

# Experimenting innovative methods adapted from learning through play methodology to empower parents and care givers in rural communities, by providing information on holistic development of children in the first 1000 days of life that includes parenting, health and nutrition.

<b>Submission date</b> 23/04/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/06/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Research on brain development suggests that experiences during the first three years of life have a major impact on child's future. Play, touch, talk and respond in a loving manner will make a significant difference in the growth and development. Children learn while they play. Playing and learning are interconnected. This project proposes to empower parents and care givers in rural communities, by providing information on all aspects of child development such as physical including health and nutrition, mental (cognitive) development, language and communication, making friendly relationships with adults, other children and also the environment and nurturing children's sense of self. The intervention is based on Learning Through Play (LTP) adapted versions of LTP developed by Bala Mandir Research Foundation (BMRF) and the Network for Information on Parenting with support from UNICEF. LTP focuses on domains of development such as Sense of self, Physical growth, Relationships, Understanding and Communications.

Nearly all early childhood development programs follow traditional theoretical training methods. The project designs the animated videos on parenting in the first 9 months of the project period and will be field tested for its effectiveness in parents'/caregivers' knowledge, skills and behaviour in child rearing. It aims to demonstrate if the initiative has a positive & measureable influence on physical, cognitive, language and socio-emotional development of children through a specially designed tool.

### Who can participate?

Primary and secondary caregivers of children aged between 18 and 24 months

What does the study involve?

Primary and secondary caregivers are randomized by village to one of two groups. Those in group A receive the video childhood development program, which includes parenting, health and nutrition, through learning to play. Those in group B form the control group and receive non-video based parenting and early childhood development.

Participants receive a series of questionnaires and assessments at baseline (before the program) and at endline (after the program).

What are the possible benefits and risks of participating?

The participants in this study are exposed to the parenting techniques during early childhood development, which may potentially bring in change in knowledge, attitude and practice in age appropriate stimulations during pregnancy and early childhood (first thousand days). There are no incentives in kind or money. The risk of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in this study is minimal or close to nil.

Where is the study run from?

Society for People's Education and Economic Change (SPEECH) (India)

When is the study starting and how long is it expected to run for?

January 2018 to November 2019

Who is funding the study?

Grand Challenges (Canada)

Who is the main contact?

Mr Arunodhayam Erskine (Public)

## Contact information

### Type(s)

Public

### Contact name

Mr Newton Ponnammuthan

### Contact details

Society for People's Education and Economic Change (SPEECH)

2/1060, Manoranjitham Street

Ezhilnagar

Tirupalai

Madurai

India

625014

+91 9842144699

mduspeech@gmail.com

## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

R-SB-POC-1707-09378 (Grand Challenges Canada, Grant Number)

## **Study information**

**Scientific Title**

Animated videos on parenting for early brain development – A pilot project in India

**Study objectives**

Animated videos on early childhood development and parenting are more effective compared to the regular theory based intervention

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Sigma - IRB, Sigma Research and Consulting Private Limited, 06/12/2017, ref: 10039/IRB/D/17-18

**Study design**

Interventional Study Design

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Community

**Study type(s)**

Quality of life

**Participant information sheet**

No participant information sheet available.

**Health condition(s) or problem(s) studied**

Child development

**Interventions**

The study proposes experimental study design. The project assesses the prevailing knowledge and practices through baseline and at the end of the project an endline is planned to assess the impact in terms of ante natal and pre-natal care, brain development, importance of psychological wellbeing and child development. The survey is supplemented with focus group discussions conducted with equal number of fathers and mothers to provide qualitative data and case studies to capture specific changes in practice.

**Baseline:** To assess the first 1000 days' development / parenting skills a knowledge attitude and practice (KAP) survey and a standardised growth and development monitoring checklist (NDDS) is administered. Nippising District Development Screen (NDDS) checklist is a standardised tool filled in by the parents to measure the emotional, fine motor, gross motor, learning and thinking, self-help, communication, vision and hearing of children belonging to the age group 0 and 24 months.

For the purpose of the study, we presumed that each child or pregnant woman has at least two primary caregivers and one secondary caregiver. Based on the estimation of three caregivers per child and per pregnant woman, total number of caregivers from all 53 villages is estimated as 3126. The sampling unit for this study is the primary and secondary caregivers of children between 18 and 24 months of age. For the baseline the sample unit of caregivers of children between 18 and 24 months is selected as they have already passed through the stages of pregnancy till the 18 months to 24 months which will make the first 1000 days of life. The total sample estimated as 423.

