ANNEX 2. NIGER STUDY PROTOCOL

[REDACTED VERSION]

FULL PROTOCOL EMBARGOED, PENDING PEER-REVIEWED PUBLICATION
SUMMARY

This University College of London (UCL)-led study will be implemented under the DFID-funded consortium on Research on Food Assistance for Nutrition Impact (REFANI). Between March 2014 and February 2017, the consortium members will undertake three studies where an NGO is implementing a Cash Transfer Programme (CTP) involving cash or voucher transfers in response to humanitarian need. The focus of the studies is to examine the effect of CTP on the nutritional status of young children.

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.

Victoria L Sibson
Carlos S Grijalva-Eternod
Hassan Haghparast-Bigdoli
Joanna Morrison
Chloe Puett
Kate Culver
Silke Pietzsch
Jolene Skordis-Worral
Andrew J Seal (Principal Investigator)

Design: In this proposed study in Tahoua, Niger, we aim to determine whether modification of a standard, emergency/seasonal unconditional cash transfer (UCT) improves its effectiveness and cost-effectiveness for reducing acute malnutrition prevalence in children 6-59 months of age. We will also explore the mechanisms by which the intervention works. Using a cluster randomised controlled design with two intervention arms, we will compare the ‘standard’ four-month emergency/seasonal UCT with an earlier, extended six-month UCT, which will be the same total value but initiated two months prior to the standard UCT. Both interventions target very poor households and for the common four months of the lean season, the cash transfers are accompanied by a nutritional supplement for children 6-<24 months and pregnant and lactating women, as well as health, hygiene and nutrition education messages. We aim to assess nutrition impact among the very poor households targeted with cash, and in the wider communities in which these households are situated. We will do this by undertaking a longitudinal cohort study of households in the two trial arms, and by undertaking cross sectional surveys of the villages in the two trial arms in which the very poor households are targeted with cash. Our primary outcome is prevalence of acute malnutrition in children 6-59 months of age. We will evaluate impact after six months of follow up to assess the effect over the lean season. The interventions will be costed and relative cost-effectiveness evaluated to explore the cost implications of the intervention modification. We will undertake additional in-depth study on the processes of action to enhance our understanding of how the interventions work and whether changing the timing and duration of the UCT programme changes these mechanisms.

Acknowledgements: A large number of individuals have provided information, advice and guidance to help us develop this study protocol. These people have represented the agencies in the REFANI Consortium, DFID and agencies working in Niger including ECHO, WFP, UNICEF, LASDEL, Save the Children, ACTED, le Cellule de Filets Sociaux (Government of Niger) and the World Bank. In particular, we would like to thank the staff of Concern Worldwide in Niger, including: Leila Bourahla - Country Director; Julia Lewis - Assistant Country Director-Programmes; Maranatha Padanou - Country Financial Controller; Cherif Lawan - Programme Coordinator; Thierry Tshangola – Logistics/Admin Coordinator; Amadou Diallo – Food Income and Markets Programme Manager; Souleymane Karidio – Cash Officer; Cheffou Idrissa – Food Income and Markets M&E Officer; Michele Goergen – Nutrition Adviser; Mariana Mahamdou – Nutrition Manager; Mahmane Sabiou – Health and Nutrition M&E Officer; Michele Seibou – Health Adviser; Raphael Makkonen – Health and Nutrition Coordinator; Almoctar Ibro - IT Manager; Fatima Harouna – Admin/HR Office and Salissou Harouna – Logistics/Purchasing Assistant.
1. BACKGROUND RATIONALE

1.2 The global burden of child undernutrition, its consequences and causes

A recent analysis estimated that 32 out of 134 countries with available data had a prevalence of acute malnutrition\(^1\) of 10% or more, a burden commonly recognised as a “public health emergency requiring immediate intervention”.\(^2\) Compared to non-acutely malnourished children, children with moderate and severe acute malnutrition have a three and nine times greater risk of dying, respectively.\(^3\) Stunting is also associated with a risk of excess mortality, and of the global burden of 165 million, 90% of stunted children under five years of age live in Africa or Asia.\(^4\) In addition, over two billion people are at risk of vitamin A, iodine and/or iron deficiency globally and deaths attributable to iron deficiency alone numbered 119,668 in 2010.\(^5\)

The risk factors for undernutrition are varied and complex, influenced by factors operating at the level of the individual, their household, community and beyond, as illustrated in Figure 2.1. Whilst children are the main focus of our research, we recognise that mothers and carers strongly influence the survival and healthy development of their children through biological and psychosocial, or care pathways. Women’s nutrition, health and empowerment are important determinants of their ability to provide adequate care for children. Yet, as for children, maternal undernutrition, underweight, stunting and micronutrient deficiencies are of great concern in many countries.\(^6\)

The causes and consequences of humanitarian disasters may exacerbate pre-existing causes of undernutrition, or create new risks for children and their mothers and carers. In particular, the pre-existing prevalence of acute malnutrition may increase substantially, leading to excess child mortality. For instance, global acute malnutrition rose to around 40% in Southern Somalia during the famine in 2011, where an estimated 258,000 deaths occurred, over half of which were children.\(^8\)

1.3 Cash Transfer Programming to prevent acute malnutrition in emergencies

Whilst a range of sectoral activities may be required to tackle the variety of causes of acute malnutrition, food based interventions have been a commonly used preventative measure in emergencies, including through general food distributions (GFD) and blanket supplementary feeding programmes (BSFP). There is, however, limited evidence of their positive impact added to which there are critical challenges associated with their practical implementation and concerns about their cost-effectiveness.\(^9\) For these and other reasons, there is a

---

\(^1\) Acute malnutrition, defined as a weight-for-height Z score (WHZ) of <-2 (WHO growth standards, 2006) and/or presence of bilateral pitting oedema, is a global problem affecting about 13% of children under 5 years.


