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Efficacy of a behavioural intervention based on food consumption, nutritional state and micronutrient deficiency in under five children, Angola

Submission date
02/06/2016

Recruitment status
No longer recruiting

Registration date
05/08/2016

Overall study status
Completed

Last Edited
22/09/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In 2013, more than 6.3 million children under 5 years of age (U5) died worldwide. According to the World Health Organization (WHO), 70% of these deaths occur in the first year of life and malnutrition is one of the main causes, associated with around 45% of deaths. Feeding practices, maternal care during infancy, sanitation and hygiene have been reported as essential factors which can help to ensure children grow healthily and develop to their full potential. In Angola, a national study performed in 2007 revealed that 8.2% of children U5 suffered from acute (sudden) malnutrition and 29.2% were in a situation of moderate chronic (long-term) malnutrition, which was recognised as a serious public health problem. This study is testing the effectiveness of two different behavioural programmes, designed to encourage good feeding and health practices (nutrition) and promote hygiene practices and malaria prevention (WASH). The aim of this study is to find out whether taking part in the nutrition or WASH programmes can help to improve growth in children U5 and reduce rates of malnutrition and parasitic disease (such as malaria).

Who can participate?
All children living in participating hamlets under 36 months old and their primary caregivers.

What does the study involve?
After agreeing to take part in the study, hamlets are randomly allocated to one of three groups. Participants living hamlets in the first group take part in a nutrition program. This involves receiving 12 personalized home-based counseling visits, delivered in blocks of three at the start of the study and then every six months for one and a half years. The visits involve caregivers learning about the best feeding practices to use to ensure their children are healthy. Participants also attend four community group meetings at the start of the study and then every six months for one and a half years which focus on the same topics. Those living in hamlets in the second group receive home visits and community meetings at the same times but these include information about good hygiene practices and malaria prevention. Those living in hamlets in the

third group do not receive any educational package during the study. For participants in all groups, the growth (through body measurements) and nutritional status (through blood testing) of the children is measured every six months from the start of the trial until one and a half years to monitor malnutrition rates. At these time, blood and feces samples are also taken to test for parasitic infections (malaria and worms).

What are the possible benefits and risks of participating?
All participants benefit from receiving individual clinical assessments and proper treatment without any financial cost. Participants also benefit from continual monitoring for health conditions. Risks of participating are minor however some participants may experience pain, bruising or infection (in rare cases) following blood testing. Additionally, some children may find it uncomfortable getting undressed when having their body measurements taken.

Where is the study run from?
The study is run from the Heath Research Centre of Angola and takes place in participating hamlets in Angola.

When is the study starting and how long is it expected to run for?
November 2014 to November 2017

Who is funding the study?
1. Calouste Gulbenkian Foundation (Angola)
2. Camões - Cooperation Institute and Language (Angola)
3. Ministry of Health of Angola (Angola)
4. Banco de Fomento Angola (Angola)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2014-2017Nutrition&WASH/malaria

Study information

Scientific Title
Randomised controlled trial – efficacy of an behavioural intervention based on feeding, WASH and malaria preventive parental practices on nutritional state, deficiency of micronutrients and parasitological infection in under five (U5) children – Angola, 2015-17

Acronym
Nutrition&WASH/malaria

Study objectives
1. A behavioural nutrition or WASH/malaria educational package has better results in the reduction of malnutrition, micronutrient deficiency and parasitological infection than treatment and usual routine counselling from the local health facilities
2. A behavioural nutrition educational package has better results in the reduction of malnutrition, micronutrient deficiency and parasitological infection than a behavioural WASH /malaria educational package

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Angolan Ministry of Health Ethics Committee

Primary study design
Interventional

Study design
Three-arm randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Malnutrition, micronutrients deficiencies and parasitological infections

Interventions
After enrolment the hamlets will be randomly assigned into either one intervention arm (nutrition or WASH/malaria) or control study arm (see table 1) of three study arms by simple randomization following lottery method.

Nutrition Arm: Participants receive 12 personalized home-based counselling visits divided in blocks of 3 monthly visits after baseline and each follow up timepoint (6, 12,18 months). These visits involve the delivering of 11 key recommendations and messages for promoting infant and young children optimal feeding practices regarding breastfeeding, complementary feeding

(dietary diversity, meal frequency and quantity of food), responsive feeding, feeding during and after illness; hygiene and food safety. Participants also attend four communitarian group meetings at baseline, 6, 12 and 18 months, which focus on the key messages along theoretical and practical sessions.

WASH Arm: Participants receive 12 personalized home-based counselling visits divided in blocks of 3 monthly visits after baseline and each follow up timepoint (6, 12,18 months). These visits involve the delivering of 11 key recommendations and messages for promoting optimal parental hygiene and health practices regarding infant personal hygiene, hand washing (supplies, techniques, critical moments), safe drinking water (treatment, collection, storage), house surrounding environment, safely disposal of faeces and malaria prevention. Participants also attend four communitarian group meetings at baseline, 6, 12 and 18 months, which focus on the key messages along theoretical and practical sessions.

Control Arm: Participants do not receive any educational package between assessments.

For all participants, data is collected at baseline and every 6 months over 2 years during face-to-face interviews administered to the parent/primary caregiver of infants under five (U5) using a questionnaire developed for this study based on ProPAN 2013. Biological samples (faeces, urine and blood) are collected at the same time.

Intervention Type
Behavioural

Primary outcome(s)
1. Linear growth of children under five (U5) is assessed by mean change in length-for-age Z-scores from baseline to 6, 12, 18 and 24 months
2. Serum micronutrient status of children U5 is assessed by mean change of vitamin A, vitamin D, vitamin E, vitamin B12, Folic Acid, Iron, Zinc from baseline to 6, 12, 18 and 24 months

Key secondary outcome(s)
1. Improvement of weight-for-length is assessed through weight-for-age Z-scores from baseline to 6, 12, 18 and 24 months
2. Energy and macronutrient intake from complementary foods measured measured using a interviewer administered 24-hour-dietary recall at baseline, 6, 12, 18 and 24 months
3. Occurrence of parasitological infection (malaria and helminths) measured using blood testing, faeces and urine analysis at baseline 6, 12, 18 and 24 months

Completion date
30/11/2017

Eligibility

Key inclusion criteria
Children
1. Aged under 36 months (inclusive) living in the selected hamlets at the baseline
2. Children whom birth record isn’t available and birth day is reported by the parent or primary caregiver
3. If a precise birth date or age I not provided, children are selected on the basis of height, only children less than 110 cm tall are included in the sample

Caregivers:
Aged 16 years or older or with authorization from the legal guardian (if younger).

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. At the baseline time, children whose parents or primary caregivers are away from home within the hamlet
2. Children whom parent or primary caregivers don't intend to move from the hamlet for the next two years
3. Children who does not have any obvious health or developmental problems that would interfere with growth, nutrition or development (excluding anaemia and malnutrition)

Date of first enrolment
12/03/2015

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
Angola

Study participating centre
Heath Research Centre of Angola
Rua Direita do Caxito
Caxito, Bengo
Angola
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Sponsor information

Organisation
Health Research Centre of Angola – CISA (Centro de Investigação em Saúde de Angola)

Funder(s)

Funder type
Government

Funder Name
Fundação Calouste Gulbenkian (Calouste Gulbenkian Foundation)

Funder Name
Camões - Instituto da Cooperação e da Língua (Camões - Cooperation Institute and Language)

Funder Name
Ministério da Saúde da República de Angola (Ministry of Health of Angola)

Funder Name
Banco de Fomento Angola (BFA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request