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

Recruitment status No longer recruiting	[X] Prospectively registered		
	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

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 Disctrict, 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

Contact information

Type(s)Scientific

Contact nameMs Bridget Fenn

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Additional identifiers

Protocol serial number 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

Study type(s)

Other

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(s)

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

Key secondary outcome(s))

- 1. Severe wasting (defined as WHZ <-3 SD or oedema); mean WHZ
- 2. Low MUAC (children: <125mm & < 115mm, mothers: <230mm & <210mm)
- 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<18.5kg/m2)
- 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

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

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)

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

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?
Results article	results	23/05/2017	7	Yes	No
Results article	cost, cost-efficiency and cost- effectiveness	15/06/2018	3 25/04 /2023	Yes	No
<u>Protocol article</u>	protocol	12/10/2015	5	Yes	No
Participant information sheet	Participant information sheet	11/11/202	11/11 /2025	No	Yes
Study website	Study website	11/11/202	11/11 /2025	No	Yes