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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

Registration date
14/12/2007

Last Edited
21/12/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jose Carlos Martines

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 2634
martinesj@who.int

Additional identifiers

Protocol serial number
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. Comite de Etica de la Investigacion (Cuba) on the 20th November 2007

Primary study design
Interventional

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

Study type(s)
Treatment

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.

Contact details for Principal Investigator:
Dr Ibargollen Negrin Longina
Ministerio de Salud Publica
MCH Division
Calle 23 entre M y N. Vedado
Havana
Cuba
Tel: +53 (0)7 833 2336

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
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

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

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

Healthy volunteers allowed
No

Age group
Child

Sex
All

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)

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, , BO3, OMS

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary