

Comprehensive care of infants: development and evaluation of an intervention strategy to enhance the promotion of health and quality of life of infants 2007 - 2010

Submission date 14/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/12/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/12/2007	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

NCH 07006

Study information

Scientific Title

Study objectives

Does a public health intervention aimed at promoting improved feeding practices delivered at home and facility levels increase the duration of exclusive breastfeeding in the first 6 months of life and reduce the prevalence of obesity among infants 6 - 12 months?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. World Health Organization (WHO) Ethics Review Committee on the 21st November 2007 (ref: NCH07006)
2. Comité de Ética de la Investigación (Cuba) on the 20th November 2007

Study design

This is a cluster-randomised controlled trial of a public health intervention

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Infant feeding practices

Interventions

Intervention group:

Promotion of improved feeding at the health facility and community levels using multiple channels:

1. Face-to-face
2. Community based media
3. Community groups

Control group:
Receives usual care.

Some of the details of the intervention, such as the frequency or duration of contact or exposure to the channels will only be fully defined at the end of the formative research phase. Interventions at the health facility level may include in-service training of the physicians and nurses in the health centres to improve their communication and counselling skills. Training of health workers and community counselors in this course will, we believe, be an important component of the intervention. The intervention may also include changes in management procedures to make them more compatible with family needs and expectations. Access to off-hour advice, privacy of consultations, triage and waiting time and characteristics of the waiting room are some of the examples of areas that may be considered for improvement.

Interventions at the community level will make maximal use of appropriate existing channels either to be the primary sources of dissemination of messages or to re-enforce them. In addition to face-to-face communications individually or in group, the team will also consider the use of local mass media (e.g. local radio, pamphlets, banners, and posters), work and social clubs. The intervention will probably include the provision of information and the development with families of problem-solving approaches/strategies to deal with significant constraints. Face-to-face counselling will be one of the key components. Additional components may be included to remove existing barriers or promote actions that will support an increase in prevalence of a desired behaviour (for example, making breastfeeding counsellors available in the community for greater ease of access to counselling and support when mothers face a feeding difficulty).

Eighteen months after the introduction of the intervention, when we expect that the intervention will have been fully functional in all intervention clusters for at least 12 months, the post-intervention survey will be conducted to measure the impact on infants up to 12 months old. The length of exposure to the intervention will depend on the age of the infant and the period he/she has been residing in the community. Control clusters will continue to be provided the usual type of health care.

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Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Prevalence of exclusive breastfeeding among infants up to 6 months of age
2. Prevalence of "recommended infant feeding practices" (continued breastfeeding and three complementary feeds/day) at 6 - 11 months
3. Prevalence of Body Mass Index (BMI)/age equal of greater than 2SD at 6 - 11 months

Secondary outcome measures

1. Diarrhoea and pneumonia in the 2 weeks before interview
2. Hospitalisations in the past year (and their cause)

Overall study start date

01/11/2007

Completion date

31/10/2010

Eligibility**Key inclusion criteria**

Participants are all infants living in the community area served by health centres included in the study.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

12800

Key exclusion criteria

The only exclusion criteria identified is the patient's refusal to participate.

Date of first enrolment

01/11/2007

Date of final enrolment

31/10/2010

Locations**Countries of recruitment**

Cuba

Switzerland

Study participating centre

World Health Organization

Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation

The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO)
(Switzerland)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.who.int/child-adolescent-health>

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

Funder Name

World Health Organization (WHO) (Switzerland) (ref: NCH 07006)

Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé,
Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Switzerland

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