

Measuring the benefits of the Reach Up early childhood parenting programme in Jamaica

Submission date 17/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/09/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

At the World Health Assembly, in May 2018 the WHO launched the Nurturing Care Framework that places responsive caregiving and opportunities to learn for children 0-3 years as important components of care for young children and calls on government to provide the necessary support and services for families who are the primary providers of care for young children.

The Reach Up early childhood parenting intervention is based on strengthening the capacity of mothers and other caregivers to promote optimal development of their children, through responsive interactions and play activities. The intervention is delivered through home visits by community workers and has been implemented in several countries with consistent benefits for children's cognition and language development.

The Jamaica Ministry of Health (MOH) plans to implement Reach Up in all parishes in Jamaica. There are 13 administrative parishes. Implementation will be through a phased rollout beginning in one health district per parish. Within each district, the intervention will be implemented in 1-3 health centres that will be supervised by the nurses trained in the intervention. The intervention will be implemented on a fortnightly basis and will be conducted through the health centres in each district. We propose to use the initial phase to evaluate the implementation process to inform the continued roll-out of the programme and the impact of the intervention on child development and parenting when implemented at a larger scale. This evaluation will inform the further rollout of the programme and assess the impact on child development and parenting attitudes and behaviours when it is carried out at a larger scale. The main research questions are:

1. What are the benefits to child development and behaviour when the Reach Up programme is delivered through government primary health care services in Jamaica?
2. What are the factors associated with a successful implementation of the Reach Up programme as delivered through routine health services across Jamaica?

Who can participate?

Children from poor circumstances between the ages of 5-24 months.

What does the study involve?

After mothers provide consent, they will be enrolled in the study, and randomly assigned to the

intervention or control groups. The control group will receive the usual care at the health centre. The intervention group will receive visits from a trained community health aide every two weeks. She will show the mother different activities that she can do with her child to help him/her develop well. The visits will be done over a 10 month period, starting June 2019, with initial enrolment in May 2019.

What are the possible benefits and risks of participating?

There are minimal risks involved in participation in the study and the study has been approved by the Ethics committee of the University of the West Indies. After the visits are completed, each child's development will be assessed. Mothers will receive these results and if there is a need, they will be referred to a health care professional. Impact and implementation evaluations will be conducted in all parishes, within the health districts participating in the study.

Where is the study run from?

The Caribbean Institute for Health Research, The University of the West Indies.

When is the study starting and how long is it expected to run for?

May 2019 to April 2024 (updated 01/04/2022, previously: March 2021; updated 05/11/2019, previously: October 2020)

Who is funding the study?

The Ministry of Health in Jamaica and the Inter-American Development Bank (IADB).

Who is the main contact?

Professor Susan Walker, Director, Caribbean Institute of Health Research, the University of the West Indies, Mona, Kingston. Email: susan.walker13@gmail.com

Study website

N/A

Contact information

Type(s)

Scientific

Contact name

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Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

001

Study information

Scientific Title

Reach up early childhood parenting programme: evaluation of implementation and benefits in Jamaica

Acronym

Reach Up Jamaica

Study objectives

1. What are the benefits to child development and behaviour when the Reach Up home visiting programme is delivered through government primary health care services in Jamaica?
2. What are the factors associated with a successful implementation of the Reach Up home visiting programme as delivered through routine health services across Jamaica?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/11/2018, The University of the West Indies Ethics Committee (Ethics Office, Faculty of Medical Sciences, The University of the West Indies, Mona Campus, Jamaica, W.I.; Telephone: 876-970-4892 or ext 8026 or 8192; ethics.committee@uwimona.edu.jm), ref: ECP 187, 17/18.

Study design

Randomized control trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Child development and behaviour

Interventions

Current intervention as of 01/04/2022:

The home visit intervention was suspended in March 2020. At that time intervention had begun in 6 of 13 health districts in which the study was planned. We modified the intervention to be conducted by remote delivery and this was implemented from September 2020 to August 2021, for participants in the 6 parishes (24 health centres) that had started the home visit intervention prior to March 2020. The new round of participants being recruited will be randomized to control or intervention using a blended approach

The remote delivery comprised a manual of play activities and a few play materials given to parent, fortnightly phone calls from the community health worker to provide guidance on activities (in place of the home visits that were also fortnightly) and 1-2 text messages to parents each week. In the blended intervention we will combine delivery by home visits and phone calls, together with other components of remote delivery (text messages, parent manual). At this time intervention duration is planned for 8 months. This may be extended to 12 months pending a further funding extension.

Measurement of child development was not possible at the end of the remote delivery due to need for face-to-face interaction. Measurement of parent practices related to child development was changed from the Home Observation for Measurement of the Environment (HOME) to an adaptation of the Family Care Indicators questionnaire which was administered by

telephone interview. Qualitative interviews with subsamples of parents, community health workers and nurses to obtain information on implementation processes were also conducted by phone interviews.

Previous intervention:

After enrolment, participants will be individually randomized to the control or intervention group using random number tables. The intervention will be conducted fortnightly for 10 months by community health aides (CHAs) already employed to the health services. The CHAs will visit the participant's homes and demonstrate activities to the mother using the Reach Up curriculum and encourage her to practice them during the visit and the next two weeks. These activities will strengthen the capacity of mothers and other caregivers to promote optimal development of their children, through responsive interactions and play activities. The play materials used during the visit will be left at the home until the CHA returns two weeks later. The control group will receive the usual health care provided by the health centres.

Intervention group: Each family will receive the usual health care provided by the health centre along with fortnightly (every 2 weeks) visits at home from a community health aide. At this visit, she will demonstrate play activities to the mother and encourage her to practice these activities during the 2-week interval. These visits will be conducted over 10 months. At the end of this period, families will be contacted by the research team and an impact evaluation conducted.

Control group: Each family will receive the usual health care provided by the health centre. After 10 months families will be contacted and an impact evaluation conducted.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 01/04/2022:

1. Child Developmental Quotient (Total Score) is measured using the Griffiths Mental Development Scales- Extended Revised (GMDS-ER) (ARICD, 2006) at the end of the trial.
2. Mother/caregiver stimulation in the home (Total Score) measured using an adaptation of the Family Care Indicators questionnaire administered by telephone interview at the end of the trial.

Previous primary outcome measure:

1. Child Developmental Quotient (Total Score) is measured using the Griffiths Mental Development Scales- Extended Revised (GMDS-ER) (ARICD, 2006) at the end of the trial.
2. Mother/caregiver stimulation in the home (Total Score) is measured using the Infant/Toddler HOME questionnaire (Caldwell, 2003) at enrollment and at the end of the trial.

Secondary outcome measures

Current secondary outcome measures as of 01/04/2022:

1. Child development Sub-scales (Hearing and Language, Eye and Hand Coordination and Performance) are measured using the Griffiths Mental Development Scales- Extended Revised (GMDS-ER) (ARICD, 2006) at the end of the trial.
2. Maternal attitudes to child development are measured using the Parenting attitudes questionnaire at enrollment and at the end of the trial.
3. Maternal depressive symptoms are measured using the Center for Epidemiological Studies- Depression Scale (CES-D) (Radloff, 1977) at enrollment and at the end of the trial.

4. Maternal/caregiver stimulation in the home (Sub-scales: Involvement, Organization, Variety, Responsivity, Acceptance and Learning Materials) measured using an adaptation of the Family Care Indicators questionnaire administered by telephone interview at the end of the trial.

Previous secondary outcome measures:

1. Child development Sub-scales (Hearing and Language, Eye and Hand Coordination and Performance) are measured using the Griffiths Mental Development Scales- Extended Revised (GMDS-ER) (ARICD, 2006) at the end of the trial.
2. Maternal attitudes to child development are measured using the Parenting attitudes questionnaire at enrollment and at the end of the trial.
3. Maternal depressive symptoms are measured using the Center for Epidemiological Studies-Depression Scale (CES-D) (Radloff, 1977) at enrollment and at the end of the trial.
4. Maternal/caregiver stimulation in the home (Sub-scales: Involvement, Organization, Variety, Responsivity, Acceptance and Learning Materials) is measured using the Infant/Toddler HOME questionnaire (Caldwell, 2003) at enrollment and at the end of the trial.

