

Effectiveness of parenting sessions focused on pre-primary education delivered by community health workers for children's cognitive development in Bhutan

Submission date 14/07/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/08/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Over the past eight years the Royal Government of Bhutan, with the assistance of development partners like Save the Children and UNICEF, has made sustained efforts to promote and institute various kinds of early childhood care and development (ECCD) interventions including school-based programs and parenting education. However, at this time the Ministry of Education only supports school-based ECCD programming in communities that have at least 15 children who are 3-5 years of age. This policy excludes the children and families living in remote parts of the country, who are also those most in need of such services. In response to the need for non-school based ECCD services in rural areas of the country, a home-based solution called the Care for Child Development Program Plus initiative was developed. The program aims to strengthen the existing Care for Child Development Program run by the Ministry of Health by adding 12 sessions about early stimulation and home learning activities, and training village health workers to deliver the program to parents/caregivers of 3-5 year-old children in their communities. The purpose of this pilot program is to both increase access to quality ECCD services and contribute towards improved learning and development outcomes for 3-5 year-old children in rural areas. The results from the intervention will inform design and program implementation for possible scale up in other districts as well as program design for 0-3 year old children in such areas.

Who can participate?

What does the study involve?

Villages in four districts are randomly allocated to one of two groups. Those in the first group are invited to join bi-monthly sessions by health care workers to promote literacy and numeracy at home. They receive 12 parenting sessions twice per month. Those in the second group receive their normal health care. Participating families fill out questionnaire focused on family characteristics and caregiver activities is used to measure impact.

What are the possible benefits and risks of participating?

Participants may benefit from enjoying playing the games in this study. There are minimal risks with participating. Children may feel uncomfortable being interviewed by a stranger but are allowed to decline to participate and stop the assessment even if their parents have given them consent to participate.

Where is the study run from?

This study is being run by Save the Children (Bhutan) and takes place in villages in Bhutan.

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

December 2016 to December 2017

Who is funding the study?

1. Save the Children (UK)
2. Investigator initiated and funded (UK)

Who is the main contact?

Ms Lauren Pisani

Contact information

Type(s)

Public

Contact name

Mrs Lauren Pisani

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Determining the effectiveness of an alternative pre-primary education program delivered by community health workers in Bhutan: A cluster-randomized control trial

Study objectives

1. Does the C4CD Plus program improve learning and development for children aged 3-5?
2. Does the C4CD Plus program improve parenting practices related to early learning?
3. Do all parents and children experience the same benefits (or lack thereof) from the C4CD Plus program?

Ethics approval required

Old ethics approval format

Ethics approval(s)

UCL Research Ethics Committee, 25/4/2017

Study design

Cluster randomised controlled trial

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

Early childhood learning and development intervention in Bhutan

Interventions

Within the four selected districts, all Gewogs (CHW catchments areas made up of 1-3 villages) are randomly assigned to either the intervention or the control group for program implementation. Then 19 catchment areas are selected for the study (9 intervention, 10 control). Due to the limited population in rural areas of Bhutan, all families with children aged 3-5 within these villages are eligible to participate in the study. A list of eligible villages (no access to center-based early childhood education services and existence of a community health worker) within target districts was compiled by the Ministry of Health and Save the Children, and then a random number generator was used to randomly assign each village into either the treatment or control arm of the study. Thirty-five villages were random selected to be part of the evaluation, and all families with children aged 3-5 were eligible for participation in the study.

Parents in the intervention group are invited to join bi-monthly sessions led by community health workers that focus on how to promote emergent literacy and numeracy at home. Participants receive 12 parenting sessions delivered by twice per month by village health

workers. The sessions focus on improving stimulation and home learning practices with children aged 3-5.

Parents in the control group continue to receive routine health care but are not offered community parenting sessions. Participants receive no new services and do not have any services withheld.

Intervention Type

Behavioural

Primary outcome measure

Children's learning and development as measured by the International Development and Early Learning Assessment (IDELA) are measured at baseline (about one month before intervention begins) and one month after completion.

Secondary outcome measures

Positive parenting-child interactions at home (self-reported) are measured at baseline (about one month before intervention begins) and one month after completion.

Overall study start date

10/12/2016

Completion date

31/12/2017

Eligibility

Key inclusion criteria

All parents of children aged 3-5 in selected communities.

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

35 villages with 12 diads (parent and child) per village

Key exclusion criteria

Parents of children older or younger than 3 - 5 years.

Date of first enrolment

01/05/2017

Date of final enrolment

31/05/2017

Locations

Countries of recruitment

Bhutan

Study participating centre

Save the Children

Bhutan Office

Chang Geydaphu

Thimphu

Bhutan

N/A

Sponsor information

Organisation

Save the Children Bhutan

Sponsor details

Chang Geydaphu GPO Box 281

Thimphu

Bhutan

N/A

Sponsor type

Other

Website

<https://bhutan.savethechildren.net>

ROR

<https://ror.org/036jr6x18>

Funder(s)

Funder type

Not defined

Funder Name

Save the Children

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Results of this study will be disseminated as part of my doctoral dissertation defense and then formatted for publication in a high-impact peer reviewed journal. Results will also be disseminated to the Ministries of Education and Health within Bhutan. Preliminary dissemination within Bhutan may occur in 2018; my dissertation defense is tentatively planned for June 2019, and peer reviewed publication would follow.

Intention to publish date

31/08/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date