Impact evaluation of the Cash for Nutrition Awareness (CNA) component of the SNACK project (Santé Nutritionnelle à Assise Communautaire à Kayes [Community Nutrition and Health Program in Kayes])

Submission date 25/10/2013	Recruitment status No longer recruiting	Prospectively registeredProtocol
Registration date 09/12/2013	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 01/10/2019	Condition category Nutritional, Metabolic, Endocrine	Individual participant data

Plain English summary of protocol

Background and study aims

The SNACK (Santé Nutritionnelle à Assise Communautaire à Kayes [Community Nutrition and Health Program in Kayes]) program is piloted by the World Food Program (WFP) in three districts of the Kayes region in Mali. The goal is to improve nutrition of mothers and children through a package of activities in nutrition and health delivered through community workers and community health centers (CSCOM). WFP is planning to carry out a new component within the SNACK project (Cash for Nutrition Awareness - CNA) from January 2014 in the same area. This component will provide cash to women during the first 1000 days (pregnancy, lactation and the childs first 2 years) and women will have to use health services during this period in return. The expected result of the CNA component is to optimize the growth of the baby during pregnancy and early childhood. In addition, the CNA component will test whether distributing supplements to children 6-24 months of age also results in better growth of children during early childhood. Our objective is to evaluate the impact of these treatments on childrens growth.

Who can participate?

Pregnant/lactating women and infants/young children in their first two years of age are the target group in the CNA program, because they are particularly vulnerable to poor nutrition and its long-term devastating consequences on survival, health, and well-being. Pregnant women will be recruited into the program when they come for prenatal consultation. Women with children less than 12 months of age will also be recruited. Once recruited, women (and their infant/child) will be included in the program until their child reaches 24 months old.

Only 12.0 to 41.9 month old children and their mothers will participate to the impact evaluation study.

What does the study involve?

Women and children will be randomly allocated to one of four groups:

Group A (control group): women and children receive SNACK activities only

Group B (intervention): women and children receive SNACK activities and cash Group C (intervention): women and children receive SNACK activities and children receive

supplements (Plumpydoz®).

Group D (intervention): women and children receive SNACK activities, women receive the cash transfer over a maximum of 33 months and 6-24 month old children receive supplements (Plumpydoz®)

For the evaluation study, samples of 12.0-41.9 month old children and their mothers will be surveyed right before the program starts (baseline) and at the end of the program (endline). Women will have to answer questions about what happened during their pregnancy, what they eat, their knowledge in nutrition, hygiene and health, their habits, as well as questions about their childs health and nutrition. Height and weight of both mothers and children will be measured.

What are the possible benefits and risks of participating?

Participants will benefit from interventions which are expected to provide a better nutrition to 6-24 month old children and a better health monitoring during and after pregnancy. This should result in a reduction of illness and growth retardation in children. The whole community will also benefit from the program since the study aims to improve this particular intervention as well as this type of interventions in general. The control group will receive SNACK activities which aims to improve health and nutrition of mothers and children.

The study does not present any risk for participants, as there will be only questionnaires and painless and non-invasive measurements. There should be no side effects in any of the groups.

Where is the study run from?

The CNA component is being set up in all functioning health centers (CSCOM) in three districts of the Kayes region, Mali: Bafoulabe, Diema and Yelimane. The study will take place in almost all of these CSCOM (76) and associated villages.

When is study starting and how long is it expected to run for? CNA component: duration of 4 years, starting in January 2014. Baseline survey for the evaluation: duration of 40 days, starting early November 2013. Endline survey for the evaluation: duration of 40 days, starting early November 2016. The study is expected to last 3 years in total.

Who is funding the study?

World Food Program (Mali), International Food Policy Research Institute (USA), UNICEF (Mali), Research Institute for Development (France).

Who is the main contact? Dr Mathilde Savy mathilde.savy@ird.fr

Contact information

Type(s) Scientific

Contact name Dr Mathilde Savy **Contact details** IRD-LARTES Camp Jérémy IFAN Dakar Senegal BP 206

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

A randomized controlled trial to determine whether distribution of cash and/or nutritive supplements during pregnancy and infancy improves the nutritional status of mothers and young children

Acronym

CNA/SNACK

Study objectives

It is hypothesised that:

1. The cash transfers used to enhance utilization of preventive health care services during the first 1,000 days (from conception to the 2 years of the child) will optimize growth in utero and during infancy and early childhood.

