Effectiveness and cost effectiveness of early initiation and longer duration of emergency /seasonal unconditional cash transfers on children's nutritional status in Tahoua, Niger

Submission date	Recruitment status No longer recruiting	Prospectively registered	
21/02/2015		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
19/03/2015	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
25/09/2018	Nutritional, Metabolic, Endocrine		

Plain English summary of protocol

Background and study aims

Concern Worldwide (also see http://www.actionagainsthunger.org/) has been implementing unconditional cash transfers (UCT) as part of their humanitarian intervention during the lean season for some years. The aim of this study is to assess the impact of two different UCT interventions on child under nutrition.

Who can participate?

Households defined as the most vulnerable by Concern Worldwide and targeted to receive cash transfers, with women aged 15-49 years and children aged 6-59 months. A small sample of non-recipients will also be investigated.

What does the study involve?

Households around about 20 distributions points will be randomly allocated to one of two groups.

One group will receive a standard seasonal UCT intervention that provides sufficient cash to households to cover 75% of the household food needs over the four-month period of the lean season (June – September). The other group will receive an earlier seasonal UCT intervention that provides the same total amount of cash but distributed over a longer period of six months, starting two months earlier (April – September). Between June and September, both groups will also receive a supplementary feeding intervention for children aged 6 to <24 months and pregnant and lactating women, and health, hygiene and nutrition education messages.

What are the possible benefits and risks of participating?

The population in Tahoua, as a whole, should benefit from the future improvement in the design of cash transfer programmes. Individual participants will get their haemoglobin results and will be referred to health facilities if identified as anaemic using local diagnostic cut-offs. They will also be referred to a therapeutic feeding programme if found to be severely malnourished according to anthropometric criteria. Participants will be asked to allocate time to answering the

study questionnaires and no material incentives or rewards will be provided. A finger stick blood sample will be collected which may cause some minor discomfort.

Where is the study run from? Tahoua region, Niger

When is the study starting and how long is it expected to run for? June 2014 to December 2015

Who is funding the study?

Department for International Development (DFID), UK

Who is the main contact? Dr Andrew Seal

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

Project ID 6543/001

Study information

Scientific Title

A cluster randomised controlled trial of the effectiveness and cost effectiveness of early initiation and longer duration of emergency/seasonal unconditional cash transfers on children's nutritional status in Tahoua, Niger

Acronym

REFANI-N (Research on Food Assistance for Nutritional Impact - Niger)

Study objectives

An earlier, extended emergency/seasonal unconditional cash transfer of equal value and longer duration than the standard intervention reduces the prevalence of acute malnutrition in children

6-59 months of age in the very poor, targeted households after six months / by the end of the lean season.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Ministry of Public Health National Ethics Committee, Niamey, Niger, 27/11/2014, ref: 021/2014/CCNE
- 2. Research Ethics Committee of University College London, 30/01/2015, Project ID: 6543/001

Study design

Cluster randomised trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Child undernutrition

Interventions

Cash transfers to households classified as very poor.

Comparing standard seasonal UCT intervention (done over the four-month period of the lean season (June – September) to earlier seasonal UCT intervention (same amount of cash but distributed over a six-month period, starting two months earlier, April – September).

To evaluate the nutrition impact of these two interventions over the lean season we will recruit a study cohort, inviting participation from all beneficiary households with an expected population of 3,500 children, aged 6-59 months. This will be adequate to detect a difference in 5 percentage points in the prevalence of global acute malnutrition between interventions arms, which is our primary outcome measure.

In addition, we aim to measure whether this intervention has a nutritional impact on the wider community. To achieve this, we will randomly recruit a sample of non-beneficiary households. We will also undertake extra in-depth studies to assess changes in household expenditure, women's well being and empowerment, food security, and the prevalence of anaemia as measured by haemoglobin concentration in blood. These quantitative and qualitative process evaluation studies will enhance our understanding of how the interventions work or fail to work. Data collection will involve anthropometric measurements such as weight, length or height, and mid-upper arm circumference in women and children using standard methods. Second, measuring haemoglobin concentration from peripheral blood in non-pregnant women and children using a portable photometer, HemoCue, following standard methods. Third, the use of standard questionnaire tools on socio-economic status, health, and health seeking behaviours that will be adapted to the local context, translated and piloted.

Intervention Type

Other

Primary outcome(s)

Prevalence of global acute malnutrition (weight-for-height <-2 z scores (WHO 2006 growth standards) and/or nutritional oedema) in children 6-59 months

Data collection will take place before and after the intervention (that is March/April and September/October for the baseline and end line data, respectively).

Key secondary outcome(s))

- 1. Prevalence of global acute malnutrition (mid upper arm circumference (MUAC) <11.5 cm and /or nutritional oedema) in children 6-59 months
- 2. Mean weight-for-height (WHO 2006 growth standards) in children 6-59 months
- 3. Mean MUAC in children 6-59 months
- 4. Mean haemoglobin in children aged 6-59 months
- 5. Prevalence of anaemia in children aged 6-59 months
- 6. Mean haemoglobin in women aged 15-49 years
- 7. Prevalence of anaemia in women aged 15-49 years
- 8. Household Diet Diversity Score
- 9. Individual Diet Diversity Score in children aged 6-59 months
- 10. Individual Diet Diversity Score in women aged 15-49 years
- 11. Household expenditure
- 12. Cost effectiveness of the modified cash transfer intervention

Data collection will take place before and after the intervention (that is March/April and September/October for the baseline and end line data, respectively).

Completion date

31/12/2015

Eligibility

Key inclusion criteria

- 1. The geographical inclusion criteria is settlements within the Affala and Takanamatt Communes of Tahoua district, Niger.
- 2. Within this geographical area settlements that have been previously targeted for inclusion within the Concern Worldwide humanitarian cash transfer programme, will be eligible for inclusion in the study. (Within eligible settlements, only households defined as the most vulnerable by Concern Worldwide are targeted to receive cash transfers.) Study clusters will include one or more settlements and will be randomly allocated to one of two study arms in a public randomisation event.
- 3. Within clusters, households receiving a cash transfer will be exhaustively sampled and a subsample of households not receiving the cast transfer will randomly selected.
- 4. Within these selected households, two groups of individuals will be exhaustively sampled::
- 4.1 Women aged 15-49 years
- 4.2 Children aged 6-59 months

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Sex

Αll

Key exclusion criteria

- 1. Households without children aged 6-59 months
- 2. Severely disabled individuals on which anthropometric measures cannot be taken
- 3. Individuals confined to bed due to illness

Date of first enrolment

03/03/2015

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

Niger

Study participating centre

Tahoua

Niger

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Sponsor information

Organisation

University College London

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Government

Funder Name

Department for International Development

Alternative Name(s)

Department for International Development, UK, DFID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
Results article	results	01/10/2018	Yes	No
<u>Protocol article</u>	protocol	23/12/2015	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes