

Evaluation of parenting interventions to promote child development through home visits or a health centre based approach in three Caribbean countries

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| Submission date 06/05/2011 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 06/06/2011 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 21/01/2019 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Home and health centre delivery of early childhood stimulation: cluster randomised trial of the impact of interventions to improve parenting of children aged 2-18 months on child development in the Caribbean countries

Study objectives

There is substantial evidence from efficacy trials of benefits to child development from parenting programs with home visits to improve mother-child interaction and demonstrate activities to promote development. The interventions were delivered by paraprofessionals who visited the homes weekly. Although low cost compared to programs in the USA, these interventions are often too expensive to take to scale in many countries. The challenge is to develop programs that are feasible at scale yet remain effective. We are evaluating a modified home visiting approach using fewer visits and materials and a new health centre approach using a specially designed video of child development messages to be shown at all child health visits from age 2-18 months.

We hypothesise:

1. A home visiting intervention delivered by trained community health workers every 2 weeks from age 6-18 months with the objective of helping mothers promote their child development will improve parent-child interaction, quality of stimulation in the home and child development.
2. A health centre based intervention at routine child health visits from age 2-18 months using videos of child development messages that demonstrate mother-child interactions followed by discussion and practice led by trained community health workers will improve parent-child interaction, quality of stimulation and child development.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University Hospital of the West Indies/ University of the West Indies/ Faculty of Medical Sciences
Ethics Committee approved on 20th January 2011, Ref: ECP 18, 10/11

Study design

Multicentre cluster randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Early child development

Interventions

1. In Jamaica 20 Health centres will be randomly assigned to one of 4 groups:
 - 1.1. Health Centre intervention
 - 1.2. Home visit
 - 1.3. Both interventions
 - 1.4. Control
2. In Antigua and St Lucia 10 health centres in each country will be randomly assigned to Health centre intervention or control
3. Participants (mothers and infants) will be recruited at the health centre at the 6 week post natal clinic visit
4. Follow-up assessment will be at age 19-20 months
5. Health centre intervention: video will be developed, in collaboration with a team experienced in effective use of media for health education, to deliver a series of child development messages. The videos will be shown at all child health clinics which are scheduled at 3, 6, 9, 12 and 18 months of age.
7. In each clinic a community health worker will be trained to discuss the video messages with the mothers, demonstrate activities mothers can do with their children and how to make simple toys from household materials
8. Opportunities will be given for mothers to try some of the activities and they will be encouraged to make them part of their daily routine
9. Home visiting intervention: will be based on that used previously in Jamaica modified to increase the feasibility of scaling up
10. Visit frequency will be reduced from weekly to twice monthly and supervision will be by nurses rather than a child development specialist
11. Children will be visited from 6 to 18 months of age by trained community health workers and play sessions conducted to improve mother-child interaction and show mothers how to promote development
12. Separate training workshops will be held for the community health aides involved in the two types of interventions
13. A supervisor will provide ongoing support to implementation of the interventions
14. Control: centres will continue to provide the usual care at all child health visits

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Child Psychomotor development: Griffiths Scales of Mental Development to assess the childrens' development at age 19-20 months
2. The scales have been used frequently in Jamaica where it has good concurrent and predictive

validity

3. Language development: the short version of the MacArthur Communicative Development Inventory (Short Communicative Development Inventory, CDI) will be used to measure language development based on mothers' report

Secondary outcome measures

1. Child growth: weight, length and head circumference will be measures on enrolment at age 6-8 weeks and at age 19-20 months
2. Child behaviour: ratings of behaviour during the developmental test session
3. Maternal parenting knowledge, practices and depressive symptoms will be measured on enrolment and at age 19-20 months
4. Mothers knowledge of child development will be assessed by questionnaire
5. Stimulation in the home will be assessed with a subset of questions from the Home Observations for Measurement of the Environment (HOME)
6. Maternal depressive symptoms will be assessed using the CES depression scale

Overall study start date

15/07/2011

Completion date

15/12/2013

Eligibility

Key inclusion criteria

1. Mothers and infants attending government (public) primary care health centres for child care
2. Mothers and infants will be recruited at the six week post natal clinics

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Total participants 600: Jamaica 400, Antigua 100, St Lucia 100

Key exclusion criteria

1. Infants with obvious mental or physical disabilities
2. Twins

Date of first enrolment

15/07/2011

Date of final enrolment

15/12/2013

Locations

Countries of recruitment

Antigua and Barbuda

Jamaica

Saint Lucia

Study participating centre

Tropical Medicine Research Institute

Kingston

Jamaica

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Sponsor information

Organisation

The University of the West Indies (Jamaica)

Sponsor details

Tropical Medicine Research Institute

The University of the West Indies

Mona

Kingston

Jamaica

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Sponsor type

University/education

Website

<http://mona.uwi.edu>

ROR

<https://ror.org/03fkc8c64>

Funder(s)

Funder type

Research organisation

Funder Name

Inter-American Development Bank (USA) Ref: ATN/SF-12300-RG

Alternative Name(s)

Banco Interamericano de Desarrollo, Banco Interamericano de Desenvolvimento, Banque Interaméricaine de Développement, IADB, BID, IDB

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United States of America

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|--|--------------|------------|----------------|-----------------|
| Results article | results | 31/10/2017 | 21/01/2019 | Yes | No |
| Results article | results of integrating a parenting intervention with routine primary health care, | 01/08/2015 | 21/01/2019 | Yes | No |
| Results article | results of the impact, acceptability and costs of delivering parenting interventions through health services in the Caribbean, | 01/11/2015 | 21/01/2019 | Yes | No |