Development of a complex public health intervention to reduce the anxiety of children aged 13-15 years attending government Sinhala medium schools in Colombo district, Sri Lanka

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Abstract

Background: Anxiety disorders (AD) are the most prevalent psychological problem among adolescents. Both anxiety disorders and anxiety symptoms can lead to adverse outcomes. The aim of the study was to develop an evidence-based intervention package to reduce anxiety among school children aged 13-15 years.

Methods: Design: UK Medical Research Council guidance for development of complex interventions were followed. Identification of evidence based was done by literature-search and expert opinions. Most suitable theory was identified based on level of evidence through consensus of Advisory committee (AC) consisting of experts. Subcomponents of the selected theory were mapped with associated factors of the AD. Eleven KII were conducted with school principals, teachers, parents, and students. Framework of the intervention package with suitable deliverables was designed with consensus of the AC by triangulating the findings. This was further fine-tuned by using Modified-Delphi technique with participation of broader group of experts. These Delphi items were systematically derived from findings of the systematic reviews, expert opinion, and inputs from intervention recipients. The content development was done based on the proposed framework. The modeling process was done by conducting four consultative meetings with stakeholders with the aim of ensuring content and consensual validity followed by a consensus workshop. Feasibility study and pretesting of deliverables were done. **Participants:** Advisory committee [n=6] and stakeholder group [n=11] in Delphi component & four consultative meetings and a wider stakeholder group [n=23] in 1-day consensus workshop were involved.

Results: Four RCTs and 12 RCTs/cRCTs were identified through literature review. Six types of intervention modalities were identified. CBT based intervention modality was shortlisted by AC considering the level of evidence. Five broad solutions, namely psycho education, realistic thinking, problem solving, graded exposure and relaxation techniques under CBT were mapped against the associated factors with consensus of the AC. Activities were developed under these broad solutions and most suitable options of these activities were selected by a stakeholder group using Modified Delphi technique. The intervention package was finalized by conducting a consensual workshop followed by feasibility study and pretesting of deliverables.

Conclusions: A CBT-based universal intervention package was developed to reduce anxiety among children with ToT workshop for teachers with a field training, eight weekly 40 minutes sessions for children and one 40-minute session for parents. Teachers' guide, Student's workbook and leaflet for parents were deliverables. A process evaluation framework was used to monitor implementation.

Keywords – CBT Based, Universal, Reduce Anxiety, Children, Intervention, Development.

I. INTRODUCTION

Anxiety-related conditions exist as a spectrum of disorders. In the society, adolescents those who are at risk of acquiring risk factors, with risk factors, with anxiety symptoms at different levels, with anxiety disorders, and with complications of anxiety disorders are found. In other words, the individuals may be having anxiety symptoms/ anxiety levels to different extents but only

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a minority would have them to a severity level of an anxiety disorder (1).

As anxiety disorders are diagnosed based on DSM /ICD criteria, an individual can have symptoms of anxiety disorders even though they do not meet the diagnosis criteria of an anxiety disorder. There is research evidence to show the presence of functional impairments due to the presence of symptoms of anxiety disorders in individuals even though they do not meet the diagnosis criteria. As Beesdo, Knappe et al. 2009 describe in their review paper, anxiety levels will fluctuate in an individual and all the time it does not come to the diagnosis threshold. Prevention plays a vital role as anxiety and anxiety disorders are associated with subsequent adverse outcomes. Anxiety disorders in children are managed with behavioral therapy (using principles of exposure and response prevention), sometimes in combination with drug treatment (1).

Anxiety preventive measures are directed either at individuals or groups. There is evidence that shows preventive measures that are targeting groups, to be more effective than those targeting an individual. Prevention programs targeting a group of people may be universal, selected, or indicated. Universal intervention is directed at the whole population irrespective of their risk status. The selective intervention involves persons who have been identified as at risk of psychological problems, whereas indicated intervention targets persons who have been identified as having the disorder (1).

The programs that had been used under universal prevention strategies comprise of elements of primordial, primary, secondary, and tertiary prevention in contrast to selective programs that concentrate on primary prevention and indicated programs that concentrate on secondary prevention (2).There are several benefits associated with universal prevention programs in contrast to selective and targeted programs. Universal interventions provide the opportunity to address individuals with limited access to treatment, no one will be omitted, show low dropout rates, and might be one way to avoid the stigma associated with participation in selected or targeted interventions (2). A systematic review of universal intervention to reduce anxiety and depressive symptoms in school-aged children had revealed that there was small but significant effects regarding reducing anxiety and depressive symptoms. The goal of prevention is to reduce the future appearance of negative outcomes, which is often attempted by reducing relevant risk factors and by strengthening relevant protective factors (3). When developed as prevention programs, these programs are designed to build skills as opposed to provide therapy, meaning strategies are learned for common situations that many people have either experienced or may experience, rather than specific situations derived from individual difficulties (4).

As per the available literature, the majority of anxiety reduction programs were delivered as a complex intervention that was built up of multiple components, which may act independently or interdependently. The aim of the current study was to develop an evidence-based intervention to reduce anxiety among school children aged 13-15 years.

II. METHOD

Identification of the evidence base, identification/development of theory, and modelling process and outcomes were done as per RC guidelines for the development of the complex intervention (5). As the first step, an advisory committee (AC) of experts was appointed consisting of a Consultant Community Physician, Consultant Child Psychiatrist, Senior Registrar in Child Psychiatry, Clinical Psychologist, and an educationist. With the guidance of this advisory committee, a method was adopted for the purpose of developing the intervention package (Figure 1).
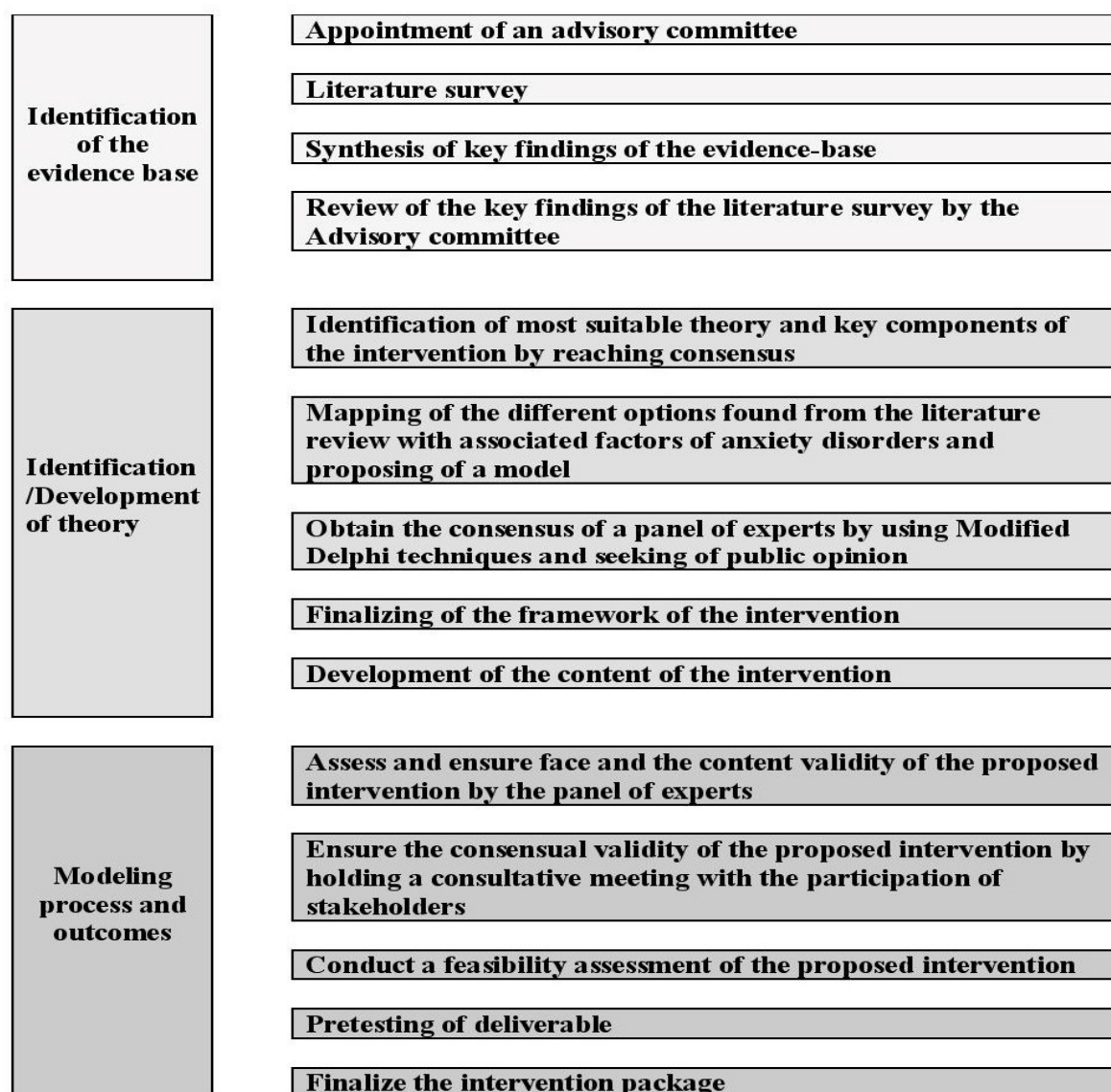
Identification of the evidence base	Appointment of an advisory committee
	Literature survey
	Synthesis of key findings of the evidence-base
	Review of the key findings of the literature survey by the Advisory committee

Identification /Development of theory	Identification of most suitable theory and key components of the intervention by reaching consensus
	Mapping of the different options found from the literature review with associated factors of anxiety disorders and proposing of a model
	Obtain the consensus of a panel of experts by using Modified Delphi techniques and seeking of public opinion
	Finalizing of the framework of the intervention
	Development of the content of the intervention

Modeling process and outcomes	Assess and ensure face and the content validity of the proposed intervention by the panel of experts
	Ensure the consensual validity of the proposed intervention by holding a consultative meeting with the participation of stakeholders
	Conduct a feasibility assessment of the proposed intervention
	Pretesting of deliverable
	Finalize the intervention package

Figure 1: The method adopted to develop the intervention package.

2.1. Identification of the evidence base

A thorough literature survey was done to identify interventions carried out to reduce anxiety among children and adolescents. Research articles were searched electronically in PubMed, Medline, the Cochrane Library, PsycINFO, Google scholar, and manually in libraries. Keywords used for literature surveys included systematic-review, meta-analysis, school-based, anxiety, depression, prevention, mental health, children, adolescents, evaluation, and these were used in different combinations to ensure the comprehensiveness of the search.

Only randomized controlled trials and cluster randomized control trials with a minimum sample size of 100 participants per study in view of ensuring validity with an evaluation of primary data were considered.

2.2. Identification/ development of the theory

Identified articles were reviewed by the advisory panel. Active ingredient i.e., appropriate theory, mode/method of delivery, approach of delivery, target groups and points of outcome assessments with tools were decided by reviewing the gathered evidence

by reaching the consensus among experts while considering their appropriateness, feasibility, and acceptability. On identified active ingredient i.e., CBT based solution, currently available effective interventions were searched and reviewed (Table 1).

Table 1: The Effective CBT Based Interventions in Reducing Anxiety

CBT based intervention	Key areas
Coping Cat (11)	-Education,
	-Modification of negative cognitions
	-Exposure,
	-Social competence training,
	-Coping behavior
	-Self-reinforcement
Cool Kids program	-Psychoeducation
	-Cognitive restructuring
	-Parent skills
	-In-vivo exposure
	-Social skills
	-Improved coping strategies
FRIENDS for Life program (12)	- be aware of feelings and regulate negative feelings
(This program was originally called "Coping Cat", but in the versions for Australia it was modified to "Coping Koala" and for Canada to "Coping Bear", Now it's called FRIENDS)	- "relaxation" including breathing, meditation and have some quiet time
	- positive thinking
	- problem-solving techniques
	- quality time together doing fun activities
	- practice skills
	- Stay happy
Skills for Academic and Social Success (13)	- Psychoeducation about what is social anxiety
	- Realistic thinking
	- Social skills—Expressing positive feelings
	- Behavioral exposure
	- Social skills—Taking initiative
	- Social skills 4—Expressing negative feelings
	-Exposure to social events
Anxiety Action Plan (AxAP) (14)	-Psychoeducation about anxiety,
	-Exposure (i.e., facing fears)

	-Cognitive restructuring (i.e., changing thoughts) - problem-solving
	-Relaxation
	-Relapse prevention
	-Anxiety-related parenting tips (including contingency management).
Intervention With Adolescents With Social Phobia (IAFS) (15)	-Education
	- Training in Social Skills
	- Exposure
Treatment of Anxiety and Physical Symptoms (TAPS)(16)	-Relaxation
	-Cognitive restructuring
	-Exposure exercises (targeting fears related to physical pain and anxiety-inducing situations)

2.3. Mapping of CBT based solutions to the findings of literature search.

The PI and the advisory committee studied the significant associations of the status of having an anxiety disorder in global, regional and local literature. Then the selected active ingredient-based solutions suitable to reduce anxiety were mapped against the associated factors identified.

The Advisory committee decided to develop a new package of CBT based intervention by considering the collection of CBT based solutions identified at the mapping phase and also considering the fact that many of these CBT based interventions (Table 1) were not available in the public domain and are not free to use.

The opinion of a broader panel consisting of experts in community medicine, child psychiatry, clinical psychology, and education was sought on appropriateness, acceptability, and feasibility by using modified Delphi techniques about the following questions that includes different options of identified CBT based solutions, number of sessions for children (either four or eight or twelve sessions), duration of each session for children (either 40 minutes or 80 minutes), number of sessions for parents (either one or two sessions), duration of each session for parents (either 40 minutes or 80 minutes), tools to assess outcomes, using a 5-point Likert scale with an option to document any other comments/ suggestions for improvements . With regard to each proposed area, for each domain, average marks of three or more were considered as agreed. For a particular proposed area, if the average marks were three or more for all three domains i.e., appropriateness, acceptability, and feasibility, it was considered to be accepted.

Furthermore, key informant interviews were conducted with an educational director, school principal, two teachers, two parents, and five students with the aim of getting their inputs from their perspective on the proposed package and their expected methods of receiving it. These inputs were also considered in finetuning of the proposed intervention with the objective of considering recipients values.

A framework of the intervention was prepared with the above-mentioned inputs.

2.4. Modelling process and outcomes

Based on the framework finalized in the above steps, key components, sequence, and suitable deliverables were identified by PI with the guidance of the advisory committee following brain storming, reviewing literature, inputs provided by the recipients at the previous stage and seeking experts' opinion.

The content for each of the above components was developed by PI with the guidance of the supervisors within the framework agreed upon. The content was developed in the Sinhala language. The guidance provided by Sauter, Heyne, and Westenberg 2009 was followed to ensure the age appropriateness of the content (6).

The face, content, and consensual validity were assessed and ensured by the advisory committee when the content development was completed. Also, the level of anxiety was chosen as the primary outcome and level of depression and level of self-esteem as secondary outcomes to assess the effectiveness of the intervention.

Also, a process evaluation framework was developed as described by Linnan and Steckler 2002 with context, reach, dose delivered, dose received, and fidelity as the components. The success of the implementation was monitored using this framework (7).

The whole package was presented at a consultative meeting conducted with the participation of stakeholders from the health and education sectors and it was further modified with their inputs.

2.5. Pretesting and feasibility assessment

The feasibility study was conducted in a selected class in a school, in order to identify the practical issues when implementing the intervention package. All the deliverables were pre-tested in their target audiences. They were further improved by considering the inputs received at the pre-test.

Ethics clearance was obtained from Ethics Review Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka.

III. RESULTS

3.1. Identification of the evidence base

Four systematic reviews and 12 RCTs/CRTs were identified. Out of the searched RCTs/CRTs, suitable RCTs/CRTs were shortlisted by applying eligibility criteria.

It was revealed that Anxiety prevention programs had been delivered either as universal or targeted (selective and indicated), effective at immediate post intervention to follow up until 12 months and their effect sizes are more or less similar. Types of successful intervention types included Cognitive Behavioural Therapy (CBT) based therapy, Interpersonal psychotherapy (IPT), Mindfulness-based psychotherapy (MBPT), Wellbeing therapy (WBT), Psycho-educational approaches, Pharmacological interventions e.g., Benzodiazepines, Beta-blockers, MAOIs, SNRIs, SSRIs

Cognitive Behavioral Therapy-based (CBT) interventions were found to be effective than no therapy in reducing symptoms of anxiety and depression and increasing self-esteem in children and young people. It was found to be the current treatment of choice suggesting medium to large effect sizes for symptom reduction without adverse side effect or withdrawal problems, was associated with a lower rate of subsequent relapse (8). But they were no more effective than other 'active therapies'. No clear evidence indicated that one way of providing CBT is more effective than another (e.g., in a group, individually, with parents). There was no significant difference in externally delivered programs to school staff delivered programs. Briefer' or 'shorter' interventions refer not only to the number of sessions but the total duration of treatment. Due to the critical need for increased access to CBT for children with anxiety disorders, there are now a number of studies reporting successful treatment of anxiety disorders with shorter treatment protocols. Previous Cochrane Reviews used a cut off of nine sessions of CBT, based on the practice and thinking at the time (9).

3.2. Identification/ development of the theory

CBT was identified as the most appropriate intervention strategy, according to the evidence synthesis. Considering the feasibility of implementation and the high prevalence of anxiety in the student population, a universal approach was considered suitable. Therefore, it was planned to deliver the intervention via schoolteachers as a universal CBT based intervention having students as the primary target while addressing parents as well.The means and standard deviations for appropriateness, acceptability, and feasibility of the proposed areas were scored by 11 experts from relevant fields (Table 2). Based on these responses, decisions were taken on which solutions to be retained, number of sessions for children, the best time duration for a session, number of sessions for parents, and on outcome measures with the consensus of the PI and the advisory committee. Options were selected

based on having an average score more than 3 out of 5 for appropriateness, acceptability, and feasibility. Accordingly, selected options included a one day teacher training workshop with a field training, eight-week-long training with eight 40 minutes sessions for children, and one 40 minutes session for parents and to prepare a handbook for teachers, a workbook for students, and a leaflet for parents to increase awareness.

Table 2: The Means and Standard Deviations for Appropriateness, Acceptability, and Feasibility of the Proposed Areas Scored by the Experts

Item No.		Appropriateness Mean (SD)	Acceptability Mean (SD)	Feasibility Mean (SD)
	CBT based solutions			
01	Providing psychoeducation to teacher and training on CBT strategies for the teacher to "coach" children to develop confidence and manage anxiety symptoms	4.36 (0.38)	4.72 (0.26)	4.81(0.28)
02	**Provision of real-life opportunities** to build confidence and success with CBT skills and anxiety management	3.91(0.30)	3.54(0.29)	**2.45(0.38)**
03	Provision of awareness and opportunities to apply principles of realistic thinking and self-talk	4.73 (0.47)	4.55 (0.69)	4.09 (0.70)
04	Provision of awareness and opportunities to apply principles of graded exposure	4.45 (0.69)	4.73(0.47)	4.82 (0.40)
05	Provision of awareness and opportunities to apply principles of graded exposure	4.82(0.40)	4.55(0.52)	4.55(0.52)
06	Provision of training and opportunities to practice relaxation techniques at school and provision of guidance to practice relaxation technique at home	4.91(0.30)	4.91(0.30)	4.91(0.30)
07	Increase awareness of parents on anxiety, its implications and CBT based strategies to overcome anxiety among adolescents	4.91(0.30)	4.91(0.30)	4.91(0.30)
	CBT based sessions for Children			
08	Number of sessions-04	**2.27 (0.65)**	**2.55(0.69)**	4.09(0.30)
09	Number of sessions-08	4.91(0.30)	4.91(0.30)	4.91(0.30)
10	Number of sessions-12	4.82 (0.40)	4.64 (0.67)	**2.18 (0.98)**
11	Duration of each session-40 minutes	4.82 (0.40)	4.73 (0.65)	4.82 (0.40)
12	Duration of each session-80 minutes	4.64 (0.81)	4.64 (0.67)	**2.45 (0.93)**
	Awareness program for parents			
13	Number of sessions-One	3.91 (0.54)	3.73 (0.47)	4.27 (0.47)
14	Number of sessions-Two	4.82 (0.40)	4.36 (0.50)	**2.64(0.81)**

15	Duration of each session-40 minutes	3.91(0.70)	3.91 (0.30)	3.55 (0.52)
16	Duration of each session-80 minutes	4.27 (0.47)	4.36 (0.67)	**2.55 (1.13)**
	Assessment of outcomes			
17	Level of anxiety with SCARED Child	4.18 (0.60)	4.27(0.47)	4.82(0.40)
18	Level of depression with DASS-21 Depression scale	3.82(0.40)	3.82(0.40)	4.91(0.30)
19	Level of self-esteem with Rosenberg Self-esteem Scale	4.27(0.47)	3.82(0.40)	3.91(0.54)

3.3. Modelling process and outcomes

On feasibility assessment, the main concern was the identification of a fixed period in the weekly timetable to deliver the intervention at regular intervals. This matter was discussed with the Director-Health and Nutrition of the Ministry of Education and was decided to utilize the weekly library period with the permission of the respective principals of the selected schools. Alternative arrangements were put forward to have access to the library for those who are participating in the intervention.

An intervention package which will be conducted in two stages was finalized with a process evaluation framework. Initially one day training of trainer's program was planned to be conducted for teachers fulfilling eligible criteria i.e., either being a science or health science teacher with minimum experience of 3 years with a field training by PI and AC. At the second stage eight 40 minutes sessions over eight consecutive weeks were planned to be conducted to selected grade 9 whole class by trained teacher while having teacher's handbook as a guide. Students will be provided with class work as well as home-based activities and student workbook will be used as a guide. One 40-minute session will be conducted for the parents of the students of the selected class by the trained teacher and a leaflet will be provided to parents to increase their awareness. The whole process will be monitored by using a process evaluation framework (Table 3).

Table 3: The Illustration of the Finalized Intervention Package Titled "Let's Beat Anxiety-for a Future Generation with Mental Wellbeing"

Resource persons	Mode	Description	Timeframe
COMPONENT 1 FOR TEACHERS [a]			
-PI -Consultant Community Physician -Consultant Child psychiatry -Director-Ministry of Education	One day Training of trainers' workshop	Lecture discussions on 1. Prevalence of AD 2.Signs and Symptoms and complications of AD 3.Prevention of AD 3.How to implement the package to children and parents 4. Introduction of handbook for teachers 5.Q and A session	One-day
Pre and post-test assessment and program evaluation			
	Field training	1.by observing and guiding 2.Feedbacks to the teachers	2-4-weeks