**Treatment and Control Group:** Once the baseline is complete the villages are randomly divided as Group A and Group B.

Group A (treatment group, 42 villages, n=2418) parents are exposed to animated videos on parenting and early childhood development that show ante natal and pre-natal practices, parenting for holistic development of children in the first 1000 days of life, age appropriate stimulation techniques to enhance brain development and parenting messages on nutrition, health and safety. The intervention is based on Learning Through Play (LTP) adapted versions of LTPC developed by Bala Mandir Research Foundation (BMRF) and the Network for Information on Parenting with support from UNICEF. LTPC focuses on the following domains of development

- Sense of self
- Physical growth
- Relationships
- Understanding
- Communications

It takes advantage of the technological advancements such as mobile phone, tablets, laptops and video players. Additionally, short video clips can be viewed repeatedly, shared and enable a larger dialogue on holistic parenting practices in the community. Facilitators selected from local area will be trained to supplement these videos with relevant information to ensure people's participation.

Group B (control group, 11 villages, n=729) are exposed to non-video based parenting and early childhood development. The homogeneity of Group A and Group is ensured by means of randomly selecting the parents from same Taluk and similar socio economic characteristics. To control spill-over effect, both the groups are selected from villages of different panchayats but from the same Taluk.

**Endline:** To measure the knowledge gain, a knowledge attitude and practice (KAP) survey and a standardised growth and development monitoring checklist is administered again with the treatment and control group. The results are compared against baseline and endline; and the hypothesis is tested using standard statistical tests between the two groups' treatment and control. The caregivers identified (2nd and 3rd trimester pregnant women and the caregivers) at the beginning of the intervention are the sample for the endline as they are going through most of the intervention stages during the proposed time period. It is estimated that for the endline the sample size is 597.

## **Intervention Type**

## Behavioural

### Primary outcome measure

1. Knowledge, attitude and practice on parenting is assessed using a survey at baseline and endline.
2. Anthropometric measures, growth and development is measured using the Nippising District Development Screen (NDDS) scale at baseline and endline.
3. Age appropriate stimulations given by parents are reported by parents at baseline and endline.

### Secondary outcome measures

Changes in parenting are assessed using survey questionnaire at baseline and endline.

### Overall study start date

01/01/2018

### Completion date

01/11/2019

## Eligibility

### Key inclusion criteria

1. Primary care givers (both father and mother) of children between 18 and 24 months
2. Secondary care giver (one) of children between 18 and 24 months

### Participant type(s)

Other

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

Experiment Group - 2418 (parents and caregivers) from 42 villages; Control Group - 729 (parents and caregivers) from 11 villages

### Key exclusion criteria

Parents and caregivers of children above the age of 24 months

### Date of first enrolment

01/04/2018

### Date of final enrolment

30/06/2018

## Locations

**Countries of recruitment**

India

**Study participating centre****Society for People's Education and Economic Change (SPEECH)**

Society for Peoples Education and Economic Change

2/1060, Manoranjitham Street

Ezhilnagar, Tirupalai,

Tamilnadu

Maduri

India

625014

**Sponsor information****Organisation**

Grand Challenges Canada

**Sponsor details**

MaRS Centre, West Tower, 661 University Avenue, Suite 1720,

Toronto, Ontario

Canada

M5G 1M1

+14165835821

info@grandchallenges.ca

**Sponsor type**

Other

**Website**

<http://www.grandchallenges.ca/>

**ROR**

<https://ror.org/02snbhr24>

**Funder(s)****Funder type**

Government

**Funder Name**

Grand Challenges Canada

**Alternative Name(s)**

Grands Défis Canada, GCC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

## **Results and Publications**

**Publication and dissemination plan**

As per our funding agreement with Grand Challenges Canada, all research related outputs must be shared with Grand Challenges Canada and its community researchers and related institutions and must be disseminated as quickly and broadly as possible to the scientific community. We expect to complete the research by the end of June 2019 and publish the report in renowned peer reviewed journal within a period of 6 months after the research.

**Intention to publish date**

10/07/2020

**Individual participant data (IPD) sharing plan**

As per the agreement with the Grand Challenges Canada Data Access policy, data from funded projects will be made openly accessible to the Grand Challenges Canada Research Community through ethical and efficient data access practices. We will be consulting with Registry of Research Data Repositories (<http://www.re3data.org>) and similar catalogues to identify suitable repositories. The data will be openly accessible within 6 months of completion of the research. After removing the identifiers, the response of respondents collected through the surveys, NDDS checklist will be made available for the scientific community. We will ensure that the relevant aspects of research will be conducive for data access. We will obtain permissions to share data from the respondents through informed consent and also in the ethics approval documents.

**IPD sharing plan summary**

Stored in repository