

# Employing public health facilities for delivering early child development package in two districts of Pakistan named Rawalpindi and Lahore

<b>Submission date</b> 04/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/11/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In Pakistan, about one third of young children are estimated to suffer from development delays. The public facilities remain an accessible source of health care for rural and poor communities. Delivering integrated Early Child Development (ECD) care for 0 – 24 month old children at public health facilities is a program priority. A package for integrated ECD care of 0 – 12 month old children is available and currently being implemented, but ECD care of 13 – 24 month old children is yet to be developed. Early child development is dependent on the mother's ability to provide the right 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. The mother's caring ability (including her mental health) and child malnutrition contribute to delayed development. This is mainly due to under-weight births, poor nutrition and recurrent infections, which have been linked to low literacy, psychosocial factors, absence of counselling for maternal mental health problems and family planning. In poor urban settings, mothers' ability to cater for child development needs is constrained by their low literacy, poor mental health, lack of skills and more child births. The aim of this study is to develop and test a set of child development products, maternal mental health products and family planning counselling that could be used in poor urban settlements.

### Who can participate?

Mothers with 1-year-old children within the catchment area

### What does the study involve?

Participating public facilities are randomly allocated into the intervention group or the control group. The intervention group receive the designed products for early child development, nutrition, maternal mental health and family planning. The control group continue with the routine practice that general practitioners follow. Child development is assessed using a questionnaire at the start of the study and when the child is 24 months old.

What are the possible benefits and risks of participating?

The intervention group may benefit from the products introduced at the facilities, resulting in better child development. The control group are not deprived of any care or referral needed to minimize any risk or ethical issues. There are no risks involved for the participants.

Where is the study run from?

12 rural health centers and 11 Tehsil headquarters in two districts of Pakistan

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

April 2017 to March 2019

Who is funding the study?

Grand Challenges Canada

Who is the main contact?

Dr Muhammad Amir Khan

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

-

## Study information

**Scientific Title**

-

Integrated ECD care of 13 – 24 month olds at public health facilities in two selected districts of Punjab, Pakistan

**Acronym**

ECD Early Child Development

**Study objectives**

Remaining within the district health care framework, the delivery of integrated ECD care of 13 – 24 month olds at public health facilities is potentially effective, feasible and replicable.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

National Bioethics Committee Pakistan, 12/09/2017, ref: NBC-225

**Study design**

Cluster randomized controlled trial with two arms

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet**

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

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

Early child development, maternal health, child nutrition

**Interventions**

The list of all the Tehsil Head Quarters and Rural Health Centers was gathered for two districts. Among these, the facilities of Gujarkhan district (Rawalpindi) were excluded because of ongoing WHO mhGAP intervention. One randomly selected facility was taken out from the eligible 25 facilities into 2 districts. The shortlisted 24 facilities were divided into intervention and control groups. The selection of 12 facilities was done by randomly picking for each group.

**Intervention arm**

1. Developing context sensitive intervention products (including guidelines, training and counseling tool)
2. Training of doctors and paramedics at selected public facilities for ECD, Maternal Health and Nutrition
3. Identifying and enabling of community advocates (for enhanced ECD care access)

4. Identifying and recruiting eligible mother-child dyads, and keeping essential baseline record
5. Conducting quarterly counseling sessions of mothers by LHV at public facilities (for promoting child and maternal mental health)
6. Identifying nutritional and/or child brain development and/or maternal mental health deficiencies, and prescribe remedial action
7. Making community aware (about ECD care) through enabled community advocates
8. Applying mobile phone technology for “client” compliance to the quarterly follow-up visits (including retrieval of delayed clients)
9. Identifying and referring (by doctor) the child and/or mothers with “need” for specialist care
10. Conducting facility and district level monitoring events

Control arm

Routine clinic practice

The treatment and follow-up for all arms will be completed in 1 year.

### **Intervention Type**

Other

### **Primary outcome measure**

Child development, assessed using the ASQ-3 questionnaire at baseline and 24 months of age

### **Secondary outcome measures**

1. Use of reversible contraception in the registered mothers, measured using questionnaire at 24 months of age
2. Child anthropometric measurements (height and weight) at baseline and 24 months of age
3. Maternal mental health, assessed using PHQ-9, GAD-7 and WHO mhGAP based questions at baseline and 24 months of age

### **Overall study start date**

01/04/2017

### **Completion date**

30/03/2019

## **Eligibility**

### **Key inclusion criteria**

All mother-child dyads with 1 year old children within catchment area (no migration during tenure of trial)

### **Participant type(s)**

Other

### **Age group**

Mixed

### **Sex**

Both

**Target number of participants**

At least 768 mother-child pairs will be registered in a total of 24 clusters (i.e. 12 clusters in each of the intervention and control arms)

**Total final enrolment**

804

**Key exclusion criteria**

1. All the mother-child dyads with children aged more or less than 1 year
2. Death of either mother or child
3. Non-residents
4. Child known to have congenital abnormality, history of delayed cry or seizures, cretinism

**Date of first enrolment**

10/10/2017

**Date of final enrolment**

28/02/2018

**Locations****Countries of recruitment**

Pakistan

**Study participating centre**

12 rural health centers and 11 Tehsil headquarters in two districts of Pakistan

Rawalpindi and Lahore

Pakistan

46000/54000

**Sponsor information****Organisation**

Grand Challenges Canada

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.grandchallenges.ca/who-we-are/>

**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**

The trialists have planned to publish papers related to the main trial and process evaluation in peer reviewed journals. The estimated date for paper drafts and submission is from 15/12/2018 to 30/06/2019.

**Intention to publish date**

30/06/2019

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

The 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		01/11/2021	27/10/2022	Yes	No
<a href="#">Results article</a>		30/11/2023	21/11/2023	Yes	No