Feedback evaluation			
COMPONENT 2 FOR STUDENTS [b]			
Pre-intervention assessment on anxiety, depression and self-esteem levels by using validated self administered questionnaires by trained data collectors (Within a week)			
Teacher	-8 weeks-one session per week -One additional session in between two weeks for those who missed the original session -40 minutes per sessions	Content- -Psychoeducation - Realistic thinking and self talk - Problem-solving skills -Graded exposure -Relaxation by breathing techniques -Home work	Eight weeks
post-intervention assessment on anxiety, depression and self-esteem levels by using validated self -administered questionnaires by trained data collectors (within a week) After completion of 3 months following the completion of the intervention -assessment on anxiety, depression and self-esteem levels by using validated self-administered questionnaires by trained data collectors (within a week)			
COMPONENT 2 FOR PARENTS			
By teacher	During the 8 sessions for children One session- 40 minutes	Content -Awareness of Anxiety Disorders -Preventive methods -Importance of practicing CBT based methods	One day
Feedback evaluation			

a- *One teachers (either Science or health science) who teach for grade 9 was trained from the selected schools from the intervention arm.*

b-*One class of students from each selected school of the intervention arm received the intervention.*

IV. DISCUSSION

Anxiety and anxiety disorders are caused by multiple modifiable as well as unmodifiable factors (1). When prevention of such issues is being considered at community level, intervention should be built up of multiple components, which may act independently or interdependently. Therefore, it is necessary to develop a complex public health intervention to suit the problem and the context. Following rigorous scientific methodology to develop such interventions is mandatory with identification of the evidence base, identification of the theory and modelling process. Current study followed the MRC guidelines on developing and evaluating complex public health interventions (5).

The evidence bases at the highest level of evidence hierarchy were identified which includes systematic reviews and randomized control trials (10). Evidence was synthesized systematically, and most suitable solutions were identified reaching consensus among panel of experts. The interventions that could be used in anxiety reduction were identified and out of them, CBT based

intervention was shortlisted. CBT aims to stop negative cycles, break down things that make the person feel bad, anxious, or scared by making his/her problems more manageable and change his/her negative thought patterns & improve the way of feeling. Also, its appropriateness, acceptability and feasibility were considered compared to other modalities of intervention. Many successful CBT based interventions in different parts of the world have been identified. Adaption of such intervention to the local setting was not considered as these interventions are not available in the public domain and are not free to use.

Identification of risk factors for anxiety disorders by preparing a conceptual frame following thorough review of literature and opinion of experts, shortlisting of the modifiable factors and mapping of the different solutions under CBT against them with the consensus of panel of experts were helpful in developing an intervention which addresses the majority of the root causes of the problem. By obtaining inputs from the spectrum of people from school principals, teachers, parents and students were helpful in inclusion of their values in the proposed package that includes aligning it to match their expectations. All the deliverables were produced with the consensus of experts and whole package underwent a feasibility assessment.

Since this package was developed to implement in two stages i.e., training of teachers and teachers delivering it to the children, it was found be feasible to replicate this model in schools in Sri Lanka. In addition, this could be easily incorporated into the existing education system in the country. As a rigorous methodology was followed, the package itself contains strong leadership and governance mechanisms, opportunity for active engagement of a range of implementers and of target community and ability to tailor the scale up approach to the local context. This will be instrumental in the success of the developed intervention package.

V. CONCLUSIONS AND RECOMMENDATIONS

An evidence-based intervention package was developed to reduce anxiety among children aged 13-15 years among children aged 13-15 years attending government Sinhala medium schools. Effectiveness of the newly developed intervention should be assessed in the Sri Lankan school setting. This complex public health intervention could be used to reduce anxiety among children, and it has been developed in a manner that could be easily incorporated into the existing education system of the country with existing resources.

VI. AKOWLWDGEMENT

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