2. The distribution of micronutrient-fortified lipid-based supplements to 6-24 month old (mo) children will optimize growth in early childhood.

3. The combination of cash transfers to women during the 1000 days and distribution of micronutrient-fortified lipid-based supplements to 6-24 mo children will further optimize growth in utero and during infancy/early childhood.

The null hypothesis is that there will be no difference in nutritional indicators between treatment groups. This may arise for hypotheses 1 and 3 if the quality of the preventive health care services is not good enough in the area. This may arise for hypothesis 2 if the supplement (or part of it) is not eaten by the target child (shared with other family members, sold to someone else, etc.)

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of the Medicine Faculty of Bamako, Mali (Comité dEthique de la Faculté de Médecine, Bamako, Mali); study submitted on 8th October 2013; oral presentation of the study to the Ethics committee board on 26th October 2013

2. Consultative Committee of Deontology and Ethics (Comité Consultatif de Déontologie et d Ethique) of Research Institute for Development [Institut de Recherche pour le Développement (IRD)]

Study design

Three-year cluster-randomised controlled trial, with repeated cross-sectional surveys (baseline, mid-term and endline)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s) Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Growth retardation

Interventions

CSCOMs (Centre de Santé Communautaire [Community Health Centres]) were randomized to treatment or control group.

Group A (control group): women and children receive SNACK activities only Group B (intervention): in addition to SNACK activities, women receive a cash transfer worth 1500 FCFA (~3 US \$) per month over a maximum of 33 months (=1000 days) Group C (intervention): in addition to SNACK activities, 6-24 mo-old children receive supplements (Plumpydoz®).

Group D (intervention): in addition to SNACK activities, women receive the cash transfer over a maximum of 33 months and 6-24 mo-old children receive supplements (Plumpydoz®)

Joint sponsor: International Food Policy Research Institute 2033 K St, NW Washington, DC 20006-1002 USA Phone:+1 202-862-5600 Fax:+1 202-467-4439 Email: ifpri@cgiar.org

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

1. Childrens stature after 3 years of intervention, expressed in Height-for-Age Z score 2. Mean birth weight after 1, 2 and 3 years

Secondary outcome measures

1. Use of preventive health care services during pregnancy, for delivery and during early childhood (pregnancy and post-natal care)

- 2. Infant and Young Children Feeding practices (IYCF indicators including dietary diversity)
- 3. Weight-for-Height Z score
- 4. Child development and well being
- 5. Knowledge, attitude and practices towards nutrition, hygiene and health

Overall study start date

07/11/2013

Completion date

17/12/2016

Eligibility

Key inclusion criteria

12.0-41.9 mo-old children and their mothers willing to participate in the study, living in the villages surrounding the CSCOMs (Health Centers)

Participant type(s)

Patient

Age group Child

Lower age limit 12 Months

Upper age limit

41 Months

Sex

Both

Target number of participants

5016 children (12.0-41.9 mo old) and their mothers.

Key exclusion criteria

Children and mothers having mental or physical disability that could affect growth and wellbeing. Date of first enrolment 07/11/2013

Date of final enrolment 17/12/2016

Locations

Countries of recruitment Mali

Senegal

Study participating centre IRD-LARTES Dakar Senegal BP 206

Sponsor information

Organisation Research Institute for Development [Institut de Recherche pour le Développement (IRD)]

Sponsor details Immeuble Le Sextant CS 90009, 44 Boulevard de Dunkerque Marseille France 13572

Sponsor type Research organisation

ROR https://ror.org/05q3vnk25

Funder(s)

Funder type Research organisation

Funder Name

International Food Policy Research Institute, Washington DC (USA)

Funder Name World Food Program (Mali)

Funder Name UNICEF (Mali)

Alternative Name(s)

United Nations Children's Fund, United Nations Children's Emergency Fund, Fonds des Nations Unies pour l'enfance, Fondo de las Naciones Unidas para la Infancia, ,

Funding Body Type Government organisation

Funding Body Subtype International organizations

Location United States of America

Funder Name

Institut de recherche pour le développement (IRD) (France)

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?
<u>Results article</u>	results	16/01/2019		Yes	Νο
	results				

Results article

01/12/2019

01/10/2019 Yes

No