



Clinical Trial Details (PDF Generation Date :- Wed, 16 Oct 2019 14:21:51 GMT)

CTRI Number	CTRI/2018/07/014998 [Registered on: 23/07/2018] - Trial Registered Prospectively	
Last Modified On	19/07/2018	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Preventive Screening Behavioral	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	Effectiveness of psycho-social intervention for anxiety, depression and self-esteem among children of alcoholic parent's	
Scientific Title of Study	A study to assess the effectiveness of psycho-social intervention for selected internalizing behaviour problems among children of alcoholic parents.	
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	Dayananda B O
	Designation	Associate Professor
	Affiliation	kempegowda College of Nursing
	Address	Associate professor, Kempegowda college of Nursing, K R Road, V V puram, Bangalore Bangalore KARNATAKA 560004 India
	Phone	9535332183
	Fax	
	Email	bodayananda@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dayananda B O
	Designation	Associate Professor
	Affiliation	kempegowda College of Nursing
	Address	Associate professor, Kempegowda college of Nursing, K R Road, V V puram, Bangalore Bangalore KARNATAKA 560004 India
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	India									
Phone	9535332183									
Fax										
Email	bodayananda@gmail.com									
Source of Monetary or Material Support	Source of Monetary or Material Support > Government High school Bangalore south-II > Kempegowda college of Nursing Bangalore									
Primary Sponsor	Primary Sponsor Details <table border="1"> <tr> <td>Name</td><td>nil</td></tr> <tr> <td>Address</td><td>nil</td></tr> <tr> <td>Type of Sponsor</td><td>Other []</td></tr> </table>	Name	nil	Address	nil	Type of Sponsor	Other []			
Name	nil									
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Details of Secondary Sponsor	<table border="1"> <tr> <th>Name</th><th>Address</th></tr> <tr> <td>NIL</td><td>NIL</td></tr> </table>	Name	Address	NIL	NIL					
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Countries of Recruitment	List of Countries India									
Sites of Study	<table border="1"> <tr> <th>Name of Principal Investigator</th><th>Name of Site</th><th>Site Address</th><th>Phone/Fax/Email</th></tr> <tr> <td>Dayananda B O</td><td>Selected Govt High school</td><td>Bangalore South Bangalore KARNATAKA</td><td>9535332183 bodayananda@gmail.com</td></tr> </table>	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email	Dayananda B O	Selected Govt High school	Bangalore South Bangalore KARNATAKA	9535332183 bodayananda@gmail.com	
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Details of Ethics Committee	<table border="1"> <tr> <th>Name of Committee</th><th>Approval Status</th><th>Date of Approval</th><th>Is Independent Ethics Committee?</th></tr> <tr> <td>Kempegowda College of Nursing</td><td>Approved</td><td>22/02/2017</td><td>Yes</td></tr> </table>	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?	Kempegowda College of Nursing	Approved	22/02/2017	Yes	
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Regulatory Clearance Status from DCGI	<table border="1"> <tr> <th>Status</th><th>Date</th></tr> <tr> <td>Not Applicable</td><td>No Date Specified</td></tr> </table>	Status	Date	Not Applicable	No Date Specified					
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Health Condition / Problems Studied	<table border="1"> <tr> <th>Health Type</th><th>Condition</th></tr> <tr> <td>Healthy Human Volunteers</td><td>School children</td></tr> </table>	Health Type	Condition	Healthy Human Volunteers	School children					
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Intervention / Comparator Agent	<table border="1"> <tr> <th>Type</th><th>Name</th><th>Details</th></tr> <tr> <td>Intervention</td><td>Psycho-social intervention</td><td>Psycho-social intervention consists of eight sessions of cognitive-behavioural therapy with group approach.</td></tr> <tr> <td>Comparator Agent</td><td>nil</td><td>nil</td></tr> </table>	Type	Name	Details	Intervention	Psycho-social intervention	Psycho-social intervention consists of eight sessions of cognitive-behavioural therapy with group approach.	Comparator Agent	nil	nil
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Inclusion Criteria	Inclusion Criteria <table border="1"> <tr> <td>Age From</td><td>12.00 Year(s)</td></tr> <tr> <td>Age To</td><td>16.00 Year(s)</td></tr> <tr> <td>Gender</td><td>Both</td></tr> <tr> <td>Details</td><td>12 years to 16 years Male & Female</td></tr> </table>	Age From	12.00 Year(s)	Age To	16.00 Year(s)	Gender	Both	Details	12 years to 16 years Male & Female	
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Method of Generating Random Sequence	Computer generated randomization									
Method of Concealment	Other									
Blinding/Masking	Not Applicable									



Primary Outcome	Outcome	Timepoints
	Anxiety, Depression and Self-esteem	6 months
Secondary Outcome	Outcome	Timepoints
	Class attendance, well-being, quality of life	6 months
Target Sample Size	Total Sample Size=240 Sample Size from India=240 Final Enrollment numbers achieved (Total)= Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)= Applicable only for Completed/Terminated trials	
Phase of Trial	N/A	
Date of First Enrollment (India)	01/08/2018	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=8 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Not Yet Recruiting	
Publication Details	none yet	
Brief Summary	<p>The burden of internalizing behavioral problems among children of alcoholic parents, in India, calls for immediate attention of political leaders, policymakers, health professionals, opinion-makers and society at large. Since not much has been done with children of alcoholic parents in India, The present study focused on reducing internalizing behavioral problems of children from alcoholic families by using psycho-social intervention.</p> <p>STATEMENT OF PROBLEM: Effectiveness of Psycho-social intervention for selected internalizing behavior problems among children of alcoholic parent's at selected school Bangalore</p> <p>HYPOTHESIS</p> <p>Ø H₁. There will be a statistically significant decrease in depression scores among children who will undergone psychosocial intervention compared to</p>	



children who will not undergone psychosocial intervention at 6 months follow-up.

Ø H₂. There will be a statistically significant decrease in anxiety scores among children who will undergone psychosocial intervention compared to children who will not undergone psychosocial intervention at 6 months follow-up.

Ø H₃. There will be a statistically significant improvement in self-esteem scores among children who will undergone psychosocial intervention compared to children who will not undergone psychosocial intervention at 6 months follow-up.

H₄. There will be a statistically significant association between anxiety, depression and self-esteem scores with selected socio-demographic variables

Conclusion:

There are no policies or national strategies which address the problems of children of alcoholics directly in India. There is an urgent need by the health care members to focus on the problems of Children of alcoholics.