Overall study start date

13/05/2019

Completion date

30/04/2024

Eligibility

Key inclusion criteria

1. The child is between 5-24 months

At least one of the following:

1. The child referred to the nutrition clinic for under-nutrition
2. Child whose last recorded height-for-age measurement was below -1SD of the WHO reference standards
3. Families where the child or mother is registered with the conditional cash transfer programme (PATH)
4. Mothers who are currently pregnant with a child under 2 years of age
5. Children who live in low socioeconomic environments
6. Adolescent mothers 16-19 years

Participant type(s)

Mixed

Age group

Child

Lower age limit

5 Months

Upper age limit

24 Months

Sex

Both

Target number of participants

1040 (40 children in the intervention group per district and another 40 children per district in the waitlist (control) group with a total of 520 per group across all parishes)

Total final enrolment

627

Key exclusion criteria

1. Child is in Daycare or has no consistent caregiver
2. The baby has a major disability likely to affect their development
3. Mother is aged under 16 years

Date of first enrolment

20/05/2019

Date of final enrolment

17/03/2023

Locations

Countries of recruitment

Jamaica

Study participating centre

Morant Bay Health Centre

Morant Bay

St. Thomas

Jamaica

-

Study participating centre

White Horses Health Centre

Morant Bay

St. Thomas

Jamaica

-

Study participating centre

Gordon Town Health Centre

Gordon Town

Kingston

Jamaica

-

Study participating centre
Mavis Bank Health Centre
Mavis Bank
St. Andrew
Jamaica

-

Study participating centre
Sydenham Health Centre
Sydenham
Spanish Town
St. Catherine
Jamaica

-

Study participating centre
Spalding Health Centre
Spalding
Clarendon
Jamaica

-

Study participating centre
Cumberland Health Centre
Spalding
Clarendon
Jamaica

-

Study participating centre
Tweedside Health Centre
Spalding
Clarendon
Jamaica

-

Study participating centre

Porus Health Centre

Porus
Manchester
Jamaica

-

Study participating centre

Harmon Health Centre

Porus
Manchester
Jamaica

-

Study participating centre

Bellefield Health Centre

Porus
Manchester
Jamaica

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Study participating centre

Santa Cruz Health Centre

Santa Cruz
St. Elizabeth
Jamaica

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Study participating centre

Brae's River Health Centre

Santa Cruz
St. Elizabeth
Jamaica

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Study participating centre

Lacovia Health Centre

Santa Cruz
St. Elizabeth
Jamaica

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Study participating centre
New Market Health Centre
Santa Cruz
St. Elizabeth
Jamaica

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Study participating centre
Grange Hill Health Centre
Grange Hill
Westmoreland
Jamaica

-

Study participating centre
Baulk Health Centre
Grange Hill
Westmoreland
Jamaica

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Study participating centre
Jerusalem Mountain Health Centre
Grange Hill
Westmoreland
Jamaica

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Study participating centre
Lucea Health Centre
Lucea
Hanover
Jamaica

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Study participating centre
Dias Health Centre
Lucea
Hanover

Jamaica

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Study participating centre

Great Valley Health Centre

Lucea

Hanover

Jamaica

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Study participating centre

Kingsvale Health Centre

Lucea

Hanover

Jamaica

-

Study participating centre

Maryland Health Centre

Lucea

Hanover

Jamaica

-

Study participating centre

Askenish Health Centre

Lucea

Hanover

Jamaica

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Study participating centre

Cascade Health Centre

Lucea

Hanover

Jamaica

-

Study participating centre

Mount Salem Health Centre
Montego Bay
St. James
Jamaica
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Study participating centre
Glen Devon Health Centre
Montego Bay
St. James
Jamaica
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Study participating centre
Green Pond Health Centre
Montego Bay
St. James
Jamaica
-

