

Improving child development in children in Madagascar

Submission date 20/05/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Over half of the world's children suffer from poor nutrition, and as a consequence they experience delays in physical and mental health and development. Previous attempts to reduce the prevalence of malnutrition in contexts of extreme poverty have not shown big effects. There is little evidence that compares the delivery of lipid-based, nutrition supplementation on growth and development during pregnancy and early childhood; furthermore, there is limited evidence on effects of scaled-up, home-visiting programs that focus on the promotion of physical, cognitive and social development. The objective of this study is to fill this gap.

Who can participate?

All pregnant women and women with age-eligible children living in the area of a project site are eligible to participate in the standard growth monitoring and nutritional education that occurs in a group setting in a community center in all sites. If a community is randomly selected to receive a treatment, then households in that community may receive nutritional supplementation.

What does the study involve?

The study involves giving a special food to children and pregnant women who are at risk of suffering from malnutrition. The special food is like peanut butter, and has a flavor that children and their mothers like.

What are the possible benefits and risks of participating?

There are benefits for children participating in the study because anyone who is found to be severely malnourished or anemic will be referred for treatment according to national treatment guidelines. In terms of risks, the study procedures are harmless, although the blood samples that will be collected (capillary blood samples for hemoglobin testing and micronutrient testing in the subgroup) may cause temporary discomfort. Any adverse events arising during the study will be treated within the national health system.

Where is the study run from?

The study is run from a number of sites in Madagascar.

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

July 2014 to December 2019

Who is funding the study?

This study is funded by Strategic Impact Evaluation Fund (SIEF), the World Bank Innovation Grant, the Early Learning Partnership Grant, and the National Nutrition Office in Madagascar.

Who is the main contact?

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A cluster-randomized, controlled trial of nutritional supplementation and promotion of responsive parenting in Madagascar: the MAHAY study

Acronym

MAHAY

Study objectives

1. Will growth faltering be prevented through intensive counseling and/or nutritional supplementation?
2. What is the optimal timing and composition of interventions (e.g. counseling and/or nutritional supplementation and/or other options) to reduce linear growth faltering?
3. What is the most cost-effective way to prevent linear growth faltering?
4. What are the synergies and complementarities of integrating nutrition and early stimulation home visits within a large scale program?
5. Can an existing service-delivery infrastructure be used to deliver the proposed interventions at scale?

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University of California, Davis Institutional Review Board and the Madagascar Ministry of Public Health Ethics Committee, 17/07/2013, ref: 481369
2. Madagascar Ministry of Public Health, 05/08/2013

Study design

Multi-arm randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

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

Poor nutrition and development of physical and mental health in children

Interventions

T0: The status quo program. The community-based nutrition program in Madagascar originated from a World Bank financed program (SEECALINE). It is a large-scale program that started in 1999 and was gradually scaled up until 2003 to cover 3,600 project sites in more than half of the country's districts. In 2004/2005 the program was institutionalized and adopted to become the national nutrition program (Programme National de la Nutrition Communautaire or PNNC), which was subsequently scaled up to cover all districts of the country. To maximize geographical coverage as well as to provide quality services on a large-scale, the program is contracted out to local NGOs for implementation (management, delivery, operations research and supervision) at the local level, reporting to the regional units of the National Nutrition Office. The services are

delivered locally by community nutrition workers (agent communautaire de la nutrition, ACN), who are usually women elected by the local communities. The basic counseling model was built upon the Essential Nutrition Actions model developed by UNICEF and GAIN. Key messages include information about maternal nutrition, early initiation of breastfeeding, exclusive breastfeeding for the first 6 months, continued breastfeeding through 2 years, dietary diversification and food conservation and preparation using locally available products, together with the promotion of age-appropriate feeding practices and hygiene practices. The messages are delivered at monthly growth monitoring sessions attended by pregnant/lactating women as well all eligible children (0-3, subsequently raised to 0-5). The promotion of behavioral change (besides the growth monitoring sessions) includes nutrition and hygiene education sessions, and cooking demonstrations by the community nutrition worker where she emphasizes the appropriate complementary feeding practices and prepares recipes that rely on locally available products to promote a healthy and diversified diet. The long term evaluation (spanning 14 years) showed that during the expansion phase, key aspects of the quality of service delivery (namely the number of children/worker ratios as well the training and the knowledge of community workers) worsened significantly over time.³⁴

