ISRCTN17580242 https://doi.org/10.1186/ISRCTN17580242

Evaluation of a responsive feeding and stimulation intervention

Submission date	Recruitment status
24/07/2008	No longer recruiting
Registration date	**Overall study status**
05/09/2008	Completed
Last Edited	**Condition category**
17/05/2019	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ICDDR,B #2008-010

Study information

Scientific Title

Evaluation of a responsive feeding and stimulation intervention

Acronym
CRF II

Study objectives
1. Mothers in the responsive program will show more verbal and nonverbal responsive behaviours in social and feeding interactions with their child, compared to mothers in the regular program. They will also provide more opportunities for stimulation as measured by the Home Observation for Measurement of the Environment (HOME) inventory.
2. Children in the responsive program will show more self-feeding behaviours, more gained weight and length, and better language development compared to the regular program children
3. Children in the responsive program plus iron supplementation will show more development and growth than those in the responsive program without iron

This trial is similar to a previously registered trial (see http://www.controlled-trials.com /ISRCTN15000469), but involves a different dataset, an extra arm to the trial and an extra outcome. Therefore this has been assigned to a different ISRCTN.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the ethics committee of the International Centre for Diarrhoeal Diseases Research Bangladesh (ICDDR,B) in April 2008.

Study design
Cluster randomised, three-armed, single-blinded field trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Malnutrition

Interventions
This is a cluster randomised field trial, with villages clusters randomly assigned to one of two interventions or a regular-program control. Mothers are not blinded; data collectors are blinded.

The Mothers in the Responsive Feeding intervention consisted of five weekly group sessions and a booster session given by trained village peer educators to mothers and their children using a Manual for Responsive Feeding and Play. Mothers observe a demonstration and then practice the behaviour with their child. Group discussions on how to handle feeding problems such as refusals without forceful feeding.

The Mothers in the Responsive Feeding and Iron Supplement intervention group also received seven sachets of Sprinkles per week and were shown how to add this to the child's food. Iron supplements continued for 6 months.

The Control mothers received the usual behaviour change communication (BCC) knowledge-transfer sessions from a Manual.

All mothers receive a laminated picture to remind them of the messages they learned. The interventions and controls last for six weeks; follow-up data collections occur five months later.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Mother: responsive feeding and responsive talking
2. Child:
2.1. Length and weight
2.2. Self-feeding
2.3. Mouthfuls eaten
2.4. Language development

Outcomes are measured at baseline, two weeks after the end of the intervention and five months after the end of the intervention.

Secondary outcome measures
1. Foods fed and messages recalled
2. Other maternal feeding behaviours such as forceful feeding and non-responsive encouragement

Outcomes are measured at baseline, two weeks after the end of the intervention and five months after the end of the intervention.

Overall study start date
01/04/2008

Completion date
30/12/2008

Eligibility

Key inclusion criteria

1. Living in four unions in Khansama, in the north of Bangladesh
2. Mothers and their children 8 to 20 months of age
3. Must have started complementary food

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
300

Total final enrolment
302

Key exclusion criteria
Children too ill or disabled to feed themselves.

Date of first enrolment
01/04/2008

Date of final enrolment
30/12/2008

Locations

Countries of recruitment
Bangladesh

Canada

Study participating centre
Department of Psychology
Montreal
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Sponsor information

Organisation
International Centre for Diarrhoeal Diseases Research (Bangladesh)

Sponsor details
Mohakhali (or GPO 128)
Dhaka
Bangladesh
1212
-
ACravioto@icddrb.org

Sponsor type
Research organisation

Website
http://www.icddrb.org/

ROR
https://ror.org/04vsvr128

Funder(s)

Funder type
Government

Funder Name
Social Science & Humanities Research Council (SSHRC) (Canada) (grant ref: 861-2006-0033)

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	01/05/2011	17/05/2019	Yes	No