



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 09:46:23 GMT)

<b>CTRI Number</b>	CTRI/2019/05/019296 [Registered on: 23/05/2019] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	30/05/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Other (Specify) [health and education interventions]	
<b>Study Design</b>	Cluster Randomized Trial	
<b>Public Title of Study</b>	A community-based intervention study to improve newborn survival and children's learning in rural areas of Satna District, Madhya Pradesh, India	
<b>Scientific Title of Study</b>	Cluster randomized trial in Madhya Pradesh, India: Community health promotion and medical provision and impact on neonates (CHAMPION 2); and support to rural India's public education system and impact on numeracy and literacy (STRIPES 2)	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	
	<b>Designation</b>	
	<b>Affiliation</b>	
	<b>Address</b>	
	<b>Phone</b>	
	<b>Fax</b>	
	<b>Email</b>	
<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
	<b>Name</b>	R Harshavardhan Reddy
	<b>Designation</b>	Project coordinator
	<b>Affiliation</b>	GH Training and Consulting
	<b>Address</b>	GH Training and Consulting Street No 4 Basantvihar Colony Rajendra nagar GH Training and Consulting Kakateeya Nagar, Habsiguda Hyderabad 500007 Tenengana Satna MADHYA PRADESH 485001 India
	<b>Phone</b>	
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	<b>Email</b>	r.harsha.reddy@gmail.com
<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	R Harshavardhan Reddy
	<b>Designation</b>	Project coordinator
	<b>Affiliation</b>	GH Training and Consulting
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	<b>Fax</b>			
	<b>Email</b>	r.harsha.reddy@gmail.com		
<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Effective Intervention UK registered charity no 1111709			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Effective Intervention		
	<b>Address</b>	Centre for Economic Performance London School of Economics Houghton Street London WC2A2AE		
	<b>Type of Sponsor</b>	Other [UK registered charity no 1111709]		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	R Harshavardhan Reddy	Satna District	Satna district Madhya Pradesh India Satna MADHYA PRADESH	9644003811  r.harsha.reddy@gmail.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	LV Prasad Eye Institute Ethics Committee	Approved	15/11/2018	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Healthy Human Volunteers		Pregnancy and children aged under 6 years	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Health intervention for CHAMPION2	1.Health promotion and community mobilization by ASHAs (Accredited Social Health Activist) 2.Fixed day health services by Nurse Midwife and ASHAs 3.Effective coordination of referrals 4.Strengthening of Healthcare services at Community Health Centres according to National Health Mission standards	
	Intervention	Education intervention for STRIPES2	1. Warm up phase: Trained instructor interacts with eligible children through playing, singing, colouring, and drawing 2.After school teaching lessons for eligible children for two hours, six days a week by a trained instructor 3. Orientation to engagement activities (door-to-door meetings, community events and creation of mothers' groups)for mothers of children	



		to promote their attendance and learning.
Comparator Agent	Control for CHAMPION2	STRIPES 2 intervention as well as the usual health services provided by the government and other Non-Governmental Organisations (NGOs).
Comparator Agent	Control for STRIPES2	CHAMPION 2 intervention as well as the usual education services provided by the government and other NGOs

**Inclusion Criteria**

Inclusion Criteria	
<b>Age From</b>	0.00 Year(s)
<b>Age To</b>	50.00 Year(s)
<b>Gender</b>	Both
<b>Details</b>	<p>Selection of villages in seven sub-districts (Tehsils) of Satna:</p> <ol style="list-style-type: none"> <li>1.Rural village with less than 2500 population and with more than 120 children under the age of 6</li> <li>2.accessible by road;</li> <li>3.not within a 5 kilometres radius of the Community Health Centres</li> <li>4.has a minimum of 3 kilometres between them to avoid contamination</li> </ol> <p>For CHAMPION 2, a woman is eligible if</p> <ol style="list-style-type: none"> <li>1.She is married;</li> <li>2.Neither she nor her husband have had a family planning operation i.e. male or female sterilisation tubectomy or vasectomy, respectively</li> <li>3.She is less than 50 years old</li> <li>4.She is resident in one of the trial villages at the time of the baseline survey</li> <li>5.She gives her consent after getting a complete explanation of the study</li> <li>6. she marries a man who was enumerated and unmarried at the time of enumeration, determined to be unmarried, resident in the village, and aged between 13 and 50 years</li> </ol> <p>For STRIPES 2, a child is eligible to participate if:</p> <ol style="list-style-type: none"> <li>1.S/he was born between 10th 16th June 2010 and 15th 1st July 2013</li> <li>2.S/he is not yet enrolled in primary school</li> <li>3.S/he is expected to be resident in the village and be enrolled in school for the first time, in the first grade in the academic year of 2018-2019</li> <li>4.Her/his parents agree that s/he participates after hearing the explanation about the programme and its evaluation tests</li> </ol>

**Exclusion Criteria**

Exclusion Criteria	
<b>Details</b>	<ol style="list-style-type: none"> <li>1. Village with less than 15 eligible children for STRIPES 2</li> <li>2. For CHAMPION2, woman who is not enumerated or get married to a man who is not enumerated or whose marriage date precedes the date of their village enumeration</li> <li>3.For CHAMPION2, woman (and their babies) who move to a trial village for other reasons (e.g. their mother's residence for delivery of their baby)</li> </ol>



	3.For STRIPES 2, children who move into the trial village after the enumeration																													
<b>Method of Generating Random Sequence</b>	Stratified randomization																													
<b>Method of Concealment</b>	Centralized																													
<b>Blinding/Masking</b>	Open Label																													
<b>Primary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>CHAMPION 2- neonatal mortality STRIPES 2- composite maths and reading literacy and numeracy test score</td> <td>CHAMPION 2-neonatal deaths between 12 months and 42 months after randomisation STRIPES 2- At the end of 2 academic years after randomisation</td> </tr> </tbody> </table>		Outcome	Timepoints	CHAMPION 2- neonatal mortality STRIPES 2- composite maths and reading literacy and numeracy test score	CHAMPION 2-neonatal deaths between 12 months and 42 months after randomisation STRIPES 2- At the end of 2 academic years after randomisation																								
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<b>Target Sample Size</b>	<p><b>Total Sample Size=20000</b>  <b>Sample Size from India=20000</b>  <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b>  <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b></p>
<b>Phase of Trial</b>	Phase 3
<b>Date of First Enrollment (India)</b>	15/06/2019
<b>Date of First Enrollment (Global)</b>	No Date Specified
<b>Estimated Duration of Trial</b>	<p><b>Years=3</b>  <b>Months=6</b>  <b>Days=0</b></p>
<b>Recruitment Status of Trial (Global)</b>	Not Applicable
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment
<b>Publication Details</b>	NIL
<b>Brief Summary</b>	<p>Background: Health care and primary education in India continues to have poor outcomes with large disparities between rural and urban regions as well as between the wealthiest and poorest populations. High neonatal mortality rates and low levels of literacy and numeracy are endemic in rural areas.</p> <p>This study aims to assess simultaneously the effect of a health intervention on neonatal survival as well as an education intervention on literacy and numeracy scores. Based on lessons learnt from original CHAMPION/STRIPES trial and relevant evidence generated since the conception of the original trial, CHAMPION 2/STRIPES 2 design will be further developed and contextualized to socio-cultural patterns in Madhya Pradesh, India.</p> <p>Methods/design: A cluster-randomised controlled trial where villages will be randomised to receive either a health (CHAMPION 2) or education (STRIPES 2) intervention. Villages randomised to receive the health intervention will serve as controls for the education intervention and conversely, villages randomised to receive the educational intervention will serve as controls for the health intervention.</p> <p>Clusters: 194 villages in Satna district, Madhya Pradesh India with less than 2,500 people, and not within a five kilometer radius of a Community Health Centre, and with 15 or more children eligible for the education intervention will be selected for the trial.</p> <p>Participants: In CHAMPION 2, women will be eligible if they meet the following criteria: resident in selected villages; married women enumerated at baseline (or newly married to a man who was enumerated at baseline); under 50 years of age; and who (and whose husband) has not had a family planning operation.</p> <p>In STRIPES 2, participants will be children resident in eligible villages, born between the 16th of June 2010 and 15th of June 2013, and (at baseline) intending to enrol in the first grade in the 2018 - 2019 school year.</p> <p>Interventions: The study design is adapted and further developed from the CHAMPION/STRIPES trial in Telangana. In CHAMPION 2 accredited Social Health Activists (ASHAs) or village health workers (VHWs) and midwives will promote health knowledge and provide healthcare through the following activities: antenatal, postnatal and neonatal care provided at a chosen community centre; community mobilisation; coordinating referrals to appropriate government health facilities; and a health education campaign through theatre, films and other media. The NICE Foundation will be strengthening selected Community Health Centres (CHC) to ensure they meet essential services criteria as is defined by the National Health Mission, Government of India. The CHAMPION 2 intervention is expected to run for three years.</p> <p>Adapted and further developed from the STRIPES trial in Telangana, the STRIPES 2 programme will offer eligible children village-based after-school support provided by a trained Pratham instructor</p>



focusing on literacy and numeracy skills, six days a week during two successive academic years.