



Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 15:46:14 GMT)

<b>CTRI Number</b>	CTRI/2017/06/008908 [Registered on: 23/06/2017] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	26/02/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Behavioral Nutraceutical	
<b>Study Design</b>	Randomized Factorial Trial	
<b>Public Title of Study</b>	A study on effect of Integrated Nutrition, Health, WASH, Care and Support Interventions during the Pre-pregnancy, Pregnancy and Early Childhood on linear growth of children	
<b>Scientific Title of Study</b>	Improving Linear Growth of Children in Low Resource Settings through Integrated Nutrition, Health, WASH, Care and Support Interventions during the Pre- and Peri-conceptional Period, Pregnancy and Early Childhood - A Randomized Controlled Trial	
<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>	Nita Bhandari
	<b>Designation</b>	Senior Scientist
	<b>Affiliation</b>	Centre for Health Research and Development, Society for Applied Studies
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<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
	<b>Name</b>	Nita Bhandari
	<b>Designation</b>	Senior Scientist
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Bill & Melinda Gates Foundation, Seattle, USA (supplementary funds approved in September 2018) > Biotechnology Industry Research Assistance Council (BIRAC) of the Department of Biotechnology, Government of India, 1st Floor ,MTNL Building ,9 , CGO Complex, Lodhi Road, New Delhi-110003 (Next to Scope Complex, Infront of Gate no. 13, JLN Stadium)			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Nita Bhandari		
	<b>Address</b>	Centre for Health Research and Development, Society for Applied Studies, 45, Kalu Sarai, New Delhi-110016, India		
	<b>Type of Sponsor</b>	Other [Not for profit research organization]		
<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>
	Nita Bhandari	Centre for Health Research and Development, Society for Applied Studies	680, Nai Basti, Devli Gaon, Khanpur, 110062 New Delhi DELHI	01146043751 01146043756 chrd@sas.org.in
<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>
	Society for Applied Studies Ethics Review Committee	Approved	03/06/2017	No
	Society for Applied Studies Ethics Review Committee	Approved	10/01/2019	No
	Society for Applied Studies Ethics Review Committee	Approved	22/07/2019	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		Screening of medical conditions that affect growth	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	PRE AND PERICONCEPTION - Health: Detect and facilitate treatment of medical conditions known to affect growth of the fetus and young children	As per hospital policy Screen and treat medical conditions known to affect fetal and infant growth, bi-annual deworming	
	Intervention	PRE AND PERICONCEPTION - Health: Birth spacing	Family planning counselling and provision of contraceptives	
	Intervention	PRE AND PERICONCEPTION - Nutrition: Adequate	Iron folic acid and, multiple micronutrients supplementation	



	micronutrient intake (provide and counsel)	
Intervention	PRE AND PERICONCEPTION - Nutrition: Detect and manage under nutrition	High quality protein and energy dense snacks Screen and manage malnutrition and anemia, egg or milk to women with BMI 21 kg/m <sup>2</sup>
Intervention	PRE AND PERICONCEPTION - WASH: Promotion of personal and menstrual hygiene	Counselling
Intervention	PRE AND PERICONCEPTION - Psychosocial support: Promotion of positive thinking and problem-solving skills	Counselling Promote positive thinking and problem-solving skills, screen and manage depressive symptoms, substance abuse and exposure to second hand smoke
Comparator Agent	PRE AND PERICONCEPTION: Standard Care	As per National Programs
Intervention	PREGNANCY - Health: Antenatal care	As per WHO recommendations Minimum 8 antenatal contacts, Screen and treat medical conditions, Tetanus Toxoid immunization, deworming
Intervention	PREGNANCY - Nutrition: Provision of a protein energy supplement	Provision of High quality protein and energy dense snacks, Iron folic acid and multiple micronutrients supplementation (Calcium and vitamin D), Weight monitoring and management for low weight gain
Intervention	PREGNANCY - WASH: Improvement of drinking water quality. Reduce fecal transmission via hand and reduce fecal load in living environment	Provision of water filters and bottles for drinking water, hand washing station and soap/sanitizer, latrine disinfectant
Intervention	PREGNANCY - Psychosocial support : Promotion of positive thinking and problem-solving skills	Counseling Promote positive thinking and problem-solving skills, screen and manage depressive symptoms, substance abuse and exposure to second hand smoke
Comparator Agent	PREGNANCY: Standard Care	As per National Programs
Intervention	EARLY CHILDHOOD - Health: Essential Newborn Care	As per WHO recommendations Educate families to identify danger signs and early care seeking for illness, Counsel on timely immunisation
Intervention	EARLY CHILDHOOD - Nutrition: Breastfeeding counselling; Micronutrient supplementation for low birth weight babies; Nutrition interventions as per WHO recommendations. Growth monitoring and management of moderate and severe malnutrition; Initiation of	As per WHO recommendations 0-6 mo: Counselling on initiation of breastfeeding within first hour of birth and exclusive breast feeding till 6 mo, lactation support, growth monitoring and management of inadequate weight gain, vitamin D supplementation, Iron supplementation for very low



	complementary feeding at 6 months; Balanced protein energy supplementation to augment complementary feeding from 6 to 24 months	birth weight infants 6-24m: Counsel on timely initiation of complementary feeding, continuing breastfeeding till 24 mo, Daily provision of locally-prepared food packets with 125 kcal/2.5 g protein and 1 RDA micronutrients, Counselling on preparing home based foods and responsive feeding, iron folic acid supplementation
Intervention	EARLY CHILDHOOD - Psychosocial: Early child play and stimulation. Strengthening mother-child bonding	Counselling demonstration and practice sessions on early child play and responsive care
Comparator Agent	EARLY CHILDHOOD: Standard Care	As per National Programs
Intervention	POSTNATAL - Mothers (Nutrition): Postnatal care	Postnatal care as per WHO recommendations Iron folic acid, Calcium, Vitamin-D and multiple micronutrients supplementation, Daily provision of locally-prepared snacks and milk supplement for 6 mo
Intervention	POSTNATAL - Mothers (WASH): Continuation of Pregnancy WASH intervention	Provision of water filters and bottles for drinking water, hand washing station and soap/sanitizer, latrine disinfectant.
Intervention	POSTNATAL - Mothers (Psychosocial support): Promotion of positive thinking and problem-solving skills	Counselling Promote positive thinking and problem-solving skills, screen and manage depressive symptoms, substance abuse and exposure to second hand smoke
Comparator Agent	POSTNATAL: Standard Care	As per National Programs
Intervention	EARLY CHILDHOOD - WASH	Provision of play mat and potty
Intervention	POSTNATAL- Mothers (Health)	Facilitate postnatal hospital visit at 6 weeks

**Inclusion Criteria**

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	30.00 Year(s)
Gender	Female
Details	Married and living with their husband with no child or 1 child and wish to have more children Consent to participate

**Exclusion Criteria**

Exclusion Criteria	
Details	Moving away Population likely to relocate

**Method of Generating Random Sequence**

Stratified block randomization
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**Method of Concealment**

Centralized
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<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>Linear growth by 24 months of age - length for age Z-score, proportion stunted</td> <td>Linear growth by 24 months of age - length for age Z-score, proportion stunted</td> </tr> <tr> <td>Birth weight, length</td> <td>Birth (within 1 week)</td> </tr> <tr> <td>Proportion low birth weight</td> <td>Birth (within 1 week)</td> </tr> <tr> <td>Proportion preterm birth</td> <td>Birth (within 1 week)</td> </tr> <tr> <td>Proportion small-for gestation age</td> <td>Birth (within 1 week)</td> </tr> </tbody> </table>	Outcome	Timepoints	Linear growth by 24 months of age - length for age Z-score, proportion stunted	Linear growth by 24 months of age - length for age Z-score, proportion stunted	Birth weight, length	Birth (within 1 week)	Proportion low birth weight	Birth (within 1 week)	Proportion preterm birth	Birth (within 1 week)	Proportion small-for gestation age	Birth (within 1 week)																							
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micronutrient deficiency, malnutrition and infectious diseases	
BEHAVIOUR OUTCOMES(WOMEN AND CHILDREN): Family planning, substance abuse, WASH behaviours	Throughout the study period
CHILD GROWTH: Weight and length growth trajectories	Between birth and 24 mo
CHILDREN GROWTH: Body composition in a subgroup	At 1 month
WOMEN: Anaemia status; Micronutrient status; inflammatory markers; Reproductive tract infections	Third trimester
POSTPARTUM OUTCOMES - Micronutrient status	6 months
POSTPARTUM OUTCOMES - Anemia status	6 months
POSTPARTUM OUTCOMES - Inflammatory markers	6 months
POSTPARTUM OUTCOMES - Severe postpartum morbidity	Day 7 of birth
POSTPARTUM OUTCOMES - Postpartum depression	2 and 12 months

