ISRCTN31299262 https://doi.org/10.1186/ISRCTN31299262

Do food supplementation and play-based stimulation benefit the development of undernourished children?

Submission date
05/12/2019

Recruitment status
No longer recruiting

Registration date
21/01/2020

Overall study status
Completed

Last Edited
20/01/2020

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Childhood stunting (low height-for-age) is associated with poor childhood development. The aims of the study are to determine the benefits for child development of nutritional supplementation (a milk-based supplement, provided weekly) and a weekly home-visit play intervention delivered by community health workers which aims to build parents skills to interact with their children in ways that promote development and early learning.

Who can participate?
Children and their main caregiver (usually their mother) identified from several poor neighbourhoods in Kingston, Jamaica. Children can participate if they are aged between 9-24 months on enrolment, and are stunted (low height-for-age). A group of non-stunted children of the same age and from the same neighbourhoods are also enrolled and followed but they do not participate in the study.

What does the study involve?
Stunted children aged 9-24 months are identified by a house-to-house survey of poor neighbourhoods in Kingston, Jamaica and randomly allocated to one of the four study groups (nutrition, play, combined interventions, no intervention). A group of non-stunted children from the same neighbourhoods are also followed but are not part of the study. Free healthcare is provided to all groups. The interventions are given singly or in combination for 2 years. Children' s development and growth are measured on enrolment and every 6 months, their home environment is assessed on enrolment and at the end of the study and information on child illnesses is obtained weekly.

What are the possible benefits and risks of participating?
The only direct benefit to children and caregivers is access to free primary health care from a family physician. The study is minimal risk. There is a possible risk that some children might not tolerate the milk-based supplement

Where is the study run from?
Tropical Metabolism Research Unit, The University of the West Indies, Kingston (Jamaica)

When is the study starting and how long is it expected to run for?
January 1986 to November 1989

Who is funding the study?
The Ford Foundation (USA)

Who is the main contact?
1. Prof. Sally Grantham-McGregor
2. Prof. Susan Walker
susan.walker@uwimona.edu.jm

Contact information

Type(s)
Scientific

Contact name
Prof Susan Walker

ORCID ID
https://orcid.org/0000-0001-9494-1116

Contact details
Caribbean Institute for Health Research
The University of the West Indies, Mona
Kingston
Jamaica
7
+876 (0)9272471
susan.walker@uwimona.edu.jm

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Nutritional supplementation, psychosocial stimulation and the development of stunted children: the Jamaica study

Study objectives
Nutritional supplementation and psychosocial stimulation will each benefit the development of stunted children and the combined intervention will have greater benefits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained in 1986 from the Ethics Committee of the University Hospital of the West Indies. The ethics committee at the time of the study was reorganised and the name changed. The current information is: Mona Campus Research Ethics Committee, Faculty of Medical Sciences, The University of the West Indies, Mona, Kingston 7, Jamaica; Tel: +876 (0)970 4892; Email: mcrec@uwimona.edu.jm, no approval number available

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Child development in stunted children (height-for-age < -2SD of reference values)

Interventions
Stunted children aged between 9 and 24 months identified by a survey of poor neighbourhoods in Kingston were stratified by age (above or below 16 months) and sex and randomly assigned to one of four groups: supplementation, stimulation, both interventions, or a control group. Interventions were provided weekly for two years A comparison group of non-stunted children from the same neighbourhoods was also followed.

Supplementation: The supplement comprised 1 kg milk-based formula per week, delivered to the home weekly. Some additional food (cornmeal and skimmed milk powder) was provided to the family to reduce the sharing of the child's supplement.

Stimulation: The objectives of the stimulation intervention were to increase the mother's ability to promote her child's development through play, to improve mother-child interaction, and to promote the self-esteem of both mother and child. At the weekly visit, the CHWs demonstrated play techniques and involved the mother in a play session with her child. Mothers were encouraged to continue play activities between the visits and to integrate them into their daily routines. Emphasis was placed on language, the use of praise and positive reinforcement, and physical punishment was discouraged. Toys made from commonly discarded household materials and simple picture books were left in the home and exchanged each week.

Control: No treatment - access to free health care only (see below)

Supervisors monitored the quality of visits for all groups. All groups were visited weekly by a community health worker (CHW) for two years and were provided free health care (in addition to routinely available primary healthcare)

Intervention Type
Mixed

Primary outcome(s)
Child development measured with the Griffiths Scales of mental development on enrollment at age 9-24 months and every 6 months for two years. Overall developmental quotient and 4 subscales

Key secondary outcome(s))
1. Growth measured using standard anthropometry (height, weight, head circumference, triceps and subscapular skinfold) on enrolment and every 6 months for 2 years
2. Home stimulation measured with HOME (home observation for measurement of the environment) on enrolment and at the end of the trial (24 months later)
3. Morbidity measured by maternal recall weekly for 2 years

Completion date
13/11/1989

Eligibility

Key inclusion criteria
1. Height-for-age below -2SD of NCHS reference values
2. Age 9-24 months
3. Weight-for-height below median of NCHS reference values
4. Standard of housing and maternal education below defined levels

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 months

Upper age limit
24 months

Sex
All

Key exclusion criteria

1. Twins
2. Birth weight equal to or below 1.8 kg
3. Significant mental or physical disability

Date of first enrolment
06/01/1987

Date of final enrolment
11/11/1987

Locations

Countries of recruitment
Jamaica

Study participating centre
Tropical Metabolism Research Unit (now Caribbean Institute for Health Research)
The University of the West Indies, Mona Campus
Kingston
Jamaica
7

Sponsor information

Organisation
University of the West Indies

ROR
https://ror.org/03fkc8c64

Funder(s)

Funder type
Charity

Funder Name
Ford Foundation

Alternative Name(s)
Ford Foundation Center for Social Justice, Ford, The Ford Foundation, FF

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data is part of ongoing longitudinal research and participant-level data from the trial is not generally available. The data is held at the Caribbean Institute for Health Research

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/07/1991	06/12/2019	Yes	No
Results article	results	01/10/1991	06/12/2019	Yes	No
Results article	results	01/01/1993	06/12/2019	Yes	No