T1 Intensive counseling: Given the disappointing long-term results of the existing nutrition support program, the ONN reviewed past experiences, engaged in a South to South exchange with Alive and Thrive/BRAC in Bangladesh, and introduced an added community nutrition worker (ACDN) fully dedicated to home visits, to complement the community worker (ACN) who delivers group growth monitoring activities. The nutrition counseling is designed to reach all children in the community up to 2 years old (one visit during pregnancy, monthly visits during the first 8 months, bimonthly visits during the window of 9-12 months and quarterly visits from 12 to 24 months). The ACDNs received training with a special emphasis on listening and communication skills, problem solving for exclusive breastfeeding, introduction of complementary feeding, and food security. The counseling interventions are based upon an underlying behavioral theory of change utilizing constructs from an Integrated Behavioral Model (IBM).³⁵

T2 Intensive counseling + LNS for children: In a second arm, 6-18 month old children are supplemented with 20 g/day of LNS, which provide 118 kcal/ day and approximately 100% of the recommended nutrient intakes (RNI) for young children.³⁶ Families are supposed to mix the 10g sachets of supplement into their children's typical food twice per day. A monthly supply of LNS is provided to mothers for all children in the household within the target age by distributing them at their monthly growth monitoring session for their monthly LNS ration. Through the project, LNS distribution logs are utilized to monitor adherence to consumption recommendations and to monitor the efficiency of the LNS deliveries.

T3 intensive counseling + LNS for pregnant and lactating women + LNS for children: In this arm, there is an added supplement for pregnant women and breastfeeding women (within the first six months postpartum). The supplement is a 40 g/day, providing about 200 kcal/day and 1-2 times the RDA of micronutrients for pregnant women (Appendix A). A monthly supply of supplements will be provided to mothers in a similar way as described above for the child supplements. For groups T2 and T3, the manufacturer worked with ONN to develop culturally appropriate brand names, packaging for the supplements, and social marketing materials. In addition, they conducted an acceptability trial including a taste test and two-week in-home trial to evaluate mothers' opinions of the product's taste, consistency, and their ability to integrate it into their usual food preparation practices.

T4: integrated counseling on nutrition and early stimulation/home visiting: A fourth arm adds home visits on early stimulation to the home visits on intensive counseling. The structured curriculum on early stimulation was adapted from the Jamaica home visiting program,³⁷ as part of a south to south collaboration. The materials, books, pictures and training modules were adapted to fit the local context by a team of child development specialists led by the psychologist in the research team [LR]. In order to ensure sufficient intensity of the cognitive

stimulation component of the home visit, and considering the workload of the added community nutrition workers (ACDN), only households selected to be participating in the baseline survey were considered eligible to be receiving the stimulation home visits in the T4 communities, and tailored to target child identified in the baseline survey. Home visits are bi-weekly, over and above the home visits for the nutrition counseling. The curriculum starts at age 6 and administered until the endline survey. Other households with children in target communities that were not sampled for the baseline survey will be offered unstructured access to the community site, supplemented by with a package of toys and books.

Intervention Type

Supplement

Primary outcome measure

1. Measures of nutrition impact including height-for-age and stunting
2. Measures of child development including language, cognitive development

Secondary outcome measures

1. Wasting
2. Being underweight
3. Iron deficiency and anemia
4. Intermediate indicators of nutrition and development pathway outcomes including:
 - 4.1. Dietary diversity
 - 4.2. Household food security
 - 4.3. Maternal knowledge of child care and feeding practices
 - 4.4. Home stimulation practices

Overall study start date

01/07/2014

Completion date

31/12/2019

Eligibility

Key inclusion criteria

All pregnant women and women with age-eligible children living in the catchment area of a project site are eligible to participate in the standard growth monitoring and nutritional education that occurs in a group setting in a community center in all sites.

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

50 communities, 30 participants from each community

Total final enrolment

3738

Key exclusion criteria

Severe malnutrition (will be referred for treatment)

Date of first enrolment

01/09/2014

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

Madagascar

Study participating centre

National Community Nutrition Program (Programme National de la Nutrition Communautaire)

Madagascar

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Sponsor information

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ROR

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Funder(s)

Funder type

Government

Funder Name

Strategic Impact Evaluation Fund, The World Bank

Funder Name

World Bank Innovation Grant

Funder Name

Early Learning Partnership Grant

Funder Name

World Bank Research Budget

Funder Name

National Nutrition Office in Madagascar

Funder Name

Berkeley Population Center, UC Berkeley

Results and Publications

Publication and dissemination plan

We plan to publish the protocol within the next year, and then the impact results in 2-3 years.

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/06/2016		Yes	No

Results article	results	01/09/2019	14/08/2019	Yes	No
Results article	results	01/04/2020	03/02/2020	Yes	No
Other publications		11/09/2019	10/07/2023	Yes	No