ISRCTN14396904 https://doi.org/10.1186/ISRCTN14396904

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

Submission date
04/10/2017

Recruitment status
No longer recruiting

Registration date
17/10/2017

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
gcc@asd.com.pk

Contact information

Type(s)
Scientific

Contact name
Dr Muhammad Amir Khan

Contact details
Association for Social Development
House No. 12
Street 48, F-7/4
Islamabad
Pakistan
44000
+92 (0)51 2611231
gcc@asd.com.pk

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
MaRS Centre, South Tower
101 College Street, Suite 406
Toronto
Canada
M5G 1L7
+1 (0)41 673 6568
infor@grandchallenges.ca

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?
Protocol article		01/11/2021	27/10/2022	Yes	No
Results article		30/11/2023	21/11/2023	Yes	No