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Promotion of Breastfeeding and Evaluation Study: a community-based maternal-focused approach to promote exclusive breastfeeding in rural Pakistan

Submission date	Recruitment status	[_] Prospectively registered
22/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/06/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/12/2020	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Integration and evaluation of a community-based maternal-focused approach to promote exclusive breastfeeding in rural Pakistan: a cluster randomised controlled trial

Acronym
PROBE Study

Study objectives
The aim of this project is to provide the National Program for Family Planning and Primary Health Care of Pakistan and their Lady Health Workers (community health workers) with a well-researched, evidence-based intervention to promote exclusive breastfeeding, which has the potential for up-scaling. The objective of the project is to integrate a community-based exclusive breastfeeding promotion intervention into the routine work of Lady Health Workers, train them in using this approach, and to evaluate its effect on rates of exclusive breastfeeding.

Hypotheses:
Compared to mothers receiving standard breastfeeding advice by Lady Health Workers, mothers who receive the experimental intervention (also by Lady Health Workers) will:
1. Have a higher rate of exclusive breastfeeding (defined as giving maternal milk at the only infant food source in the previous week, with no other liquids or food given) at 6 months post-natally
2. Have a longer duration of exclusive breastfeeding
3. Have reduced levels of psychosocial distress

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Development Research Foundation, registered with the Office of Human Research Protections (OHRP), gave approval on the 10th December 2008 (ref: HDRF/IRB/002)

Study design
Cluster randomised single-blind parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Breastfeeding

Interventions
The proposed study is a cluster randomised controlled trial with two parallel arms. The intervention arm will receive seven sessions of this maternal focused approach to promote breastfeeding through Lady Health Workers. The control arm will receive a similar number of visits of routine counselling for breastfeeding through different Lady Health Workers.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All assessments will be carried out using instruments that have been translated, field-tested and validated in the local population through our previous work. Assessments will be carried out at baseline (third trimester), and prospectively for 6 months after birth.

Baseline measures:
1. Socioeconomic status (household income and assets)
2. Maternal age
3. Education
4. Body mass index
5. Scores of psychosocial distress on the Self-Reporting Questionnaire (SRQ)
6. Number of children
7. Family structure
8. Levels of post-traumatic stress and depressive reactions to the 2005 earthquake in the study area, assessed using the Earthquake Exposure Scale

Main outcome:
The duration of exclusive breastfeeding (EBF) and its rate at 6 months, measured prospectively using the following method: each mother enrolled into the study will be visited fortnightly by an independent team, blind to the allocation status of the mother, to record the breastfeeding status and practice in the last 24 hours. For this study, EBF was defined as: only breastfeeding being practiced with no other semi-solid or liquid foods (other than medication and/or oral rehydration solutions).

Secondary outcome measures
1. Psychological distress, measured at baseline, 3 and 6 months using the Self-Reporting Questionnaire (SRQ-20). This psychiatric screening instrument, which was developed specifically for use in primary care by health workers in developing countries, has 20 items with a 'yes' or 'no' response to questions about psychological and somatic symptoms in the past 30 days.

2. Rates and duration of predominant and partial breastfeeding, assessed at 6 months of infant's age prospectively using the above mentioned method
3. Process outcomes: studied qualitatively using key-informant interview and focus groups. At the 'system' level, the opinion of key personnel from the programme and primary health care (including LHWs), will be obtained on all aspects of training, delivery, usefulness and potential costs of the intervention (in terms of extra time and material needed to deliver the intervention). At the family level, we will obtain feedback from mothers and other significant family members about the intervention.

Overall study start date
01/05/2009

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Married, consenting women
2. Aged 17 - 40 years
3. Pregnant; in their 3rd trimester of pegnancy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
440 third trimester pregnant women

Total final enrolment
452

Key exclusion criteria
1. A diagnosed medical or mental illness
2. Currently under treatment, e.g., tuberculosis, hepatitis B or C or a mental health illness

Date of first enrolment
01/05/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment

England

Pakistan

United Kingdom

Study participating centre
Child & Adolescent Psychiatry
Liverpool
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Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.liv.ac.uk/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research organisation

Funder Name
United States Agency for International Development (USAID) (USA) - International Rescue Committee, Inc (IRC-PRIDE)

Funder Name
University of Liverpool (UK)

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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?
Results article	results	01/02/2015	29/12/2020	Yes	No