ISRCTN10412166 https://doi.org/10.1186/ISRCTN10412166

1000 Dreams: a community-based integrated early life intervention program to help babies survive and thrive

Submission date
14/03/2018

Recruitment status
No longer recruiting

Registration date
26/03/2018

Overall study status
Completed

Last Edited
26/03/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Globally, more than 6.3 million children die before reaching the age of 5 years, of whom about 3 million die within the first month of life, mostly due to preventable causes. More than 200 million children under 5 years fail to reach their cognitive and developmental potential due to poor health, nutrition and deficient care in disadvantaged communities. Further, the failure of children to fulfil their developmental potential contributes to a vicious cycle of intergenerational transmission of poverty. Poor child development is therefore, at the root of poverty, inequality and human development challenges.
The 1000 Dreams project is therefore envisaged as a community-centric program with a “whole mother – whole child’ approach, aiming to impact the survival and ability to thrive of children by empowering mothers, fathers, families and communities to make better and informed choices and improve care behaviors, with a focus on nutrition, hygiene and infection prevention, infant massage, loving and responsive care practices, active stimulation and interaction, and care-seeking.
We hypothesize that the intervention program will lead to improvements in both survival and development of infants. Our primary hypotheses are as below:
The proposed program for antenatal care and ECD until 12 months of age will lead to at least 35% reduction in stunting prevalence in the intervention group versus the control group at 12 months of age and at least 20% improvement in the developmental scores of infants in the intervention group versus the control group at 12 months of age.12 clusters per study arm were required to test the hypothesis.

Who can participate?
A total of 528 pregnant women from 24 clusters were enrolled in each study arm.

What does the study involve?
The intervention package included counselling and handholding support for pregnant women and their families on nutrition (during pregnancy, lactation and complementary feeding), hygiene, early child stimulation including massage and play, early initiation of skin-to-skin contact for all babies, and care-seeking. The intervention was designed around 6 domains

(Nutrition, Hygiene & Infection Prevention, Infant Massage, Loving and Responsive Care Practices, Active Stimulation & Interaction and Care Seeking).
The study is tracking vital events (pregnancies, births, newborn deaths) and practices prevalent in the entire study area through a prospective follow-up of all mothers and babies up to the age of 12 months and measure other key outcomes. Newborn deaths in the intervention and control groups will be statistically compared, along with changes in practices and other key outcome indicators to evaluate the impact of the intervention.

What are the possible benefits and risks of participating?
The activities in the intervention arm are expected to cause no harm to babies and may potentially reduce the prevalence of stunting and improvement in the neurodevelopmental scores of the babies.
The evaluation procedures are standard, and include measuring parameters such as weight, head circumference, calf circumference, mid upper arm circumference and crown-heel length of the baby. Mothers are being asked detailed questionnaires regarding the dietary intake of themselves, mental health, domestic violence and newborn care practices, illnesses and care seeking etc. These involve minimal risk to participants.

Where is the study run from?

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

How long will the trial be recruiting participants for?
The study is supported by Grand Challenges Canada.

Who is the main contact?
The primary contact for the study is the Principal Investigator, Ms Aarti Kumar (aarti.kumar@shivgarh.org)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CELIEC/2015001

Study information

Scientific Title
1000 Dreams: a community-based integrated early life intervention program to help babies survive and thrive

Acronym
1000 Dreams

Study objectives
An integrated intervention from pregnancy to the first 12 months of life comprising of nutrition, infection prevention, early childhood stimulation and responsive care will lead to at least 50% reduction in all-cause infant mortality rate (IMR), 20% reduction in stunting prevalence and 20% improvement in developmental scores of infants at 12 months of age.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CELIEC (Community Empowerment Lab Institutional Ethics Committee), CELIEC/2015001

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)

Community

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Newborn survival and child development

Interventions
24 clusters (village administrative units) were randomly allocated equally to intervention or control prior to initiation of enrollment. A restricted randomization approach, balancing the population of clusters and proportion of lower castes, was adopted to ensure balanced allocation. The two allocation sequences generated through the restricted randomization scheme were allocated to intervention and control by a community member through the toss of a coin. Due to the nature of the intervention (home visitations by special workers called 'life coaches', etc), it was not possible to mask the intervention clusters. However, the entire evaluation was conducted by a separate set of workers, following the same process in both intervention and control clusters. The intervention package included counselling and handholding support for pregnant women and their families on nutrition (during pregnancy, lactation and complementary feeding), hygiene, early child stimulation including massage and play, early initiation of skin-to-skin contact for all babies, and care-seeking. The intervention was designed around 6 domains (Nutrition, Hygiene & Infection Prevention, Infant Massage, Loving and Responsive Care Practices, Active Stimulation & Interaction and Care Seeking).

Intervention Type
Behavioural

Primary outcome measure
1. Infant mortality rate
2. Stunting (as measured at 6, 9 and 12 months of age)
3. Developmental scores (as measured at 6 and 9 months of age)

Secondary outcome measures
1. Neonatal mortality rate
2. Infant mortality rate
3. Mean birth weight
4. Rates of exclusive breastfeeding at 6 months
5. Prevalence of maternal depression

Overall study start date
01/10/2014

Completion date
01/12/2016

Eligibility

Key inclusion criteria

1. All pregnant women who are identified in the first, second or early third trimester, and reside in the village of identification till the baby is at least 6 months of age will be considered as eligible for analysis of trial outcomes.
2. All women/babies who are found to be residing in a particular cluster at the time of first identification will be analyzed as part of the same cluster, irrespective of migration after the baby is 6 months of age, as per principles of intention to treat.

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
528 women-baby pairs in 24 clusters

Key exclusion criteria
Inclusion criteria not met

Date of first enrolment
01/10/2015

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
India

Study participating centre
Community Empowerment Lab
26/11 Wazir Hasan Road
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Sponsor information

Organisation
Grand Challenges Canada

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Sponsor type
Research organisation

ROR
https://ror.org/02snbhr24

Funder(s)

Funder type
Not defined

Funder Name
Canadian Government

Results and Publications

Publication and dissemination plan

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request