

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

Submission date 22/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/06/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/12/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Intentional

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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.

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 pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Pakistan

Study participating centre

Child & Adolescent Psychiatry

Liverpool

United Kingdom

L12 2AP

Sponsor information

Organisation

University of Liverpool (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**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