined the psychometric properties of the tool, internal consistency (Cronbach’s alpha), interrater and temporal reliability. The questionnaires were included. Next, we examined the external validity of the tool: the interviewer administered the PSYCa 3–6 followed by a clinical evaluation as the gold standard (questionnaire and individual interview were compared). The psychologist completed the Clinical Global Impression-Severity Scale (CGI-S), a seven-point severity scale, assessing a patient’s current symptom severity, and answered the question ‘does the child need psychological/psychiatric care?’ The CGI-S is used widely in medical care and clinical research because of its face validity and practicability with the same wording irrespective of the pathology.^{37,38}

The clinician also completed a semi-structured clinical interview, and performed a diagnosis based on ICD-10 classification.³⁹ For operational and security reasons, only one psychologist was

able to be included in the validation in Colombia while two participated in the study in Kenya. The psychologists were under the supervision of a senior clinical psychologist. In case of detection of psychological difficulties, individual home based care was proposed and provided. Mental health care providers in the area were informed of the study and were aware of any referrals for additional care.

Clinical psychologists trained in child development and cross-cultural psychology carried out the individual interviews. They were blinded to the score of the tool which had been administered immediately prior to the interviews. Each individual interview was direct and confidential. A translator was present and participated in the training for Mathare. A translator was not needed for the validation in Buenaventura.

To ensure data quality, completed questionnaires were reviewed daily. At the end of the day, the study team, including the interviewers and translators as well as supervisors, met and discussed any difficulties.

Data analysis

For the confirmatory validations, a minimum of 100 children were needed to evaluate the external validity of the scale,⁴⁰ tested by comparing the reported PSYCa 3–6 scores against the clinical psychologists' evaluation using the CGI-S.^{41,42} Total scores were correlated with CGI-S scores, and receiver operating characteristic (ROC) curve analyses performed to evaluate the tool's screening properties (compared to decision of an orientation of a child or not by the psychologist) and determine an optimal cut-off. Kruskal-Wallis tests were used to assess the association between PSYCa 3–6 scores and each child's socio-demographic characteristics. A total of 25 children completed the scale twice to assess interrater reliability and 100 for internal consistency and external validity of the scale.

After the primary validation in Niger, an item reduction procedure was implemented and the final scale validated in Buenaventura and Mathare. The factorial structure of the PSYCa 3–6 final version was investigated with a maximum likelihood factor analysis with varimax rotation. The number of subscales was determined from the observation of the scree plot, parallel analysis (random simulations of data sets) and from the clinical interpretability of subscales.^{42,43} Finally, an expert panel consisting of a child psychiatrist, research psychologists and a statistician reviewed the results. R software (R foundation for Statistical Computing, Vienna, Austria, version 2.10.0) was used for all analyses. Additional details on the item reduction are presented elsewhere.¹⁹

Ethical considerations

The protocol was submitted and approved by the Committee for the Protection of Persons (CPP) Ile de France XI, the Ethical Committee of University of Los Andes, Bogota, Colombia, and the Kenya Medical Research Center Institute (KEMRI), Nairobi, Kenya. After informed consent was obtained, caregivers were asked to complete the questionnaire. The consent process included two documents, an information sheet and consent form, both translated into the local language. Patient data were confidential unless it was deemed necessary to protect the health of the patient. The study database contained no identifying information to ensure anonymity. Children requiring psychological care

received appropriate and free care by a clinical psychologist. In study sites, the children identified were referred for care to the Médecins sans Frontières supported Ministry of Health program, which included specific mental health evaluation and consultation for children. The PSYCa 3–6 will be made publicly available.

Results

A total of 148 caregivers were recruited between 18 and 29 November 2011 in Buenaventura, Colombia and 160 caregivers were recruited between 16 and 24 February 2012 in Mathare, Nairobi, Kenya. We included additional children beyond the sample size required to ensure that all families identified for participation had the possibility to be included if they so wished.

The validation in Buenaventura enrolled 148 children in total (two were not found for the second administration of the tool, one child presented with severe developmental delay). Internal consistency was calculated on 145 questionnaires, interrater reliability on 36 children and 109 children were included for the examination of the external validity of the tool. In Mathare, a total of 160 children were enrolled, 10 children were excluded (six were not found for the second administration of the tool, three did not speak Swahili fluently and one presented with a severe developmental disorder). The analysis consisted of 29 questionnaires concerning the examination of interrater reliability and 121 for the external validity. Internal consistency was analysed on 150 questionnaires. Demographic information on the two samples is summarized in Figure 1, Tables 1 and 2.

In both sites, the proportion of missing data per item was low suggesting good acceptability and that items were easy to complete. In Buenaventura, 98.6% (143/145) questionnaires were completed and 1.4% (2/145) questionnaires had one answer missing; and in Mathare (Nairobi), 97.3% (146/150) questionnaires were completed and 2.7% (4/150) questionnaires had one answer missing.

The final tool demonstrated acceptable internal consistency for a screening tool including several dimensions (depression, anxiety, post traumatic component) (Table 3).²⁰ The internal consistency was lower for Colombia but still considered acceptable. Interrater reliability varied between the sites. There was no significant difference between the PSYCa 3–6 scores of boys and girls, or between children 36, 48 or 60 months of age. In Buenaventura, 109 children were evaluated by one clinical psychologist (CM) and in Mathare (Nairobi), 121 children were evaluated by two clinical psychologists (CM, HM). A total of 8 children (7.3%, 8/109) were orientated after the individual interview in Buenaventura and in Mathare, 14 children (11.6%, 14/121).

Correlation between the final tool and CGI were acceptable. ROC analyses resulted in an area under the curve of 0.95 (95% CI 0.89–1.0) for Buenaventura and 0.95 (95% CI 0.84–0.96) for Mathare (Figure 2).

Factor analysis

Factor analysis was used to explore the variation of scale dimensions in different contexts. It was not unexpected that dimensions would be unstable considering the scope of variation of psychological difficulties manifested in diverse settings and cultures.⁴⁴ Prior to the implementation of the study, we presumed that the structure would be different and that this difference could be

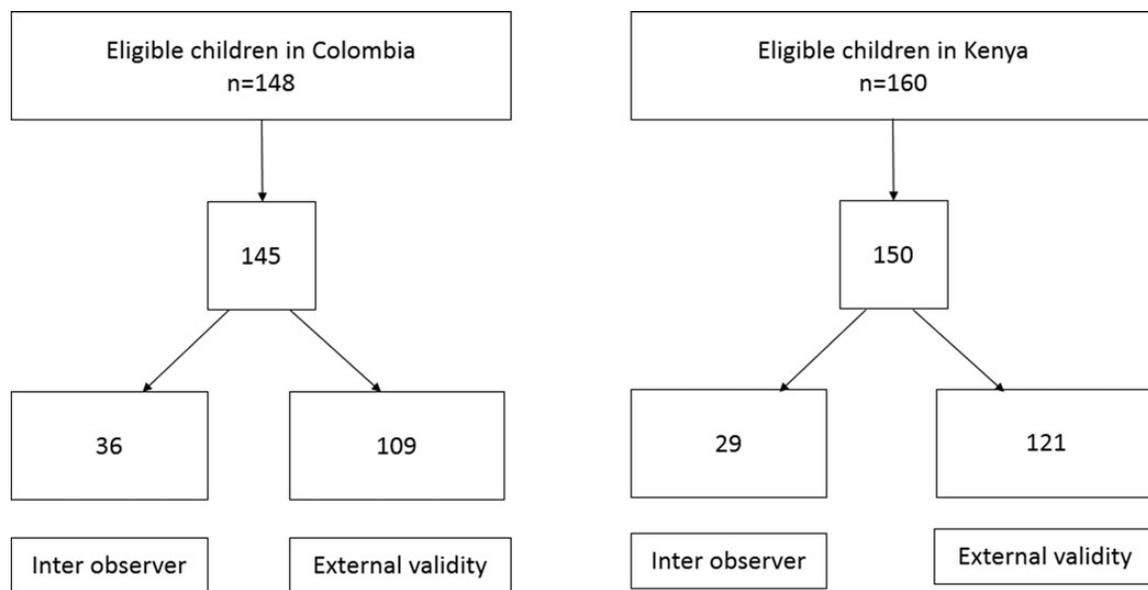


Figure 1. Flow chart of the participants included in the study, and number of participants included in the interrater analysis and external validity analysis.

Table 1. Description of the study period, the study population (number of children included in each step of analysis) and numbers of interviewers

Sites	Colombia	Kenya
Study period	18–29 November 2011	16–24 February 2012
Number of children included	148	160
Number of interviewers	2	3
Sample for interrater reliability	36	29
Sample for clinical interview	109	121

Table 2. Socio-demographic characteristics of the children (sex and age) included in the two complementary validations, by country

Characteristics	Colombia n = 145 (%)	Kenya n = 150 (%)
Male	70 (48.3)	74 (49.3)
Female	75 (51.7)	76 (50.7)
Age, years		
3	50 (34.5)	78 (52)
4	49 (33.8)	46 (30.7)
5	46 (31.7)	26 (17.3)

interesting from a clinical point of view, especially from a cross-cultural perspective (Figures 3A and 3B). The structure was in favour of a 1-factor solution and 2-factor solution for both sites.

For the two complementary validations, the interpretation, after adaptation of the original tool, conveyed a one dimensional structure (psychological difficulties) but further analysis should be performed and additional data collected to explore dimensionality.

Discussion

We present the results of the two confirmatory cross-cultural validations of a screening tool for psychological difficulties in children aged 3 to 6 years. The tool is simple and quick to implement and could be an important addition in settings where mental health care professionals and programs are limited. The results of the validations, without adaptation in two diverse contexts, demonstrate its potential for wide-scale use. In addition to the acute phase of a crisis, the tool could be used to identify difficult to reach children (due to either distance or isolation, for example) and refer only those in need of further evaluation to health structures. As the number of mental health professionals is limited, the ability for non-specialists to screen children in need of specific evaluation, can help to improve the possibility that needs are met.

Due to the lack of previously cross-cultural validated scales for young children in crises or low resource settings, we chose to use a classic individual interview by a psychologist as our gold standard. Concordance between the clinical interview and the PSYCa 3–6 suggest that use of the ICD-10 did not influence the results. Scale validation methodology is debated. The conventional process of validation of psychometric tools stems from the lack of objective measurements which are widely accepted. We considered the response to the question asked of clinicians: ‘does the child need psychological/psychiatric care?’ as the gold standard. This approach follows other similar methodologies used in medical scale validation.⁴⁵

In terms of differences between the populations, there was greater variability in the data from Mathare; the number of

children presenting psychological difficulties was higher and also severity with higher total scores at administration and higher CGI. These results are not unexpected and suggest that its use in crises is appropriate, as the tool is more specific in a higher prevalence context. In Colombia, the number of referrals was lower, possibly due to the close (spatial proximity) relationship of mothers in this context where children remain close their mothers for long periods. Interrater reliability also varied between the two study sites. This variation can be explained by the expertise gained by the supervisor in supervision and training of the interviewers and also because in Kenya two clinical psychologists were used providing very close supervision.

The scree plots for the two confirmatory validations are more in favor of a one-dimensional instrument, reflecting the capacity of the tool to detect the psychological difficulties of young children including several areas of psychopathology. Each dimension can include many scores. Consequently, differences found between individual children and between groups can be conceptualized in relation to a range of possible scores on each dimension. Rather than viewing all children of one cultural group as categorically different from all children of another group, we can view each child in terms of quantified profile patterns consisting of scores on dimensions that can be compared with distributions of scores in normative samples drawn from particular cultural groups. The use of quantified dimensions to evaluate children in relation to norms for particular cultural groups is analogous to the evaluation of children’s heights in relation to norms for their age and gender.²⁷ Although use of these norms is subject to debate, we show here that a simple generalist tool performs well cross-culturally.

It is also important to highlight that systematic analysis of validity is uncommon in transcultural epidemiology. The debate about the validity of transcultural studies spans the extremes of dismissal based on the social construct of the medicalization of distress to the other extreme presumption that methods and findings are independent of context. In psychopathology, it is not unexpected to find different structures for the same scale.⁴ The correlation structure changes depending settings and severity of

Table 3 Psychometrics properties and external validity of PSYCa 3–6 scale

Sites	Colombia n=148	Kenya n=160
Internal consistency		
Alpha Cronbach (95% CI)	0.56 (0.42–0.66)	0.78 (0.72–0.81)
Reliability (95% CI)		
Interrater (ICC)	0.69 (0.4–0.84)	0.87 (0.75–0.94)
External validity		
ρ (CGI)	0.49 ($p=0.000$)	0.41 ($p=0.000$)
AUC (95% CI)	0.95 (0.89–1)	0.90 (0.84–0.96)

Principal results concerning the psychometric properties (internal consistency and reliability of the tool) and external validity (the score obtained compared to the gold standard [clinical interview]).

AUC: area under the curve; CGI: clinical global impression; ICC: intraclass correlation.

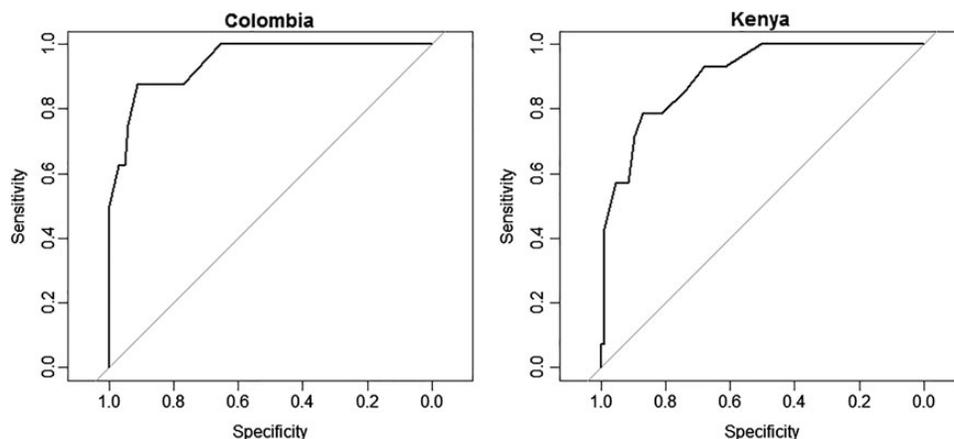


Figure 2. Receiver operating characteristics (ROC) curve of the Psychological Screening for Young Children aged 3 to 6 years old (PSYCa 3–6) scale. ROC curve analyses resulted in an area under the curve of 0.95 (95% CI 0.89–1.0) for Buenaventura (Colombia) and 0.95 (95% CI 0.84–0.96) for Mathare (Kenya).

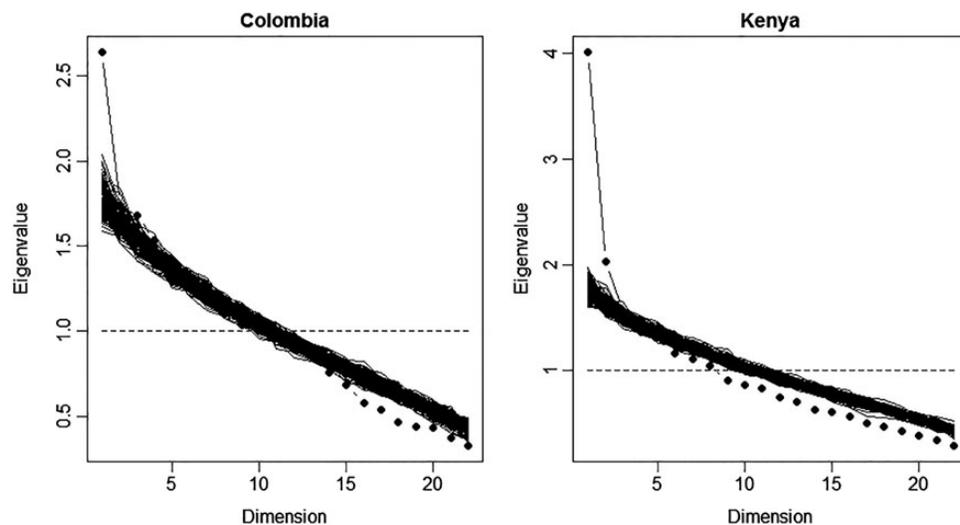


Figure 3. (A) The scree plot analysis was used to determine the number of subscales. The structure was in favour of a 1-factor solution for Colombia. (B) The scree plot analysis was used to determine the number of subscales. The structure was in favour of a 2-factor solution for Kenya.

the difficulties presented. In this cross-cultural validation, the comparison between the scale score and the gold standard was the most important, but acknowledgement of cultural variation is essential.

Limitations

The key limitation of the results presented here concern the scale-up of the PSYCa 3–6 and other screening scales. It is important to note that although screening scales may help facilitate care, mental health programs for children in crises are few and far between. As a result, it is important to recognize that a screening scale should be used only in contexts where referral to appropriate care is possible. Although there is an important need to develop affordable and scalable screening tools that are easy to understand, simple to administer, with precise goals and a well-structured response set, without mental health programs these tools will remain limited. We aimed to ensure that the scale was sufficiently flexible, evidence-based, culturally, socially and age appropriate, and also standardized to enable cross-cultural comparisons. However, we performed only two confirmatory validations in two populations. Without additional experiences with this tool, and others, their potential use will remain limited and the lessons learned from these experiences restricted.

Conclusions

Despite the identified limitations, the Spanish and Swahili versions show appropriate psychometric properties for screening psychological difficulties in young children. PSYCa 3–6 has advantages for use in crises or low resource settings such as brevity, easy administration by non-specialist interviewers, and the inclusion of several domains of psychopathology allowing the detection of post trauma difficulties. From a public health perspective, the ability to identify potential psychological difficulties in young children represents a significant advancement for the possibility of addressing childrens' mental health needs in difficult contexts.

At the onset of crises, rapid screening and needs identification allows for the design and implementation of specific programs to address these needs. This is often accomplished through the support of local and international non-governmental organizations (NGOs). One possible use of this tool would be to use the results of screening to advocate and ensure that specific programs are implemented. As children's mental health often remains unaddressed in crises, use of the tool may support the need for specific programs. Additional efforts to adapt and validate simple screening scales for use in other low resource settings should be encouraged.

Authors' contributions: RFG, CM and CB wrote the report and assessed all data, with input from other investigators. RFG and MRM conceived the study and the protocol, participated in its design and implementation. CM coordinated the implementation of the study. YM, DMD, MLM participated in the design of the study. CM, YM, HM provided the clinical interview on the field. CB performed the statistical analysis. BF participated in the design of the study, statistical analysis, and interpretation of the results. EMTM, SG, GC, BWK supported and participated in the implementation of the study. All authors read and approved the final version of the paper. CM is guarantor of the paper.

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