Study participating centre
Salt Spring Health Centre
Montego Bay
St. James
Jamaica
-

Study participating centre
Ulster Spring Health Centre
Albert Town
Trelawny
Jamaica
-

Study participating centre
Troy Health Centre
Albert Town
Trelawny
Jamaica
-

Study participating centre
Worsop Health Centre
Albert Town
Trelawny
Jamaica

-

Study participating centre
Rock Spring Health Centre
Albert Town
Trelawny
Jamaica

-

Study participating centre
Alexandria Health Centre
Alexandria
St. Ann
Jamaica

-

Study participating centre
Stepney Health Centre
Alexandria
St. Ann
Jamaica

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Study participating centre
Bohemia Health Centre
Alexandria
St. Ann
Jamaica

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Study participating centre
Borobridge Health Centre
Alexandria
St. Ann

Jamaica

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Study participating centre

Clarksonville Health Centre

Alexandria

St. Ann

Jamaica

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Study participating centre

Muirhead Health Centre

Alexandria

St. Ann

Jamaica

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Study participating centre

Gayle Health Centre

Gayle

St. Mary

Jamaica

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Study participating centre

Woodpark Health Centre

Gayle

St. Mary

Jamaica

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Study participating centre

Huntstown Health Centre

Gayle

St. Mary

Jamaica

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Study participating centre

Fellowship Hall Health Centre

Gayle
St. Mary
Jamaica

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Study participating centre

Labrynth Health Centre

Gayle
St. Mary
Jamaica

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Study participating centre

Retreat Health Centre

Gayle
St. Mary
Jamaica

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Study participating centre

Jeffrey Town Health Centre

Gayle
St. Mary
Jamaica

-

Study participating centre

Manchioneal Health Centre

Manchioneal
Portland
Jamaica

-

Study participating centre

Fair Prospect Health Centre

Manchioneal
Portland
Jamaica

-

Study participating centre
Fairy Hill Health Centre
Manchioneal
Portland
Jamaica
-

Sponsor information

Organisation

The University of the West Indies

Sponsor details

Caribbean Institute for Health Research
The University of the West Indies
Mona
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876-927-2471
caihr.eru@uwimona.edu.jm

Sponsor type

University/education

Website

<http://mona.uwi.edu>

ROR

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

Funder(s)

Funder type

Government

Funder Name

Ministry of Health

Alternative Name(s)

Ministry of Health Jamaica, Ministry of Health, Jamaica, MOH

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Jamaica

Funder Name

Inter-American Development Bank

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

Current publication and dissemination plan as of 01/04/2022:

We intend to publish the following:

1. The main impact of the intervention on the child and maternal outcomes with an intention-to-treat analysis
2. How impact varies by child and family characteristics e.g. gender, maternal education; and whether change in parenting attitudes or practices (HOME) mediates any impact of the intervention on child development
3. Papers focusing on the implementation of the intervention and how implementation factors may be linked to the outcomes
4. Presentations at conferences and regional/international meetings will also be included in the dissemination plans

We intend to publish after data collection has been completed.

We are submitting a manuscript for publication on the impact of the remote delivery on parent practices and on the implementation process of the remote delivery. We anticipate further publications based on the blended intervention.

Previous publication and dissemination plan:

We intend to publish up to 4 publications:

- 1. The main impact of the intervention on the child and maternal outcomes with an intention-to-treat analysis
- 2. How impact varies by child and family characteristics e.g. gender, maternal education; and whether change in parenting attitudes or practices (HOME) mediates any impact of the intervention on child development
- 3. Papers focusing on the implementation of the intervention and how implementation factors may be linked to the outcomes
- 4. Presentations at conferences and regional/international meetings will also be included in the dissemination plans

We intend to publish in mid-2021 after data collection has been completed.

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2023	15/04/2024	Yes	No