

Promoting early child development within a conditional cash transfer program

Submission date 02/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/06/2015	Condition category 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