

# REFANI Pakistan study - effect of differing modalities of cash transfers on reducing the risk of wasting in children in Pakistan

<b>Submission date</b> 05/03/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/04/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The nutritional situation of children in Pakistan is one of the worst in the world with few improvements seen during the past decade. Wasting (thinness) is particularly high in Sindh Province, especially during the summer lean period. Sindh is also prone to natural disasters, especially flooding, and mitigation strategies are necessary to deal with the increased risk of wasting in children. Cash transfer programmes are an emerging strategy increasingly being used for the prevention of wasting, especially targeted at vulnerable households, who have children at risk of undernutrition, during periods of food insecurity or during emergencies. This study aims to (1) compare the nutrition status of children receiving a seasonal unconditional cash transfer (standard or double) or a food voucher with those receiving standard care only after 6 months and at 1 year; (2) assess the costs and cost-effectiveness of the different interventions; (3) understand the factors that determine the ways in which households use the different transfers; and (4) explore the role of the different processes involved in the study outcomes and how they interact with the context.

### Who can participate?

All poor and very poor households with a child or children aged between 6-48 months at the beginning of the study.

### What does the study involve?

Participants are asked to answer a number of questions relating to their households, themselves and their children. Some of these questions focus on household expenditures and incomes, some on nutrition, food security and water and sanitation and some on health. They are also asked to participate in having their height measured and then to help the enumerators to measure their children's weight, height and arm circumference. These measurements are done every month for 6 months. At 3 points in time (6 months apart) participants are asked to have a test for anaemia. This involves a very quick and non-harmful procedure to take a small droplet of blood from their own and then their children's finger. The whole study takes place over 1 year. Participants are visited once a month for the first 6 months and then once again 6 months later. The first visit requires more time, about 1 hour; follow-up visits are shorter than this.

What are the possible benefits and risks of participating?

Participants are regularly tested for the presence of anaemia. If anaemia is present then they are referred to an ACF treatment centre. Furthermore their children are assessed for severe wasting, and referred if necessary to the nearest ACF nutrition treatment centre. For those households receiving a cash transfer (either cash or voucher) an improvement in their economic situation is expected, which could help to improve food security and reduce vulnerability, ultimately improving nutritional status. The comparison area continues to receive the same nutrition interventions under the current WINS programme as the intervention groups. Even though there is no additional intervention they are providing vital information that is used to support the government and donors to better understand the potential importance of emergency cash transfer programmes as part of the prevention of wasting and anaemia during periods where vulnerabilities are high. If it is found that either the cash or the voucher transfer does have an impact on child wasting then this information may be used to direct ACF future cash transfer programming in Dadu. This study would not just inform programming in Pakistan but also the current global debate around the 'best' modality of CTPs that impact nutrition status. There are minimal risks from participation in this study.

Where is the study run from?

Action Contre la Faim (ACF) base in Dadu town, Dadu District, in Sindh Province, Pakistan

When is the study starting and how long is it expected to run for?

June 2014 to July 2016

Who is funding the study?

Department for International Development (DFID) (UK)

Who is the main contact?

Bridget Fenn

### **Study website**

<http://www.actionagainsthunger.org/refani>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Ms Bridget Fenn

### **Contact details**

32 Leopold Street  
Oxford  
United Kingdom  
OX4 1TW

## **Additional identifiers**

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

6-250215

## **Study information**

### **Scientific Title**

A cluster randomised controlled trial of the effectiveness and cost-effectiveness of cash transfer programmes on child nutrition status in Sindh, Pakistan

### **Acronym**

REFANI-P (Research on Food Assistance for Nutritional Impact - Pakistan)

### **Study objectives**

Cash transfer interventions reduce the prevalence of wasting and of anaemia in children less than five years of age from poor and very poor households.

This four-arm cluster randomised controlled trial (with integral economic evaluation and mixed-methods process evaluation) is set in Action Against Hunger | ACF International (ACF) EU-WINS programme villages in Dadu District, Sindh Province, Pakistan. All arms will have access to the 'standard' ACF Women and Children/Infant Improved Nutrition in Sindh (EU-WINS) programme. Villages will be randomised to one of four groups receiving either one of two seasonal unconditional cash transfers (intervention), a food voucher (intervention) or the ACF standard care (control).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. National Bioethics Committee (NBC) Pakistan, 12/02/2015, ref: 4-87/14/NBC-170/RDC/2304
2. Western International Review Board, 11/03/2015

### **Study design**

Single-centre trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

Community

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Low weight-for-height: Wasting or thinness indicates in most cases a recent and severe process of weight loss, which is often associated with acute starvation and/or severe disease.

### **Interventions**

Intervention 1: Seasonal unconditional cash transfer (UCT), with a value of approximately 1500PRs (GBP 9), distributed monthly over 6 months.

Intervention 2: Seasonal unconditional cash transfer (UCT), with a value of approximately 3000PRs (GBP 18), distributed monthly over 6 months.

Intervention 3: Seasonal Food vouchers, with an equivalent value to the smallest UCT 1500PRs (GBP 9), distributed monthly over 6 months.

Control group: Standard care whereby villages will receive the interventions delivered by the ACF WINS programme only.

All arms will get the same elements of the ACF WINS programme

### **Intervention Type**

Other

### **Primary outcome measure**

Prevalence of wasting (as measured by weight-for-height Z-score (WHZ)  $<-2$  or the presence of bilateral pitting oedema) in children  $<5$  years old, assessed at baseline and then monthly during the intervention period and then again at 1 year after baseline

### **Secondary outcome measures**

1. Severe wasting (defined as WHZ  $<-3$  SD or oedema); mean WHZ
  2. Low MUAC (children:  $<125\text{mm}$  &  $<115\text{mm}$ , mothers:  $<230\text{mm}$  &  $<210\text{mm}$ )
  3. Stunting (defined as height-for-age (HAZ)  $<2$  SD; severe stunting  $<3$  SD)
  4. Anaemia (children and women); haemoglobin Hb g/dl(means)
  5. Body Mass Index (BMI) (non PLW  $>19$  years old) ( $<16$ ,  $<17$   $<18.5\text{kg/m}^2$ )
  6. Morbidity in children (diarrhoea, malaria and respiratory illness).
  7. Individual Diet Diversity Score (children and mothers)
- 1-7 will be assessed at baseline and then monthly during the intervention period and then again at 1 year after baseline.
8. Cost effectiveness of the different cash transfer modalities, assessed at the end of the intervention

### **Overall study start date**

01/06/2014

### **Completion date**

31/07/2016

## **Eligibility**

### **Key inclusion criteria**

1. Households identified as poor and very poor (according to wealth index criteria) and with a child or children aged 6-48 months
2. Households with children born in the area during the study period

**Participant type(s)**

Other

**Age group**

Child

**Sex**

Both

**Target number of participants**

5680 children in 2580 households

**Key exclusion criteria**

1. Poor and very poor households with no eligible child
2. Households with children who moved to the area within 6 months before the intervention (and may not be typical of households in the village e.g. those migrating due to drought in their area)
3. Households who do not give consent
4. Children who are chronically ill (with prescribed medical treatment)

**Date of first enrolment**

15/04/2015

**Date of final enrolment**

31/05/2015

**Locations****Countries of recruitment**

Pakistan

**Study participating centre****ACF base Dadu**

Dadum Berhamani Housing Society

Jamali Colony

Behind General Bus stand

Sehwan Road

Dadu

Pakistan

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**Sponsor information**

**Organisation**

UK Department for International Development (DFID)

**Sponsor details**

22 Whitehall  
London  
United Kingdom  
SW1A 2EG

**Sponsor type**

Government

**ROR**

<https://ror.org/05rf29967>

**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**

The trialists plan to publish in a variety of journals including open access. They will publish at least three papers; the protocol (August 2015), the main results from the study (April 2016) and the results from the CEA (April 2016). There will be the potential for other papers relating to the process evaluation and the qualitative work, though this is still to be decided. They have, as a consortium, a dedicated research uptake strategy team to organise a thorough dissemination of

the research including (apart from journals) conferences, lectures, other relevant non-peer reviewed publications (e.g., Field Exchange), the ACF/REFANI website, and through the DFID R4D open access database.

### **Intention to publish date**

01/08/2015

### **Individual participant data (IPD) sharing plan**

Not provided at time of registration

### **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	12/10/2015		Yes	No
<a href="#">Results article</a>	results	23/05/2017		Yes	No
<a href="#">Results article</a>	cost, cost-efficiency and cost-effectiveness	15/06/2018	25/04/2023	Yes	No