



Clinical Trial Details (PDF Generation Date :- Fri, 07 May 2021 05:57:39 GMT)

CTRI Number	CTRI/2018/01/011471 [Registered on: 22/01/2018] - Trial Registered Prospectively	
Last Modified On	02/03/2021	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Behavioral	
Study Design	Single Arm Trial	
Public Title of Study	Feasibility study of teacher delivered behavioral health services in rural primary schools.	
Scientific Title of Study	Task-Shifting Childrens Mental Health Treatment to Classroom Teachers: A Feasibility Study	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Christina Cruz
	Designation	MD, MEd
	Affiliation	University of North Carolina - Chapel Hill
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	Phone	19849743237
	Fax	
	Email	Christina.Cruz@uncdhealth.unc.edu
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Priscilla Giri
	Designation	
	Affiliation	Darjeeling Ladenla Road Prerna
	Address	19 Cooch Behar Road Department of Child Health Division of School Health Room 2 Darjeeling Darjiling WEST BENGAL 734101 India
	Phone	919564339400
	Fax	
	Email	priscillagiri22@gmail.com
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	Phone	919564339400		
	Fax			
	Email	priscillagiri22@gmail.com		
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> American Academy of Child and Adolescent Psychiatry 3615 Wisconsin Avenue, N.W. Washington, D.C 20016 USA			
Primary Sponsor	Primary Sponsor Details			
	Name	Darjeeling Ladenla Road Prerna		
	Address	42 Ladenla Road Darjeeling West Bengal 734101		
	Type of Sponsor	Other [non-governemental development organisation]		
Details of Secondary Sponsor	Name	Address		
	Broadleaf Health and Education Alliance	919 Main Street Stroudsburg, PA 18360 USA		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Priscilla Giri	Rural Darjeeling Hills	19 Cooch Behar Road Darjiling WEST BENGAL	91-9564336400 priscillagiri22@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Ethics Committee AACAP	Approved	21/01/2019	Yes
	University of North Carolina	Approved	11/02/2019	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Students will be enrolled for targeted intervention based on the observation of atypical behaviors that are suggestive of a behavioral and/or mental health challenge.	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Broadleaf Behavioral Health	A child mental health intervention that leverages classroom teachers to deliver evidence-based psychological treatment to selected children exhibiting atypical behaviors.	
	Comparator Agent	Not Applicable	Not Applicable	
Inclusion Criteria	Inclusion Criteria			
	Age From	6.00 Year(s)		
	Age To	89.00 Year(s)		
	Gender	Both		
	Details	Inclusion criteria for school eligibility: 1. Does not receive government aid 2. At least 4 full-time classroom teachers on staff 3. Annual Fees (inclusive of monthly tuition, yearly enrollment fees, and other compulsory payments of 11,500 INR or less. 4. Located within the Mirik, Kurseong, or Darjeeling Sadar		



	<p>sub-divisions of the Darjeeling District and outside the major (statutory) towns of Darjeeling, Kurseong, and Mirik.
 5. At least 50 children enrolled in the primary grade levels (class I-IV).

 Inclusion criteria for classroom teachers eligibility:
 1. 1 or more years of experience in the enrolled school
 2. Primary teaching responsibility for a single academic class (for a minimum of 2 hours per day and minimum of 4 days per week)
 3. Be 18 years or older
 4. Has not been convicted and is not under investigation for any child-related misconduct or maltreatment.

 Inclusion criteria for student eligibility:
 1. Placement in the primary classroom of a teacher that is enrolled in the study.</p>					
Exclusion Criteria	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="395 539 1458 584">Exclusion Criteria</th> </tr> </thead> <tbody> <tr> <td data-bbox="395 584 715 1189">Details</td> <td data-bbox="715 584 1458 1189"> <p>Exclusion criteria for schools:</p> <ol style="list-style-type: none"> 1. Government aided 2. Less than 4 full-time classroom teachers on staff 3. Annual fees more than 11,500 INR 4. Located within the major (statutory) towns of Darjeeling, Kurseong, and Mirik. 5. Less than 50 children enrolled in the primary grade levels. <p>Exclusion criteria for classroom teachers:</p> <ol style="list-style-type: none"> 1. Less than one full year of experience in the enrolled school. 2. Does not have primary teaching responsibility for a single academic class or spends less than 2 hours per day and less than 4 days per week with a single academic class. 3. Younger than 18 years old 4. Has been convicted or is under investigation for any child-related misconduct or maltreatment. <p>Exclusion criteria for student eligibility:</p> <ol style="list-style-type: none"> 1. Placement in the primary classroom of a teacher that is not enrolled in the study. </td> </tr> </tbody> </table>		Exclusion Criteria		Details	<p>Exclusion criteria for schools:</p> <ol style="list-style-type: none"> 1. Government aided 2. Less than 4 full-time classroom teachers on staff 3. Annual fees more than 11,500 INR 4. Located within the major (statutory) towns of Darjeeling, Kurseong, and Mirik. 5. Less than 50 children enrolled in the primary grade levels. <p>Exclusion criteria for classroom teachers:</p> <ol style="list-style-type: none"> 1. Less than one full year of experience in the enrolled school. 2. Does not have primary teaching responsibility for a single academic class or spends less than 2 hours per day and less than 4 days per week with a single academic class. 3. Younger than 18 years old 4. Has been convicted or is under investigation for any child-related misconduct or maltreatment. <p>Exclusion criteria for student eligibility:</p> <ol style="list-style-type: none"> 1. Placement in the primary classroom of a teacher that is not enrolled in the study.
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Method of Generating Random Sequence	Not Applicable					
Method of Concealment	Not Applicable					
Blinding/Masking	Not Applicable					
Primary Outcome	<table border="1"> <thead> <tr> <th data-bbox="395 1368 927 1413">Outcome</th> <th data-bbox="927 1368 1458 1413">Timepoints</th> </tr> </thead> <tbody> <tr> <td data-bbox="395 1413 927 1547">The aim of this study is to evaluate the feasibility of a school-based, teacher-led program to selectively provide mental health care to individual children in need.</td> <td data-bbox="927 1413 1458 1547"> Baseline assessment: March 1, 2018 Mid-point assessment: August 1, 2018 End-point assessment: Dec 1, 2018 </td> </tr> </tbody> </table>	Outcome	Timepoints	The aim of this study is to evaluate the feasibility of a school-based, teacher-led program to selectively provide mental health care to individual children in need.	Baseline assessment: March 1, 2018 Mid-point assessment: August 1, 2018 End-point assessment: Dec 1, 2018	
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Secondary Outcome	<table border="1"> <thead> <tr> <th data-bbox="395 1547 927 1592">Outcome</th> <th data-bbox="927 1547 1458 1592">Timepoints</th> </tr> </thead> <tbody> <tr> <td data-bbox="395 1592 927 1626">Teachers ability to identify students in need</td> <td data-bbox="927 1592 1458 1626">At 3 months</td> </tr> </tbody> </table>	Outcome	Timepoints	Teachers ability to identify students in need	At 3 months	
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Teachers ability to identify students in need	At 3 months					
Target Sample Size	<p>Total Sample Size=500 Sample Size from India=500 Final Enrollment numbers achieved (Total)=400 Final Enrollment numbers achieved (India)=400</p>					
Phase of Trial	N/A					
Date of First Enrollment (India)	31/01/2018					
Date of First Enrollment (Global)	No Date Specified					
Estimated Duration of Trial	<p>Years=1 Months=1 Days=0</p>					



Recruitment Status of Trial (Global)	Completed
Recruitment Status of Trial (India)	Completed
Publication Details	1. Cruz, C.M. et al., 2021. Teacher Nomination of School-aged Children for Mental Health Services in a Low and Middle Income Country. <i>Global health action</i> , 14(1), p.1861921.
Brief Summary	<p>Expanding access to mental health care is a crucial global health challenge, especially true for children. Ten to twenty percent of all children suffer from a diagnosable mental health condition, the majority of which will remain undiagnosed and untreated. These conditions adversely impact children's emotional wellbeing through life. The fundamental underlying cause of this treatment gap is insufficient professional human resources. Innovative care models are urgently needed to address this challenge.</p> <p>In this study, we aim to evaluate the feasibility of training classroom teachers to deliver evidence-based mental health care as a first step in overcoming the treatment gap and increasing access to care for children in resource-limited settings. Within five rural, low-cost private primary schools of the Darjeeling Himalayas, we will enroll 20 students (4 per school) to receive training and support in delivering the intervention and 40 students (2 per teacher) as targets of the intervention. A parent-guardian for each student will also be enrolled. The study was extended into a second academic year (2019) with the aim of evaluating acceptability as a component of feasibility.</p> <p>A mixed methods approach will be utilized to assess the feasibility of utilizing classroom teachers to deliver evidence-based psychological treatment. Quantitative process indicators are mapped to the core components of the intervention; qualitative data will be integrated with quantitative data to validate/refute and provide a richer understanding of the primary outcome.</p>