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Cash for Improved Nutrition in Somalia

Submission date
05/11/2018

Recruitment status
No longer recruiting

Registration date
19/12/2018

Overall study status
Completed

Last Edited
24/03/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[X] Individual participant data

Plain English summary of protocol

Background and study aims
Cash transfers have gained popularity as a tool to address humanitarian needs in many countries around the world. However, evidence on their effectiveness at reducing malnutrition, sickness, and mortality is scant and inconclusive. In 2016, we conducted a study (REFANI-S) to look at the impact of unconditional cash transfers, together with free piped water and a non-food item kit, on child malnutrition in Somalia. We found that although household expenditure, food security, and dietary intake all improved, there was no impact on child malnutrition. Somalia continues to be affected by recurrent natural disasters and ongoing conflict. This results in some of the highest malnutrition and child mortality statistics globally. The aim of this study is to assess the impact of a conditional cash transfer together with behaviour change communication on the risk factors for child undernutrition.

Who can participate?
Twenty camps for internally displaced people (IDP), located on the outskirts of Mogadishu, Somalia will be selected. The camps will be selected based on their size, proximity to the Concern health and nutrition centre, and socio-economic characteristics. All children, aged 6-59 months old, and their Caregivers living in these twenty camps will be eligible to take part.

What does the study involve?
The twenty selected camps will be randomly allocated to 4 study arms. All households in the 20 camps will be eligible to receive a monthly cash transfer for 9 months. Before they can get the cash transfer households in 10 randomly selected camps will be required to take any children below 5 years of age to the local health clinic for a health screening, where they will be issued with a health record card. During the 9 months of the cash distribution, households in 10 camps selected during a second randomisation exercise will receive audio health and nutrition promotion messages on their mobile phones. They will still receive the cash transfer whether they listen to the messages or not.
Households that agree to take part in the study will be asked to answer a questionnaire on risk factors for children developing under nutrition. This will cover topics such as household expenditure on food, access to water and sanitation, dietary intake (what they eat), and illness. They will also be asked questions about the topics covered in the audio messages. Children and their mothers will also be weighed and their height and mid-upper arm circumference measured so their nutritional status can be assessed. What people think regarding malnutrition, who is most at risk of malnutrition and how useful cash transfers are at tackling malnutrition is

collected through interviews and group discussions. The study will also collect data to monitor how well the cash transfer and audio message programme is running and to monitor factors that may affect the impact that the cash transfer may have. These factors include what other humanitarian interventions are being carried out in the study area.

What are the possible benefits and risks of participating?
The population in Somalia, as a whole, should benefit from the future improvement in the design of cash transfer and health and nutrition behaviour change programmes. Individual participants will benefit from receiving a cash transfer for 9 months and being screened each month to see if they have received the correct vaccinations and if they are malnourished. They will be referred to a clinic for treatment if necessary. The caregivers of half of the participating children will need to attend a health clinic so their child can receive a health screening before they are eligible to receive the cash transfer. Half of the participants will also receive audio messages through their mobile phones which they may find useful and enjoyable but will also take time to listen to. Participants will be asked to allocate time to answering the study questionnaires and no material incentives or rewards will be provided.

Where is the study run from?
The study is being run by Concern Worldwide Somalia. It is taking place in camps for internally displaced people (IDP) on the outskirts of Mogadishu, Somalia.

When is the study starting and how long is it expected to run for?
We started work on the detailed planning of the study in September 2017 and expect to finish data collection by January 2020.

Who is funding the study?
The USAID Office for Foreign Disaster Assistance (OFDA)

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: 842405

Study information

Scientific Title
Cash for Improved Nutrition in Somalia (CINS)

Acronym
CINS

Study objectives
1. Humanitarian cash transfer conditionality improves health service utilization, increases vaccination coverage by 20%, and reduces morbidity in children aged 6-59 months. This hypothesis will be tested by comparing the 10 clusters receiving unconditional cash with the 10 clusters receiving conditional cash transfers.
2. A mHealth mobile phone behaviour change communication (BCC) messaging intervention, linked to cash transfers, will improve health knowledge and nutrition related behaviours in a complex emergency context. This hypothesis will be tested by comparing the 10 clusters who receive the mHealth intervention with those that do not. We will also test the secondary hypothesis that a combined conditional cash transfers and mHealth mobile phone BCC messaging intervention reduces the risk of acute malnutrition compared to those receiving unconditional cash transfers or no mHealth intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of University College London, 19/10/2018, ref: 4684/001
2. Ministry of Health, Mogadishu, 27/06/2018, ref: MOH&HS/DGO/0993/Jun/2018

Study design
The study is a 2x2 factorial randomised cluster intervention trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Child undernutrition

Interventions
The clusters being studied comprise camps for internally displaced people within the Afgooye Corridor area of peri-urban Mogadishu. The camps vary in size and contain makeshift, temporary, houses. All camps in the area are regarded as requiring humanitarian assistance and twenty camps will be selected to take part in the study. There are 2 interventions being tested in this study; a cash transfer conditionality and a mHealth intervention.

Cash will be provided to households as either an unconditional (UCT) or conditional (CCT) cash transfer. For ethical reasons all groups will receive cash transfers, as all households are considered to be suffering from extreme poverty and highly vulnerable. Randomization will be done at the cluster (camp) level and households in 10 camps will receive a CCT and the remainder will receive a UCT. Households living in the selected camps will be listed and registered by the Concern cash distribution team.

The conditional cash transfer will require households with children, aged 6-59 months, to have first attended the local health clinic where they will receive a health screening, any necessary vaccinations, de-worming, and vitamin A supplementation as required; and they will be issued with a child health record card. All the study camps have similar access to local health clinics. Compliance with the health clinic visit will be verified by asking for the child health record cards during registration of the household for cash transfers. Checks of the child health card will be carried out monthly during the monthly monitoring household visits by CHW. The check will monitor whether all children in the household 0-59 months are up to date on routine vaccination, vitamin A supplementation, and de-worming.

Cash transfers will follow the standard amounts set by the major donors of humanitarian cash transfers in Somalia, DFID and ECHO, which are based on a percentage of the Monthly Expenditure Basket (MEB). For the first 3 months the amount provided will be that given during a humanitarian cash transfer programme (US$ 70 per household per month); for the following 6 months the amount provided will be aligned with that given by social safety net (welfare) programmes (US$35 per household per month).

The cash distribution will be done electronically each month and sent to the registered SIM card of the beneficiary in US$. The cash transfers will be implemented by Hormuud Telecom via their EVC Plus money transfer service. Once the beneficiaries receive the cash transfer they can then use it to purchase items electronically or exchange for physical cash at a wide range of local shops. If they experience problems with use of the cash transfer they can contact the local Hormuud Telecom office for assistance. Problems can also be reported to the Concern beneficiary help line.

The CCT and the UCT will provide the same total amount per month, with equal total amounts in all arms. Those receiving unconditional cash will not be required to visit to the health clinic prior to cash distribution (although they are fully entitled to do so if they choose to) and they will not be required to show a health record card for their children before being registered on the cash distribution list.

All study arms will receive behaviour change communication (BCC) provided by CHW during their monthly household visits. The mHealth intervention arms will receive the additional mHealth BCC that will consist of audio messages transmitted to the recipient's mobile phone. Provision of BCC messaging will be randomized among the groups at cluster (camp) level.

Messaging will be developed in collaboration with companies based in Somalia that are specialists in interactive voice response (IVR) technology and creative message development. Currently, we plan to deliver 12 audio messages, with two messages focused on each of 6 health and nutrition topics: Vaccination; Water, Sanitation, and Hygiene (WASH); Infant and Young Child Feeding (IYCF); Identifying signs of serious illness and seeking care; Prevention, recognition, and treatment of acute malnutrition; Maximizing health and nutrition for everyone in the household. These topics were identified as major barriers to optimal nutrition and health during the preceding REFANI-S study. Messaging will be designed based on pre-existing theoretical behaviour change frameworks, will be culturally appropriate, and will be produced using local voice actors. Message content will be tested to ensure it is compelling and effective. Different formats for message delivery will be tested, such as a 6-12 episode soap opera series, or standalone short/succinct messages. The messages produced will be piloted with small groups of IDP living in the same area as the study population, and revised during several iterative rounds of development prior to general use. Full consideration will be given to ensuring the messaging will be acceptable to all parties of the ongoing conflicts in Somalia. This will ensure that listening to the message does not put any beneficiaries at risk.

Intervention Type
Mixed

Primary outcome measure
1. Measles vaccination coverage - % of children 9-<59 months of age who received measles vaccine - EPI vaccination coverage - % of children 0-<59 months of age who received all vaccines required by the national vaccination protocols (measured at baseline and endline via Caregiver interview and health record card examination)
2. Child diet diversity score of children 6--<24 months of age (measured at baseline and endline via Caregiver 24 hour dietary recall)
3. Parental/caretakers knowledge of BCC health and nutrition topics (measured monthly via questionnaire)

Secondary outcome measures
1. Incidence of acute malnutrition - MUAC<12.5 cm or oedema among children 6-59 months (measured monthly during household visits)
2. Incidence of mortality among children 6-59 months (assessed monthly by questionnaire during household visits)
3. Exclusive breastfeeding prevalence - % of infants 0-5 months who were exclusively breastfed during the last 24 hours (measured at baseline and endline via Caregiver 24 hour dietary recall)
4. Incidence of child morbidity (assessed monthly by questionnaire during household visits)
5. Causes of death ascertained by Verbal Autopsy (assessed by Caregiver interview following a mourning period)

Overall study start date
29/09/2017

Completion date
01/01/2020

Eligibility

Key inclusion criteria
Males and females between the ages of 0 and 59 months will be eligible to be recruited

Participant type(s)
Mixed

Age group
Child

Lower age limit
0 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
Our target sample size is a total of 1,700 children in all 4 arms of the trial. These will be sampled from 20 clusters with an average of 85 children per cluster and an assumed refusal or loss to follow up of 24%.

Key exclusion criteria
1. Children with a disability that prevents taking weight or height measures
2. Children with a medical condition that prevents them eating a normal diet
3. Children confined to bed due to illness
4. Children living in a household in which the mother/carer is unable to respond to questions due to a speech or hearing impairment

Date of first enrolment
01/01/2019

Date of final enrolment
28/02/2020

Locations

Countries of recruitment
Somalia

Study participating centre
Concern Worldwide, Somalia
Mogadishu
Somalia
N/A

Sponsor information

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University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
United States Agency for International Development

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication of the trial results in a high impact journal and dissemination online. Presentation of results at technical meetings and scientific conferences.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository. Details re public access to the trial data and repository choice will all be decided towards the end of the trial taking into account the best practice and legal context pertaining at the time. Consent from participants will be obtained in the normal way.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		12/11/2018	04/10/2022	No	No
Results article		27/02/2023	28/02/2023	Yes	No
Dataset	dataset	06/02/2023	24/03/2023	No	No