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Supporting adolescent mothers in El Salvador

Submission date 08/02/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 22/02/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/02/2016	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Becoming a new mother is a very challenging time, particularly when the mother is an adolescent herself. For these girls, bonding and interacting with their babies can be difficult and so steps must be taken to help them form a healthy and nurturing relationship with their children. A possible reason for this is that many young mothers do not have a strong support network, and so can feel alone and unhappy while caring for an infant. This study is looking at an early parenting project which is designed to help new parents to bond with their babies. Trained community workers will visit first-time adolescent mothers (aged 10-19) in their homes during late pregnancy and the post-partum (after the child is born) period, demonstrating sensitive interactive behavior and providing constructive feedback to help parents understand and respond to the developmental needs of their infants. The aim of this study is to look at the effects of this project on new mothers in the Sonsonate province (El Salvador) in order to find out whether it is an effective way of helping new mothers to build nurturing, non-violent relationships from the moment their babies are born.

Who can participate?

Girls aged between 10 and 19 who are in their last 11 weeks of pregnancy with their first child, who live in Sosonate province, El Salvador.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive 16 visits from by community workers (CW), which take place twice in late pregnancy, weekly for the first eight weeks after they have given birth, every two weeks for a further two months and then monthly visits for two additional months up to six months. During the visits, the CW's provide support to the new mothers, in order to help mothers to better understand their child and their development. The sessions cover a range of topics, such as the mother's immediate support network, the birth process, infant care and early child development. The mothers are also given taught how to sympathetically manage infant behavioral problems (sleeping, feeding and crying) and encouraged to talk to their babies and to engage in play. Participants in the second group receive standard post-partum care only which consists of regular doctors' appointments for both mother and baby. At the start of the study and then again after six months, participants in both groups are observed interacting with their babies in order to judge parenting skills and how well the mother is able to interact with her baby.

What are the possible benefits and risks of participating?
Participants who take part in the parenting project may benefit from improvements to their parenting skills which could improve the relationship with their child. Participants also benefit from receiving help at no cost if postpartum depression or violence in their relationship is found. There is a risk that some participants may find talking about their problems to be distressing, however they can be referred to counseling or specialized services if this is the case.

Where is the study run from?
Clinics in the municipalities of Nahuizalco, Acajutla, Izalco and Juayúa, in Sosonate province (El Salvador)

When is the study starting and how long is it expected to run for?
January 2016 to June 2017

Who is funding the study?
International Planned Parenthood Federation, Western Hemisphere Region (USA)

Who is the main contact?
1. Dr Jose Angel Portillo Henriquez (public)
2. Professor Peter J Cooper (scientific)

Contact information

Type(s)
Public

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Type(s)
Scientific

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Study information

Scientific Title
An early parenting intervention for adolescent mothers in El Salvador: A pilot randomized control trial

Study objectives
1. Participation in an early parenting intervention increases maternal sensitivity for first-time mothers aged 10-19 in El Salvador
2. Participation in the intervention decreases maternal intrusiveness for first-time mothers aged 10-19 in El Salvador
3. Participation in the intervention results in better emotional regulation for infants aged 6 months in El Salvador

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité Nacional de Ética de la Investigación en Salud, del Consejo Superior de Salud Publica (CSSP), del Ministerio de Salud de la República de El Salvador, 16/12/2015, ref: CNEIS/2015/035

Primary study design
Interventional

Study design
Pilot randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
1. Early childhood care and development
2. Gender based violence

Interventions
The intervention is a home visiting program developed and evaluated by Peter Cooper and Lynne Murray in Khayelitsha, South Africa (Cooper et al, 2009), targeted at first-time mothers aged 10-19 in the last stage of pregnancy and up to 6 months post-partum. A total of 64 first-time adolescent mothers will be recruited to participate in the study, during their last trimester, and will be randomly assigned to either control (32) or intervention groups (32) at the time of recruitment using a random number generator. All participants will be screened for maternal depression and gender-based violence.

