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# 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
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Susan Walker

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# Additional identifiers

# 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

## Primary study design
Interventional

## Study design
Randomized controlled trial

## 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
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## 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 |