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Employing general practitioners for delivering a child development package in Pakistan

Submission date
18/11/2014

Recruitment status
No longer recruiting

Registration date
31/12/2014

Overall study status
Completed

Last Edited
01/11/2019

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
Dr Muhammad Amir Khan
asd@asd.com.pk

Study website
http://mhinnovation.net/innovations/sustainable-public-private-partnership-integrated-child-development-care

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
asd@asd.com.pk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Cluster randomised trial

Study setting(s)
Not specified

Study type(s)
Other

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/10/2014

Completion date
30/09/2016

Eligibility

Key inclusion criteria
All mother-infant dyads ≤1 month of full-term (≥36 weeks) delivery within catchment area (no migration during tenure of trial)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
2,200 mother-infant dyads (1,100 in each arm) in 22 clusters (where clusters refer to General Practitioner clinics)

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

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

Sponsor type
Government

Website
http://www.grandchallenges.ca/saving-brains/

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
We are intending to publish four papers: protocol paper, main trial paper, costing paper and a qualitative article.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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