

Employing general practitioners for delivering a child development package in Pakistan

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Registration date 31/12/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/11/2019	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

Early child development is dependent on the mother's ability to provide the right physical and social environment and support to her young child. In Pakistan, like most developing countries, early child development has been a grossly neglected area of public health importance, where the main challenges include tackling the problem of high numbers of children suffering from chronic malnutrition, the low level of mothers' skills for child development, and maternal mental health problems. Child malnutrition and the mother's caring ability (including her mental health) are considered to contribute significantly to the delayed development of child milestones: this is mainly due to under-weight births, poor breastfeeding and weaning practice, and recurrent infections. It is suggested that these are linked to low literacy, psychosocial factors and lack of counselling for maternal mental health problems. In poor urban settings, the mothers' ability to cater for child development needs is constrained by their low literacy, poor mental health and lack of skills. The aim of the study is to develop and evaluate a set of infant nutrition and development products along with maternal mental health products that could be implemented in poor urban settlements. For this purpose private clinics will be employed to promote the development of poor urban infants (age ≤ 1 year). The main objectives are to:

1. Develop an integrated early child development (infant) care package with three key components: infant development, nutrition counselling, and maternal mental health.
2. Arrange, implement and monitor the care products at 22 selected private clinics in poor urban localities.
3. Design and conduct a study to evaluate the effectiveness and feasibility of the intervention.

Who can participate?

Mothers with infants who were delivered within 1 month of full-term (≥ 36 weeks) and who live within the catchment area of the study.

What does the study involve?

The selected 22 private clinics are randomly allocated into one of two groups. Those mothers and infants attending clinics in group 1 (intervention group) are given the designed products for nutrition, early child development and maternal depression. Mothers and infants attending clinics in group 2 (control group) receive the usual care.

What are the possible benefits and risks of participating?

It has been assumed that the intervention group will benefit from the products introduced at the clinics with better infant nutrition and better progress for developmental milestones. The control group will not be deprived of any care or referral needed to minimize any risk or ethical issue.

Where is the study run from?

Association for Social Development (Pakistan).

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

October 2014 to September 2016.

Who is funding the study?

Grand Challenges Canada (Canada)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A sustainable public-private partnership for delivering integrated child development care in Pakistan: a clustered randomized controlled trial

Acronym

N/A

Study objectives

Primary hypothesis: the introduction of context-sensitive early child development (ECD) packages will reduce childhood development delay (i.e., motor skills: from 20% to 16%; cognition: from 10% to 03%; and language: from 30% to 22%) in the catchment area.

Secondary hypotheses:

1. There will be a decrease in the prevalence of maternal depression from 36% to 29% through a counseling package facilitated by General Practitioner's Paramedic
2. Promotion of nutrition packages and medications will lead to a reduction in stunting prevalence (2SD HAZ)

Ethics approval required

Old ethics approval format

Ethics approval(s)

NBC 154, National Bioethics Committee Pakistan, 11/09/2014

Study design

Randomized controlled cluster trial with two arms

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Child development, maternal depression, child nutrition

Interventions

Intervention arm:

1. Developing context-sensitive intervention products through TWG (including guidelines, training and counseling tool)
2. Mapping and selection of priority locations and a private clinic in each selected location
3. Training of doctors and paramedics at selected private clinics for ECD, Maternal Health and Nutrition
4. Identifying and enabling of community advocates (for enhanced ECD care access)
5. Branding of selected private clinics
6. Identifying and recruiting (by doctor) eligible mother-child dyads, and keeping essential baseline record
7. Conducting quarterly counseling sessions of mothers (by paramedic) at a private clinic (for promoting child and maternal mental health)
8. Offering low-dose quarterly Vitamin A supplement, mainly as a client retention measure
9. Identifying nutritional and/or child brain development and/or maternal mental health deficiencies, and prescribe remedial action

10. Making community aware (about ECD care) through enabled community advocates and clinic branding
11. Applying mobile phone technology for client compliance to the quarterly follow-up visits (including retrieval of delayed clients)
12. Identifying and referring (by doctor) the child and/or mothers with need for specialist care
13. Conducting facility and district level monitoring events

Control arm:
Routine clinic practice

Intervention Type

Mixed

Primary outcome(s)

Reduction in the percentage of early childhood development delays through the context-sensitive packages delivered. The primary outcomes will be measured according to the baseline i.e one month after delivery (infants less than or equal to one month of age; infant development, nutrition and maternal mental health will be assessed at this point). Subsequent measurements will be made at 3 months, 6 months, 9 months and endline at the 12th month.

Key secondary outcome(s)

1. Decrease in the prevalence of maternal depression through counseling
 2. Decrease in the prevalence of stunting through nutrition counseling
- The secondary outcomes will be measured according to the baseline i.e one month after delivery (infants less than or equal to one month of age; infant development, nutrition and maternal mental health will be assessed at this point). Subsequent measurements will be made at 3 months, 6 months, 9 months and endline at the 12th month.

Completion date

30/09/2016

Eligibility

Key inclusion criteria

All mother-infant dyads \leq 1 month of full-term (\geq 36 weeks) delivery within catchment area (no migration during tenure of trial)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Child known to have congenital abnormality, history of delayed cry or seizures, cretinism, low birth weight
<2500 g, death of either mother or child

Date of first enrolment

01/02/2015

Date of final enrolment

01/11/2015

Locations**Countries of recruitment**

Pakistan

Study participating centre**Association for Social Development**

Islamabad

Pakistan

44000

Sponsor information**Organisation**

Grand Challenges Canada

ROR

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

Funder(s)**Funder type**

Government

Funder Name

Grand Challenges Canada

Alternative Name(s)

Grands Défis Canada, gchallenges, Grand Challenges Canada / Grands Défis Canada, grandchallengescanada, GCC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/01/2017	01/11/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes