## Clinical Trial Details (PDF Generation Date: Tue, 26 Apr 2022 13:08:43 GMT)

<table>
<thead>
<tr>
<th>CTRI Number</th>
<th>CTRI/2018/01/011471 [Registered on: 22/01/2018] - Trial Registered Prospectively</th>
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<tbody>
<tr>
<td>Last Modified On</td>
<td>02/03/2021</td>
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<tr>
<td>Post Graduate Thesis</td>
<td>No</td>
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<tr>
<td>Type of Trial</td>
<td>Interventional</td>
</tr>
<tr>
<td>Type of Study</td>
<td>Behavioral</td>
</tr>
<tr>
<td>Study Design</td>
<td>Single Arm Study</td>
</tr>
<tr>
<td>Public Title of Study</td>
<td>Feasibility study of teacher delivered behavioral health services in rural primary schools.</td>
</tr>
<tr>
<td>Scientific Title of Study</td>
<td>Task-Shifting Childrens Mental Health Treatment to Classroom Teachers: A Feasibility Study</td>
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<tr>
<td>Secondary IDs if Any</td>
<td>NIL</td>
</tr>
</tbody>
</table>
| 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  
Address: Fellow Department of Psychiatry Division of Child and Adolescent Psychiatry 101 Manning Drive, CB 7160 Chapel Hill, NC 27514 United States of America  
Phone: 19849743237  
Fax:  
Email: Christina.Cruz@uncedhealth.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 |
| Details Contact Person (Public Query) | Details Contact Person (Public 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:  
Fax:  
Email:  
Details Contact Person (Public Query) |
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

- 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: Broadleaf Health and Education Alliance
- Address: 919 Main Street Stroudsburg, PA 18360 USA

Countries of Recruitment

- India

Sites of Study

- Name of Principal Investigator: Priscilla Giri
- Name of Site: Rural Darjeeling Hills
- Site Address: 19 Cooch Behar Road Darjiling WEST BENGAL
- Phone/Fax/Email: 91-9564336400 priscillagiri22@gmail.com

Details of Ethics Committee

- Name of Committee: Ethics Committee AACAP
- Approval Status: Approved
- Date of Approval: 21/01/2019
- Is Independent Ethics Committee?: Yes

- Name of Committee: University of North Carolina
- Approval Status: Approved
- Date of Approval: 11/02/2019
- Is Independent Ethics Committee?: Yes

Regulatory Clearance Status from DCGI

- Status: Not Applicable
- Date: No Date Specified

Health Condition / Problems Studied

- Health Type: Healthy Human Volunteers
- Condition: 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: Intervention
- Name: Broadleaf Behavioral Health
- Details: A child mental health intervention that leverages classroom teachers to deliver evidence-based psychological treatment to selected children exhibiting atypical behaviors.

- Type: Comparator Agent
- Name: Not Applicable
- Details: Not Applicable

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
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.

Exclusion Criteria

<table>
<thead>
<tr>
<th>Details</th>
<th>Exclusion criteria for schools:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Government aided</td>
</tr>
<tr>
<td></td>
<td>2. Less than 4 full-time classroom teachers on staff</td>
</tr>
<tr>
<td></td>
<td>3. Annual fees more than 11,500 INR</td>
</tr>
<tr>
<td></td>
<td>4. Located within the major (statutory) towns of Darjeeling, Kurseong, and Mirik.</td>
</tr>
<tr>
<td></td>
<td>5. Less than 50 children enrolled in the primary grade levels.</td>
</tr>
</tbody>
</table>

Exclusion criteria for classroom teachers:
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.

Exclusion criteria for student eligibility:
1. Placement in the primary classroom of a teacher that is not enrolled in the study.

Method of Generating Random Sequence
Not Applicable

Method of Concealment
Not Applicable

Blinding/Masking
Not Applicable

Primary Outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>Baseline assessment: March 1, 2018</td>
</tr>
<tr>
<td>Mid-point assessment: August 1, 2018</td>
<td></td>
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<tr>
<td>End-point assessment: Dec 1, 2018</td>
<td></td>
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</tbody>
</table>

Secondary Outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teachers ability to identify students in need</td>
<td>At 3 months</td>
</tr>
</tbody>
</table>

Target Sample Size

| Total Sample Size=500 |
| Sample Size from India=500 |
| Final Enrollment numbers achieved (Total)=400 |
| Final Enrollment numbers achieved (India)=400 |

Phase of Trial

| 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>
<table>
<thead>
<tr>
<th>Recruitment Status of Trial (Global)</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment Status of Trial (India)</td>
<td>Completed</td>
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</tbody>
</table>

**Publication Details**


**Brief Summary**

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.

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.

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.