

# Promoting early child development within a conditional cash transfer program

<b>Submission date</b> 02/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/06/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Our long term goal is to understand what interventions work most best at improving early child development in vulnerable populations in the long term. Our objective here is to examine how well Mexico's CCT (Oportunidades) works to achieve this when used with an innovative and well-designed parenting intervention (Educación Inicial). Having done some preliminary work, we believe that when CCT participation is linked to a program to improve parenting practices, there will be more consistently positive effects of CCT participation on child development than CCT program alone.

### Who can participate?

Rural communities (less than 2500 inhabitants each) in Chiapas State in Mexico, and along the bordering area of Puebla and Oaxaca States in Southern Mexico identified as having had a minimum of 15 families with children 0 to 18 months of age, a high proportion of families in the community (>70%) taking part in the Oportunidades, Mexico's CCT program, and where there was no prior history or current implementation of the Educación Inicial program.

### What does the study involve?

Communities are randomly assigned into one of three groups. In those communities in group 1, households are given the standard conditional cash transfer benefits from the CCT and the parenting program (Educación Inicial) is made available. The same is the case for those households living in group 2 communities, but with the CCT program being responsible for promoting the parenting program and encouraging households to participate. Households in group 3 communities are given the standard conditional cash transfer benefits but the parenting program is not made available.

### What are the possible benefits and risks of participating?

There were no benefits or risks for the participants of the study. Participation in the study was in no way linked to receipt of program benefits.

### Where is the study run from?

The study is run from three states in southern Mexico.

When is the study starting and how long is it expected to run for?  
September 2008 to October 2012

Who is funding the study?  
The Mexican government is funding the study, as is the UBS-Optimus Foundation.

Who is the main contact?  
Dr Lia Fernald  
fernald@berkeley.edu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Lia Fernald

**ORCID ID**  
<http://orcid.org/0000-0003-1555-4607>

**Contact details**  
50 University Hall  
MC 7360  
Berkeley  
United States of America  
94720  
5106439113  
fernald@berkeley.edu

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Supporting early child development within a conditional cash transfer program: a cluster-randomized effectiveness trial of a group-based parenting intervention in Mexico

**Study objectives**  
1. Participation in a group-based parenting education can result in greater benefits to children than participating in a CCT program alone

2. There will be differences between children in a community randomized to an arm in which participation in parenting classes was promoted and supported by the CCT and children in an arm where classes were available but not promoted by the CCT program
3. There will be differences in effects by indigenous status and other variables

### **Ethics approval required**

Old ethics approval format

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

1. Comisión de Ética, Instituto Nacional de Salud Pública, Cuernavaca, Mexico, 08/08/2008
2. UC Berkeley, Center for the Protection of Human Subjects, 07/22/2010, 2010-05-1528

### **Study design**

Stratified cluster randomized control design

### **Primary study design**

Interventional

### **Secondary study design**

### **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**

Delayed early child development

### **Interventions**

The intervention was a group-based parenting program for families with children ages 4 and under implemented at the community level. There were two treatment arms and one comparison arm.

1. First treatment arm: households received the standard conditional cash transfer benefits from the CCT, and the parenting program made available
2. Second treatment arm: households received the standard CCT benefits, and the parenting program made available; in this arm, though, the CCT program was responsible for promoting the parenting program and encouraging community members to participate
3. Comparison arm: households received the standard conditional cash transfer benefits, but the parenting program was not offered in the community

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Measures of early child development (cognitive, language, motor).

## **Secondary outcome measures**

1. Maternal mental health: Maternal depressive symptoms were measured using the Spanish version of the CES-D (Center for Epidemiologic Studies-Depression Scale), a 20-item questionnaire with a range from 0-60. The CES-D has been validated for use in diverse Mexican populations. We will examine outcomes with respect to the total score on the 20-item measure as well as subscale scores. We will also use the sum of the Perceived Stress Scale, which was included to assess the frequency of stressful situations in the prior month.

2. Maternal caregiving and responsiveness: The extent to which caregivers respond to their children and provide stimulation for cognitive development is a critical factor contributing to child development, and we will measure this responsiveness using the Home Observation for Measurement of the Environment (HOME) Inventories. The HOME inventories are administered by naturalistic observation and interview at the child's home, and include scales measuring the provision of activities/materials that encourage learning and maternal knowledge of appropriate caregiving practices, and have been associated with better social, motor, cognitive, language and academic performance across a range of ages in the US and in various countries. We have previously used the HOME scale in many other studies.

3. Food consumption: For children 0 to 18 mo of age (baseline), mothers were asked a series of questions regarding breastfeeding and complementary feeding practices. At follow up, mothers were asked to report on the types and frequency of foods consumed by their children, as well as other information related to the use of bottles and feeding style (responsive feeding). Although we cannot quantify dietary intake of energy or other nutrients, these methods have been used extensively in Mexico and have been shown to distinguish children whose dietary patterns follow international recommendations and those who do not.

## **Overall study start date**

01/09/2008

## **Completion date**

31/10/2012

## **Eligibility**

### **Key inclusion criteria**

To be eligible to participate in the study, communities needed to:

1. have a minimum of 15 families with children 0 to 2 years of age
2. have a high proportion of families in the community (>70%) incorporated into the CCT
3. have no current implementation of the parenting program or prior participation for at least the previous five years

Additionally only rural communities (fewer than 2500 inhabitants) in Chiapas and bordering areas in Puebla and Oaxaca were considered for inclusion.

### **Participant type(s)**

Healthy volunteer

### **Age group**

Child

### **Sex**

Both

**Target number of participants**

1113

**Key exclusion criteria**

Age out of range of interest for study

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

31/08/2009

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

Mexico

**Study participating centre**

Oportunidades community centers in Chiapas, Puebla and Oaxaca

Mexico

**Sponsor information****Organisation**

UC Berkeley

**Sponsor details**

50 University Hall

MC 7360

Berkeley

United States of America

94720

5106439113

fernald@berkeley.edu

**Sponsor type**

University/education

**ROR**

<https://ror.org/01an7q238>

**Funder(s)**

**Funder type**

Government

**Funder Name**

Secretary of Social Development of Mexico

**Funder Name**

UBS-Optimus Foundation

## **Results and Publications**

**Publication and dissemination plan**

To be confirmed at a later date

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available