

Stepping Stones: scaling early childhood development at Anganwadi Centers in India

Submission date 12/04/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/04/2016	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Anganwadi centers are early childhood development centers under the Integrated Child Development Programme of India (ICDS). Over time, their focus on early childhood education and development activities has reduced and their current activities mostly revolve around nutritional supplementation and assisting the health workers in Maternal and Child Health services. This study aims to enhance the behavioural and cognitive development of children under 6 years of age by actively engaging with Anganwadi workers, parents, caregivers and the community, improving the curriculum, and assisting Anganwadi workers, caregivers and parents through continuous guidance. We also intended to increase the parents' and caregivers' knowledge and skills for health and early childhood development.

Who can participate?

Children under 6 years and their families

What does the study involve?

Participating anganwadi centers are randomly allocated to either the intervention or the control group. The control group receive the standard Anganwadi Worker Program. The intervention group receive the intervention described below. A family centred early childhood development and positive parenting curriculum is developed and delivered through the Anganwadi centers, targeting children aged 3 to 6 years. The parenting program is delivered through group meetings and home visits and primarily targets the parents of children under three years of age. The project actively engages with private preschool, higher education institutions and the community for assessments and continues monitoring and coaching Anganwadi workers and project staff for continued quality improvement. The study participants are assessed for changes in cognitive development at the end of the study.

What are the possible benefits and risks of participating?

Participating children may benefit from improved cognitive and behavioural development. Parents and caregivers may benefit from improved knowledge and skills for positive parenting. The Anganwadi Workers and teachers may benefit from improved knowledge and skills to deliver the enhanced curriculum. We anticipate no risks for participants.

Where is the study run from?
Datta Meghe Institute of Medical Sciences (India)

When is the study starting and how long is it expected to run for?
December 2015 to September 2016

Who is funding the study?
Grand Challenges Canada

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Scaling early childhood development at Anganwadi Centers in India

Study objectives

400 (50%) of the total children enrolled in the intervention arm show at least 0.3SD changes in cognitive/behavioral measures compared to the control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Datta Meghe Institute of Medical Sciences Ethics Committee, 30/03/2015, Ref. No. DMIMS (DU) /IEC/2014-15/1203

Study design

Interventional multicenter cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Six domains of child development

Interventions

Anganwadi workers (AWW), local community-based workers under the Integrated Child Development Scheme (ICDS), established in 1975, provide supplementary nutrition, preschool education, nutrition and health education and referral services. Despite their significant role in child development, AWW are often overburdened due to administrative and documentation related work.

Our innovation is the integration and enhancement of the existing government Anganwadi Program (AWP) and Anganwadi Worker (AWW) with local resources in the private and education sectors to create a higher-impact program for early childhood development (ECD) of indigenous tribal groups. Novel elements are:

1. Creation of a tailored curriculum for a family-centered approach and certification of baby-friendly couples (BFC) to increase caregiver capacities for health and ECD
2. Deploying a tablet-PC smart register application as a tool for the AWW to adequately track child growth and ECD and progress through the curriculum, highlight gaps in care for targeted action, and reduce administrative and reporting burdens
3. Creating training and apprentice partnerships between the public AWP/AWW and private high quality preschools as a mechanism for AWW performance incentives and training including recognition as an upgraded Anganwadi Center (Anganwadi Plus)
4. Establish partnerships with local community colleges and medical schools for continuous data driven quality improvement and training.

Research Assistants in the project will support the impact evaluation, coordinate between community colleges/medical colleges and private school teachers with the AWW, and provide technical support for the application.

The proof of concept for this project is that the intervention can be effectively delivered through a public-private partnership (shown by attendance in AWC increasing from 30% to at least 50%).

We are using a cluster randomized controlled trial to evaluate the impact of the intervention. This will include 50 clusters comprised of an Anganwadi Center (AWC). The selected AWC will be randomly allocated to either intervention or control. We anticipate equal distribution of unaccounted variables across both groups. The baseline comparability will be assessed as a proxy for general comparability.

The intervention group is receiving the intervention as described steps 1-7 below, and the control will receive the standard Anganwadi Worker Program. Information on the fidelity of implementation related to training and deployment will be collected. Attendance of children at the AWC, engagement with parents and use of the smart register application to manage clients and provide customized feedback to parents will also be tracked.

Intervention:

Step 1: to develop an enhanced AWP curriculum through integration and adaptation of early childhood education tools. The curriculum will be family-focused with a substantial parental role in child interaction skills and a supportive home environment.

Step 2: training and certification of staff to deliver the new curriculum and procedures, first for private preschool teachers who will also be trained as trainers, and then for AWW.

Step 3: concurrent with Step 2, we will develop the smart register application and tablet PCs for the AWW to manage their clients.

Step 4: the AWW workers in tribal areas “go live” with the enhanced curriculum, BFC sessions and tablets.

Step 5: private preschool teachers will begin their role as mentors by visiting AWC/AWW for coaching and quality assessments.

Step 6: engaging local academics and scholars at a local college/medical school and train them to

review the AWW register data, and analyse and identify service gaps.

Step 7: monthly community meetings held with the AWW, supervisors, mentors from the private preschools, academics and community members. At these meetings the stakeholders discuss the successes and failures at the AWC/AWW and formulate a plan to improve services based on the data.

Intervention Type

Other

Primary outcome measure

1. 400 (50%) of the total children enrolled in the intervention arm show at least 0.3SD changes in cognitive/behavioral measures compared to the control.
2. Increase in AWC attendance from 30% to 50%
3. Increase in the number of Baby Friendly Couples

Primary and secondary outcomes will be measured at Endline i.e. in September 2016. Battery of tools to be used for assessment are Developmental Milestones Checklist - III (DMC-III), Profile of Socio-Emotional Development (PSED), Home Scale Coding, Early Childhood Home Inventory, Memory Game and Windows Task, Maternal Depression Agency and Depression.

Secondary outcome measures

1. Number of Anganwadi workers enrolled and benefited in the intervention arm
2. Number of families benefited through positive parenting sessions

Primary and secondary outcomes will be measured at Endline i.e. in September 2016

Overall study start date

01/12/2015

Completion date

30/09/2016

Eligibility

Key inclusion criteria

1. Children aged 0-6 years
2. Family members of children aged 0-6 years

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

50 clusters with total 1600 children minimum

Key exclusion criteria

Children older than 6 years of age

Date of first enrolment

01/12/2015

Date of final enrolment

30/09/2016

Locations**Countries of recruitment**

India

Study participating centre

Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha

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Sponsor information**Organisation**

Grand Challenges Canada

Sponsor details

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Government

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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

We intend to publish the overall process of the development of the curriculum and enhanced ECD and parenting curriculum manuals.

We intend to publish the study protocol and findings from the baseline data.

The report on the effectiveness of our intervention on cognitive and behavioural development in children will be published in a peer-reviewed international journal after completion of end-line assessment and analysis.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request