\(^9\) E.g. Sguassero Y. De Onis M. Bonotti AM. & Carroli G. (2012). Community-based supplementary feeding for promoting the growth of children under five years of age in low and middle income countries. Cochrane Database of Systematic Reviews, 114.


need to consider both the role of non-food interventions, and alternative or complementary forms of food assistance, including Cash Transfer Programmes.

Cash transfer programmes (CTP) encompass the use of cash\textsuperscript{12} or vouchers\textsuperscript{13}. In the context of programming to prevent acute malnutrition, they are typically given to vulnerable households who have young children during periods of food insecurity or in response to emergencies, with the intention to ensure access to food and to meet other basic needs. Receipt of transfers can be conditional, where beneficiaries need to meet a defined set of standards (such as attending an education session, or getting a child vaccinated) or unconditional. The choice of food, cash or voucher transfer should be made on the basis of an assessment of cost efficiency, the availability of basic goods on the market (i.e. food, where the objective is food assistance), the functioning of markets and secondary market impacts (low likelihood of inflation), the flexibility of the transfer, targeting and risks of insecurity and corruption\textsuperscript{14} and beneficiary preferences\textsuperscript{15}.

**Figure 2.1. ACF adopted Nutrition Framework based on the UNICEF model**

Figure 2.1, which illustrates the different causal pathways leading to undernutrition, may also be used to conceptualise the entry points for interventions such as food, cash and vouchers, to prevent this outcome. CTP programmes have the potential to address the underlying and basic determinants of undernutrition\textsuperscript{16}. However, and nutrition status with ready-to-use food in addition to food assistance in urban Chad: a cost-effectiveness analysis. Cost Eff Resour Alloc, 11, 27.

\textsuperscript{12} Cash transfers (CT) are made as direct cash payments or bank transfers using various modalities such as paper vouchers, debit/smart cards and mobile phones.

\textsuperscript{13} Voucher transfers can be exchangeable for fixed quantities of specific items (foods or non-food items or a service) or for cash value (exchangeable for a choice of specified food or non-food items with the equivalent value of the voucher.


at present, there is limited and inconsistent evidence of their impact on nutrition outcomes and the pathways which may be influenced.

There is good evidence that CTPs can impact positively on diets and food security at a household level\(^{17}\), and indeed they may be designed explicitly to enable this (e.g. through provision of a cash amount equivalent to the cost of a food basket during the months of the year when food is most scarce). However, relatively little is known about individual level impact, and this may not be sufficient to impact on nutrition indicators. Evidence from longer term conditional cash transfers suggests that they can improve uptake of health services where services are available, but also, by itself, this does not often translate into improved health or nutrition outcomes\(^{18}\). Nonetheless, and regardless of the varied nutrition impact pathways by which they may work in theory, there is a general consensus that CTPs are not likely to be efficacious when implemented as stand-alone interventions\(^{19,20,21}\). CTPs may be one means of addressing a range of the causes of undernutrition, including but not limited to protecting food access. There is, however, insufficient empirical evidence to demonstrate that cash or vouchers are an appropriate substitute for food-based interventions to prevent acute malnutrition in children or mothers, or to help determine the circumstances in which CTP interventions are likely to be effective and to identify which are the enabling causal pathways, whether food, health and/or care.

The reasons put forward for explaining the mixed results which are available, includes among many factors, different CTP design features. These include the timing and duration of the CT and the gender of the target recipient\(^{22}\). Timing matters because the determinants of undernutrition are often seasonal and are likely to change in response to shocks and disasters; e.g. Bailey found “seasonality influences the effectiveness of different types of transfers in improving food consumption, at least in certain contexts”\(^{23}\) and Bazzi et al, working in Indonesia showed that delaying the delivery of UCT was associated with a lower expenditure on food items\(^{24}\). To date, however, there is little evidence on the impact of these two design features.

In addition, as we can observe in Niger, there is some precedence for CTs to be targeted to women where the CTP is intended to impact on the child. Evidence suggests that giving cash to women, rather than men, will often lead to a greater improvement in children’s well-being by increasing women’s control of household resources\(^{25}\) and subsequently increasing spending that will benefit children’s health and nutrition\(^{26}\). However, there is also evidence that suggests that any impact of transfers received by women, on the outcomes of their children, does not work through these pathways\(^{27}\). Some evidence suggests gender-based targeting may upset household gender relations and lead to violence\(^{28}\), but again, results are context specific and inconsistent. Ultimately, the

---


\(^{18}\) Ibid.


\(^{22}\) Ibid.


impacts of CTPs based on the gender of the transfer recipient show mixed results and there is limited insight into the impact pathways and timeframes causing such variability.