Control group: Participants will receive standard postpartum care consisting of regular checkups with obstetricians and pediatrician.

Intervention group: In addition to standard care, participants will receive a home visiting program provided by community workers (CW). Each mother will be visited by the CW 16 times, two visits in the late antenatal period, weekly visits in the first eight postnatal weeks, followed by a visit every two weeks for a further two months and then monthly visits for two additional months up to six months postpartum. The visits will follow a fully specified manual that covers topics related to mother's support structure, the birth process, infant care and early child development. In the context of a supportive counseling framework, CW will provide will provide support to the first time mothers, seeking to enhance maternal sensitivity to infant communication and development. In addition, mothers will be given support in sympathetically managing infant behavioral problems (sleeping, feeding and crying) and encouraged to talk to their babies and to engage in play. Other caregivers, particularly fathers, will be strongly encouraged to participate in the intervention sessions. The total duration of the intervention could range between 8-6 months depending on the delivery date of each participant.

All participants (control and intervention groups) will receive a follow-up assessment at six months post-partum.

Intervention Type
Behavioural

Primary outcome(s)
1. Maternal style (sensitivity and intrusiveness) is rated from the mother-infant face-to-face interaction task using the Global Rating Scale at 6 months
2. Infant emotion regulation is rated from the mother-infant face-to-face still-face (FFSF) task using the Regulatory Scoring System at 6 months

Key secondary outcome(s)
1. Maternal Depression is measured using the Edinburgh Postnatal Depression Scale at baseline, 3 and 6 months
2. Gender Based Violence is measured using the GBV screening protocol (IPPF/WHR, 2004) at baseline and 6 months

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Adolescents between 10 and 19 years of age.
2. Primiparous women in their third trimester of pregnancy
3. Lack of medical complications during pregnancy
4. Delivery not before 36 weeks gestation
5. Women who have a permanent residency so that they are available for the duration of the project (up to 6 months of age of the infant)
6. Resident in urban and rural communities of the municipalities of Nahuizalco, Acajutla, Izalco and Juayúa, Sosonate province
7. Willing and capable to give their written consent (informed consent for minors will be obtained according to the specific age limits of the country)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Maternal physical or mental disability
2. Significant infant congenital abnormality

Date of first enrolment
14/03/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
El Salvador

Study participating centre
Nahuizalco Clinic
1ª. Calle Poniente
Barrio La Trinidad
Frente a Casa Comunal
Nahuizalco
Sonsonate
El Salvador
-

Study participating centre
Los Arenales Clinic
Carretera a los Naranjos
Hacienda El Águila
Cantón Los Arenales
Nahuizalco
Sonsonate
El Salvador
-

Study participating centre
Acajutla Clinic
Av. Pedro de Alvarado
Blvd. 25 de Febrero
Frente Alcaldía Municipal de Acajutla
Acajutla
Sonsonate
El Salvador
-

Study participating centre
Metalio Clinic
Colonia San José
Calle Principal
Cantón Metalío
Acajutla
Sonsonate
-

Study participating centre
Izalco Clinic
9ª Calle Oriente
Barrio La Otra Banda
Izalco
Sonsonate
El Salvador
-

Study participating centre
Dr. Francisco Magaña Herrera (Juayúa) Clinic
Calle Monseñor Romero Poniente y 5ª. Av. Sur
Barrio San José
Juayúa
Sonsonate
El Salvador
-

Study participating centre
San Jose La Majada
Carretera a los Naranjos

Cantón San José de la Majada
Juayúa
Sonsonate
El Salvador
-

Study participating centre
Pro-Familia Clinic
5ta. Calle Poniente #1-3
Barrio El Calvario
Sonsonate
El Salvador
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Sponsor information

Organisation
International Planned Parenthood Federation, Western Hemisphere Region

ROR
https://ror.org/03rhhf773

Funder(s)

Funder type
Charity

Funder Name
International Planned Parenthood Federation, Western Hemisphere Region

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available