

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

<b>Submission date</b> 21/02/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/09/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**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**

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 measure**

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).

## **Secondary outcome measures**

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).

## **Overall study start date**

01/06/2014

## **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 sub-sample of households not receiving the cash 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

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

All eligible women and children within the randomly selected clusters. 4000 children (6-59 months) and 3000 women (15-49 years); 7000 in total

**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

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## 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

## Publication and dissemination plan

Publish the main trial results and any associated analysis within one year of the end of the data collection.

## Intention to publish date

31/12/2016

## 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?
<a href="#">Protocol article</a>	protocol	23/12/2015		Yes	No
<a href="#">Results article</a>	results	01/10/2018		Yes	No