2. STUDY CONTEXT

2.1 Niger, national level

Niger is the poorest country in the world, ranked last of 187 countries on the Human Development Index. The population relies on agriculture, and poverty rates are rising, exacerbated by domestic political instability, economic inequality and weak infrastructure, extreme weather events and the global financial downturn. Nearly half of all households live below the poverty line. Very high fertility rates are driving an expanding population numbering 16 million in 2011. This is leading to increasing pressure on a limited area of productive land, particularly because 14 million are rural dwellers, which in turn, is fuelling food insecurity. The seasonal calendar is dominated by a single, short, rainy season from June to September, on which the great majority of people entirely depend for both crop cultivation and pasture renewal. Dependence on a single harvest is inherently risky; there is no second season to alleviate crop failure in the event of inadequate rains. Roughly one fifth of the rural population is chronically food insecure and every year poorer people suffer a lean season between June and September “when household stocks are long gone and money for food is very tight. This season is made harder because it is a time of peak physical agricultural activity and also of malaria, which inhibits work and increases the risk of acute malnutrition.”

Recurrent food crises create chronic and cyclical humanitarian needs in Niger. Malnutrition rates in Niger are chronically high: 18% wasting and 44% stunting among children under five and 18% chronic energy deficiency in women of reproductive age (BMI <18.5 kg/m²). In addition, rates of anaemia are 73% in children 6-59 months and 23% in women of reproductive age. Acute malnutrition rates vary annually, on a seasonal basis as a result of the widespread reliance on agriculture, single rainy season, and the implications for food availability and access, but also incidence of diseases such as malaria. This makes effective early warning and timely seasonal and humanitarian intervention vital to protect the nutritional status of the most vulnerable groups, including children under five years of age.

32 http://data.worldbank.org/indicator/SP.POP.GROW
2.2 Tahoua District, Concern Worldwide’s operational area

UCL and ACF will collaborate with Concern Worldwide in Tahoua, Niger to complete this study. Tahoua region has a population of 2,650,000 people with a density of 23.4 habitants /km². Tahoua is divided into 8 districts, one of which is also called Tahoua. In Tahoua district, there are 6 communes, four of which form Concern Worldwide’s core operational area for cash transfer programming: Bambeye, Tebaram, Takanamatt and Affala (see figure 2.2). Tahoua town is 550km northeast of Niamey, 120km from the Malian border and 200km from the Nigerian border. The population of Tahoua is mostly of the Hausa ethnic group, but there are also Fulani/Peul, Tuareg and Djerma. The livelihood zone is broadly agropastoral, but within the four communes, there are three livelihood zones: zone 4. Agropastoral belt (majority coverage), zone 5. Rain-fed sorghum and millet (southern edge of Bambeye only) and zone 6. Cropping and herding with high work outmigration (pockets in Tebaram and Takanamatt)\textsuperscript{36}. All of these zones are considered high priority for monitoring food security. The lean season across the zones is June - September\textsuperscript{37}.

Concern Worldwide has been undertaking bi-annual SMART surveys in Tahoua district in July and December every year since 2010. The trends of the available data provide a snap-shot of the chronically high rates of acute malnutrition affecting children under five, which are persistently above 10% in July during the lean season and frequently close to this (and not statistically different\textsuperscript{38}) in December which is the post-rains, post-harvest period (see figure 2.3)\textsuperscript{39}.

\textsuperscript{37} The FEWSNET report suggests that the lean season varies in timing of initiation and duration by livelihood zone. However personal communication with author Julius Holt clarified that this may not be the case, rather the conceptualisation of the lean season varies depending on the extent to which the initiation of food price rises and increasing reliance on food purchase is taken in to account. This difference in conceptualisation provides an important rationale for the study design.
\textsuperscript{38} 95% confidence intervals are available for some data as follows : December 2010: GAM 13.0% (10.6-15.8), SAM 2.7% (1.9-4.0); December 2011: GAM 9.8% (7.8-12.1), SAM 1.7% (0.9-3.0); December 2012: GAM 9.3% (7.2-12.1), SAM 1.1% (no CIs reported); July 2013: GAM 11.4% (8.8-14.6), SAM 1.7% (0.8-3.5)
\textsuperscript{39} Draft Rapport enquête nutritionnelle SMART, District de Tahoua, Juillet 2013, Concern Worldwide Niger
2.3 Causes of malnutrition in Niger and in Tahoua

Whilst food insecurity is entrenched as a consequence of harsh climatic conditions, the causes of undernutrition in Niger are multiple. Notwithstanding some seasonal variations, the fact that rates of acute malnutrition in children are high year-round indicates that it is not just short-term food shortages that cause malnutrition and require timely action. Inadequacies in health and care implicate that particularly high prevalence for infectious diseases/symptoms are documented in national and more localised data\(^{40}\). This raises important questions about the likely impact of lean season CTs on nutritional status and about the appropriateness of their timing and duration.

**Food insecurity and poor quality diets**

Most households are unable to produce sufficient cereals for their own consumption even in “normal” years\(^{41}\). They rely heavily on labour and labour migration, petty trade, loans and the sale of animals to access food. The disruption of livelihoods activities and coping strategies lead to acute malnutrition and one bad season reduces resilience to cope with the next as food stocks are depleted and households are left with debts to pay off. Diets are staple based with limited diversity, inadequate to meet the needs of growing children and pregnant and lactating women. The national picture is one of low exclusive breastfeeding (23%\(^{42}\)) but this may be better in Tahoua, possibly as a result of Concern Worldwide and other actors’ efforts\(^{43}\). Whilst there is some suggestion of improvements in feeding practices\(^{44}\), diets for children 6-<24 months may still be inadequate for the majority with reliance on millet porridge, with or without milk, depending on its availability. Men are served first and the best foods (such as meat) whilst children over one year of age must eat from a common plate with other children\(^{45}\).

**Disease and a poor public health environment**

Rates of childhood morbidity are high and illness is frequent, particularly diarrhoea, Acute Respiratory Infection (ARI) and malaria. Two week retrospective, national, morbidity rates from the last DHS, conducted between

---


\(^{43}\) Draft Rapport enquete nutritionnelle SMART, District de Tahoua, Juillet 2013, Concern Worldwide Niger


February and June (not in the rainy season) were 14% for fever, 14% for diarrhoea and 4% for ARI\textsuperscript{46}. Rates of fever were similar during the rains in Tahoua in 2013\textsuperscript{47}. However, despite free health care for children under five and pregnant women, the geographic inaccessibility and poor quality of the formal health service may prohibit uptake; ‘pharmacies ambulantes’ remain popular, including in Tahoua\textsuperscript{48}. Local information also reveals that parents do not distinguish between discrete episodes of illness, another barrier to health-seeking\textsuperscript{49}. In this arid environment, there is a chronic lack of access to water, whether clean or potable, or not, and low coverage of latrines and poor hygiene and sanitation practices. Malaria is endemic in the south including Tahoua, but bed net use is low\textsuperscript{50,51}.

**Social and care environment**

Niger's ethnic groups follow a patriarchal culture in which women may be disempowered and have little access to family income\textsuperscript{52}. Early marriage is the norm leading to young age at first delivery and a high total fertility rate, and there are low antenatal coverage rates. Education and literacy rates are also very low, particularly among women\textsuperscript{53}. Rural women bear very heavy workloads and have limited time for child care\textsuperscript{54}. Anthropological fieldwork in Tahoua provides explanation on the socio-cultural reasons for poor child caring practices\textsuperscript{55,56}. The chronic nature of livelihoods insecurity and the need to maintain productive and social capital to preserve dignity and self-respect, means that the needs of a vulnerable young, sick or malnourished child will rarely be prioritised. Intra-household gender relations and bargaining power are affected, among other factors, by presence or absence of the husband and whether the household is polygamous or monogamous and the status of each wife. These are key determinants, and in this context men and women control separate budgets. Male household heads are the key decision makers and they control the majority of the household’s resources. Decisions on cash spending often take a long term perspective and are motivated by a desire to protect the household’s livelihood rather than invest in a single individual. Nevertheless, women do influence household decisions, their bargaining power varying by their social capital, determined by reproductive success, family background and sexual desirability. There are cultural beliefs and proscriptions, but differing practices as a result of individual choice and/or negotiation.

**Basic level causes:**

There are longer term structural challenges underlying the deficiencies in household food security and the health and care environments, including: unequal land distribution, poor soil quality and erosion, lack of knowledge of good agricultural practices, recurrent drought, animal disease and improper animal husbandry, low education levels and infrastructural underdevelopment, growing population pressure, weak markets and reduced income generating opportunities\textsuperscript{57,58,59,60}.


\textsuperscript{49} Ibid.


2.4 Experience of seasonal Cash Transfer Programmes in Tahoua and in Niger, and knowledge about their impact and how they work

Seasonal cash transfer programmes have been implemented by NGOs in Niger since the last extreme lean season in 2004 and a number of operational research projects and studies have already been undertaken. Several include examination of nutrition impacts which the interventions were designed to achieve through protecting or increasing food access (see Annex 2A). The seven studies or evaluations we found were initiated at varying degrees of timeliness, as judged against two factors: firstly, by the month of the first cash distribution in relation to June, the first month of the national, annual, lean season, and secondly, whether the authors reported a crisis to have had any impact on this timing in the year of study. Against these factors we could judge that two of the cash interventions were initiated on time, two were early and three were late.

Authors of four studies reported a positive impact on the nutritional status of children in the targeted households, attributed or contributed to, by the cash intervention. This was despite two of these interventions being classified as late, one as on time and one early. One was delivered in a crisis year and one in a more typical year. They gave similar amounts of cash relative to the price of food and they varied from four to six months in duration. Three of the interventions involved the delivery of complementary nutrition programmes. The authors of two of the intervention evaluations concluded that the cash programme did not impact nutritional status as intended due to an absence of appropriate complementary interventions. But whilst it is acknowledged that cash programmes seeking to impact on nutritional status require complementary programmes in Niger, a question on what is the appropriate timing, amount and duration of cash programmes remains unanswered. Results from a study of a seasonal CTP in southern Niger indicated that the children with a low weight-for-height z-score at the start of the lean season were at greater risk of becoming acutely malnourished, suggesting that the CT could potentially had a greater impact on nutrition outcomes if initiated earlier.

**Figure 2.4. Admissions of children with Severe Acute Malnutrition to Outpatient Therapeutic Programme in Tahoua, 2013.**

---


Additionally, the importance of health related drivers of acute malnutrition, how these vary seasonally and how, if at all, cash programmes can address them, need to be acknowledged. A CTP evaluation in the southern Maradi region of Niger found that in households receiving cash, children’s mean WHZ improved after a first distribution in June but the improvement was not sustained during the season, very likely due to increasing prevalence of sickness. In another more recent study in the same area, cited above, in households receiving cash, children’s mean WHZ also improved but an increase in morbidity was also observed, raising a question about the extent to which improvements may be limited by sickness. Concern Worldwide’s analysis of trends of admissions of children with acute malnutrition to therapeutic and supplementary feeding programmes in Tahoua, by month over the year, highlights the possibility that peaks in acute malnutrition incidence may not coincide with the June – September lean season, in part because of morbidity risks and trends. For example, figure 2.4 depicts the admissions of severely acutely malnourished children to the Concern Worldwide outpatient programme in 2013. The rise in admissions in March is reported to coincide with the rise of food price rises leading to reduced purchasing power, as well as increasing incidence of meningitis and measles. The higher rise in September, at the end of the rainy season, is driven by a rise in the incidence of malaria and a time of lower opportunity costs for many caretakers who have finished weeding and are starting to harvest.

To conclude, it is not clear from these prior studies and evaluations in Niger, all giving cash to female household representatives, whether, to what extent and by what mechanisms the timing of initiation and duration of emergency/seasonal cash transfers may be affecting their nutritional impact. In addition, previous studies have focused on eligible households only (whether receiving cash or as a comparison group) and do not allow for the assessment of a population level, public health impact, which is particularly pertinent in a humanitarian context.

3. ONGOING OR PLANNED HUMANITARIAN INTERVENTIONS IN TAHOUA, NIGER
Concern Worldwide have been working in Tahoua since 2003 and undertook their first emergency CTP in the lean season of 2010 in response to a severe drought which caused food shortages and price rises. Thereafter, they have implemented emergency UCTs every lean season to meet the needs of the most vulnerable in the population whilst also building up a body of evidence included in the summary above. The UCT is usually implemented from June until September as these are perceived to be the peak lean season months. Cash transfers are one component of a comprehensive package of interventions in health, nutrition, food security and livelihoods, education, water, sanitation and hygiene, and natural resource management intended in the longer term to tackle poverty and improve resilience.

Concern Worldwide started another four-month, ECHO-funded UCT in June 2014 to enable the poorest households to meet their food and other basic needs during the lean season. The cash is intended to ensure access to food, to prevent household members resorting to harmful coping strategies and ultimately to prevent acute malnutrition. Cash transfers are Concern Worldwide’s preferred intervention in this context in which the markets function and there is food available, to enable households to choose what to purchase to meet their self-perceived priorities and support the local economy. They are targeting 4,000 ‘very poor’, ‘D’ group households classified using the Household Economy Approach in about 80 villages in the communes of Bambeye, Tebaram, Affala and Takanamatt (see Figure 2.2). Cash is given to the female head of household or the spouse of the male head of the household. The number and list of villages is based on primarily on production deficit reports from the Systeme d’Alerte Precoce (SAP) [the government early warning system]. Cash is distributed manually, with a nutrient supplement for individuals in the household who are 6<24 months of age or pregnant or lactating, at distribution points no more than 5km from the recipient’s home village; most villages have a distribution point. Women are the chosen recipients because of a belief that cash in the hands of

---

women will more likely benefit the child. This is despite the absence of published evidence of this process in Niger, and evaluations which indicate that a large proportion is given back to the husband or male family member\textsuperscript{69,70}. Four monthly transfers of 32,500 CFA (about £39) will be disbursed between June and September where the amount has been determined by the government on the basis of the average cost of a WFP household food basket. Using local market data and forecasts, it is calculated that this will enable a household of seven to meet 75\% of their calorie requirements (using the planning figure of 2100kcal per person) and it is anticipated that the shortfall will be met by normal livelihood strategies.

The programme design includes contingency to switch to commodity vouchers in the event that the markets fail to function in a manner that will enable cash transfer beneficiaries to purchase their food and cover other basic needs; although this is not anticipated\textsuperscript{71}. Three other complementary interventions perceived necessary to optimise the effectiveness of the UCT are: 1. provision of complementary-supplementary foods through monthly feeding for children 6-<24 months of age and PLW in the same very poor households given cash, called Nutrition Supplementation for the Prevention of Acute Malnutrition and Mortality (NSPAMM); 2. education/sensitisation sessions on improved ‘family practices’, covering optimal infant and young child feeding practices, hygiene, identification and referral for acute malnutrition and sickness, deworming, vitamin A supplementation and dietary diversity; 3. regular community-wide screening for acute malnutrition among children under five and pregnant and lactating women using mid upper arm circumference, and their treatment through CMAM (community-based management of acute malnutrition).

Using Irish Aid humanitarian funding, this year Concern Worldwide gave a proportion of households their first cash disbursement earlier than the majority (early June instead of late June) and these households will also be given an extra disbursement at the end of the season, in October (although the original plan was to give two earlier transfers and end in September as usual); these households will receive six smaller disbursements totalling the same as the larger four that the majority will receive. The rationale for starting the seasonal intervention earlier is that households who receive earlier assistance (between January and April when food starts running out for the poorest) will have to sell fewer assets (including land and animals) and can save and spend when they need making them better able to meet needs at the peak of the season, which may also be diminished as a result of earlier assistance. Other negative coping mechanisms that could be prevented include taking children out of school, using family members to work for the better-off and contracting debts. The goal is to more effectively protect children’s nutritional status. A second motivation is a desire to modify the short term seasonal intervention to better align with the national social safety net approach, currently being implemented at small scale. This is designed on a similar rationale, providing 10,000 CFA a month, year-round, to ‘very poor’ households (via female representatives), classified using a proxy means test. Given the chronic and widespread needs, Concern Worldwide and other stakeholders recognise that robust study of a modification in timing and duration of the standard emergency/seasonal programme would be appropriate to test these assumptions and thereby inform any change in practice to improve the impact of these cash programmes.

There are several reasons for being confident that a similar UCT will be needed and implemented in 2015, providing an opportunity for research meeting REFANI’s objectives and building on the research done to date by Concern Worldwide and their academic partners. Firstly, poverty is structural and food insecurity and high rates of acute malnutrition persistent; secondly, Concern Worldwide’s four-year plan includes a commitment to continue the provision of seasonal cash transfers to meet emergency needs; thirdly, Concern Worldwide have a proven track record securing ECHO funds for UCT and meetings with the head of the ECHO Niger, officer and his staff indicated likely support and funding for an intervention covering sufficient households to meet the study’s requirements.


\textsuperscript{71} Personal communication with Leila Bourahla, Country Director, in June 2014.
4. JUSTIFICATION FOR THE STUDY

Rates of food insecurity and acute malnutrition in Tahoua are chronically high and vary seasonally. But whilst the lean season is assumed to be between June and September, data on admissions to feeding programmes suggest that peak incidence of acute malnutrition may occur outside of this window, potentially rising from March or April and again after September. Whilst the government is working to roll out a national safety net which provides cash to female representatives of the poorest households, monthly and year round, to better enable them to meet their consumption needs, the coverage remains low. To address acute food insecurity during the lean season in areas suffering significant production deficits, a humanitarian approach is therefore applied annually. This includes the implementation of short term, emergency cash transfers over the four month period, also provided to women, to enable the most vulnerable, very poor households to maintain access to food and meet their other basic needs and it is anticipated, to protect the nutritional status of their children.

However, in light of concerns about rising incidence of acute malnutrition before the onset of the lean season, Concern Worldwide, their main donor ECHO and other actors in Niger are interested in robustly testing whether an earlier initiation and therefore a longer duration of the emergency/seasonal UCT, of the same overall value, will have a better impact on child nutritional status than current practice. The rationale for the two month earlier start date is to capture the period before June when admissions to feeding programmes start to rise. The rationale for providing the same amount of cash in total over the longer period is firstly, because it is anticipated that earlier assistance will reduce the household’s food gap during the lean season, and secondly, because raising the cash amount would make the modified intervention more costly overall, and this would be undesirable to a humanitarian donor.

Insight is also needed into the processes through which a differential impact of the modified intervention may operate, as well as into the effects of providing the cash to female representatives of the household. In addition, there is an absence of evidence in Niger and elsewhere on the population level impact of this intervention which is targeted at only the very poor households. Data on cost and cost-effectiveness is also lacking and needed to inform policy and donor decision making. The study is necessary to inform the design of future similar humanitarian operations and potentially also the national safety net, in order to maximise their nutrition impacts at a population level.

5. AIMS

The overall aim of the REFANI consortium is to enhance the understanding of the mechanisms by which cash transfers work to reduce the risk of acute malnutrition in emergencies. This aim will be achieved through conducting a series of comparative studies in different contexts.

In this proposed UCL-led study in Tahoua, Niger we aim to determine whether modification of a standard, emergency/seasonal UCT improves its effectiveness and cost-effectiveness for reducing acute malnutrition prevalence in children 6-59 months of age. We will also explore the mechanisms by which the intervention works. Using a cluster randomised controlled trial design with two intervention arms, we will compare the ‘standard’ four-month emergency/seasonal UCT with an earlier, extended six-month UCT, which will be the same total value but initiated two months prior to the standard UCT. Both interventions target very poor households and for the common four months of the lean season, the cash transfers are accompanied by a nutritional supplement for children 6-<24 months and pregnant and lactating women, and health, hygiene and nutrition education messages. We aim to assess nutrition impact among the very poor households targeted with cash, as well as in the wider communities in which these households are situated. We will do this by undertaking a longitudinal cohort study of children in the two trial arms, and by undertaking cross sectional surveys of the villages in the two trial arms in which the very poor households are targeted with cash. Our primary outcome is prevalence of acute malnutrition in children 6-59 months of age. We will evaluate impact after six months of follow up to assess the effect over the lean season. The interventions will be costed and relative cost-effectiveness evaluated to explore the cost implications of the intervention modification.
We will undertake additional in-depth study on the intervention processes to enhance our understanding of how the interventions work and whether changing the timing and duration of the UCT programme changes these mechanisms. This will include exploring decision-making related to cash use and its effect on the household’s tangible assets as well as intangible assets such as time and social capital. It will also include the effects on the women targeted as beneficiaries, including on their wellbeing and how this may impact on the nutritional status of the children in their household. We will undertake qualitative data collection with cash beneficiaries and non-beneficiaries to understand how the interventions work or fail to work. We will use the Theory of Change (ToC) developed to facilitate a common approach across the REFANI studies to guide our data collection and analysis plans, particularly in the exploration of the causal pathways between cash receipt and child nutrition status (see figure 2.5). Using our results we will refine the ToC to make it a context specific example of how and why the modified cash intervention works or fails to work in Tahoua, Niger.

6. OBJECTIVES

- To implement a two armed community cluster randomised controlled trial in the communes of Affala and Takanamatt, within Tahoua district. The unit of randomisation will be ‘cash distribution points’ set up by Concern Worldwide to service very poor households in villages selected to receive seasonal assistance due to production deficit. We will randomly allocate distribution points to the ‘standard’ or ‘earlier, extended’ UCT and within the villages covered by the distribution point, the very poor households will be targeted to receive the UCT from Concern Worldwide.

- To conduct a cohort study, collecting data on a sample of children and households in the two trial arms at baseline before the modified cash intervention starts and six month later at end-line, in September, after the last cash distribution and at the end of the lean season. We will measure prevalence of acute malnutrition among children 6-59 months of age as our main outcome. Additional outcomes will include anaemia prevalence in children and mothers.

- To implement cross sectional surveys of households in all wealth groups, in the villages allocated to the two trial arms before and after the intervention, which will also measure the prevalence of acute malnutrition and anaemia.

- To assess costs and cost-effectiveness of the UCTs, including analysis of accounting data, estimation of implementing staff time allocation, and calculation of costs to beneficiary households using both household survey data from the second cohort and focus group discussions.

- To undertake formative research before the intervention starts to describe the context and inform the design of the intervention and data collection tools.

- To conduct a process evaluation using quantitative and qualitative methods. We will describe the context in which the interventions are delivered, including the factors influencing the design and delivery of the UCT by Concern Worldwide. We will also assess the fidelity of implementation of the UCTs in comparison to what was planned.

- To undertake monthly, longitudinal qualitative data collection during the intervention among purposively selected cash beneficiary and non-beneficiary households, through open interviews, direct observation and focus group discussions to understand the mechanisms of action of the UCTs.

7. RESEARCH QUESTIONS [REDACTED]

The Niger Study’s main research questions revolve around whether earlier initiation and extended duration of CTP interventions reduces the prevalence of acute malnutrition. Additional research questions delve deeper into how timing and duration of the CTP affect a variety of factors, such as household decision-making patterns, expenditure patterns, intangible assets, etc. A detailed account of the REFANI Niger Study research questions has been embargoed, pending future publication in peer-reviewed journals.
8. HYPOTHESES [REDACTED]

The Niger Study’s primary hypothesis explores the link between an earlier and longer CTP intervention and the reduction in the prevalence of acute malnutrition. A detailed account of the REFANI Pakistan Study hypotheses has been embargoed, pending future publication in peer-reviewed journals.

9. ETHICAL CONSIDERATIONS

UCL will submit this study protocol to the national ethics board (Comité Consultatif National d'Ethique) at the Ministry of Health in Niger for approval, as well as to the ethics review committee of the University College of London. The trial will be registered for an International Standard Randomised Controlled Trial Number (ISRCTN).

Concern Worldwide’s community based staff and volunteers will lead a campaign of community sensitisation at the commune level, prior to the commencement of the study. The campaign will explain the study design and rationale and, through permitting dialogue and promoting transparency, will seek to gain the consent of community gatekeepers such as village leaders/elders to support the studies activities. Through Concern Worldwide, the Study Coordinator will also notify and seek approval from the relevant authorities about the study activities; this includes the mayor/town hall administration, governor, health centre administrators and the head of the communes. The study enumerators and fieldworkers will explain the study’s aims and objectives to every potential study participant. Thumb prints will be taken from those willing to participate as a sign of informed consent. The consent procedure will include reading an information sheet which will be translated into the local dialect of Hausa. Agreement to participate in the study will be voluntary and will not be associated with provision or withdrawal of any offered intervention or other assistance.

If deemed necessary to ensure public understanding and adherence to the protocol, the process of randomisation of cash distribution points to trial arms (see below) may be conducted at a public meeting to which community members will be invited.

Any child found by the study staff to be acutely malnourished, regardless of the status of consent to participate in the study, will be referred to the nearest nutritional rehabilitation programme and the carer of any child found to be sick will be advised to attend the nearest health centre. Mothers or children also found to be anaemic will also be encouraged to attend the nearest health centre. Health centre administration will be notified about the likelihood of referrals by the study staff and Concern Worldwide will provide support as necessary through their ongoing programming.

Concern Worldwide staff will provide feedback on the results of the study to the participating communities through focus group discussions guided by briefing notes. The results of the study will be documented and disseminated at national, regional and international level to promote improved practice that may benefit the populations participating in the study. More details on communications around the research findings are articulated in the consortium’s Research Uptake Strategy.

10. METHODS [REDACTED]

10.1 Study design

The study is a two-armed, community cluster randomised controlled trial of timing and duration of an emergency/seasonal UCT on the nutritional status of children aged 6 – 59 months of age, living in selected villages of the communes of Affala and Takanamatt in the district of Tahoua, Niger.

A detailed account of the REFANI Niger Study methodology – including information on the study arms, study area, selection criteria, assignment to intervention arms, sample size, and data management, collection, processing and analysis – has been embargoed, pending future publication in peer-reviewed journals.
11. STUDY STAFFING, TRAINING AND MANAGEMENT

An implementation plan for the studies is presented in a Gantt chart in Annex 2B. This is a condensed version of a detailed plan we have developed in consultation with Concern Worldwide staff and intend to use it jointly to facilitate a collaborative effort to deliver on the activities required for the successful implementation of the study.

Our main points of contact in Concern Worldwide in Niger are Leila Bourahla - Country Director and her deputy Julia Lewis - Assistant Country Director-Programmes. We also have direct lines of communication and will work closely with key staff designing, implementing, monitoring and evaluating the interventions and supporting the operations requirements, both in Tahoua and in Niamey. These include Cherif Lawan - Programme Coordinator; Thierry Tshangola – Logistics/Admin Coordinator; Amadou Diallo – Food Income and Markets Programme Manager; Souleymane Karidio – Cash Officer; Cheffou Idrissa – Food Income and Markets M&E Officer; Mariama Mahamoudou – Nutrition Manager; Almoctar Ibro - IT Manager; Fatima Harouna – Admin/HR Officer and Salissou Harouna – Logistics/Purchasing Assistant. The Cost Effectiveness Analysis staff will work closely with the Niamey based Country Financial Controller, Maranatha Padanou, and his staff. A proportion of individual Concern Worldwide staff time has been included in the study budget to strengthen the collaboration and ensure appropriate levels of support for the study staff and activities.

The UCL staff, field-based Study Coordinator and Qualitative Study Coordinators, will be supported by academic advisers at UCL; Andrew Seal, Principal Investigator; Carlos Eternod-Grijalva, Research Manager; Joanna Morrison, Anthropology adviser; Hassan Haghpastar-Bidgoli, Economics adviser; and Melissa Neumann, Statistics Adviser. The Study Coordinator and cost effectiveness research officer and team will be supported by Chloe Puett, ACF CEA advisor.

Field staff recruitment and training

The study staff and organogram are presented in figure 2.8. Except for the international Study Coordinator already hired by UCL, we will recruit the field staff in Niamey or in Tahoua. The Field Coordinator and Qualitative Study Coordinators will be required to speak, read and write English and French. The Field Coordinator will have a minimum of a third level qualification and the Qualitative Study Coordinator will have a PhD. The Field Coordinator will be required to have significant project management experience, including managing large teams and budgets. Experience in conducting community based nutrition research in Niger, including anthropometric measurements will be desirable. The Qualitative Study Coordinator will be required to have excellent communication skills and experience of undertaking ethnographic research and be able to speak, read and write the local dialect of Hausa. Project management experience will be desirable. Enumerator supervisors and enumerators will be required to speak, read and write French and the local dialect of Hausa, and will have a minimum of a second level qualification for supervisors, and BACS for enumerators, with some experience in conducting community based research in Niger, involving either quantitative nutrition (anthropometric) and/or food security data. Qualitative fieldworkers will be required to speak, read and write French and the local dialect of Hausa and will have a minimum of a second level qualification with some experience in conducting community based research in Niger using qualitative methodologies. Support will be sought from the Nigerien anthropological research institute LASDEL (Laboratoire d'Etudes et de Recherche sur les Dynamiques Sociales et le Développement Local) for staff hire and training for the qualitative components of the study.

We will train enumerators and quantitative supervisors through class room-based lessons, role plays and anthropometry demonstrations and practice. Training will be conducted by Concern Worldwide’s IT adviser on DDG use with the support of the Study Coordinator who will receive training from Concern Worldwide in Dublin. The two to three week training prior to the first round of data collection will include piloting in villages not sampled for the study. The anthropometric data collection training will apply best practice procedures, and we will use standard equipment and the standardisation and validation tests in ENA for SMART to assess...
enumerator reliability. More staff will be trained than hired to enable selection of the best performing. We anticipate retaining most of the staff for each of the two periods of quantitative data collection and to enable this, we will pay a one month bonus to staff that complete both rounds of data collection. However, to limit the impact of attrition of staff on data quality, we will provide a one week refresher training to the quantitative staff before the end-line cohorts/surveys. The Qualitative Study Coordinator will lead the training of the qualitative fieldworkers with the support of LASDEL as required. UCL academic advisers will support in the design and potentially the delivery of the trainings. The CEA research officer will train the enumerators working with him or her on the facilitation and documentation of the focus group discussions, in terms of facilitation skills, note-taking and documentation. This will occur during one day at the beginning of the field visit in Tahoua.

12. RISK MANAGEMENT
We have consulted with Concern Worldwide to prepare a risk management matrix, see Annex 2C. Built into this process is a consideration of the contingencies in study design to be able to answer the research questions if unforeseen events disrupt field activities. To summarise, if follow-up of the cohort is disrupted beyond a conservative 20% loss which is factored into the sample size, the end-line cohorts could be replaced by cross sectional surveys of very poor households without compromising our ability to answer the primary research question. In addition, the cross sectional surveys could be dropped without impacting on our ability to answer the primary research question around impact of the modified intervention on targeted households. Because the duration of the study is relatively short, generally, we do not anticipate unforeseen periods of insecurity or inaccessibility disrupting the data collection.
This document is an output from a project funded by the UK Aid from the UK Department for International Development (DFID) for the benefit of developing countries. However, the views expressed and information contained in it are not necessarily those of or endorsed by DFID, which can accept no responsibility for such views or information or for any reliance placed on them.