

Evaluation of a responsive feeding and stimulation intervention

Submission date

24/07/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

05/09/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

17/05/2019

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

Canada

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Sponsor information

Organisation

International Centre for Diarrhoeal Diseases Research (Bangladesh)

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

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