ISRCTN14939508 https://doi.org/10.1186/ISRCTN14939508

Promoting early child development within a conditional cash transfer program

Submission date	Recruitment status	[ ] Prospectively registered
02/06/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/06/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/06/2015	Nutritional, Metabolic, Endocrine	[ ] 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?
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Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Stratified cluster randomized control design

Study type(s)
Prevention

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

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Sex
All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available