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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
21/02/2015

Recruitment status
No longer recruiting

Registration date
19/03/2015

Overall study status
Completed

Last Edited
25/09/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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 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

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
-

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?
Protocol article	protocol	23/12/2015		Yes	No
Results article	results	01/10/2018		Yes	No