<b>Target Sample Size</b>	<p><b>Total Sample Size=13500</b>  <b>Sample Size from India=13500</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>	N/A
<b>Date of First Enrollment (India)</b>	01/07/2017
<b>Date of First Enrollment (Global)</b>	No Date Specified
<b>Estimated Duration of Trial</b>	<p><b>Years=6</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>	Closed to Recruitment of Participants
<b>Publication Details</b>	Taneja S, Chowdhury R, Dhabhai N, Mazumder S, Upadhyay RP, Sharma S, Dewan R, Mittal P, Chellani H, Bahl R, Bhan MK, Bhandari N; Women and Infants Integrated Growth Study (WINGS) Group. Impact of an integrated nutrition, health, water sanitation and hygiene, psychosocial care and support intervention package delivered during the pre- and peri-conception period and/or during pregnancy and early childhood on linear growth of infants in the first two years of life, birth outcomes and nutritional status of mothers: study protocol of a factorial, individually randomized controlled trial in India. <i>Trials</i> . 2020 Jan 31;21(1):127. doi: 10.1186/s13063-020-4059-z.
<b>Brief Summary</b>	<p>The study will be conducted in urban neighbourhoods in South Delhi. Prior to selection of the population, a survey was conducted to ascertain stunting and wasting rates in undertwos.</p> <p>In this study, married women aged 18 to 30 years, with no or one child, living with her husband, who consent for participation, will be enrolled and followed up till they become pregnant or have completed 18 months of follow up. Once a woman is confirmed to be pregnant, she will be consented again for her and her infant's participation in the trial.</p> <p>Once enrolled, the intervention group women will be visited by different teams. Women diagnosed with medical conditions that affect growth of the fetus and young children will</p>





be referred to Safdarjung Hospital for management. Women diagnosed with anemia or undernutrition will be treated according to the government guidelines. They will also be counselled on personal and menstrual hygiene and assisted to deal with stressful conditions through a positive frame of mind. The women in control group will continue to avail routine standard care as per National Programs.

Once women are pregnant, consent will be sought for their, and their infants participation in the trial.

During pregnancy, women in the intervention group will be encouraged for regular antenatal follow up in Safdarjung Hospital and counselled about benefits of diets consisting of adequate energy, protein, vitamins and minerals obtained from a variety of locally available foods. To account for the additional requirement of energy during pregnancy, food supplements would also be provided. In the postnatal period and early childhood, women will be encouraged to go for postnatal visits. Women will be counselled for exclusive breastfeeding, timely initiation of complementary feeding and for seeking prompt care for illness. The women in control group will continue to avail routine standard care as per National Programs.

An independent outcome ascertainment team will visit to document outcomes in the pre- and peri-conception period, pregnancy, postnatal and early childhood period

The Data Safety Monitoring Board (DSMB) will review all sample size assumptions when 50% of babies expected to be included in the study have been born and make recommendations on sample size.

The Data Safety Monitoring Board will do a second review when 50% of babies expected to be included in the study have reached 2 years of age.

We propose to disseminate and publish the outcomes on disease burden and prevalence of different behaviours prior to completion of the study as these will be of immense value to national program planners. These include:

- Prevalence of non-communicable diseases (diabetes, pre-diabetes, hypothyroidism, hypertension, depression)
- Prevalence of anemia, micronutrient deficiency, malnutrition
- Prevalence of reproductive tract infection, tuberculosis
- Family planning practices
- Practices pertaining to WASH (including menstrual hygiene, hand and personal hygiene)
- Prevalence of substance use (including use of tobacco and alcohol)

The factorial design allows us to assess the efficacy of pre pregnancy interventions independently. These findings will be reported when birth outcome data are available.